

Biotechnology

PRESENTED BY AMERICA'S PHARMACEUTICAL RESEARCH COMPANIES

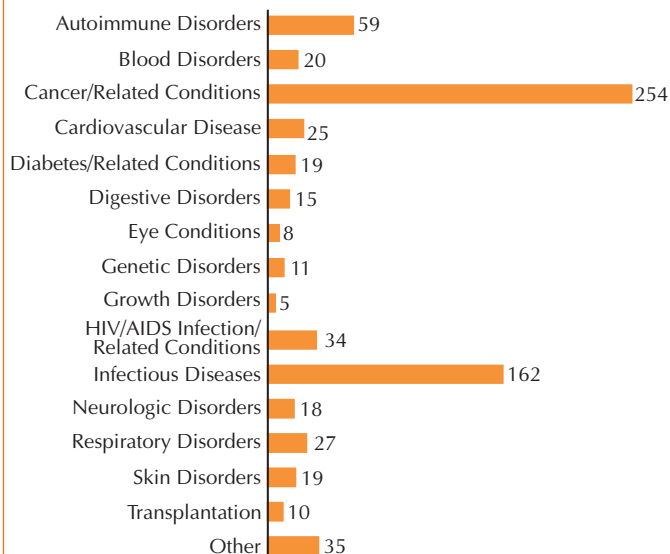
Biotechnology Research Continues to Bolster Arsenal Against Disease with 633 Medicines in Development

Millions of people have already benefited from medicines and vaccines developed through biotechnology, and a new report offers hope that in the future many more will benefit. The report found 633 biotechnology medicines in development for more than 100 diseases. These include 254 medicines for cancer, 162 for infectious diseases, 59 for autoimmune diseases, and 34 for HIV/AIDS and related conditions. These potential medicines are either in human clinical trials or under review by the Food and Drug Administration.

Approved biotechnology medicines already treat or help prevent heart attacks, stroke, multiple sclerosis, leukemia, hepatitis, rheumatoid arthritis, breast cancer, diabetes, congestive heart failure, lymphoma, kidney cancer, cystic fibrosis, and other diseases. These medicines rely on many cutting-edge technologies. For example, most early biotechnology medicines were protein drugs, produced by splicing genes into bacteria. They include recombinant insulin, human growth hormone, clotting factor for hemophilia patients, and erythropoietin to stimulate the production of red blood cells in kidney dialysis and cancer patients. Another type of biotechnology medicine, the monoclonal antibody, is a laboratory-made version of the naturally occurring protein that binds to and neutralizes foreign invaders. Interferons, proteins that interfere with the ability of a cell to reproduce, are the basis of existing medicines for osteoporosis, chronic granulomatous disease, genital warts, multiple sclerosis, hairy cell leukemia and other diseases. Antisense drugs are medicines that interfere with the communication process that tells a cell to produce an unwanted protein.

The biotechnology medicines now in development make use of these and other state-of-the-art technologies. For

BIOTECHNOLOGY MEDICINES IN DEVELOPMENT—BY THERAPEUTIC CATEGORY*



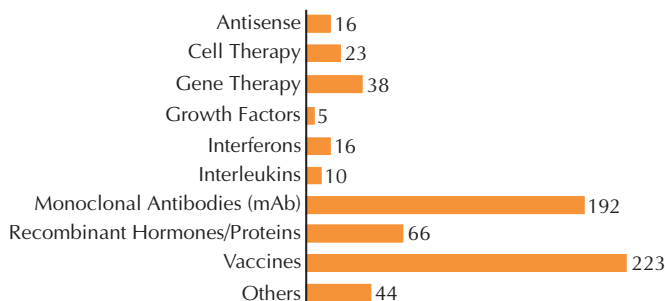
*Some medicines are listed in more than one category.

example, one medicine in the pipeline for rheumatoid arthritis is a recombinant protein that may help treat autoimmune disorders. Monoclonal antibody medicines in the pipeline target asthma, Crohn's disease, rheumatoid arthritis, lupus, and various types of cancer. Therapeutic vaccines, designed to jump-start the immune system to fight disease, are in development for AIDS and several types of cancer. Medicines based on antisense technology are potential treatments for several types of cancer, Crohn's disease and heart disease. Gene therapies, which augment normal gene functions or replace or inactivate disease-causing genes, are being tested for several cancers and heart disease.

These are only a few examples of new ways America's pharmaceutical research and biotechnology companies are attacking disease. The 633 biotechnology medicines in development promise to push the frontiers of science and bring more and better treatments to patients.

Billy Tauzin
President and CEO
PhRMA

BIOTECHNOLOGY MEDICINES IN DEVELOPMENT—BY PRODUCT CATEGORY



Biotechnology Medicines in Development

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
315234	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	mAb	rheumatoid arthritis	Phase I (888) 825-5249
1827771	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	antibody	rheumatoid arthritis	Phase I (888) 825-5249
Actemra® tocilizumab	Roche Nutley, NJ	mAb	rheumatoid arthritis	application submitted (973) 235-5000
AIN 457	Novartis Pharmaceuticals East Hanover, NJ	mAb	rheumatoid arthritis	Phase I (888) 669-6682
Alferon N Injection® interferon alfa-n3	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	interferon	multiple sclerosis (see also infectious)	Phase II (215) 988-0080
AME-527	Applied Molecular Evolution San Diego, CA	mAb	rheumatoid arthritis	Phase I/II (858) 597-4990
AMG 108	Amgen Thousand Oaks, CA	mAb	rheumatoid arthritis	Phase II (805) 447-1000
AMG 557	Amgen Thousand Oaks, CA	mAb	systemic lupus erythematosus (SLE)	Phase I (805) 447-1000
AMG 623	Amgen Thousand Oaks, CA Anthera Pharmaceuticals San Mateo, CA	peptide fusion protein	SLE	Phase I (805) 447-1000 (650) 931-8868
AMG 714	Amgen Thousand Oaks, CA Genmab Princeton, NJ	mAb	rheumatoid arthritis (see also skin)	Phase II (805) 447-1000 (609) 430-2481
AMG 811	Amgen Thousand Oaks, CA	mAb	SLE	Phase I (805) 447-1000
AMG 827	Amgen Thousand Oaks, CA	mAb	rheumatoid arthritis	Phase I (805) 447-1000
Ampligen®	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	RNA product	chronic fatigue syndrome	application submitted (215) 988-0080
anti-CD16 mAb (GMA-161)	Genzyme Cambridge, MA MacroGenics Rockville, MD	mAb	immune thrombocytopenic purpura, immunological disorders	Phase I (617) 679-2000 (301) 251-5172
anti-interferon alpha	Genentech South San Francisco, CA	mAb	SLE	Phase I (650) 225-1000

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
anti-interferon-gamma	Advanced Biotherapy <i>Woodland Hills, CA</i>	polyclonal antibody	alopecia, epidermolysis bullosa, vitiligo (see also skin)	in clinical trials (818) 883-6716
atacept (TACI-Ig)	EMD Serono <i>Rockland, MA</i> Zymogenetics <i>Seattle, WA</i>	recombinant fusion protein	lupus nephritis (see also cancer)	Phase II/III (800) 283-8088 (206) 442-6000
			rheumatoid arthritis (second-line therapy)	Phase II (800) 283-8088 (206) 442-6000
			SLE	Phase I (800) 283-8088 (206) 442-6000
Avonex [®] interferon beta-1a	Biogen Idec <i>Cambridge, MA</i>	interferon	chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)	Phase II (617) 679-2000
baminercept	Biogen Idec <i>Cambridge, MA</i>	recombinant fusion protein	rheumatoid arthritis	Phase II (617) 679-2000
briobacept (BR3-Fc)	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	mAb	rheumatoid arthritis, Sjögren's syndrome	Phase II (617) 679-2000 (650) 225-1000
CAM 3001	MedImmune <i>Gaithersburg, MD</i>	mAb	rheumatoid arthritis	Phase I (301) 398-0000
Campath [®] alemtuzumab	Bayer HealthCare Pharmaceuticals <i>Wayne, PA</i> Genzyme <i>Cambridge, MA</i>	mAb	multiple sclerosis	Phase III (888) 842-2937 (617) 679-2000
canakinumab (ACZ885)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	early-stage rheumatoid arthritis (see also diabetes, respiratory, other)	Phase II/III (888) 669-6682
			rheumatoid arthritis	Phase II (888) 669-6682
Cimzia [™] certolizumab pegol	Nektar Therapeutics <i>San Carlos, CA</i>	mAb	rheumatoid arthritis	application submitted (650) 631-3100
CNTO-136	Centocor <i>Horsham, PA</i>	mAb	rheumatoid arthritis, SLE	Phase II (610) 651-6000
denosumab (AMG 162)	Amgen <i>Thousand Oaks, CA</i>	mAb	rheumatoid arthritis (see also cancer, other)	Phase II (805) 447-1000
edratide (TV-4710)	Teva Pharmaceuticals <i>North Wales, PA</i>	mAb	SLE	Phase II (215) 591-3000

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
golimumab	Centocor <i>Horsham, PA</i>	mAb	ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis (IV) (see also digestive)	application submitted (610) 651-6000
			rheumatoid arthritis (subcutaneous)	Phase III (610) 651-6000
HuMax-CD20 (ofatumumab)	Genmab <i>Princeton, NJ</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	rheumatoid arthritis (see also cancer)	Phase III (609) 430-2481 (888) 825-5249
IL-1 beta antibody	Eli Lilly <i>Indianapolis, IN</i>	interleukin	rheumatoid arthritis	Phase II (800) 545-5979
IL-1 receptor type 2	Amgen <i>Thousand Oaks, CA</i>	recombinant protein	rheumatoid arthritis	Phase I (805) 447-1000
Leukine [®] sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte- macrophage colony stimulating factor	multiple sclerosis (see also cancer, HIV/AIDS, infectious, respiratory, skin, other)	Phase I (888) 842-2937
LymphoCide [®] epratuzumab	Immunomedics <i>Morris Plains, NJ</i> UCB <i>Smyrna, GA</i>	mAb	SLE (see also cancer)	Phase III (973) 605-8200
			Sjögren's syndrome	Phase II (973) 605-8200
LymphoStat-B [®] belimumab	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> Human Genome Sciences <i>Rockville, MD</i>	mAb	SLE	Phase III (888) 825-5249 www.hgsi.com
			rheumatoid arthritis	Phase II completed (888) 825-5249 www.hgsi.com
MDX-1100	Medarex <i>Princeton, NJ</i>	mAb	rheumatoid arthritis (see also digestive)	Phase II (609) 430-2880
MEDI-545 (MDX-1103)	Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	mAb	SLE (see also skin)	Phase I (609) 430-2880 (301) 398-0000
MLN-1202	Millennium Pharmaceuticals <i>Cambridge, MA</i>	mAb	multiple sclerosis (see also cardiovascular)	Phase II (800) 589-9005
MM-093 (recombinant human alpha-fetoprotein) (Orphan Drug)	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	recombinant protein	rheumatoid arthritis (see also eye, skin)	Phase II (617) 441-1000
			multiple sclerosis, myasthenia gravis	Phase I (617) 441-1000

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
NeoFuse™ mesenchymal stem cell therapy	Angioblast Systems <i>New York, NY</i> Mesoblast <i>Melbourne, Australia</i>	stem cell therapy	spondylosis (see also cardiovascular)	Phase II (212) 880-2060
Neumega® oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	interleukin	rheumatoid arthritis (see also cancer, digestive, transplantation)	Phase II (800) 934-5556
NeuroVax™ multiple sclerosis vaccine	Orchestra Therapeutics <i>Carlsbad, CA</i>	vaccine	multiple sclerosis	Phase II (760) 431-7080
Nplate™ romiplostim (Orphan Drug)	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	immune thrombocytopenic purpura (see also cancer)	application submitted (805) 447-1000
			immune thrombocytopenic purpura in children	Phase I/II (805) 447-1000
ocrelizumab (2nd generation anti-CD20)	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	mAb	lupus nephritis, rheumatoid arthritis,	Phase III (650) 225-1000 (617) 679-2000
			multiple sclerosis	Phase II (650) 225-1000 (617) 679-2000
Orencia™ abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant protein	early rheumatoid arthritis (see also digestive)	Phase III (212) 546-4000
			lupus	Phase II/III (212) 546-4000
			delay or prevention of rheumatoid arthritis onset, psoriatic arthritis	Phase II (212) 546-4000
PMI-001	Phytomedics <i>Jamesburg, NJ</i>	root extract	rheumatoid arthritis	Phase II (609) 665-0715
Remicade® infliximab (Orphan Drug)	Centocor <i>Horsham, PA</i>	mAb	juvenile rheumatoid arthritis (see also cancer, respiratory)	Phase III (610) 651-6000
			sarcoidosis	Phase II (610) 651-6000

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
Rituxan® rituximab	Genentech South San Francisco, CA Biogen Idec Cambridge, MA	mAb	lupus nephritis (see also cancer, skin)	Phase III (650) 225-1000 (617) 679-2000
			multiple sclerosis, SLE	Phase II/III (650) 225-1000 (617) 679-2000
			immune thrombocytopenic purpura	Phase II (650) 225-1000 (617) 679-2000
SAR153191	sanofi-aventis Bridgewater, NJ	mAb	rheumatoid arthritis	Phase I (800) 633-1610
tadekinig alfa (r-IL-18bp)	EMD Serono Rockland, MA	recombinant protein	autoimmune disorders	Phase I (800) 298-8088
Tauferon™ interferon-tau	Pepgen Alameda, CA	interferon	multiple sclerosis	Phase II (510) 473-0010
teplizumab (anti-CD3 mAb)	MacroGenics Rockville, MD	mAb	multiple sclerosis (see also diabetes)	Phase I (301) 251-5172
tgAAC 94 gene therapy	Targeted Genetics Seattle, WA	gene therapy	rheumatoid arthritis	Phase I/II (206) 623-7612
Tovaxin® autologous T-cell vaccine	Oprexa Therapeutics The Woodlands, TX	vaccine	multiple sclerosis	Phase II (281) 272-9331
TRX 1 (anti-CD4 mAb)	TolerRx Cambridge, MA	mAb	cutaneous lupus erythematosus	Phase I completed (617) 354-8100
ustekinumab (CNTO 1275)	Centocor Horsham, PA	mAb	multiple sclerosis (see also digestive, skin)	Phase II (610) 651-6000
VEL-0230	Velcura Therapeutics Ann Arbor, MI	cell therapy	rheumatoid arthritis (see also cancer, other)	Phase I (734) 973-1000
Veldona® human interferon-alpha (Orphan Drug)	Amarillo Biosciences Amarillo, TX	interferon	Sjögren's syndrome (see also blood, infectious, respiratory)	Phase III (806) 376-1741
			fibromyalgia	Phase II (806) 376-1741
veltuzumab (IMMU-106)	Immunomedics Morris Plains, NJ	mAb	immune thrombocytopenic purpura (see also cancer)	Phase I/II (973) 605-8200
Zenapax® daclizumab	PDL BioPharma Fremont, CA Biogen Idec Cambridge, MA	mAb	multiple sclerosis (see also respiratory, transplantation)	Phase II (510) 574-1400 (617) 679-2000

BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
anti-fibrin monoclonal antibody 3B6/22 Tc 99m	AGEN Biomedical <i>Queensland, Australia</i>	mAb	diagnostic imaging of blood clots	Phase II www.agenix.com
Arcalyst™ rilonacept	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	recombinant fusion protein	inflammation of anemia (see also other)	Phase II (914) 345-7400
ART-123	Artisan Pharma <i>Waltham, MA</i>	recombinant protein	disseminated intravascular coagulation	Phase II (781) 419-1919
BAY-794980	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	recombinant protein	hemophilia A	Phase II (888) 842-2937
Bosatria™ mepolizumab (anti-IL5 mAb) (Orphan Drug)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	hypereosinophilic syndrome (see also respiratory)	Phase III (888) 825-5249
			eosinophilic esophagitis	Phase I/II (888) 825-5249
ecallantide (DX-88)	Cubist Pharmaceuticals <i>Lexington, MA</i> Dyax <i>Cambridge, MA</i>	recombinant protein	blood loss in patients undergoing coronary artery bypass graft, bypass grafting procedures (see also genetic)	Phase II (617) 225-2500
INSC01	Inseption Biosciences <i>Mississauga, Ontario</i>	stem cell therapy	hematologic disorders	Phase I/II (866) 606-2790
NN-7128	Neose Technologies <i>Horsham, PA</i> Novo Nordisk <i>Princeton, NJ</i>	recombinant protein	hemophilia	Phase I (215) 315-9000
PHP (pyridoxalated hemoglobin polyoxyethylene)	Curacyte <i>Chapel Hill, NC</i>	nitric oxide scavenger	septic shock (see also cancer)	Phase III (919) 405-4002
recombinant erythropoietin	EMD Serono <i>Rockland, MA</i>	recombinant erythropoietin	anemia	Phase I (800) 238-8088
recombinant factor IX-Fc	Syntonic Pharmaceuticals <i>Waltham, MA</i>	recombinant fusion protein	hemophilia B	Phase I/II (781) 547-6000
recombinant human serum albumin	Mitsubishi Tanabe Pharma <i>Osaka, Japan</i>	recombinant protein	hypoalbuminemia	Phase I
Recothrom® thrombin alfa	Zymogenetics <i>Seattle, WA</i>	recombinant human thrombin	control bleeding during spinal and vascular surgery	Phase II (206) 442-6600
reslizumab (Orphan Drug)	Ception Therapeutics <i>Malvern, PA</i>	mAb	eosinophilia	Phase II/III (610) 640-2940

BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
RF-1010	Supergen <i>Dublin, CA</i>	growth factor	anemia, neutropenia	Phase II (925) 560-0100
rFX111	Novo Nordisk <i>Princeton, NJ</i>	recombinant enzyme	acquired or congenital factor XIII deficiency	Phase I (800) 727-6500
Segard™ afelimomab	Abbott Laboratories <i>Abbott Park, IL</i>	mAb	sepsis, septic shock	Phase III (847) 937-6100
talactoferrin alfa	Agennix <i>Houston, TX</i>	recombinant protein	sepsis (see also cancer, diabetes)	Phase II (713) 552-1091
urtoxazumab	Teijin Pharma <i>Tokyo, Japan</i>	mAb	hemolytic uremic syndrome	Phase I
Veldona® human interferon-alpha (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	polycythemia vera, thrombocytosis (see also autoimmune, infectious, respiratory)	Phase II (806) 376-1741

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
1018-ISS	Dynavax Technologies <i>Emeryville, CA</i>	DNA molecule	non-Hodgkin's lymphoma	Phase II (510) 848-5100
			colorectal cancer	Phase I (510) 848-5100
1572932A (mage 3)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant protein	non-small-cell lung cancer (NSCLC)	Phase III (888) 825-5249
			malignant melanoma	Phase II (888) 825-5249
3F8 mAb	United Therapeutics <i>Silver Spring, MD</i>	mAb	central nervous system cancer, leptomeningeal cancer, neuroblastoma	Phase II (301) 608-9292
8H9 I-131 mAb	United Therapeutics <i>Silver Spring, MD</i>	mAb	brain cancer	Phase I (301) 608-9292
A33	Life Science Pharmaceuticals <i>Greenwich, CT</i>	mAb	colorectal cancer	Phase I (203) 422-6500
abagovomab (Orphan Drug)	Menarini <i>Florence, Italy</i>	mAb	ovarian cancer	Phase II/III www.menarini.com
Ablvax™ VAX100	Breakthrough Therapeutics <i>Greenwich, CT</i>	peptide vaccine	chronic myeloid leukemia (CML)	Phase II
adecatumumab (MT-201)	EMD Serono <i>Rockland, MA</i> Micromet <i>Bethesda, MD</i>	mAb	breast cancer, prostate cancer	Phase II (800) 801-8088 (240) 752-1420

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Advexin® contusogene ladenovec (Orphan Drug)	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	head and neck cancer	application submitted (512) 708-9310
			breast cancer (combination therapy), NSCLC (combination therapy)	Phase II (512) 708-9310
			bladder cancer, bronchiolo-alveolar adenocarcinoma, glioblastoma, ovarian cancer, prostate cancer	Phase I (512) 708-9310
			Li-Fraumeni syndrome	in clinical trials (866) 631-4646
AE37	Antigen Express <i>Worcester, MA</i>	vaccine	breast cancer	Phase II (508) 852-8783
AEG 35156	Aegera Therapeutics <i>Montreal, Quebec</i> Idera Pharmaceuticals <i>Cambridge, MA</i>	antisense	acute myeloid leukemia (AML) (combination therapy)	Phase II (514) 288-5532 (617) 679-5500
aflibercept (VEGF trap)	Regeneron Pharmaceuticals <i>Tarrytown, NY</i> sanofi-aventis <i>Bridgewater, NJ</i>	recombinant fusion protein	second-line metastatic colorectal cancer, second-line NSCLC, ovarian cancer, first-line metastatic pancreatic cancer, first-line metastatic prostate cancer (see also eye)	Phase III (914) 345-7400 (800) 633-1610
AGS-003	Argos Therapeutics <i>Durham, NC</i> Kirin Pharma <i>Tokyo, Japan</i>	cell therapy	metastatic renal cancer	Phase I/II (919) 287-6300
AGS-005	Argos Therapeutics <i>Durham, NC</i> Kirin Pharma <i>Tokyo, Japan</i>	cell therapy	chronic lymphocytic leukemia (CLL)	Phase I/II (919) 287-6300
AGS-PSCA	Agensys <i>Santa Monica, CA</i> Merck <i>Whitehouse Station, NJ</i>	mAb	prostate cancer	Phase I (310) 820-8029 (800) 672-6372
Allovectin® velimogene aliplasmid (Orphan Drug)	Vical <i>San Diego, CA</i>	gene therapy	malignant melanoma	Phase III (858) 646-1100
ALT-801	Altor BioScience <i>Miramar, FL</i>	recombinant fusion protein	cancer	Phase I/II (954) 443-8600

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AME-133	Applied Molecular Evolution <i>San Diego, CA</i>	mAb	non-Hodgkin's lymphoma	Phase I/II (858) 597-4990
AMG 102	Amgen <i>Thousand Oaks, CA</i>	mAb	glioma, renal cancer ----- solid tumors	Phase II (805) 447-1000 Phase I (805) 447-1000
AMG 386	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	breast cancer, fallopian tube cancer, gastrointestinal cancer, ovarian cancer, peritoneal cancer, renal cancer	Phase II (805) 447-1000
AMG 479	Amgen <i>Thousand Oaks, CA</i>	mAb	breast cancer, sarcoma ----- pancreatic cancer	Phase II (805) 447-1000 Phase I/II (805) 447-1000
AMG 655	Amgen <i>Thousand Oaks, CA</i>	mAb	colorectal cancer, pancreatic cancer, sarcoma	Phase I/II (805) 447-1000
AMG 951 (Apo2L/TRIAL)	Amgen <i>Thousand Oaks, CA</i> Genentech <i>South San Francisco, CA</i>	recombinant protein	non-Hodgkin's lymphoma, NSCLC ----- colorectal cancer	Phase II (805) 447-1000 (650) 225-1000 Phase I (805) 447-1000 (650) 225-1000
amolimogene	Eisai Medical Research <i>Ridgefield Park, NJ</i>	vaccine	cervical dysplasia	Phase II/III (877) 873-4724
anti-CD3 activated T-cells	TransTarget <i>Mountain View, CA</i>	mAb	metastatic breast cancer	Phase I
anti-idiotypic cancer vaccine (105AD7)	Onyvox <i>London, England</i>	vaccine	prostate cancer	Phase II www.onyvox.com
anti-IGF-1R mAb	Genentech <i>South San Francisco, CA</i>	mAb	solid tumors	Phase I (650) 225-1000
anti-PEM mAb	Somanta Pharmaceuticals <i>Irvine, CA</i>	mAb	breast cancer	Phase I/II (949) 477-8090
Anyara naptumomab estafenatox (ABR-217620)	Active Biotech <i>Lund, Sweden</i>	mAb	NSCLC, pancreatic cancer, renal cancer	Phase I completed www.activebiotech.com

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
apomab	Genentech <i>South San Francisco, CA</i>	mAb	non-Hodgkin's lymphoma (combination therapy), NSCLC (combination therapy, late-stage disease), sarcoma	Phase II (650) 225-1000
			solid tumors	Phase I (650) 225-1000
Archexin™ RX-0201 (Orphan Drug)	Rexahn Pharmaceuticals <i>Rockville, MD</i>	antisense	late-stage renal cancer	Phase II (240) 268-5300
AS-1402	Antisoma <i>Princeton, NJ</i>	mAb	breast cancer	Phase I www.antisoma.com
atacept (TACI-Ig)	EMD Serono <i>Rockland, MA</i> Zymogenetics <i>Seattle, WA</i>	recombinant fusion protein	multiple myeloma (see also autoimmune)	Phase II (800) 275-7376 (206) 442-6000
			CLL, non Hodgkin's lymphoma	Phase I (800) 275-7376 (206) 442-6000
Aurimune™ (CYT-6091)	Cytimmune Sciences <i>Rockville, MD</i>	tumor necrosis factor	solid tumors	Phase I (240) 864-2796
Avastin® bevacizumab	Genentech <i>South San Francisco, CA</i>	mAb	colorectal cancer (adjunctive treatment), diffuse large B-cell lymphoma (first-line therapy), fallopian tube cancer, gastric cancer (combination therapy), gastrointestinal stromal tumors (GIST), ovarian cancer, pancreatic cancer (combination therapy, first-line therapy), peritoneal cancer, prostate cancer, renal cancer	Phase III (650) 225-1000
			metastatic brain cancer, glioblastoma, liver cancer, multiple myeloma (combination therapy), non-Hodgkin's lymphoma, pancreatic cancer, small-cell lung cancer (SCLC)	Phase II (650) 225-1000
			solid tumors	Phase I (650) 225-1000

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AVE1642 (anti-IGF-1R naked mAb)	sanofi-aventis <i>Bridgewater, NJ</i>	mAb	multiple myeloma, solid tumors	Phase I (800) 633-1610
AVE9633 (maytansin-loaded anti-CD33 mAb)	sanofi-aventis <i>Bridgewater, NJ</i>	mAb	AML	Phase I (800) 633-1610
AVR-118	Advanced Viral Research <i>Yonkers, NY</i>	immune-based therapy	cancer (see also diabetes, infectious, skin)	Phase II (914) 376-7383
AVX701	AlphaVax <i>Rsch. Triangle Park, NC</i>	vaccine	prevention of colorectal cancer	Phase I/II (919) 595-0400
bectumomab	Immunomedics <i>Morris Plains, NJ</i>	mAb	non-Hodgkin's lymphoma	Phase II (973) 605-8200
Bexxar [®] tositumomab	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	lymphoma, myeloablation ----- CLL	Phase II (888) 825-5249 Phase I (888) 825-5249
BIIB 022	Biogen Idec <i>Cambridge, MA</i>	mAb	solid tumors	Phase I (617) 679-2000
BiovaxID [™] B-cell lymphoma vaccine	Accentia Biopharmaceuticals <i>Morrisville, NC</i> Biovest International <i>Minneapolis, MN</i>	vaccine	non-Hodgkin's lymphoma	Phase III (877) 654-6052
BLX 883	Biolex Therapeutics <i>Pittsboro, NC</i>	interferon	cancer (see also infectious)	Phase I (919) 542-9901
BMS-663513 (anti-CD137 antibody)	Bristol-Myers Squibb <i>Princeton, NJ</i>	mAb	melanoma (second-line treatment)	in clinical trials (212) 546-4000
breast cancer vaccine	Quantum Immunologics <i>Tampa, FL</i>	dendritic cell vaccine	breast cancer	Phase I/II (866) 213-4594
BrevaRex [™] anti-MUC1 monoclonal antibody	ViRexx <i>Edmonton, Alberta</i>	mAb	breast cancer, multiple myeloma, pancreatic cancer	Phase I completed (780) 433-4411
CA9-scan	Wilex <i>Munich, Germany</i>	mAb	renal cancer (diagnosis)	Phase III www.wilex.com
cadi-05	Cadila Pharmaceuticals <i>Bhat, India</i>	vaccine	malignant melanoma ----- solid tumors	Phase I/II www. cadilapharma.com Phase I www. cadilapharma.com

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
cancer vaccine	Genzyme <i>Cambridge, MA</i>	cellular vaccine	breast cancer, malignant melanoma, renal cancer	Phase II (617) 252-7500
cancer vaccine	Mojave Therapeutics <i>Hawthorne, NY</i>	recombinant peptide vaccine	malignant melanoma	Phase I/II (914) 347-0290
CAT-8015	MedImmune <i>Gaithersburg, MD</i>	mAb	CLL, hairy cell leukemia, non-Hodgkin's lymphoma	Phase I (301) 398-0000
CD40 ligand	Amgen <i>Thousand Oaks, CA</i>	tumor necrosis factor	head and neck cancer, renal cancer ----- non-Hodgkin's lymphoma, solid tumors	Phase II (805) 447-1000 Phase I (805) 447-1000
CD154 gene therapy	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	gene therapy	CLL	Phase I (888) 842-2937
CDX-110 (Orphan Drug)	Pfizer <i>New York, NY</i> AVANT Immunotherapeutics <i>Needham, MA</i>	vaccine	newly diagnosed glioblastoma ----- brain cancer ----- solid tumors	Phase II/III (860) 732-5156 Phase II (860) 732-5156 Phase I (860) 732-5156
CDX-1307	AVANT Immunotherapeutics <i>Needham, MA</i>	mAb	bladder cancer, breast cancer, colorectal cancer, pancreatic cancer	Phase I (781) 433-0771
CG-201	CG Therapeutics <i>Seattle, WA</i>	protein vaccine	solid tumors	Phase II (206) 336-5604
chronic lymphocytic leukemia cell therapy	MaxCyte <i>Gaithersburg, MD</i>	cell therapy	CLL	Phase I/II (301) 944-1700
cintredekin besudotox (IL13-PE38QQR) (Orphan Drug)	NeoPharm <i>Lake Forest, IL</i>	recombinant protein	glioblastoma	Phase III (847) 295-8678
CLT 001	Cellerant Therapeutics <i>San Carlos, CA</i>	stem cell therapy	cancer	Phase II (650) 232-2122
CNTO-95	Centocor <i>Horsham, PA</i>	mAb	prostate cancer ----- malignant melanoma ----- solid tumors	Phase II (610) 651-6000 Phase I/II (610) 651-6000 Phase I completed (610) 651-6000

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Product Name	Sponsor	Product Category	Indication	Development Status
CNTO-328	Centocor <i>Horsham, PA</i>	mAb	hormone-refractory prostate cancer	Phase II (610) 651-6000
			renal cancer	Phase I (610) 651-6000
CNTO-888	Centocor <i>Horsham, PA</i>	mAb	solid tumors	Phase I (610) 651-6000
Cotara™ mAb TNT (Orphan Drug)	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	glioblastoma	Phase II (714) 508-6000
CovX 045	CovX Research <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	fusion protein	solid tumors	Phase I (860) 732-5156
CovX 060	CovX Research <i>San Diego, CA</i> Pfizer <i>New York, NY</i>	fusion peptide	cancer	Phase I (860) 732-5156
CP-751871	Pfizer <i>New York, NY</i>	mAb	breast cancer, prostate cancer	Phase II (860) 732-5156
			NSCLC	Phase I/II (860) 732-5156
			multiple myeloma, sarcoma	Phase I (860) 732-5156
CP-870893	Pfizer <i>New York, NY</i>	mAb	solid tumors	Phase I (860) 732-5156
CR011-vcMMAE	CuraGen <i>Branford, CT</i>	mAb	breast cancer, malignant melanoma	Phase II (888) 868-9026
CRS-207	Anza Therapeutics <i>Concord, CA</i>	vaccine	mesothelioma, NSCLC, ovarian cancer, pancreatic cancer	Phase I
CT-011	CureTech <i>Yavne, Israel</i>	mAb	B-cell lymphoma	Phase II www.curetechbio.com
CT-322	Bristol-Myers Squibb <i>Princeton, NJ</i>	adnectin	glioblastoma	Phase II (212) 546-4000
custirsen sodium (OGX-011)	Isis Pharmaceuticals <i>Carlsbad, CA</i> OncoGenex Technologies <i>Vancouver, British Columbia</i>	antisense	NSCLC	Phase I/II (760) 931-9200 (604) 736-3678
CYT-107	Cytheris <i>Rockville, MD</i>	interleukin	malignant melanoma, renal cancer (see also HIV)	Phase I/II (301) 231-0450
			myeloid leukemia, solid tumors	Phase I (301) 231-0450

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
CYT-500	Cytogen <i>Princeton, NJ</i>	mAb	prostate cancer	Phase I (800) 833-3533
dacetuzumab (anti-CD40 antibody) (Orphan Drug)	Genentech <i>South San Francisco, CA</i> Seattle Genetics <i>Bothell, WA</i>	mAb	diffuse large B-cell lymphoma ----- CLL ----- multiple myeloma	Phase II (650) 225-1000 ----- Phase I/II (650) 225-1000 ----- Phase I (650) 225-1000
DCVax®-Brain brain cancer vaccine (Orphan Drug)	Northwest Biotherapeutics <i>Bethesda, MD</i>	dendritic cell vaccine	glioblastoma	Phase II (240) 497-9024
DCVax®-L	Northwest Biotherapeutics <i>Bethesda, MD</i>	dendritic cell vaccine	ovarian cancer	Phase I/II (240) 497-9024
denosumab (AMG 162)	Amgen <i>Thousand Oaks, CA</i>	mAb	prevention and treatment of metastatic bone cancer, bone loss induced by hormone ablation therapy for breast or prostate cancer, multiple myeloma (see also autoimmune, other)	Phase III (805) 447-1000
Dimericine® T4N5 liposome lotion	AGI Dermatics <i>Freeport, NY</i>	liposome encapsulated DNA	skin cancer (see also skin)	Phase II (516) 868-9026
ecromeximab	Life Science Pharmaceuticals <i>Greenwich, CT</i>	mAb	malignant melanoma	Phase I/II (203) 422-6500
EGEN-001 (Orphan Drug)	Expression Genetics <i>Huntsville, AL</i>	interleukin	ovarian cancer	Phase I (256) 512-0077
elotuzumab	PDL BioPharma <i>Fremont, CA</i>	mAb	multiple myeloma (combination therapy) ----- multiple myeloma	Phase I/II (510) 574-1400 ----- Phase I (510) 574-1400
EMD 273063	EMD Lexigen Pharmaceuticals <i>Billerica, MA</i>	mAb	malignant melanoma, neuroblastoma	Phase II (978) 294-1100
EMD 6407744	EMD Serono <i>Rockland, MA</i>	peptide vaccine	solid tumors	Phase I/II (800) 283-8088
Epstein-Barr virus vaccine	MedImmune <i>Gaithersburg, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	post-transplant lymphoproliferative disorder (see also infectious)	Phase II (301) 398-0000 (888) 825-5249

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Erbix™ cetuximab	Bristol-Myers Squibb <i>Princeton, NJ</i> ImClone Systems <i>New York, NY</i>	mAb	NSCLC, adjuvant colorectal cancer, first-line colorectal cancer, second-line colorectal cancer, solid tumors	Phase III (212) 546-4000
farletuzumab (MORAb-003) (Orphan Drug)	Ludwig Institute for Cancer Research <i>New York, NY</i> Morphotek <i>Exton, PA</i>	mAb	ovarian cancer	Phase II (877) 873-4724
Fibrovax™ cancer vaccine	Cytokine PharmaSciences <i>King of Prussia, PA</i>	vaccine	cancer	Phase I (610) 687-1776
galiximab (anti-CD80 mAb)	Biogen Idec <i>Cambridge, MA</i>	mAb	non-Hodgkin's lymphoma	Phase III (617) 679-2000
GC-1008	Genzyme <i>Cambridge, MA</i> MedImmune <i>Gaithersburg, MD</i>	mAb	malignant melanoma, renal cancer (see also respiratory, other)	Phase I (617) 252-7500 (301) 398-0000
Genasense® oblimersen	Centa <i>Berkeley Heights, NJ</i>	antisense	CLL (combination therapy)	application submitted (908) 286-9800
			AML, malignant melanoma (combination therapy)	Phase III (908) 286-9800
			NSCLC (combination therapy)	Phase II/III (908) 286-9800
			breast cancer, non-Hodgkin's lymphoma	Phase II (908) 286-9800
			solid tumors (brief, high-dose IV-fusion)	Phase I/II (908) 286-9800
			solid tumors (intermittent therapy)	Phase I (908) 286-9800
GliAtak™ cancer gene therapy	Advantagene <i>Boston, MA</i> <i>San Diego, CA</i>	gene therapy	brain cancer	Phase I/II (617) 916-5445 (760) 943-8981
GVAX® Breast cancer immunotherapy	Cell Genesys <i>South San Francisco, CA</i>	genetically- modified vaccine	breast cancer	Phase I (650) 266-3000
GVAX® Leukemia cancer immunotherapy	Cell Genesys <i>South San Francisco, CA</i>	genetically- modified vaccine	AML, CML	Phase II (650) 266-3000
			myelodysplastic syndromes	Phase I (650) 266-3000

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Product Name	Sponsor	Product Category	Indication	Development Status
GVAX® Pancreatic cancer immunotherapy	Cell Genesys <i>South San Francisco, CA</i>	genetically-modified vaccine	pancreatic cancer	Phase II (650) 266-3000
GVAX® Prostate cancer immunotherapy	Cell Genesys <i>South San Francisco, CA</i>	genetically-modified vaccine	prostate cancer	Phase III (650) 266-3000
Her2/neu breast cancer vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	treatment of breast cancer	Phase I/II (888) 835-5249
Herceptin® trastuzumab	Genentech <i>South San Francisco, CA</i>	mAb	gastric cancer	Phase III (650) 225-1000
			colorectal cancer, ovarian cancer, pancreatic cancer, prostate cancer, salivary gland cancer	Phase II (650) 225-1000
HGS-ETR1 (mapatumumab)	Human Genome Sciences <i>Rockville, MD</i>	mAb	multiple myeloma, (combination therapy) non-Hodgkin's lymphoma, NSCLC	Phase II www.hgsi.com
			solid tumors	Phase I/II www.hgsi.com
HGS-ETR2 (lexatumumab)	Human Genome Sciences <i>Rockville, MD</i>	mAb	solid tumors	Phase I www.hgsi.com
HRC 302	Hemosol BioPharma <i>Mississauga, Ontario</i>	cell therapy	CML	Phase I (905) 286-6200
HuC242-DM4 (IMGN 242)	ImmunoGen <i>Cambridge, MA</i>	mAb	metastatic gastric cancer (second-line therapy)	Phase II (617) 995-2500
			solid tumors	Phase I (617) 995-2500
HuMax-CD4™ zanolimumab (Orphan Drug)	Genmab <i>Princeton, NJ</i>	mAb	cutaneous T-cell lymphoma	Phase III (609) 430-2481
			non-cutaneous T-cell lymphoma	Phase II (609) 430-2481
HuMax-CD20 (ofatumumab)	Genmab <i>Princeton, NJ</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	CLL (second-line therapy), non-Hodgkin's lymphoma (second-line therapy) (see also autoimmune)	Phase III (609) 430-2481 (888) 825-5249
			CLL (first-line therapy), non-Hodgkin's lymphoma (first-line therapy)	Phase II (609) 430-2481 (888) 825-5249
HuMax-EGFr (zalutumumab)	Genmab <i>Princeton, NJ</i>	mAb	head and neck cancer, NSCLC	Phase II (609) 430-2481

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Product Name	Sponsor	Product Category	Indication	Development Status
huN901-DM1	ImmunoGen <i>Cambridge, MA</i>	mAb conjugate	SCLC	Phase II (617) 995-2500
			multiple myeloma, solid tumors	Phase I (617) 995-2500
HyperAcute® Lung lung cancer vaccine	NewLink Genetics <i>Ames, IA</i>	vaccine	NSCLC	Phase I/II (515) 296-5555
HyperAcute® Melanoma lung cancer vaccine	NewLink Genetics <i>Ames, IA</i>	vaccine	malignant melanoma	Phase I/II (515) 296-5555
HyperAcute® Pancreas pancreatic cancer vaccine	NewLink Genetics <i>Ames, IA</i>	vaccine	pancreatic cancer	Phase I/II (515) 296-5555
HyperAcute® Prostate lung cancer vaccine	NewLink Genetics <i>Ames, IA</i>	vaccine	prostate cancer	Phase I/II (515) 296-5555
iboctadekin	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant human cytokine	non-Hodgkin's lymphoma (combination therapy)	Phase I (888) 825-5249
ICT-107	ImmunoCellular Therapeutics <i>Los Angeles, CA</i>	dendritic cell vaccine	glioblastoma	Phase I (818) 992-2907
IDM-2101	IDM Pharma <i>Irvine, CA</i>	vaccine	NSCLC	Phase II (949) 470-4751
			colorectal cancer	Phase I/II (949) 470-4751
IL-2/EP (VCL-IMO1)	Vical <i>San Diego, CA</i>	gene therapy	malignant melanoma	Phase I (888) 646-1100
IL-21 (Orphan Drug)	Zymogenetics <i>Seattle, WA</i>	interleukin	renal cancer (combination therapy)	Phase II (206) 442-6600
			malignant melanoma, ovarian cancer	Phase I/II (206) 442-6600
			colorectal cancer (combination therapy), metastatic malignant melanoma, metastatic renal cancer, non-Hodgkin's lymphoma (combination therapy)	Phase I (206) 442-6600

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Product Name	Sponsor	Product Category	Indication	Development Status
IMC-3G3 (PDGFRa)	ImClone Systems New York, NY	mAb	solid tumors	Phase I (212) 645-1405
IMC-18F1 (VEGFR-1)	ImClone Systems New York, NY	mAb	cancer	Phase I (212) 645-1405
IMC-1121b (VEGFR-2/KDR)	ImClone Systems New York, NY	mAb	liver cancer, metastatic malignant melanoma, metastatic renal cell cancer	Phase II (212) 645-1405
IMC-A12 (IGF-1R)	ImClone Systems New York, NY	mAb	colorectal cancer, head and neck cancer, liver cancer, prostate cancer, soft tissue sarcoma	Phase II (212) 645-1405
			pancreatic cancer (combination therapy, first-line therapy), solid tumors in adolescents and children	Phase I/II (212) 645-1405
			lymphoma (combination therapy), solid tumors (combination therapy)	Phase I (212) 645-1405
IMMU-102 (epratuzumab Y-90)	Immunomedics Morris Plains, NJ	mAb	non-Hodgkin's lymphoma	Phase I/II (973) 605-8200
IMMU-105 (tacatuzumab Y-90)	Immunomedics Morris Plains, NJ	mAb	liver cancer	Phase I (973) 605-8200
IMMU-107 (hPAM4 Y-90) (Orphan Drug)	Immunomedics Morris Plains, NJ	mAb	pancreatic cancer (combination therapy, first-line therapy)	Phase I/II (973) 605-8200
IMMU-111 (labetuzumab I-131)	Immunomedics Morris Plains, NJ	mAb	colorectal cancer	Phase II (973) 605-8200
IMT-1012	Immunotrope Doylestown, PA ImmunoVaccine Technologies Halifax, Nova Scotia	immuno-therapeutic vaccine	breast cancer, ovarian cancer	Phase I (215) 253-4180 (902) 492-1819
ING-1	Aduro Biotech Berkeley, CA	mAb	adenocarcinoma	Phase I (510) 848-4400
INGN 225 (p53 immunotherapy)	Introgen Therapeutics Austin, TX	dendritic cell vaccine	SCLC	Phase II (512) 708-9310
			breast cancer	Phase I/II (512) 708-9310

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Product Name	Sponsor	Product Category	Indication	Development Status
INGN 241 (mda-7 gene therapy)	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	head and neck cancer (combination therapy)	Phase III (512) 708-9310
			malignant melanoma	Phase II (512) 708-9310
			solid tumors	Phase I/II (512) 708-9310
INGN 401 (FUS-1 gene therapy)	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	NSCLC	Phase I (512) 708-9310
INNO-305 immunotherapeutic	INNOVIVE Pharmaceuticals <i>New York, NY</i>	peptide vaccine	AML, myelodysplastic syndromes, solid tumors	Phase I (212) 716-1811
inotuzumab ozogamicin (CMC-544)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	mAb	non-Hodgkin's lymphoma (combination therapy)	Phase III (800) 934-5556
IPH 2101 (NN 1975)	Innate Pharma <i>Marseille, France</i> Novo Nordisk <i>Princeton, NJ</i>	mAb	multiple myeloma	Phase I (609) 987-5800
ISF35	Memgen <i>Dallas, TX</i>	gene therapy	CLL	Phase I (214) 731-3141
KRN-330	Kirin Pharma USA <i>La Jolla, CA</i>	mAb	solid tumors	Phase I (858) 952-7000
L19-1311	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Philogen <i>Siena, Italy</i>	mAb	solid tumors	Phase I/II (888) 842-2937
			hematological malignancies	Phase I (888) 842-2937
L19-IL2 fusion protein	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Philogen <i>Siena, Italy</i>	recombinant fusion protein	malignant melanoma (combination therapy), pancreatic cancer (combination therapy), renal cancer	Phase II (888) 842-2937
L19-TNF	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Philogen <i>Siena, Italy</i>	recombinant fusion protein	colorectal cancer	Phase I (888) 842-2937
LE-SN38	NeoPharm <i>Lake Forest, IL</i>	liposome	colorectal cancer (second-line therapy)	Phase II (847) 295-8678
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte- macrophage colony stimulating factor	malignant melanoma (see also autoimmune, HIV/AIDS, infectious, respiratory, skin, other)	Phase III (888) 842-2937
			non-Hodgkin's lymphoma, prostate cancer	Phase II (888) 842-2937

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Product Name	Sponsor	Product Category	Indication	Development Status
lintuzumab Ac-225	Actinium Pharmaceuticals <i>Florham Park, NY</i>	mAb	AML	Phase I (973) 377-0713
lintuzumab Bi-213	Actinium Pharmaceuticals <i>Florham Park, NY</i>	mAb	AML	Phase I/II (973) 377-0713
LOR-2040 (Orphan Drug)	Lorus Therapeutics <i>Toronto, Ontario</i>	antisense	AML, metastatic breast cancer, colorectal cancer, metastatic renal cancer	Phase II (416) 798-1200
			CML, myelodysplastic syndromes	Phase I (416) 798-1200
Lucanix™ belagen- pumatu- cel-L	NovaRx <i>San Diego, CA</i>	genetically- modified vaccine	NSCLC	Phase II (858) 552-8600
			brain cancer	Phase I (858) 552-8600
lucatumumab (CHIR 12.12)	Novartis Pharmaceuticals <i>East Hanover, NJ</i> XOMA <i>Berkeley, CA</i>	mAb	lymphoma	Phase I/II (888) 669-6682 (510) 204-7200
			CLL, multiple myeloma	Phase I (888) 669-6682 (510) 204-7200
lumiliximab (anti-CD23 mAb) (Orphan Drug)	Biogen Idec <i>Cambridge, MA</i>	mAb	CLL	Phase II/III (617) 679-2000
LungVax®	AVAX Technologies <i>Philadelphia, PA</i>	cell vaccine	NSCLC	Phase I/II (215) 241-9760
LY 2181308	Eli Lilly <i>Indianapolis, IN</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	AML	Phase II (800) 545-5979 (800) 679-4747
			solid tumors	Phase I (800) 545-5979 (800) 679-4747
LY 2275796	Eli Lilly <i>Indianapolis, IN</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	solid tumors	Phase I (800) 545-5979 (800) 679-4747
LymphoCide® epratuzumab (Orphan Drug)	Immunomedics <i>Morris Plains, NJ</i> UCB <i>Smyrna, GA</i>	mAb	ALL in children, non-Hodgkin's lymphoma (see also autoimmune)	Phase II (973) 605-8200
MAXY-G34	Maxygen <i>Redwood City, CA</i>	granulocyte colony stimulating factor	chemotherapy-induced neutropenia	Phase I (650) 298-5300

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Product Name	Sponsor	Product Category	Indication	Development Status
MDX-010 (ipilimumab) (Orphan Drug)	Bristol-Myers Squibb <i>Princeton, NJ</i> Medarex <i>Princeton, NJ</i>	mAb	adjuvant melanoma, metastatic melanoma	Phase III (212) 546-4000
			-----	-----
			solid tumors	Phase II (212) 546-4000
MDX-060 (iratumumab) (Orphan Drug)	Medarex <i>Princeton, NJ</i>	mAb	Hodgkin's disease, lymphoma, non-Hodgkin's lymphoma	Phase II (609) 430-2880
MDX-1106	Medarex <i>Princeton, NJ</i>	mAb	solid tumors (see also infectious)	Phase I (609) 430-2880
MDX-1307	Medarex <i>Princeton, NJ</i>	mAb	solid tumors	Phase I (609) 430-2880
MDX-1401	Medarex <i>Princeton, NJ</i>	mAb	Hodgkin's disease	Phase I (609) 430-2880
melanoma vaccine	Ichor Medical Systems <i>San Diego, CA</i>	DNA vaccine	malignant melanoma	Phase I (858) 550-2022
melanoma vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	melanoma (stage III and IV)	Phase I/II (570) 839-7187
milatuzumab (IMMU-115) (Orphan Drug)	Immunomedics <i>Morris Plains, NJ</i>	mAb	multiple myeloma	Phase I/II (973) 605-8200
			-----	-----
			CLL, non-Hodgkin's lymphoma	Phase I (973) 605-8200
MKC1106-MT	Mannkind <i>Valencia, CA</i>	vaccine	malignant melanoma (treatment)	Phase I (661) 775-5300
MKC1106-PP	Mannkind <i>Valencia, CA</i>	vaccine	solid tumors (treatment)	Phase I (661) 775-5300
MORAb-009 (Orphan Drug)	Morphotek <i>Exton, PA</i>	mAb	mesothelioma, pancreatic cancer	Phase II (877) 873-4724
Multikine® leukocyte interleukin (Orphan Drug)	CEL-SCI <i>Vienna, VA</i>	interleukin	cervical cancer, cervical dysplasia, head and neck cancer	Phase II (703) 506-9460
MVA-BN® Breast	BN ImmunoTherapeutics <i>Mountain View, CA</i>	cell vaccine	breast cancer	Phase I/II (650) 681-4660
MVA-BN®-PRO	BN ImmunoTherapeutics <i>Mountain View, CA</i>	vaccine	prostate cancer	Phase I/II (650) 681-4660
MVax®	AVAX Technologies <i>Philadelphia, PA</i>	cell vaccine	malignant melanoma	Phase III (215) 241-9760
mycobacterium cell wall-DNA complex (MCC)	Bioniche Life Sciences <i>Belleville, Ontario</i>	mycobacterial DNA	superficial (non-muscle invasive) bladder cancer (second-line therapy)	Phase III (800) 265-5464
Neumega® oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	interleukin	chemotherapy-induced mucositis (see also autoimmune, digestive, transplantation)	Phase II (800) 934-5556

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Product Name	Sponsor	Product Category	Indication	Development Status
Neuradiab™ anti-tenascin mAb (Orphan Drug)	Bradmer Pharmaceuticals <i>Louisville, KY</i>	mAb	newly diagnosed glioblastoma (adjunctive therapy)	Phase III (502) 657-6038
NeuVax™ E75 cancer vaccine	Apthera <i>Scottsdale, AZ</i>	vaccine	breast cancer	Phase II (480) 348-9707
			prostate cancer	Phase I/II (480) 348-9707
Neuvenge™ lapuleucel-T	Dendreon <i>Seattle, WA</i>	dendritic cell vaccine	breast, colorectal, ovarian cancers	Phase I (206) 256-4545
Nplate™ romiplostim	Amgen <i>Thousand Oaks, CA</i>	recombinant fusion protein	myelodysplastic syndromes, thrombocytopenia associated with chemotherapy (see also autoimmune)	Phase II (805) 447-1000
NU206	Nuvelo <i>San Carlos, CA</i>	recombinant protein	cancer, chemotherapy- and radiotherapy-induced mucositis (see also digestive)	Phase I (650) 517-8000
NY-ESO-1 cancer vaccine	PowderMed (Pfizer) <i>Oxford, United Kingdom</i>	vaccine	NSCLC	Phase I (860) 732-5156
Omnitarg™ pertuzumab	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i>	mAb	metastatic breast cancer (first-line therapy)	Phase III (650) 225-1000
			ovarian cancer	Phase II completed (650) 225-1000
Onconase® ranpirnase	Alfacell <i>Somerset, NJ</i>	ribonuclease	mesothelioma (combination therapy)	Phase III (732) 652-4525
			NSCLC	Phase I/II (732) 652-4525
Oncophage™ vitespen (Orphan Drug)	Antigenics <i>New York, NY</i>	heat shock protein	metastatic melanoma	Phase III (781) 674-4400
			glioma, renal cancer	Phase II (781) 674-4400
OncoVAX® colorectal cancer vaccine	Vaccinogen <i>Frederick, MD</i>	cell vaccine	colorectal cancer	Phase I/II (301) 668-8400
OncoVEX®	BioVex <i>Woburn, MA</i>	gene therapy	malignant melanoma	Phase II (781) 376-4900
			pancreatic cancer	Phase I (781) 376-4900
ONTAK® denileukin diftitox	Eisai Medical Research <i>Ridgefield Park, NJ</i>	interleukin	peripheral T-cell lymphoma	Phase II/III (877) 873-4724

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Product Name	Sponsor	Product Category	Indication	Development Status
Onyvox™P	Onyvox <i>London, United Kingdom</i>	cell vaccine	prostate cancer	Phase II www.onyvox.com
OPT-822	Optimer Pharmaceuticals <i>San Diego, CA</i>	vaccine	breast cancer	Phase I (858) 909-0736
OvaRex® oregovomab (Orphan Drug)	ViRexx <i>Edmonton, Alberta</i>	mAb	ovarian cancer	Phase III (780) 433-4411
OVax®	AVAX Technologies <i>Philadelphia, PA</i>	cell vaccine	ovarian cancer	Phase I/II (215) 241-9760
PancAtak™ cancer gene therapy	Advantagene <i>Boston, MA</i> <i>San Diego, CA</i>	gene therapy	pancreatic cancer	Phase I (617) 916-5445 (760) 943-8981
Pegasys® peginterferon alfa-2a	Roche <i>Nutley, NJ</i>	interferon	cancer metastases, renal cancer (see also HIV/AIDS)	Phase II (973) 235-5000
			neurofibromatoses	Phase I (973) 235-5000
PEG-IntronA® peginterferon alfa-2b	Schering-Plough <i>Kenilworth, NJ</i>	interferon	malignant melanoma (adjunctive therapy)	application submitted (908) 298-4000
			CML	Phase II (908) 298-4000
PF-3446962	Pfizer <i>New York, NY</i>	mAb	cancer	Phase I (860) 732-5156
PF-3732010	Pfizer <i>New York, NY</i>	mAb	cancer	Phase I (860) 732-5156
PHP (pyridoxalated hemoglobin polyoxyethylene)	Curacyte <i>Chapel Hill, NC</i>	nitric oxide scavenger	malignant melanoma (see also blood)	Phase II (919) 405-4002
PR1 cancer vaccine	The Vaccine Company <i>South San Francisco, CA</i>	peptide vaccine	AML	Phase III (650) 244-4100
			CML, myelodysplastic syndromes	Phase II (650) 244-4100
Procrit® epoetin alfa	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	recombinant erythropoietin	neuroprotection in chemotherapy-induced peripheral neuropathy	Phase II (800) 817-5286
Proleukin® aldesleukin (Orphan Drug)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	interleukin	AML (see also HIV/AIDS)	Phase III (888) 669-6682
			cancer	Phase II (888) 669-6682

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
ProMune® agatolimod (PF-3512676)	Pfizer <i>New York, NY</i>	oligonucleotide	NSCLC (combination therapy)	Phase III (860) 732-5156
			breast cancer	Phase I/II (860) 732-5156
ProstAtak™ cancer gene therapy	Advantagene <i>Boston, MA</i> <i>San Diego, CA</i>	gene therapy	prostate cancer	Phase II (617) 916-5445 (760) 943-8981
			prostate cancer subunit vaccine	Phase I (914) 789-2800
prostate cancer vaccine	Cosmo Bioscience <i>San Diego, CA</i>	vaccine	prostate cancer	Phase II (858) 535-9141
prostate cancer vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i> Pepscan Therapeutics <i>Lelystad, The Netherlands</i>	vaccine	prostate cancer (treatment)	Phase I/II (888) 669-6682
prostate cancer vaccine	YM Biosciences <i>Mississauga, Ontario</i>	vaccine	prostate cancer	Phase II (905) 629-9761
Prostvac®-VF recombinant vaccinia virus- expressing PSA	Therion Biologics <i>Cambridge, MA</i>	recombinant vaccine	prostate cancer	Phase II (617) 876-7779
Provenge® sipuleucel-T	Dendreon <i>Seattle, WA</i>	dendritic cell vaccine	prostate cancer (hormone refractory, metastatic disease)	application submitted (206) 256-4545
			prostate cancer (non-metastatic, androgen-dependent disease)	Phase III (206) 256-4545
Proxinium™ VB4845 (Orphan Drug)	Viventia Biotech <i>Mississauga, Ontario</i>	mAb	bladder cancer, head and neck cancer	Phase II (905) 361-8686
PRX-321 (Orphan Drug)	Protox Therapeutics <i>Vancouver,</i> <i>British Columbia</i>	recombinant fusion protein	glioblastoma	Phase II (604) 688-0199
			solid tumors	Phase I completed (604) 688-0199
R 1507	Genmab <i>Princeton, NJ</i> Roche <i>Nutley, NJ</i>	mAb	sarcoma	Phase II (973) 235-5000
			solid tumors	Phase I (973) 235-5000
RAV12	Raven Biotechnologies <i>South San Francisco, CA</i>	mAb	pancreatic cancer (combination therapy)	Phase II (650) 624-2600
			adenocarcinoma	Phase I/II (650) 624-2600

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Remicade® infliximab	Centocor <i>Horsham, PA</i>	mAb	cachexia in patients with pancreatic cancer (see also autoimmune, respiratory)	Phase II (610) 651-6000
Rencarex® WX G250 (Orphan Drug)	Wilex <i>Munich, Germany</i>	mAb	non-metastatic, clear-cell renal cell cancer	Phase III www.wilex.com
Reximmune-C™	Epeius Biotechnologies <i>San Marino, CA</i>	gene therapy	breast cancer	Phase I/II (626) 441-6695
Rexin-G™	Epeius Biotechnologies <i>San Marino, CA</i>	gene therapy	osteosarcoma	Phase II (626) 441-6695
			metastatic breast cancer, pancreatic cancer, sarcoma	Phase I/II (626) 441-6695
rhIGFBP-3 (rinfabate)	Insmed <i>Glen Allen, VA</i>	recombinant protein	solid tumors	Phase I completed (804) 565-3000
RIGScan® CR49 radiodiagnostic agent	Neoprobe <i>Dublin, OH</i>	mAb	diagnosis of colorectal cancer	Phase III (800) 793-0079
Rituxan® rituximab	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	mAb	CLL (see also autoimmune, skin)	Phase III (650) 225-1000 (617) 679-2000
RO 5083945	Roche <i>Nutley, NJ</i>	mAb	solid tumors	Phase I (973) 235-5000
SAR3419 (maytansin-loaded anti-CD19 mAb)	sanofi-aventis <i>Bridgewater, NJ</i>	mAb	non-Hodgkin's lymphoma	Phase I (800) 633-1610
SCH 58500 (p53 gene therapy)	Schering-Plough <i>Kenilworth, NJ</i>	gene therapy	NSCLC	Phase II (908) 298-4000
			bladder cancer, head and neck cancer, liver cancer, myeloablation	Phase I (908) 298-4000
SCH 717454	Schering-Plough <i>Kenilworth, NJ</i>	mAb	colorectal cancer, osteosarcoma, sarcoma	Phase II (908) 298-4000
SCH 721015	Schering-Plough <i>Kenilworth, NJ</i>	gene therapy	bladder cancer	Phase I (908) 298-4000
SGN-30 (anti-CD30) (Orphan Drug)	Seattle Genetics <i>Bothell, WA</i>	mAb	cutaneous T-cell lymphoma, Hodgkin's disease	Phase II (425) 527-4000
SGN-33 (lintuzumab) (Orphan Drug)	Seattle Genetics <i>Bothell, WA</i>	mAb	AML (combination therapy in elderly patients)	Phase II (425) 527-4000
			myelodysplastic syndromes	Phase I (425) 527-4000

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
SGN-35 (cAC10-vcMMAE) (Orphan Drug)	Seattle Genetics <i>Bothell, WA</i>	mAb	hematological malignancies	Phase I (425) 527-4000
sibrotuzumab	Life Science Pharmaceuticals <i>Greenwich, CT</i>	mAb	colorectal cancer, head and neck cancer, NSCLC	Phase II (203) 422-6500
SL-401	Stemline Therapeutics <i>New York, NY</i>	recombinant fusion protein	AML	Phase I/II (212) 831-1111
SPC-2996	Santaris Pharma <i>Horsholm, Denmark</i>	antisense	CLL	Phase I/II www.santaris.com
StemEx [®] hematopoietic stem cell therapy	Gamida Cell <i>Jerusalem, Israel</i> Teva Pharmaceutical <i>North Wales, PA</i>	stem cell therapy	hematological malignancies	Phase II/III (215) 591-3000
Stimuvax [®] liposomal cancer vaccine	Oncothyreon <i>Bellevue, WA</i>	vaccine	NSCLC	Phase III (425) 450-0370
talactoferrin alfa (Orphan Drug)	Agennix <i>Houston, TX</i>	recombinant protein	NSCLC, renal cancer (see also blood, diabetes)	Phase II (713) 552-1091
TALL-104	Abiogen Pharma <i>Pisa, Italy</i> Fred Hutchinson Cancer Research Center <i>Seattle, WA</i>	cell therapy	CML	Phase II www.abiogen.it
Tarvacin [™] bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	solid tumors (see also HIV/AIDS, infectious)	Phase I (714) 508-6000
TB-403	Roche <i>Nutley, NJ</i>	mAb	cancer (see also eye)	Phase I (973) 235-5000
T-cell gene therapy	Immunomedics <i>Morris Plains, NJ</i>	gene therapy	colorectal cancer	Phase I (973) 605-8200
TG 1042 (adenovirus IFN gamma)	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene therapy	cutaneous B-cell lymphoma	Phase II (301) 816-5404
TG 4001 (MVA HPV IL2)	Roche <i>Nutley, NJ</i> Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene vaccine	cervical intraepithelial neoplasia	Phase II (973) 235-5000 (301) 816-5404
TG 4010 (MVA MUC1 IL2)	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene vaccine	lung cancer	Phase I (301) 816-5404

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
TheraCIM nimotuzumab (Orphan Drug)	YM Biosciences <i>Mississauga, Ontario</i>	mAb	cervical cancer (first-line therapy), glioma in children, esophageal cancer, hormone-refractory prostate cancer (first-line therapy)	Phase II (905) 629-9761
			breast cancer (refractory disease)	Phase I (905) 629-9761
ticilimumab (CP-675206)	Pfizer <i>New York, NY</i>	mAb	colorectal cancer, NSCLC, prostate cancer	Phase II (860) 732-5156
			renal cancer	Phase I (860) 732-5156
tigatuzumab (CS-1008)	Daiichi Sankyo <i>Parsippany, NJ</i>	mAb	pancreatic cancer	Phase II (973) 359-2600
			lymphoma, solid tumors	Phase I completed (973) 359-2600
TNFerade™ tumor necrosis factor-alpha gene therapy	GenVec <i>Gaithersburg, MD</i>	gene therapy	pancreatic cancer	Phase III (877) 943-6832
			colorectal cancer, esophageal cancer, malignant melanoma,	Phase II (877) 943-6832
			head and neck cancer	Phase I/II (877) 943-6832
TNX-650	Tanox <i>Houston, TX</i>	mAb	Hodgkin's disease (see also respiratory)	Phase I (713) 578-4000
TRC-093	TRACON Pharmaceuticals <i>San Diego, CA</i>	mAb	solid tumors	Phase I (858) 550-0780
TRC-105	TRACON Pharmaceuticals <i>San Diego, CA</i>	mAb	cancer	Phase I (858) 550-0780
TroVax® (SAR109659)	Oxford BioMedica <i>Oxford, United Kingdom</i> sanofi-aventis <i>Bridgewater, NJ</i>	gene vaccine	renal cancer	Phase III (800) 633-1610
tucotuzumab celmoleukin	EMD Lexigen <i>Billerica, MA</i>	fusion protein	colorectal, NSCLC, ovarian, prostate, SCLC, cancers	Phase II (978) 294-1100
Uvidem™ IDD-3	IDM Pharma <i>Irvine, CA</i>	dendritic cell vaccine	malignant melanoma	Phase II (949) 470-4751
V505	Merck <i>Whitehouse Station, NJ</i>	vaccine	cervical cancer (see also infectious)	Phase II (800) 672-6372
V930	Merck <i>Whitehouse Station, NJ</i> Vical <i>San Diego, CA</i>	vaccine	cancer	Phase I (800) 672-6372 (858) 646-1100

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Vectibix® panitumumab	Amgen <i>Thousand Oaks, CA</i>	mAb	head and neck cancer	Phase III (510) 608-6500 (805) 447-1000
			NSCLC	Phase II (510) 608-6500 (805) 447-1000
veglin (VEGF antisense)	VasGene Therapeutics <i>Los Angeles, CA</i>	antisense	cancer, Kaposi's sarcoma	Phase I (323) 221-7818
VEL-0230	Velcura Therapeutics <i>Ann Arbor, MI</i>	cell therapy	multiple myeloma (see also autoimmune, other)	Phase I (734) 973-1000
veltuzumab (IMMU-106)	Immunomedics <i>Morris Plains, NJ</i>	mAb	non-Hodgkin's lymphoma (see also autoimmune)	Phase I/II (973) 605-8200
verpasep caltespen (HspE7)	Nventa Biopharmaceuticals <i>San Diego, CA</i>	recombinant vaccine	cervical intraepithelial neoplasia	Phase I (858) 202-4900
volociximab	PDL BioPharma <i>Fremont, CA</i> Biogen Idec <i>Cambridge, MA</i>	mAb	malignant melanoma, NSCLC (combination therapy), ovarian cancer (combination therapy), pancreatic cancer (combination therapy)	Phase II (510) 574-1400 (617) 679-2000
Voraxaze™ glucarpidase (Orphan Drug)	Protherics <i>Brentwood, TN</i>	recombinant enzyme	chemoprotection	Phase III (615) 327-1027
XmAb™2513	Xencor <i>Monrovia, CA</i>	mAb	Hodgkin's disease, T-cell lymphoma	Phase I (626) 305-5900
ZRx-101	ZelleRx <i>Chicago, IL</i>	cell therapy	malignant melanoma, multiple myeloma, renal cancer (see also transplantation)	Phase I (312) 243-5200
ZYC300	Eisai Medical Research <i>Ridgefield Park, NJ</i>	gene therapy	solid tumors	Phase I/II (877) 873-4724

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
AC2592 (GLP-1)	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide	congestive heart failure	Phase II (858) 552-2200
AMR-001	Amorcyte <i>Hackensack, NJ</i> Progenitor Cell Therapy <i>Hackensack, NJ</i>	cell therapy	myocardial infarction	Phase I (201) 883-5303
Angiomax® bivalirudin	The Medicines Company <i>Parsippany, NJ</i>	recombinant protein	acute coronary syndromes	application submitted (800) 388-1183

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
Aranesp [®] darbepoetin alfa	Amgen <i>Thousand Oaks, CA</i>	recombinant erythropoietin	heart failure	Phase III (805) 447-1000
bepermingene perplasmid	Daiichi Sankyo <i>Parsippany, NJ</i> AnGes <i>Gaithersburg, MD</i>	gene therapy	peripheral arterial disease	Phase II (973) 359-2600
CYT006-AngQb	Cytos Biotechnology <i>Schlieren, Switzerland</i>	therapeutic vaccine	hypertension	Phase I www.cytos.com
FGF-2 (fibroblast growth factor)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	growth factor	atherosclerosis, cardiovascular disorders, peripheral arterial occlusive disorder	Phase II (888) 669-6682
fibroblast growth factor-1	CardioVascular BioTherapeutics <i>Las Vegas, NV</i>	fibroblast growth factor	angina pectoris, peripheral vascular disorder (see also diabetes, skin)	Phase II (702) 248-1174
Generx [™] alferminogene tadenovec	Cardium Therapeutics <i>San Diego, CA</i>	gene therapy	myocardial ischemia	Phase III (858) 436-1000
HIF-1 alpha gene therapy	Genzyme <i>Cambridge, MA</i>	gene therapy	peripheral arterial disease	Phase II (617) 252-7500
Lantus [®] insulin glargine (rDNA origin) injection	sanofi-aventis <i>Bridgewater, NJ</i>	recombinant insulin	reduction of cardiovascular morbidity and mortality	Phase III (800) 633-1610
mipomersen sodium (Orphan Drug)	Genzyme <i>Cambridge, MA</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	hypercholesterolemia	Phase III (617) 252-7500 (800) 679-ISIS
MLN-1202	Millennium Pharmaceuticals <i>Cambridge, MA</i>	mAb	atherosclerosis (see also autoimmune)	Phase II (800) 589-9005
Mydicar [™]	Celladon <i>La Jolla, CA</i> Targeted Genetics <i>Seattle, WA</i>	gene therapy	congestive heart failure	Phase I/II (858) 366-4288 (206) 623-7612
NeoFuse [™] mesenchymal stem cell therapy	Angioblast Systems <i>New York, NY</i> Mesoblast <i>Melbourne, Australia</i>	stem cell therapy	prevention of heart failure (see also autoimmune)	Phase II (212) 880-2060
NX-CP105	Neuronix <i>Malvern, PA</i>	stem cell therapy	myocardial infarction	Phase I (610) 240-4150
Prochymal [™] human mesenchymal stem cell therapy	Osiris Therapeutics <i>Baltimore, MD</i>	stem cell therapy	heart failure (see also diabetes, digestive, transplantation)	Phase I (410) 522-5005

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
R 1512	Roche <i>Nutley, NJ</i>	mAb	peripheral vascular disorder	Phase I (973) 235-5000
ReoPro® abiximab	Centocor <i>Horsham, PA</i> Eli Lilly <i>Indianapolis, IN</i>	mAb	myocardial infarction	Phase III (610) 651-6000 (800) 545-5979
			arterial occlusive disorders	Phase II (610) 651-6000 (800) 545-5979
Resten-MP™	AVI BioPharma <i>Portland, OR</i> Cook Medical <i>Bloomington, IN</i>	antisense	cardiovascular restinosis	Phase II (503) 227-0554
saratin	BioVascular <i>San Diego, CA</i>	recombinant protein	thrombosis	Phase I/II (858) 455-5000
tissue repair stem cell therapy	Aastrom Biosciences <i>Ann Arbor, MI</i>	stem cell therapy	ischemia (see also other)	Phase II (734) 930-5555
Trinam® (EG004) (Orphan Drug)	Ark Therapeutics <i>London, England</i>	gene therapy	vascular restenosis	Phase II completed
VM-202	ViroMed <i>Seoul, Korea</i>	gene therapy	ischemic heart disease, peripheral arterial disease	Phase I
XRP0038 (NV1FGF)	sanofi-aventis <i>Bridgewater, NJ</i>	gene therapy	critical limb ischemia	Phase III (800) 633-1610

DIABETES AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AVE0010 (glucagon-like-peptide-1)	sanofi-aventis <i>Bridgewater, NJ</i>	peptide	type 2 diabetes	Phase II (800) 633-1610
AVE0010 (glucagon-like-peptide-1) (prolonged-release)	sanofi-aventis <i>Bridgewater, NJ</i>	peptide	type 2 diabetes	Phase I (800) 633-1610
AVR-118	Advanced Viral Research <i>Yonkers, NY</i>	immune-based therapy	type 2 diabetes mellitus (see also cancer, infectious, skin)	Phase I (914) 376-7383
BHT-3021	Bayhill Therapeutics <i>Palo Alto, CA</i>	vaccine	type 1 diabetes mellitus	Phase I (650) 320-2800
canakinumab (ACZ885)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	type 2 diabetes mellitus (see also autoimmune, respiratory, other)	Phase II/III (888) 669-6682
Excellerate™	Cardium Therapeutics <i>San Diego, CA</i>	gene therapy	diabetic foot ulcer	Phase II (858) 436-1000

DIABETES AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
exenatide LAR	Alkermes Cambridge, CA Amylin Pharmaceutical San Diego, CA Eli Lilly Indianapolis, IN	peptide	type 2 diabetes mellitus	Phase III (858) 552-2200
FG-3019	FibroGen South San Francisco, CA	mAb	diabetic nephropathies (see also respiratory)	Phase I (650) 866-7200
fibroblast growth factor-1	CardioVascular Therapeutics Las Vegas, NV	fibroblast growth factor	diabetic foot ulcers (see also cardiovascular, skin)	Phase I (702) 248-1174
INGAP peptide	Kinexum Metabolics Harper's Ferry, WV	peptide fragment	type 1 and type 2 diabetes mellitus	Phase I completed (954) 745-3510
ISIS 113715	Isis Pharmaceuticals Carlsbad, CA	oligoribonucleotide	type 2 diabetes mellitus	Phase II (800) 679-4747
liraglutide (NN2211)	Novo Nordisk Princeton, NJ	peptide	type 2 diabetes mellitus	application submitted (800) 727-6500
NBI-6024	Neurocrine Biosciences San Diego, CA	peptide ligand	type 1 diabetes mellitus	Phase II (858) 617-7600
otelixizumab (anti-CD3) (Orphan Drug)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC TolerRx Cambridge, MA	mAb	type 1 diabetes mellitus (see also skin)	Phase II (888) 825-5249 (617) 354-8100
Prochymal™ human mesenchymal stem cell therapy	Osiris Therapeutics Baltimore, MD	stem cell therapy	type 1 diabetes mellitus (see also cardiovascular, digestive, transplantation)	Phase II (410) 522-5005
SB-509	Sangamo BioSciences Richmond, CA	DNA-binding protein	diabetic neuropathies	Phase II (510) 970-6000
talactoferrin alfa	Agennix Houston, TX	recombinant protein	diabetic foot ulcer (see also blood, cancer)	Phase II (713) 552-1091
teplizumab (anti-CD3 mAb)	MacroGenics Rockville, MD	mAb	type 1 diabetes mellitus (see also autoimmune)	Phase II/III (301) 251-5172
XOMA052	XOMA Berkeley, CA	mAb	type 2 diabetes mellitus	Phase I (510) 204-7200

DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ABT-874	Abbott Laboratories Abbott Park, IL	mAb	Crohn's disease (see also skin)	Phase II (847) 937-6100
alicaforfen	Atlantic Healthcare Cambridge, MA	antisense	Crohn's disease, pouchitis, distal ulcerative colitis, proximal ulcerative colitis	Phase III www.atlantiche.com

DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
AMG 220	Amgen <i>Thousand Oaks, CA</i>	recombinant protein	Crohn's disease	Phase I (805) 447-1000
basiliximab	Cermion Pharmaceuticals <i>South San Francisco, CA</i>	mAb	ulcerative colitis (see also eye)	Phase II (650) 827-4000
Gattex™ teduglutide (Orphan Drug)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	peptide	short bowel syndrome	Phase III (801) 583-4939
			----- Crohn's disease	Phase II (801) 583-4939
golimumab	Centocor <i>Horsham, PA</i>	mAb	ulcerative colitis (see also autoimmune)	Phase II/III (610) 651-6000
Humira® adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	mAb	ulcerative colitis	Phase III (847) 937-6100
MDX-1100	Medarex <i>Princeton, NJ</i>	mAb	ulcerative colitis (see also autoimmune)	Phase II (609) 430-2880
MLN-0002	Millennium Pharmaceuticals <i>Cambridge, MA</i>	mAb	Crohn's disease, ulcerative colitis	Phase II (800) 589-9005
Neumega® oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	interleukin	Crohn's disease, inflammatory bowel disease (see also autoimmune, cancer, transplantation)	Phase III (800) 934-5556
NU206	Nuvelo <i>San Carlos, CA</i>	recombinant protein	inflammatory bowel disease (see also cancer)	Phase I (650) 517-8000
Orencia™ abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant protein	Crohn's disease, ulcerative colitis (see also autoimmune)	Phase II/III (212) 546-4000
Probactrix® <i>Escherichia coli</i> M17 vaccine	BioBalance <i>New York, NY</i>	vaccine	gastroesophageal reflux disease	Phase III (212) 679-7778
			----- pouchitis	Phase I/II (212) 679-7778
Prochymal™ human mesenchymal stem cell therapy	Osiris Therapeutics <i>Baltimore, MD</i>	stem cell therapy	Crohn's disease (see also cardiovascular, diabetes, transplantation)	Phase III (410) 522-5005
ustekinumab (CNTO 1275)	Centocor <i>Horsham, PA</i>	mAb	Crohn's disease (see also autoimmune, skin)	Phase II (610) 651-6000

EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AdPEDF	GenVec <i>Gaithersburg, MD</i>	gene therapy	wet age-related macular degeneration	Phase I (877) 943-6832

EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
afibercept (VEGF trap)	Bayer HealthCare Pharmaceuticals Wayne, NJ Regeneron Pharmaceuticals Tarrytown, NY	recombinant fusion protein	age-related macular degeneration (see also cancer)	Phase III (888) 842-2937 (914) 345-7400
			diabetic macular edema	Phase I (888) 842-2937 (914) 345-7400
basiliximab	Cermion Pharmaceuticals South San Francisco, CA	mAb	uveitis (see also digestive)	Phase II (650) 827-4000
Lucentis™ ranibizumab	Genentech South San Francisco, CA	mAb	diabetic macular edema, retinal vascular occlusion (see also genetic)	Phase III (650) 225-1000
MM-093 (recombinant human alpha-fetoprotein)	Merrimack Pharmaceuticals Cambridge, MA	recombinant protein	uveitis	Phase II (617) 441-1000
NT 501 (ciliary neurotrophic factor) (Orphan Drug)	Neurotech USA Lincoln, RI	cell therapy	retinitis pigmentosa	Phase II/III (401) 333-3880
			age-related macular degeneration	Phase II (401) 333-3880
PF-4523655	Pfizer New York, NY	small interfering RNA	diabetic macular edema	Phase II (860) 732-5156
			age-related macular degeneration	Phase I/II (860) 732-5156
TB-403	Roche Nutley, NJ	mAb	age-related macular degeneration (see also cancer)	Phase I (973) 235-5000

GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
Actimmune® interferon gamma-1b	InterMune Brisbane, CA	interferon	cystic fibrosis (see also infectious)	Phase II (415) 466-2200
AGTC 0106 (Orphan Drug)	Applied Genetic Technologies Alachua, FL	gene therapy	alpha-1-antitrypsin deficiency	Phase I (386) 462-2204
conestat alfa (C1 inhibitor) (Orphan Drug)	Pharming Group Leiden, The Netherlands	recombinant protein	hereditary angioedema	Phase II www.pharming.com
depelestat (DX-890) (Orphan Drug)	Debiopharm Lausanne, Switzerland Dyax Cambridge, MA	recombinant protein	cystic fibrosis	Phase II (617) 225-2500

GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
DNA nanoparticle gene therapy (Orphan Drug)	Copernicus Therapeutics <i>Cleveland, OH</i>	gene therapy	cystic fibrosis	Phase I/II (216) 231-0227
ecallantide (DX-88) (Orphan Drug)	Dyax <i>Cambridge, MA</i>	recombinant protein	treatment of hereditary angioedema (see also blood)	Phase III (617) 225-2500
GA-GCB (gene-activated glucocerebrosidase)	Shire <i>Wayne, PA</i>	enzyme replacement therapy	Gaucher disease type 1	Phase II (484) 595-8800
HuCNS-SC™ adult neural stem cell therapy	StemCells <i>Palo Alto, CA</i>	stem cell therapy	infantile and late-infantile neuronal ceroid lipofuscinosis (NCL) – Batten disease	Phase I (650) 475-3100
Lucentis™ ranibizumab	Genentech <i>South San Francisco, CA</i>	mAb	hereditary hemorrhagic telangiectasia (see also eye)	Phase I/II (650) 225-1000
recombinant human arylsulfatase A (Orphan Drug)	Shire <i>Wayne, PA</i>	recombinant protein	metachromatic leukodystrophy	Phase II (484) 595-8800
Trizyte™ ALTU-135 (Orphan Drug)	Altus Pharmaceuticals <i>Cambridge, MA</i>	enzyme replacement therapy	treatment of malabsorption as a result of pancreatic insufficiency	Phase III (617) 299-2900

GROWTH DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ALTU-238 (somatropin)	Altus Pharmaceuticals <i>Cambridge, MA</i>	growth hormone	somatotropin deficiency in adults	Phase II (617) 299-2900
			somatotropin deficiency in children	Phase I (617) 299-2900
Increlex™ mecasermin (rDNA origin) for injection	Tercica <i>Brisbane, CA</i>	growth factor	short stature in children with primary IGF-1 deficiency	Phase III (650) 624-4900
oral recombinant human growth hormone (somatropin)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant human growth hormone	growth disorders	Phase I (914) 347-2220 (888) 669-6682
somatropin (sustained-release)	LG Life Sciences <i>Seoul, South Korea</i>	recombinant human growth hormone	somatropin deficiency	Phase III
somatropin (sustained-release)	Pacira Pharmaceuticals <i>San Diego, CA</i>	growth hormone	growth disorders	Phase I (858) 625-2424

HIV INFECTION/AIDS AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AGS-004	Argos Therapeutics <i>Durham, NC</i>	dendritic cell vaccine	HIV infection	Phase II (919) 287-6300
Alferon N LDO [®] interferon alfa-n3	Hemispherx Biopharma <i>New Brunswick, NJ</i> <i>Philadelphia, PA</i>	interferon	HIV infection (see also infectious)	Phase II (215) 988-0080
anti-CCR5 mAb	Human Genome Sciences <i>Rockville, MD</i>	mAb	HIV infection	Phase I www.hgsi.com
anti-HIV-1 mAb (2G12, 2F5, 4E10)	Polymun Scientific <i>Vienna, Austria</i>	mAb	HIV infection treatment	Phase II www.polymun.com
AVX101	AlphaVax <i>Rsch. Triangle Park, NC</i>	gene vaccine	HIV-1 infection	Phase I completed (919) 595-0400
BAY-504798	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	interleukin	HIV infection	Phase I/II (888) 842-2837
CYT-107	Cytheris <i>Rockville, MD</i>	interleukin	HIV infection (see also cancer)	Phase I/II (301) 231-0450
Cytolin [®] anti-CD8 mAb	CytoDyn <i>Santa Fe, NM</i>	mAb	HIV infection	Phase II (505) 988-5520
DermaVir [™] Patch HIV DNA topical vaccine	Genetic Immunity <i>McLean, VA</i>	DNA vaccine	HIV-1 infections	Phase I/II (703) 287-8720
DP-6001 (HIV DNA vaccine)	CytRx <i>Los Angeles, CA</i>	DNA vaccine	HIV-1 DNA vaccine with protein vaccine boost (prevention)	Phase I (310) 826-5648
EP-1043	Pharmexa-Epimmune <i>San Diego, CA</i>	recombinant vaccine	prevention of HIV-1 infection	Phase I (858) 860-2500
EP-1090	Pharmexa-Epimmune <i>San Diego, CA</i>	DNA vaccine	HIV-1 infection	Phase I/II (858) 860-2500
EP-1233 and MVA-BN polytype combination	Bavarian Nordic <i>Washington, DC</i> Pharmexa-Epimmune <i>San Diego, CA</i>	vaccine	HIV infection prevention	Phase I (202) 536-1581 (858) 860-2500
gag DNA vaccine and IL-12 adjuvant	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	DNA vaccine	HIV infection, HIV infection prevention	Phase I (800) 934-5556
gag DNA vaccine and IL-15 adjuvant	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	DNA vaccine	HIV infection, HIV infection prevention	Phase I (800) 934-5556
HGTV43 [™]	Enzo Therapeutics <i>New York, NY</i>	antisense	HIV-1 infection	Phase I/II (212) 583-0100
HIV combination vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	HIV infection prevention	Phase I (888) 825-5149
HIV multi-antigen vaccine	Bavarian Nordic <i>Washington, DC</i>	vaccine	HIV-1 infections	Phase I/II (202) 536-1581
HIV vaccine	GeoVax <i>Atlanta, GA</i>	vaccine	HIV infection prevention	Phase I (404) 727-0971

HIV INFECTION/AIDS AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
HIV vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	HIV infection	Phase I/II (888) 825-5249
HIV vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	HIV infection	Phase I (888) 669-6682
HIV vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	prevention of HIV infection (Thailand)	Phase III (570) 839-7187
ibalizumab (TNX-355)	TaiMed Biologics <i>Taipei, Taiwan</i>	mAb	HIV infection	Phase II
Iplex™ mecasermin rinsatate	Insmed <i>Richmond, VA</i>	recombinant protein	HIV-associated lipodystrophy syndrome (see also neurologic)	Phase II completed (804) 565-3000
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte- macrophage colony stimulating factor	HIV infection (see also autoimmune, cancer, infectious, respiratory, skin, other)	Phase III (888) 842-2937
lexgenleucel-T (VRX496)	VIRxSYS <i>Gaithersburg, MD</i>	gene therapy	HIV infection	Phase II (301) 987-0480
Pegasys® peginterferon alfa-2a	Roche <i>Nutley, NJ</i>	interferon	HIV infection (see also cancer)	Phase III (973) 235-5000
PRO 140	Progenics Pharmaceuticals <i>Tarrytown, NY</i>	mAb	HIV infection	Phase II (914) 789-2800
Proleukin® aldesleukin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	interleukin	HIV-1 infection (see also cancer)	Phase III (888) 669-6682
Serostim® somatropin (rDNA origin) for injection (Orphan Drug)	EMD Serono <i>Rockland, MA</i>	recombinant growth hormone	HIV-related adipose redistribution syndrome	application submitted (800) 275-7376
Tarvacin™ bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	HIV infection (hepatitis C co-infection) (see also cancer, infectious)	Phase I (714) 508-6000
V526	Merck <i>Whitehouse Station, NJ</i>	gene vaccine	HIV infection	Phase II (800) 672-6372
VRC-HIVADV 014-00-VP	GenVec <i>Gaithersburg, MD</i>	gene vaccine	HIV infection (prevention)	Phase II (240) 632-0740
			HIV infection (treatment)	Phase I (240) 632-0740
VRC-HIVDNA 016-00-VP	NIH Vaccine Research <i>Bethesda, MD</i>	DNA vaccine	HIV infection (prevention)	Phase II www.vrc.nih.gov

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
1024850A pneumococcal vaccine conjugate (pediatric)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	otitis media, pneumococcal infections	Phase III (888) 825-5249
1492903A (cytomegalovirus glycoprotein vaccine)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of cytomegalovirus (CMV) infections	Phase I (888) 825-5249
ABthrax™ raxibacumab (Orphan Drug)	Human Genome Sciences <i>Rockville, MD</i>	mAb	anthrax	Phase II/III www.hgsi.com
ACAM-FLU-A™	Acambis <i>Cambridge, MA</i>	vaccine	prevention of influenza virus infections	Phase I (617) 761-4200
ACE-393	ACE BioSciences <i>Odense, Denmark</i> Naval Medical Research Center <i>Silver Spring, MD</i>	vaccine	<i>Campylobacter</i> infections	Phase I www.acebio sciences.com
Actimmune® interferon gamma-1b	InterMune <i>Brisbane, CA</i>	interferon	hepatitis C (see also genetic)	Phase II (415) 466-2200
Adacel™ DTP	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	diphtheria, tetanus, pertussis (4-6-years-old)	Phase III (570) 839-7187
AERAS-402	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> Crucell <i>Leiden, The Netherlands</i>	vaccine	tuberculosis	Phase I (301) 547-2900
Aflunov™ H5N1 pre-pandemic influenza vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	influenza A virus infections H5N1 subtype (prevention)	Phase II (888) 669-6682
AG-707 vaccine	Antigenics <i>New York, NY</i>	recombinant protein	herpes simplex virus infections	Phase I (866) 805-8994
Albuferon™ albinterferon alpha-2b	Human Genome Sciences <i>Rockville, MD</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	interferon	hepatitis C	Phase III (301) 309-8504 (888) 669-6682
Alferon N Injection® interferon alfa-n3	Hemispherx Biopharma <i>New Brunswick, NJ</i> <i>Philadelphia, PA</i>	interferon	hepatitis C (see also autoimmune)	Phase II/III (215) 988-0080
			West Nile virus prevention	Phase II (215) 988-0080
			coronavirus infections, influenza virus infections	Phase I (215) 988-0080

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
Alferon N LDO [®] interferon alfa-n3	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	interferon	influenza virus infections (see also HIV/AIDS)	Phase I (215) 988-0080
			human papillomavirus infections	in clinical trials (215) 988-0080
Amvax [®] DTaP vaccine, adult	Baxter International Deerfield, IL	vaccine	diphtheria, pertussis, tetanus in adults	Phase I (800) 422-9837
Anthim [™] (ETI-204) (Orphan Drug)	Elusys Therapeutics Pine Brook, NJ	mAb	anthrax	Phase I (973) 808-0222
anthrax vaccine	BioSante Pharmaceuticals Lincolnshire, IL	vaccine	anthrax	Phase I/II (847) 478-0500
anthrax vaccine	PharmAthene Annapolis, MD	recombinant vaccine	anthrax	Phase II (410) 269-2600
anthrax vaccine (transdermal)	Iomai Gaithersburg, MD	vaccine	anthrax	Phase I (301) 556-4500
AV 7909	Emergent BioSolutions Rockville, MD Lansing, MI	vaccine	anthrax	Phase I (301) 795-0400
AVI-005	AviGenics Athens, GA	interferon	infections	Phase I (706) 227-1170
AVR-118	Advanced Viral Research Yonkers, NY	immune- based therapy	human papillomavirus infection (see also cancer, diabetes, skin)	Phase II (914) 376-7383
AVX502	AlphaVax Rsch. Triangle Park, NC	vaccine	influenza virus infections	Phase I (919) 595-0400
AVX601	AlphaVax Rsch. Triangle Park, NC	vaccine	prevention of CMV infections	Phase I (919) 595-0400
BioThrax [™] anthrax vaccine	Emergent BioSolutions Rockville, MD	vaccine	prevention of post-exposure anthrax infection	in clinical trials (301) 795-1800
BLX-883	Biolex Therapeutics Pittsboro, NC	interferon	hepatitis C (see also cancer)	Phase I (919) 542-9901
BLX-883 (controlled-release)	Biolex Therapeutics Pittsboro, NC	interferon	hepatitis C	Phase II (919) 542-9901
botulinum toxin vaccine	DynPort Vaccine Frederick, MD	recombinant vaccine	botulism	Phase I (301) 607-5000
Cervarix [®] HPV vaccine	MedImmune Gaithersburg, MD GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	recombinant vaccine	prevention of human papillomavirus infection	application submitted (301) 398-0000 (888) 825-5249
CholeraGarde [®] cholera vaccine, live	AVANT Immunotherapeutics Needham, MA	vaccine	cholera	Phase II (781) 433-0771

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
CHRONVAC-C® hepatitis C DNA vaccine	Inovio Biomedical <i>San Diego, CA</i> Tripep <i>Huddinge, Sweden</i>	gene therapy vaccine	hepatitis C	Phase I/II (877) 446-6846
Civacir™ hepatitis C immune globulin (Orphan Drug)	Biotest Pharmaceuticals <i>Boca Raton, FL</i>	polyclonal antibody	hepatitis C prevention	Phase II (800) 327-7106
<i>Clostridium difficile</i> vaccine	Acambis <i>Cambridge, MA</i>	vaccine	<i>Clostridium</i> infections	Phase I (617) 761-4200
CMV glycoprotein vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	CMV infections	Phase II (888) 669-6682
CMV vaccine	AstraZeneca <i>Wilmington, DE</i>	vaccine	CMV infections	Phase I (800) 236-9933
CMV vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	prevention of congenital infection	Phase II (570) 839-7187
dengue vaccine	Acambis <i>Cambridge, MA</i> sanofi pasteur <i>Swiftwater, PA</i>	vaccine	moderate to severe dengue fever	Phase II (617) 761-4200 (570) 839-7187
dengue vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	dengue	Phase II (888) 825-5249
DNA vaccine (cytomegalovirus) (Orphan Drug)	Vical <i>San Diego, CA</i>	DNA vaccine	prevention of CMV infections	Phase II (858) 646-1100
DNA vaccine (ebola)	Vical <i>San Diego, CA</i>	DNA vaccine	prevention of ebola virus infections	Phase I completed (858) 646-1100
DNA vaccine (influenza)	Vical <i>San Diego, CA</i>	DNA vaccine	prevention of influenza A (H5N1 subtype) virus infections	Phase I (858) 646-1100
DNA vaccine (West Nile)	Vical <i>San Diego, CA</i>	DNA vaccine	prevention of West Nile virus infection	Phase I (858) 646-1100
DR-5001	Barr Laboratories <i>Montvale, NJ</i>	vaccine	adenovirus infections (types 4 and 7)	Phase III (800) 222-0190
DTaP adult vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	diphtheria, pertussis, tetanus in adults	application submitted (888) 825-5249
DTaP-poliovirus vaccine	Baxter International <i>Deerfield, IL</i>	vaccine	diphtheria, pertussis, tetanus, poliomyelitis	Phase II (800) 422-9837
DTP-HepB-polio-Hib vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, <i>Haemophilus influenzae</i> type b	Phase II (570) 839-7187

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
DTwP-HepB-Hib vaccine	Bena Biotech <i>Basel, Switzerland</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	diphtheria, tetanus, pertussis, hepatitis B prevention, <i>Haemophilus</i> infections	Phase III (888) 669-6682
Ebola virus vaccine	GenPhar <i>Mt. Pleasant, SC</i>	vaccine	Ebola virus infections	in clinical trials (843) 884-0120
Epstein-Barr virus vaccine	MedImmune <i>Gaithersburg, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	Epstein-Barr virus infection (see also cancer)	Phase II (301) 398-0000 (888) 825-5249
<i>Escherichia coli</i> vaccine transdermal	Iomai <i>Gaithersburg, MD</i>	vaccine	<i>Escherichia coli</i> infections, traveler's diarrhea	Phase II (301) 556-4500
FluBIOk™ derived from recombinant hemagglutinin (rHA)	Protein Sciences <i>Meriden, CT</i>	recombinant vaccine	prevention of influenza virus infections in adults and children	application submitted (203) 686-0800
flu cell vaccine (new production method)	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	influenza virus infections	Phase II (570) 839-7187
Fludase™ DAS-181	NexBio <i>San Diego, CA</i>	recombinant fusion protein	influenza virus infections	Phase I (858) 452-2631
flu micro-injection vaccine (new delivery)	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	influenza virus infections	Phase II (570) 839-7187
flu pandemic vaccine (H7 cell culture, low dose)	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	influenza virus infections	Phase I (570) 839-7187
flu vaccine (new formulation)	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	influenza virus infections	Phase III (570) 839-7187
GNI-102	GENImmune <i>Gent, Belgium</i>	gene therapy vaccine	hepatitis B	Phase I
group B streptococcus (GBS) type II and type V vaccine	Roche <i>Nutley, NJ</i>	vaccine	streptococcal infections	in clinical trials (973) 235-5000
H5N1 avian influenza intranasal vaccine	MedImmune <i>Gaithersburg, MD</i>	vaccine	influenza virus infections	Phase I (301) 398-0000
H5N1 influenza virus vaccine	Baxter International <i>Deerfield, IL</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase I (800) 422-9837
H5N1 influenza virus vaccine	Novavax <i>Rockville, MD</i>	vaccine	prevention of influenza A virus H5N1 subtype	Phase II (240) 268-2000

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
H5N1 pre-pandemic influenza virus vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	influenza A virus H5N1 subtype (prevention)	Phase I/II (888) 825-5249
H9N2 pandemic influenza vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	influenza virus infections	Phase II (888) 825-5249
<i>Helicobacter pylori</i> vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	helicobacter infections	Phase I (888) 669-6682
hepatitis A vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	hepatitis A	Phase III (888) 669-6682
hepatitis B DNA vaccine	PowderMed (Pfizer) <i>Oxford, England</i>	gene therapy vaccine	hepatitis B treatment	Phase I (860) 732-5156
hepatitis B vaccine	GenPhar <i>Mt. Pleasant, SC</i>	vaccine	hepatitis B	Phase I (843) 884-0120
hepatitis C vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant vaccine	hepatitis C	Phase II (888) 669-6682
hepatitis C vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	DNA vaccine	prevention of hepatitis C	Phase I (888) 825-5249
hepatitis E recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	hepatitis E	Phase II completed (888) 825-5249
HepCVax hepatitis C vaccine	Virionics <i>Scottsdale, AZ</i>	vaccine	hepatitis C prevention and treatment	Phase I www.virionics.com
HEPLISAV™	Dynavax Technologies <i>Emeryville, CA</i>	DNA vaccine	hepatitis B prevention	Phase II (510) 848-5100
herpes simplex DNA vaccine	PowderMed (Pfizer) <i>Oxford, United Kingdom</i>	gene therapy vaccine	herpes simplex virus infections	Phase I (860) 732-5156
herpes simplex glycoprotein vaccine	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	herpes simplex virus infections	Phase III (888) 669-6682
Hexaxim™ DTP-HepB-polio-Hib	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, <i>Haemophilus influenzae</i> type b	Phase III (570) 839-7187
Hib-MenC-TT conjugated vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	<i>Neisseria meningitidis</i> group C disease, <i>Haemophilus influenzae</i> type b disease prevention	Phase II/III (888) 825-5249
Hib-MenCY-TT conjugated vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	<i>Haemophilus</i> infections, meningococcal group C and Y infections prevention	Phase III (888) 825-5149
human papillomavirus vaccine	Biogen Idec <i>Cambridge, MA</i>	vaccine	human papillomavirus infections	Phase I (617) 679-2000

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
human papillomavirus vaccine	Novavax <i>Rockville, MD</i>	vaccine	human papillomavirus infection	Phase II (240) 268-2000
IC-41	Intercell <i>Vienna, Austria</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	hepatitis C	Phase I/II (888) 669-6682
IC-43	Intercell <i>Vienna, Austria</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	fusion protein vaccine	pseudomonal infections	Phase II (888) 669-6682
IC-51	Intercell <i>Vienna, Austria</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	Japanese encephalitis (prevention)	application submitted (888) 669-6682
Imvamune® smallpox vaccine	Bavarian Nordic <i>Kvistgaard, Denmark</i> <i>Washington, DC</i>	vaccine	smallpox	Phase II (202) 536-1581
			smallpox in treatment-naive patients	Phase I/II (202) 536-1581
inactivated split-trivalent seasonal influenza vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	influenza virus infection (prevention)	Phase III (888) 825-5249
Infanrix IPV Hib® DTaP-poliovirus vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	<i>Haemophilus</i> infections, diphtheria, tetanus, pertussis, poliomyelitis	Phase III (888) 825-5249
Infergen® interferon alfacon-1	Three Rivers Pharmaceuticals <i>Cranbury Township, NJ</i>	interferon	hepatitis C (combination therapy)	Phase III (800) 405-8506
influenza vaccine with IC31 adjuvant	Intercell <i>Vienna, Austria</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	influenza virus infections (prevention)	Phase I (888) 669-6682
influenza virus intranasal vaccine	Vaxin <i>Birmingham, AL</i>	vaccine	influenza virus infections	Phase I (205) 413-8238
influenza virus M2e vaccine	VaxInnate <i>Cranbury, NJ</i>	recombinant vaccine	influenza virus infections (prevention)	Phase I (609) 860-2260
influenza virus transdermal vaccine	Iomai <i>Gaithersburg, MD</i>	vaccine	influenza virus infections	Phase I/II (301) 556-4500
influenza virus vaccine	Antigen Express <i>Worcester, MA</i>	vaccine	influenza virus infection	Phase I (508) 852-8783
influenza virus vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	influenza virus infection	Phase II (888) 825-5249

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
influenza virus vaccine	Solvay Pharmaceuticals <i>Marietta, GA</i>	cell vaccine	influenza virus infections	Phase I (770) 578-9000
interferon-alpha	Nautilus Biotech <i>Cedex, France</i>	interferon	hepatitis C	Phase I www.nautilusbiotech.com
interferon-omega	Intarcia Therapeutics <i>Emeryville, CA</i>	interferon	hepatitis C	Phase II (510) 652-2600
Japanese encephalitis vaccine	Acambis <i>Cambridge, MA</i> sanofi pasteur <i>Swiftwater, PA</i>	vaccine	prevention of Japanese encephalitis	Phase II (570) 839-7187
KB001	KaloBios Pharmaceuticals <i>Palo Alto, CA</i>	mAb	pseudomonal infections	Phase I/II (650) 843-1897
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte-macrophage colony stimulating factor	mycoses (see also autoimmune, cancer, HIV/AIDS, respiratory, skin, other)	Phase III (888) 842-2937
			mycobacterium avium complex infections, neonatal infections	in clinical trials (888) 842-2937
malaria vaccine	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	vaccine	malaria (prevention)	Phase I/II (847) 478-0500
malaria vaccine	Crucell <i>Leiden, The Netherlands</i>	vaccine	malaria	Phase I www.crucell.com
malaria vaccine	GenVec <i>Gaithersburg, MD</i>	vaccine	malaria	Phase I/II (877) 943-6832
MDX-066 + MDX-1388 combination	Medarex <i>Princeton, NJ</i>	mAb	<i>Clostridium difficile</i> -associated diarrhea	Phase II (609) 430-2880
MDX-1106	Medarex <i>Princeton, NJ</i>	mAb	hepatitis C (see also cancer)	Phase I (609) 430-2880
MDX-1303 (Orphan Drug)	Medarex <i>Princeton, NJ</i> PharmAthene <i>Annapolis, MD</i>	mAb	anthrax	Phase I (609) 430-2880
MEDI-557 (third-generation anti-RSV mAb)	MedImmune <i>Gaithersburg, MD</i>	mAb	respiratory syncytial virus (RSV) infections	Phase I (301) 398-0000
Menactra® meningococcal groups ACYW-135 conjugate vaccine (micro-injection, new delivery)	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	meningococcal groups A,C,Y,W-135	Phase I (570) 839-7187

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
Menactra® Toddler meningococcal groups ACYW-135 conjugate vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	meningococcal groups A,C,Y,W-135 (9 months and older)	Phase III (570) 839-7187
meninge A,C,Y,W second-generation vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	meningitis in infants	Phase I (570) 839-7187
meningococcal group B vaccine (rLP2086)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	recombinant vaccine	meningococcal group B infections	Phase I/II (800) 934-5556
meningococcal vaccine groups ACYW-135 conjugate	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	meningococcal group A, C, W-135, Y infections	Phase II/III (888) 669-6682
meningococcal vaccine group B	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant vaccine	meningococcal group B infections	Phase II/III (888) 669-6682
meningococcal vaccine group B	Roche <i>Nutley, NJ</i>	vaccine	meningococcal group B infections	in clinical trials (973) 235-5000
Menveo® meningococcal vaccine groups ACYW-135 conjugate	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	meningococcal group A, C, W-135, Y infections	Phase III (888) 669-6682
MGAWN1	MacroGenics <i>Rockville, MD</i>	mAb	West Nile virus infections	Phase I (301) 251-5172
Mosquirix™ malaria vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	malaria prevention	Phase I (888) 825-5249
Mtb72F/AS02A	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	tuberculosis	Phase II completed (888) 825-5249
Mycograb® efungumab (anti-hsp90 mAb) (Orphan Drug)	NeuTec Pharma <i>Manchester, England</i>	mAb	candidiasis	Phase III
NB-001	NanoBio <i>Ann Arbor, MI</i>	nanoemulsion	herpes simplex virus infections	Phase II (734) 302-4000
NB-002	NanoBio <i>Ann Arbor, MI</i>	nanoemulsion	onychomycosis	Phase II (734) 302-4000
Neuprex® opebacan	XOMA <i>Berkeley, CA</i>	recombinant protein	postoperative infections, wound infections (see also transplantation)	Phase I/II (510) 204-7200
norovirus vaccine, intranasal	LigoCyte Pharmaceuticals <i>Bozeman, MT</i>	vaccine	norovirus infections	Phase I (406) 585-2733

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
Numax® motavizumab	MedImmune Gaithersburg, MD	mAb	RSV prevention	application submitted (301) 398-0000
			RSV treatment	Phase II (301) 398-0000
Optaflu® influenza virus vaccine	Novartis Pharmaceuticals East Hanover, NJ	vaccine	influenza virus infections	Phase I/II (888) 669-6682
parvovirus B19 vaccine	Meridian Bioscience Cincinnati, OH	vaccine	parvovirus infections	Phase I/II (800) 543-1980
PEG-IFNβ-1a	EMD Serono Rockland, MA	interferon	viral infections	Phase I (800) 283-8088
PEG-IL-29	ZymoGenetics Seattle, WA	interleukin	hepatitis C, viral infections	Phase I (800) 775-6686
Pentacel® DTP, polio, Hib vaccine	sanofi pasteur Swiftwater, PA	vaccine	diphtheria, tetanus, pertussis, poliomyelitis, <i>Haemophilus influenzae</i> type b infections	application submitted (570) 839-7187
PF-4522625	Pfizer New York, NY	gene therapy vaccine	influenza virus infections	Phase I (860) 732-5156
plague vaccine, injectable	DynPort Vaccine Frederick, MD	recombinant vaccine	<i>Yersinia</i> infections	Phase II (301) 607-5000
pneumococcal vaccine conjugate 7-valent	Wyeth Pharmaceuticals Collegeville, PA	vaccine	pneumococcal infections in the elderly	Phase III (800) 934-5556
pneumococcal vaccine conjugate 13-valent	Wyeth Pharmaceuticals Collegeville, PA	vaccine	pneumococcal infections	Phase III (800) 934-5556
pneumo vaccine (single antigen)	sanofi pasteur Swiftwater, PA	vaccine	meningitis and pneumonia in infants	Phase I (570) 839-7187
rabies vaccine	sanofi pasteur Swiftwater, PA	mAb	rabies post-exposure prevention	Phase I (570) 839-7187
recombinant neuraminidase (rNA)	Protein Sciences Meriden, CT	recombinant vaccine	influenza virus infections	Phase II (203) 686-0800
respiratory syncytial virus, parainfluenza virus vaccine	Wyeth Pharmaceuticals Collegeville, PA	vaccine	parainfluenza virus infections, RSV infections	Phase I (800) 934-5556
respiratory syncytial virus PFP-1 vaccine	Wyeth Pharmaceuticals Collegeville, PA	vaccine	RSV infections	Phase II (800) 934-5556
respiratory syncytial virus PFP-2 vaccine	Wyeth Pharmaceuticals Collegeville, PA	vaccine	RSV infections	Phase II (800) 934-5556
respiratory syncytial virus vaccine, live	Wyeth Pharmaceuticals Collegeville, PA	vaccine	RSV infections	Phase II (800) 934-5556

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
rhMBL (recombinant human mannose-binding lectin [MBL])	Enzon Pharmaceuticals <i>Bridgewater, NJ</i>	recombinant protein	severe infections in MBL-deficient individuals	Phase I/II (908) 541-8600
RiVax™ ricin vaccine	DOR BioPharma <i>Ewing, NJ</i>	vaccine	ricin poisoning	Phase I (609) 538-8200
rPA102 (recombinant protective antigen)	Emergent BioSolutions <i>Rockville, MD</i>	recombinant vaccine	anthrax	Phase II (301) 795-1800
seasonal influenza virus vaccine	Baxter Healthcare <i>Deerfield, IL</i>	vaccine	influenza virus infections	Phase III (800) 422-9837
Segard™ afelimomab	Abbott Laboratories <i>Abbott Park, IL</i>	mAb	sepsis, septic shock	Phase III (847) 937-6100
Simplirix™ herpes simplex glycoprotein vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	herpes simplex virus infections	Phase III (888) 825-5249
<i>S. pneumoniae</i> recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of pneumococcal infections	Phase I (888) 825-5249
Tarvacin™ bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	mAb	hepatitis C (see also HIV/AIDS, cancer)	Phase I (714) 508-6000
tifacogin (TFPI)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant protein	community-acquired pneumonia	Phase III (888) 669-6682
tuberculosis vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	tuberculosis prevention	Phase I (570) 839-7187
tularemia vaccine	DynPort vaccine <i>Frederick, MD</i>	vaccine	tularemia	Phase I (301) 607-5000
Ty800 (typhoid fever vaccine)	AVANT Immunotherapeutics <i>Needham, MA</i>	gene vaccine	typhoid fever	Phase II (781) 433-0771
typhoid vaccine, oral	Emergent BioSolutions <i>Rockville, MD</i>	vaccine	typhoid	Phase II (301) 795-1800
Unifive™ DTP-HepB-Hib	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	diphtheria, tetanus, pertussis, hepatitis B, <i>Haemophilus influenzae</i> type b	Phase III (570) 839-7187
urinary tract infections vaccine (transmucosal)	Xanodyne Pharmaceuticals <i>Newport, KY</i>	vaccine	urinary tract infections	Phase II (859) 371-6383
V419	Merck <i>Whitehouse Station, NJ</i>	vaccine	hepatitis B	Phase II (800) 672-6372
V502	Merck <i>Whitehouse Station, NJ</i>	vaccine	human papillomavirus infections	Phase II (800) 672-6372

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
V505	Merck <i>Whitehouse Station, NJ</i>	vaccine	human papillomavirus infections (see also cancer)	Phase II (800) 672-6372
V512	Merck <i>Whitehouse Station, NJ</i>	vaccine	influenza virus infection	Phase I (800) 672-6372
V710	Merck <i>Whitehouse Station, NJ</i>	vaccine	staphylococcal infections	Phase I (800) 672-6372
varicella zoster virus recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of varicella zoster infections	Phase II (888) 825-5249
Veldona [®] human interferon-alpha (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	human papillomavirus infections (see also autoimmune, blood, respiratory)	Phase II (806) 376-1741
VRC-SRSDNA 015-00-VP	GenVec <i>Gaithersburg, MD</i> NIH Vaccine Research Center <i>Bethesda, MD</i>	DNA vaccine	coronavirus infections	Phase I completed
West Nile virus vaccine	MacroGenics <i>Rockville, MD</i>	vaccine	West Nile virus infections (prevention)	Phase I/II (301) 251-5172
West Nile virus vaccine	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	prevention of West Nile virus infections	Phase II (570) 839-7187

NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
249320	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	central nervous system (CNS) trauma	Phase I (888) 825-5249
Altropane [®] E-IACFT	Alseres Pharmaceuticals <i>Hopkinton, MA</i>	molecular imaging agent	diagnosis of Parkinson's disease	Phase III (508) 497-2360
anti-Nogo-AmAb IN1	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	spinal cord injury	Phase I (888) 669-6682
AV 201	Genzyme <i>Cambridge, MA</i>	gene therapy	Parkinson's disease	Phase I/II (617) 252-7500
BA 210 (Orphan Drug)	Alseres Pharmaceuticals <i>Hopkinton, MA</i> BioAxone <i>Montreal, Quebec</i>	recombinant fusion protein	spinal cord injury	Phase I/II (508) 497-2360
bapineuzumab (AAB-001)	Elan <i>New York, NY</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	mAb	Alzheimer's disease	Phase III (800) 934-5556
			Alzheimer's disease (subcutaneous form)	Phase I (800) 934-5556

NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
Biostrophin™ muscular dystrophy gene therapy	Asklêpios BioPharmaceuticals <i>Chapel Hill, NC</i>	gene therapy	Duchenne muscular dystrophy	in clinical trials (919) 933-4990
CERE-110	Ceregene <i>San Diego, CA</i>	gene therapy	Alzheimer's disease	Phase I (858) 458-8800
CERE-120	Ceregene <i>San Diego, CA</i>	gene therapy	Parkinson's disease	Phase II (858) 458-8800
desmoteplase	Lundbeck Research USA <i>Paramus, NJ</i>	recombinant protein	ischemic stroke	Phase III (201) 261-1331
Iplex™ mecasermin rinsatate (Orphan Drug)	Insmed <i>Richmond, VA</i>	recombinant protein	muscular dystrophy (see also HIV/AIDS)	Phase II (804) 565-3000
LY 2062430	Eli Lilly <i>Indianapolis, IN</i>	mAb	Alzheimer's disease	Phase II (800) 545-5979
MYO-029 (stamulumab)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	mAb	muscular dystrophy	Phase II (800) 934-5556
Neo-Bladder Augment™	Tengion <i>East Norriton, PA</i>	cell therapy	neurogenic bladder	Phase II www.tengion.com
NLX P101	Neurologix <i>Fort Lee, NJ</i>	gene therapy	Parkinson's disease	Phase I (201) 592-6451
PF-4360365 (RN1219)	Pfizer <i>New York, NY</i> Rinat Neuroscience <i>South San Francisco, CA</i>	mAb	Alzheimer's disease	Phase I (860) 723-5156
tanezumab (PF-4383119)	Pfizer <i>New York, NY</i> Rinat Neuroscience <i>South San Francisco, CA</i>	mAb	back pain, cancer pain, musculoskeletal pain, neuralgia, pain associated with interstitial cystitis	Phase II (860) 732-5156
V950	Merck <i>Whitehouse Station, NJ</i>	vaccine	Alzheimer's disease	Phase I (800) 672-6372

RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
679586	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	asthma	Phase I/II (888) 825-5249
ABN912	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	asthma, chronic obstructive pulmonary disease (COPD)	Phase I (888) 669-6682
ABX-IL8	Amgen <i>Thousand Oaks, CA</i>	mAb	COPD	Phase II (805) 447-1000

RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
Aerovant™ pitrakinra	Aerovance <i>Berkeley, CA</i>	recombinant protein	acute asthma	Phase II (510) 549-5500
AIR 645	Altair Therapeutics <i>San Francisco, CA</i>	antisense oligonucleotide	asthma	Phase I (415) 541-8600
ALT-836	Altor BioScience <i>Miramar, FL</i>	mAb	acute lung injury, adult respiratory distress syndrome	Phase I/II (954) 443-8600
AMG 317	Amgen <i>Thousand Oaks, CA</i>	mAb	asthma	Phase II (805) 447-1000
anrukinzumab (IMA-638)	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	mAb	asthma	Phase II (800) 934-5556
AVE0675	sanofi-aventis <i>Bridgewater, NJ</i>	oglionucleotide	asthma	Phase I (800) 633-1610
BIW-8405	MedImmune <i>Gaithersburg, MD</i>	mAb	asthma	Phase I (302) 398-0000
Bosatria™ mepolizumab (anti-IL5 mAb)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	mAb	asthma, nasal polyposis (see also blood)	Phase II (888) 825-5249
canakinumab (ACZ885)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	COPD (see also autoimmune, diabetes, other)	Phase I/II (888) 669-6682
CAT-354	MedImmune <i>Gaithersburg, MD</i>	mAb	asthma	Phase I (301) 398-0000
FG-3019	FibroGen <i>South San Francisco, CA</i>	mAb	pulmonary fibrosis (see also diabetes)	Phase I (650) 866-7200
GC-1008	Genzyme <i>Cambridge, MA</i> MedImmune <i>Gaithersburg, MD</i>	mAb	pulmonary fibrosis (see also cancer, other)	Phase I (617) 252-7500 (301) 398-0000
house dust mite allergy vaccine tablet	Schering-Plough <i>Kenilworth, NJ</i>	oral vaccine	allergic asthma	Phase II/III (908) 298-4000
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte-macrophage colony stimulating factor	pulmonary alveolar proteinosis (see also autoimmune, cancer, HIV/AIDS, infectious, skin, other)	Phase II (888) 842-2937
MEDI-528 (anti-IL-9 mAb)	MedImmune <i>Gaithersburg, MD</i>	mAb	asthma	Phase II (301) 398-0000
MPL103	Allergy Therapeutics <i>West Sussex, United Kingdom</i>	vaccine	ragweed allergies	Phase III
QAX-576	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	mAb	allergic rhinitis, pulmonary fibrosis	Phase II (888) 669-6682
			respiratory tract disorders	Phase I completed (888) 669-6682

RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
R 1671	Roche <i>Nutley, NJ</i>	mAb	asthma	Phase I (973) 235-5000
Remicade [®] infliximab	Centocor <i>Horsham, PA</i>	mAb	asthma, COPD (see also autoimmune, cancer)	Phase II (610) 651-6000
TNX-650	Tanox <i>Houston, TX</i>	mAb	asthma (see also cancer)	Phase I (713) 578-4000
TPI-ASM8	Topigen Pharmaceuticals <i>Randolph, NJ</i>	antisense	asthma	Phase II (973) 809-5582
Veldona [®] human interferon-alpha	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	pulmonary fibrosis (see also autoimmune, blood, infectious)	Phase II (806) 376-1741
Xolair [®] omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	mAb	allergic asthma in children (see also skin, other)	Phase III (650) 225-1000
Zenapax [®] daclizumab	PDL BioPharma <i>Fremont, CA</i>	mAb	asthma (see also autoimmune, transplantation)	Phase II (510) 574-1400

SKIN DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ABT-874	Abbott Laboratories <i>Abbott Park, IL</i>	mAb	plaque psoriasis (see also digestive)	Phase III (847) 937-6100
Allox [™] allogeneic human skin replacement	Healthpoint <i>Fort Worth, TX</i>	cell therapy	skin ulcers	Phase II (800) 441-8227
AMG 714	Amgen <i>Thousand Oaks, CA</i> Genmab <i>Princeton, NJ</i>	mAb	psoriasis (see also autoimmune)	Phase I (805) 447-1000 (609) 430-2481
anti-interferon-gamma	Advanced Biotherapy <i>Woodland Hills, CA</i>	polyclonal antibody	psoriasis (see also autoimmune)	in clinical trials (818) 883-6716
ATL 1101	Antisense Therapeutics <i>Toorak, Australia</i>	antisense	psoriasis	Phase I
avotermin (RN-1001)	Renovo <i>Manchester, United Kingdom</i> Shire <i>Wayne, PA</i>	recombinant protein	prevention of scars	Phase I/II (484) 595-8800

SKIN DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
AVR-118	Advanced Viral Research <i>Yonkers, NY</i>	immune-based therapy	wounds (topical) (see also cancer, diabetes, infectious)	Phase II (914) 376-7383
			wounds (intralesional)	Phase I (914) 376-7383
Dimericine® T4N5 liposome lotion (Orphan Drug)	AGI Dermatics <i>Freeport, NY</i>	liposome-encapsulated DNA	xeroderma pigmentosa (see also cancer)	Phase III (516) 868-9026
Enbrel® etanercept	Amgen <i>Thousand Oaks, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	recombinant fusion protein	plaque psoriasis in adolescents and children	application submitted (805) 447-1000 (800) 934-5556
Epidex™ autologous human skin replacement	Healthpoint <i>Fort Worth, TX</i>	cell therapy	skin ulcers	Phase II (800) 441-8227
fibroblast growth factor-1	CardioVascular Therapeutics <i>Las Vegas, NV</i>	fibroblast growth factor	wounds (see also cardiovascular, diabetes)	Phase I (702) 248-1174
ICX-PRO	Intercytex <i>Woburn, MA</i>	fibroblast cell therapy	varicose ulcers	Phase III (781) 569-0990
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte-macrophage colony stimulating factor	varicose ulcers (see also autoimmune, cancer, HIV/AIDS, infectious, respiratory, other)	Phase II (888) 842-2937
MEDI-545 (MDX-1103)	Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	mAb	psoriasis (see also autoimmune)	Phase I (609) 430-2880 (301) 398-0000
MM-093 (recombinant human alpha-fetoprotein)	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	recombinant protein	psoriasis (see also autoimmune, eye)	Phase II (617) 441-1000
otelixizumab (anti-CD3)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i> TolerRx <i>Cambridge, MA</i>	mAb	psoriasis (see also diabetes)	Phase I completed (888) 825-5249 (617) 354-8100
Rituxan® rituximab	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	mAb	dermatomyositis (see also autoimmune, cancer)	Phase II (650) 225-1000 (617) 679-2000
			urticaria	Phase I/II (650) 225-1000 (617) 679-2000

SKIN DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ustekinumab (CNTO 1275)	Centocor <i>Horsham, PA</i>	mAb	plaque psoriasis (see also autoimmune, digestive)	application submitted (610) 651-6000
Xolair® omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	mAb	urticaria (see also respiratory, other)	Phase II (650) 225-1000

TRANSPLANTATION

Product Name	Sponsor	Product Category	Indication	Development Status
Amevive® alefacept	Astellas Pharma US <i>Deerfield, IL</i>	recombinant fusion protein	transplant rejection	Phase II (800) 695-4321
belatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant fusion protein	prevention of solid organ transplantation rejection	Phase III (212) 546-4000
Neumega® oprelvekin	Wyeth Pharmaceuticals <i>Collegeville, PA</i>	interleukin	graft-versus-host disease (see also autoimmune, cancer, digestive)	Phase I/II (800) 934-5556
Neuprex® opebacan	XOMA <i>Berkeley, CA</i>	recombinant protein	graft-versus-host disease in patients undergoing allogeneic hematopoietic stem cell transplantation (see also infectious)	Phase I/II (510) 204-7200
Prochymal™ human mesenchymal stem cell therapy (Orphan Drug)	Osiris Therapeutics <i>Baltimore, MD</i>	stem cell therapy	graft-versus-host disease (see also cardiovascular, diabetes, digestive)	Phase III (410) 522-5005
Raptiva™ efalizumab	Genentech <i>South San Francisco, CA</i> XOMA <i>Berkeley, CA</i>	mAb	renal transplant rejection (see also other)	Phase II (650) 225-1000 (510) 204-7200
TP 10	AVANT Immunotherapeutics <i>Needham, MA</i>	recombinant protein	allograft rejection, reperfusion injury	Phase II (781) 433-0771
YPSL (Orphan Drug)	Y's Therapeutics <i>Tokyo, Japan</i>	recombinant fusion protein	reperfusion injury associated with liver transplantation	Phase II www.ysthera.com
			delayed graft function associated with kidney transplantation	Phase I/II www.ysthera.com

TRANSPLANTATION

Product Name	Sponsor	Product Category	Indication	Development Status
Zenapax® daclizumab	PDL BioPharma Fremont, CA	mAb	heart transplant rejection (see also autoimmune, respiratory)	Phase III (510) 574-1400
ZRx-101	ZelleRx Chicago, IL	cell therapy	graft-versus-host disease (see also cancer)	Phase I (312) 243-5200

OTHER

Product Name	Sponsor	Product Category	Indication	Development Status
ABX-PTH	Amgen Thousand Oaks, CA	mAb	hyperparathyroidism	Phase I (805) 447-1000
AC162352 (PYY 3-36)	Amylin Pharmaceuticals San Diego, CA	peptide	obesity	Phase I (858) 552-2200
ACE-011	Acceleron Pharma Cambridge, MA Celgene Summit, NJ	recombinant fusion protein	postmenopausal osteoporosis	Phase I (617) 649-9200 (908) 673-9000
AMG 785	Amgen Thousand Oaks, CA UCB Smyrna, GA	mAb	osteoporosis	Phase I (805) 447-1000
Arcalyst™ rilonacept	Regeneron Pharmaceuticals Tarrytown, NY	recombinant fusion protein	gout (see also blood)	Phase II (914) 345-7400
BMP-7 (eptoterminal alfa)	Stryker Biotech Hopkinton, MA	recombinant protein	periodontal disorders spinal fusion	Phase II (866) 476-2663 in clinical trials (866) 476-2663
canakinumab (ACZ885)	Novartis Pharmaceuticals East Hanover, NJ	mAb	Muckle-Wells syndrome (see also autoimmune, diabetes, respiratory)	Phase III (888) 669-6682
cat allergy vaccine	Curalogic Copenhagen, Denmark	vaccine	cat allergy	Phase II www. curalogic.com
cat allergy vaccine	Greer Laboratories Lenoir, NC	vaccine	perennial allergic rhinitis caused by cat hair	Phase I (800) 378-3906
Chondrogen™ mesenchymal stem cell therapy for meniscal repair	Osiris Therapeutics Baltimore, MD	stem cell therapy	knee injuries	Phase I/II (410) 522-5005
CR 002 (Orphan Drug)	CuraGen Branford, CT	mAb	IgA nephropathy	Phase I (888) 868-9026

OTHER

Product Name	Sponsor	Product Category	Indication	Development Status
denosumab (AMG 162)	Amgen <i>Thousand Oaks, CA</i>	mAb	postmenopausal osteoporosis (see also autoimmune, cancer)	Phase III (805) 447-1000
FGF-18 (fibroblast growth factor)	EMD Serono <i>Rockland, MA</i>	growth factor	osteoarthritis	Phase I (800) 283-8088
GC-1008	Genzyme <i>Cambridge, MA</i> MedImmune <i>Gaithersburg, MD</i>	mAb	kidney sclerosis (see also cancer, respiratory)	Phase I (617) 252-7500 (301) 398-0000
GEM OS1™	BioMimetic Therapeutics <i>Franklin, TN</i>	recombinant protein	fractures	Phase III (615) 844-1280
grass pollen allergy tablet vaccine	Schering-Plough <i>Kenilworth, NJ</i>	oral vaccine	seasonal allergic rhinitis	Phase III (908) 298-4000
hMaxi-K gene therapy	Ion Channel Innovations <i>New York, NY</i>	gene therapy	erectile dysfunction, overactive bladder	Phase I (212) 639-1561
KB003	KaloBios Pharmaceuticals <i>Palo Alto, CA</i>	mAb	inflammation	Phase I (650) 546-4000
Leukine® sargramostim	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i>	granulocyte-macrophage colony stimulating factor	vaccine adjuvant (see also autoimmune, cancer, HIV/AIDS, infectious, respiratory, skin)	in clinical trials (888) 842-2937
LeukoScan® tc 99m sulesomab	Immunomedics <i>Morris Plains, NJ</i>	mAb	diagnostic imaging of bone infections, atypical appendicitis	application submitted (973) 605-8200
NIC 002	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	vaccine	smoking withdrawal	Phase II (888) 669-6682
NicVax™ nicotine abuse vaccine	Nabi Biopharmaceuticals <i>Boca Raton, FL</i>	vaccine	smoking withdrawal	Phase II (800) 685-1766
onercept	EMD Serono <i>Rockland, MA</i>	recombinant protein	endometriosis	Phase I (800) 283-8088
Preos™ recombinant human parathyroid hormone (rhPTH) (Orphan Drug)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	recombinant hormone	hypoparathyroidism	Phase II (801) 583-4939
Puricase® peglicase (Orphan Drug)	Savient Pharmaceuticals <i>East Brunswick, NJ</i>	recombinant enzyme	gout	Phase III (800) 284-2480
QRX-431 (sobetirome)	QuatRx Pharmaceuticals <i>Ann Arbor, MI</i>		lipid metabolism disorders, obesity	Phase I (734) 913-9900

OTHER

Product Name	Sponsor	Product Category	Indication	Development Status
ragweed allergy vaccine	Curalogic <i>Copenhagen, Denmark</i>	vaccine	ragweed allergy	Phase II www.curalogic.com
ragweed allergy vaccine, sublingual	Greer Laboratories <i>Lenoir, NC</i>	vaccine	seasonal allergic rhinitis due to ragweed	Phase III (800) 378-3906
ragweed allergy vaccine, tablet	Schering-Plough <i>Kenilworth, NJ</i>	vaccine	allergic rhinitis due to ragweed	Phase I (908) 298-4000
TA-CD	Celtic Pharma <i>Hamilton, Bermuda</i>	immuno-therapeutic vaccine	cocaine abuse	Phase II (441) 299-7440
teriparatide oral (oral recombinant parathyroid hormone 1-34)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant hormone	postmenopausal osteoporosis	Phase I (914) 347-2220 (888) 669-6682
TG-C	TissueGene <i>Dallas, TX</i>	cell therapy	bone regeneration	Phase I (214) 351-1922
tissue repair stem cell therapy (Orphan Drug)	Aastrom Biosciences <i>Ann Arbor, MI</i>	stem cell therapy	osteonecrosis (see also cardiovascular) ----- non-union fracture, vertebral fracture	Phase III (734) 930-5555 Phase I/II (734) 930-5555
VEL-0230	Velcura Therapeutics <i>Ann Arbor, MI</i>	cell therapy	osteoporosis (see also autoimmune, cancer)	Phase I (734) 973-1000
Xolair® omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	mAb	peanut allergy (see also respiratory, skin)	Phase II (650) 225-1000

The content of this survey has been obtained through industry sources and the Adis "R&D Insight" database based on the latest information. **Survey current as of July 31, 2008.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's web site.

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adjunct—An auxiliary treatment that is secondary to the main treatment.

adjuvant—Substance or drug that aids another substance in its action.

allogeneic (transplantation)—Refers to having cell types that are distinct and cause reactions in the immune system.

angioedema—Swelling of the mucous membranes, tissues beneath the skin, or an internal organ due to an allergic reaction.

ankylosing spondylitis—An inflammatory disorder of unknown cause that primarily affects the spine. The vertebrae may fuse together and form a rigid back that is impossible to bend.

antisense—An antisense drug is the mirror or complementary image of a small segment of messenger RNA (mRNA), the substance that carries instructions (“sense”) from the genes to the cell’s protein-making machinery. The antisense drug readily binds to the mRNA strand, keeping it from transmitting its instructions to the cell, and thus inhibiting the production of an unwanted protein.

application submitted—Application for marketing has been submitted to the Food and Drug Administration (FDA).

autologous (transfusion; transplantation)—Autologous refers to a graft in which the donor and recipient are the same individual.

biotechnology—The collection of processes that involve the use of biological systems. For some of the industries, these processes involve the use of genetically engineered organisms. For the purpose of this report, only those products that involve recombinant DNA, monoclonal antibody/hybridoma, continuous cell lines, cellular therapy, gene therapy and vaccines technology are included.

Clostridium difficile—A bacterium that produces an irritating toxin that causes a form of colitis characterized by profuse, watery diarrhea with cramps and low-grade fever.

colony stimulating factor (CSF)—Protein responsible for controlling the production of white blood cells.

Crohn’s disease—A subacute chronic gastrointestinal disorder, involving the small intestine, characterized by patchy deep ulcers that may cause fistulas and a narrowing and thickening of the bowel.

cytomegalovirus (CMV)—A DNA virus related to the herpes virus, affecting mostly neonatal infants and immunocompromised individuals. CMV is sexually transmitted and can occur without symptoms or result in mild flu-like symptoms.

demyelinating polyneuropathy, chronic inflammatory—CIPD is a neurological disorder characterized by progressive weakness and impaired sensory function in the legs and arms. The disorder, which is sometimes called chronic relapsing polyneuropathy, is caused by damage to the myelin sheath (the fatty covering that wraps around and protects nerve fibers) of the peripheral nerves.

erythropoietin—Hormone that stimulates red blood cell production in the bone marrow.

Gaucher disease—An inherited disease caused by a lack or deficiency of an enzyme (glucocerebrosidase). Primarily affects the liver, spleen and bone marrow, usually resulting in death.

gene therapy—Therapy at the intracellular level to replace or inactivate the effects of disease-causing genes or to augment normal gene functions to overcome illness.

genital herpes (herpes simplex 2)—A strain of herpes virus that may lie

dormant in nerve tissue and can be reactivated to produce painful sores of the anus or genitals.

glioblastoma—The most common primary brain tumor and one of the most aggressive forms of brain cancer, primarily affecting adults over the age of 50.

growth factors—Factors responsible for regulating cell proliferation (rapid and repeated reproduction), function and differentiation.

heat shock protein—A natural adjuvant (a substance that enhances the immune response to an antigen) linked to molecular signals or antigenic peptides, which are capable of stimulating an immune response. The heat shock protein (HSP) core is an invariable molecule that remains the same for each patient; the antigenic peptides are patient- and tumor-specific or pathogen-specific. When purified in a certain way, HSP-peptide complexes constitute the “fingerprint” of the cell from which they were derived. When injected into a patient, these antigenic peptides are re-expressed on the surface of important immune cells—macrophages—that play a major role in activating the immune system, resulting in a much more potent immune response than the one achieved by the expression of these same peptides by the tumor or pathogen-infected cell.

hemophilia A and B—Hemophilia A, the “classic” hemophilia, is a genetic bleeding disorder due to deficiency of the coagulation factor VIII. Hemophilia B, or “Christmas” disease, is caused by deficiency of coagulation factor IX.

hepatitis—Inflammation of the liver with accompanying liver cell damage or death, caused most often by viral infection, e.g., **hepatitis A, B, and C.**

human growth hormone—Pituitary hormone that stimulates the growth of long bones in prepubertal children.

human papillomavirus—Viral agent of warts, believed to be contagious and usually harmless, but it can lead to cervical cancer.

interferon—A glycoprotein naturally produced by cells that interferes with the ability of a virus to reproduce after it invades the body.

interleukin—An endogenous substance that stimulates the production of different types of white blood cells or leukocytes.

ischemia—Insufficient supply of blood to an organ or tissue, which can cause organ damage such as an **ischemic stroke**.

lipodystrophy—A disturbance in the way the body produces, uses and distributes fat.

lymphoma—Cancers in which the cells of lymphoid tissue, found mainly in the lymph nodes and spleen, multiply unchecked. Lymphomas fall into two categories: One is called **Hodgkin's disease**, characterized by a particular kind of abnormal cell. All others are called **non-Hodgkin's lymphomas**, which vary in their malignancy according to the nature and activity of the abnormal cells.

mAb (monoclonal antibodies)—Large protein molecules produced by white blood cells that seek out and destroy harmful foreign substances.

macular degeneration—A progressive disorder that affects the central part of the retina, causing gradual loss of vision. It is a painless condition, usually affects both eyes and is common in the elderly.

metastases/metastatic—Secondary cancers that have spread from the primary or original cancer site.

multiple myeloma—A malignant condition characterized by uncontrolled proliferation of plasma cells (a class of white blood cells) in bone marrow. Symptoms include pain and destruction of bone tissue, numbness and paralysis, kidney damage, anemia, and frequent infections.

myelodysplastic syndromes (MDS)—Blood disorders that ultimately are fatal. Patients usually succumb to infections or bleeding. The term "preleukemia" has been used to describe these disorders.

myeloid—(Also called **myelogenous**.) Pertaining to, derived from, or manifesting certain features of the bone marrow. In some cases, myeloid also pertains to certain types of non-lymphocyte white blood cells found in the bone marrow.

myocardial infarction—Damage to the heart muscle caused by stoppage or impairment of blood flow to the heart, also known as heart attack.

neuroblastoma—A tumor of the adrenal glands or sympathetic nervous system (the part of the nervous system responsible for certain automatic body functions, such as the "fight or flight response").

neutropenia—An abnormally low neutrophil count (certain white blood cells).

Orphan Drug—A drug to treat a disease that has a patient population of 200,000 or less in the United States, or a disease that has a patient population of more than 200,000 and a development cost that will not be recovered from sales in the United States.

peripheral vascular disorder—The obstruction of blood supply to the extremities, particularly the legs, caused by atherosclerosis.

Phase I—Safety testing and pharmacological profiling in humans.

Phase II—Effectiveness testing in humans.

Phase III—Extensive clinical trials in humans.

prophylaxis—Preventive treatment intended to preserve health and prevent the development of disease.

pulmonary hypertension—High blood pressure in the arteries that supply blood to the lungs.

pulmonary fibrosis—Scarring and thickening of lung tissue.

respiratory syncytial virus (RSV) disease—One of the most important causes of lower respiratory tract disease in children, accounting for more than 90 percent of cases of bronchiolitis.

restenosis—A condition where an artery plugs up again following treatment to open it up.

sepsis—A condition associated with a serious bacterial infection of the blood.

short bowel syndrome—The malabsorptive condition that arises after significant segments of the small intestine are removed.

systemic lupus erythematosus (SLE)—The most serious form of lupus, a chronic autoimmune disorder causing inflammation and damage to multiple organs.

thrombocytopenia—A reduction in the number of platelet cells in the blood, which causes a tendency to bleed, especially from the smaller blood vessels.

ulcerative colitis—A chronic inflammation and ulceration of the lining of the colon and rectum. It causes bloody diarrhea and mainly involves the left colon.

uveitis—Inflammation of the uvea, the middle layer of the eye.

xeroderma pigmentosa—A rare, inherited skin disease caused by extreme sensitivity to sunlight.

THE DRUG DISCOVERY, DEVELOPMENT AND APPROVAL PROCESS

It takes 10-15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.

Discovery/ Preclinical Testing		Clinical Trials			FDA	Phase IV
		Phase I	Phase II	Phase III		
Years	6.5	1.5	2	3.5	1.5	
Test Population	Laboratory and animal studies	20 to 100 healthy volunteers	100 to 500 patient volunteers	1,000 to 5,000 patient volunteers	Review process/ approval	Additional post-marketing testing required by FDA
Purpose	Assess safety, biological activity and formulations	Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use		
Success Rate	5,000 compounds evaluated	5 enter trials			1 approved	

THE DRUG DEVELOPMENT AND APPROVAL PROCESS

The U.S. system of new drug approvals is perhaps the most rigorous in the world.

It takes 10-15 years, on average, for an experimental drug to travel from lab to U.S. patients, according to the Tufts Center for the Study of Drug Development, based on drugs approved from 1994 through 1998. Only five in 5,000 compounds that enter preclinical testing make it to human testing. And only one of those five is approved for sale.

On average, it costs a company \$1.3 billion to get one new medicine from the laboratory to U.S. patients, according to a 2007 study by the Tufts Center for the Study of Drug Development.

Once a new compound has been identified in the laboratory, medicines are developed as follows:

Preclinical Testing. A pharmaceutical company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety.

Investigational New Drug Application (IND). After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND becomes effective if FDA does not disapprove it within 30 days. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the compound; how it is thought to work in the body; any toxic effects found in the animal studies; and how the compound is manufactured. All clinical trials must be reviewed and approved by the Institutional Review Board (IRB) where the trials will be conducted. Progress reports on clinical trials must be submitted at least annually to FDA and the IRB.

Clinical Trials, Phase I. These tests involve about 20 to 100 normal, healthy volunteers. The tests study a drug's safety profile, including the safe dosage range. The studies also determine how a drug is absorbed, distributed, metabolized, and excreted as well as the duration of its action.

Clinical Trials, Phase II. In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug's effectiveness.

Clinical Trials, Phase III. This phase usually involves 1,000 to 5,000 patients in clinics and hospitals. Physicians monitor patients closely to confirm efficacy and identify adverse events.

New Drug Application (NDA)/Biologic License Application (BLA). Following the completion of all three phases of clinical trials, a company analyzes all of the data and files an NDA or BLA with FDA if the data successfully demonstrate both safety and effectiveness. The applications contain all of the scientific information that the company has gathered. Applications typically run 100,000 pages or more. The average review time for the 26 new therapeutics approved by the FDA in 2007 was 11.1 months.

Approval. Once FDA approves an NDA or BLA, the new medicine becomes available for physicians to prescribe. A company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional trials (Phase IV) to evaluate long-term effects.

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. Pharmaceutical companies invested an estimated \$58.8 billion in research and development in 2007.

'Sharing Miracles' Television Program Features Inspirational Stories of Real Patients

Sharing Miracles—a new 30-minute public affairs television program—tells the compelling and inspirational stories of real patients. Previous episodes of *Sharing Miracles* have featured:

- Four-time Olympic Gold Medal-winner Greg Louganis, who suffers from HIV infection;
- Emmy Award-winning actor Joey Pantoliano, who suffers from clinical depression;
- *Leave It To Beaver* star Jerry Mathers, who is affected by diabetes;
- Pop icon and Broadway star Deborah Gibson, who has suffered from devastating anxiety attacks;
- Former White House Press Secretary Tony Snow, who bravely battled colon cancer;
- North Carolina State University women's basketball coach Kay Yow, a breast cancer survivor.

Future programs will highlight Academy Award winner and patient advocate Marcia Gay Harden; Olympic Gold Medal winners Mark Spitz (high cholesterol) and Bruce Jenner (attention deficit disorder); Pro Football Hall of Fame inductee and Super Bowl MVP Len Dawson (prostate cancer); and **syndicated television talk show host Montel Williams**, who suffers from **multiple sclerosis**. *Sharing Miracles* is produced by PhRMA's Communications & Public Affairs Department.

Sharing Miracles airs on Sunday mornings on 160 television stations across the United States, reaching more than 50 million households.

The show's corresponding Web site, www.sharingmiracles.com, is an interactive forum for people to relate their own personal stories of hope and survival. Every patient's battle is unique, but the collective power of shared experiences can offer great help and courage to others who are fighting for their lives.

You can find out where *Sharing Miracles* is showing in your area and order free DVDs of the show on the web site or by calling 202-835-3460.

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