

Biotechnology

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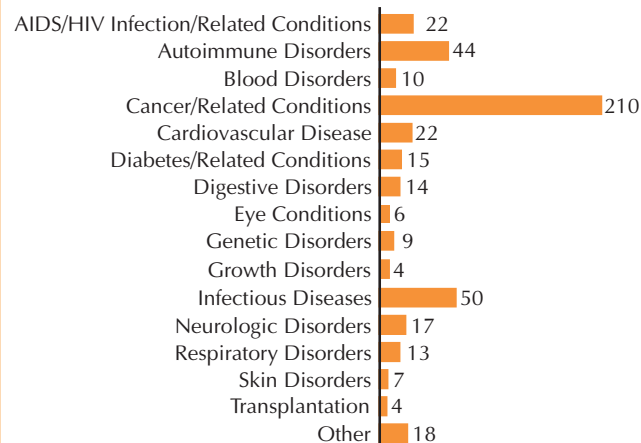
418 Biotechnology Medicines in Testing Promise to Bolster the Arsenal Against Disease

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 418 biotechnology medicines in development for more than 100 diseases. These include 210 medicines for cancer, 50 for infectious diseases, 44 for autoimmune diseases, and 22 for AIDS/HIV and related conditions. These potential medicines, all of which are either in human clinical trials or under review by the Food and Drug Administration, will add to the list of 125 biotechnology medicines already approved and available to patients.

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. The first monoclonal antibody that inhibits angiogenesis (the formation of new blood vessels) was approved for the treatment of metastatic colorectal cancer in 2004. 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 first antisense drug, for the treatment of cytomegalovirus retinitis in AIDS patients, was approved in 1998.

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

BIOTECHNOLOGY MEDICINES IN DEVELOPMENT— BY THERAPEUTIC CATEGORY*



*Some medicines are listed in more than one category.

For 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 pharmaceutical and biotechnology companies are attacking disease. The 418 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

AIDS/HIV INFECTION AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
825780 DNA antiviral vaccine	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	DNA vaccine	HIV infection	Phase I (888) 825-5249
ALVAC E120TMG	sanofi pasteur Swiftwater, PA	vaccine	HIV infection (Thailand)	Phase III (570) 839-4267
ALVAC MN120 TMGMP	sanofi pasteur Swiftwater, PA	therapeutic vaccine	HIV disease	Phase I/II completed (570) 839-4267
Ampligen®	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	immune modulator	HIV infection/AIDS (see also autoimmune)	Phase II (215) 988-0080
anti-HIV-1 MAb	Polymun Scientific Vienna, Austria	MAb	HIV infection treatment	Phase II www.polymun.com
AVX101	AlphaVax Rsch. Triangle Park, NC	gene vaccine	HIV infection	Phase I (919) 595-0400
CCR5 MAb	Human Genome Sciences Rockville, MD	MAb	HIV infection	Phase I www.hgsi.com
Cytolin® anti-CD8 MAb	CytoDyn Santa Fe, NM	MAb	HIV infection	Phase II (505) 988-5520
HGTV43 gene medicine	Enzo Therapeutics Farmingdale, NY	gene therapy	HIV-1 infection	Phase I (631) 755-5500
HIV recombinant vaccine	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	recombinant vaccine	HIV prophylaxis	Phase I (888) 825-5249
HIV DNA vaccine	Merck Whitehouse Station, NJ	recombinant vaccine	treatment and prevention of HIV infection/AIDS	Phase II (800) 672-6372
IL-2	Bayer West Haven, CT	interleukin	HIV infection	Phase I (203) 812-2000
IR103 with/ Amplivax™	Immune Response Carlsbad, CA Ideara Pharmaceuticals Cambridge, MA	immune-based therapy	HIV infection	Phase I/II (760) 431-7080 (617) 679-5500
KP-1461	Koronis Pharmaceuticals Redmond, WA	nucleoside analog	HIV/AIDS	Phase I (425) 825-0240
NM01	SRD Pharmaceuticals Los Angeles, CA	MAb	HIV infection	Phase I (617) 670-2167
PRO 140	Progenics Pharmaceuticals Tarrytown, NY	MAb	HIV infection	Phase I (914) 789-2800
Remune® HIV-1 immunogen	Immune Response Carlsbad, CA	immune-based therapy	HIV seropositive	Phase II (760) 431-7080
Serostim® somatotropin (rDNA origin) for injection (Orphan Drug)	Serono Rockland, MA	recombinant growth hormone	HIV-related adipose redistribution syndrome	Phase III (800) 275-7376

AIDS/HIV INFECTION AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
T-cell replacement therapy	Targeted Genetics <i>Seattle, WA</i>	cell therapy	HIV infection (see also autoimmune, cancer, infectious)	Phase II (206) 623-7612
TNX-355	Tanox <i>Houston, TX</i>	MAB	HIV infection	Phase II (713) 578-4000
VRC-HIVADV 014-00-VP	GenVec <i>Gaithersburg, MD</i>	vaccine	HIV infection	Phase II (240) 632-0740
VRX 496	VIRxSYS <i>Gaithersburg, MD</i>	gene therapy	HIV infection	Phase II (301) 987-0480

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ABT 325	Abbott Laboratories <i>Abbott Park, IL</i>	interleukin	autoimmune disorders	Phase I (847) 937-6100
ABT 874	Abbott Laboratories <i>Abbott Park, IL</i>	MAB	multiple sclerosis, rheumatoid arthritis (see also digestive)	Phase II (847) 937-6100
Actemra tocilizumab	Roche <i>Nutley, NJ</i>	MAB	rheumatoid arthritis, systemic-onset juvenile idiopathic arthritis	Phase III (973) 235-5000
Alferon N Injection [®] interferon alfa-n3	Hemispherx Biopharma <i>New Brunswick, NJ</i> <i>Philadelphia, PA</i>	interferon	multiple sclerosis (see also infectious)	Phase II (215) 988-0080
AME 527	Applied Molecular Evolution <i>San Diego, CA</i>	MAB	rheumatoid arthritis	Phase I (858) 597-4990
AMG 108	Amgen <i>Thousand Oaks, CA</i>	MAB	rheumatoid arthritis	Phase II (805) 447-1000
AMG 531	Amgen <i>Thousand Oaks, CA</i>	peptibody	immune thrombocytopenic purpura (ITP)	Phase III (805) 447-1000
AMG 623	Amgen <i>Thousand Oaks, CA</i>		systemic lupus erythematosus (SLE) (see also cancer)	Phase I (805) 447-1000
AMG 714	Amgen <i>Thousand Oaks, CA</i> Genmab <i>Princeton, NJ</i>	MAB	rheumatoid arthritis	Phase II completed (805) 447-1000 (609) 430-2481
Ampligen [®]	Hemispherx Biopharma <i>New Brunswick, NJ</i> <i>Philadelphia, PA</i>	immune modulator	chronic fatigue syndrome/ myalgic encephalomyelitis (CFS/ME) (see also AIDS/HIV)	Phase III completed (215) 988-0080
anti-CD16 MAB	MacroGenics <i>Rockville, MD</i>	MAB	immune thrombocytopenic purpura	Phase I (301) 251-5172

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, psoriasis, vitiligo	in clinical trials (818) 883-6716
AT-1001	Alba Therapeutics <i>Baltimore, MD</i>		celiac disease	Phase II
ATL 1102	Antisense Therapeutics <i>Toorak, Australia</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	multiple sclerosis	Phase II (760) 931-9200
Avonex [®] interferon beta-1a	Biogen Idec <i>Cambridge, MA</i>	interferon	chronic inflammatory demyelinating polyneuropathy (CIDP)	Phase II (617) 679-2000
BR3-Fc	Genentech <i>South San Francisco, CA</i>		rheumatoid arthritis	Phase I (650) 225-1000
Cimzia [™] certolizumab pegol	Nektar Therapeutics <i>San Carlos, CA</i>	pegylated antibody fragment	rheumatoid arthritis (see also digestive)	Phase III (650) 631-3100
CNTO 1275	Centocor <i>Horsham, PA</i>	MAb	multiple sclerosis (see also digestive, skin)	Phase II (610) 651-6000
daclizumab (anti-CD25 MAb)	PDL BioPharma <i>Fremont, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAB	multiple sclerosis (see also respiratory)	Phase II (510) 574-1400 (617) 679-2000
denosumab (AMG 162)	Amgen <i>Thousand Oaks, CA</i>	MAB	rheumatoid arthritis (see also cancer, other)	Phase II (805) 447-1000
ETI-201	Elusys Therapeutics <i>Pine Brook, NJ</i>	MAB	SLE	Phase I (973) 808-0222
golimumab	Centocor <i>Horsham, PA</i>	MAB	rheumatoid arthritis (see also eye)	Phase III (610) 651-6000
HuMax-CD20 (ofatumumab)	Genmab <i>Princeton, NJ</i>	MAB	rheumatoid arthritis (see also cancer)	Phase II (609) 430-2481
Humira [®] adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	MAB	ankylosing spondylitis	application submitted (847) 936-1189
			juvenile rheumatoid arthritis (see also digestive, skin)	Phase III (847) 936-1189
HuZAF [™] fontolizumab	PDL BioPharma <i>Fremont, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAB	rheumatoid arthritis	Phase II (510) 574-1400 (617) 679-2000
IMMU-106 (hCD20)	Immunomedics <i>Morris Plains, NJ</i>	MAB	autoimmune disease (see also cancer)	Phase I (973) 605-8200
interferon alpha	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	Sjogren's syndrome (see also infectious)	Phase III (806) 376-1741
			fibromyalgia	Phase II (806) 376-1741

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
interferon gamma-1b	InterMune <i>Brisbane, CA</i>	interferon	idiopathic pulmonary fibrosis	Phase III (415) 466-2200
interleukin-1 trap	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	interleukin	inflammatory diseases	Phase II (914) 345-7400
LymphoStat-B™ belimumab	Human Genome Sciences <i>Rockville, MD</i>	MAb	rheumatoid arthritis, SLE	Phase II www.hgsi.com
MEDI-545 (MDX-1103)	Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	MAb	lupus	Phase I (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)	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	recombinant protein	rheumatoid arthritis (see also skin)	Phase II (617) 441-1000
			multiple sclerosis, uveitis	Phase I (617) 441-1000
NBI-5788	Neurocrine Biosciences <i>San Diego, CA</i>	peptide therapeutic vaccine	multiple sclerosis	Phase II (858) 617-7600
ocrelizumab (2nd anti-CD20) (R1594)	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i> Roche <i>Nutley, NJ</i>	MAb	rheumatoid arthritis (see also cancer)	Phase II (650) 225-1000 (617) 679-2000 (973) 235-5000
OKT3-gamma-1	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	MAb	psoriatic arthritis (see also diabetes, transplantation)	Phase I (800) 817-5286
Orencia™ abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant soluble receptor	rheumatoid arthritis prevention, juvenile rheumatoid arthritis early rheumatoid arthritis, lupus (intravenous formulation)	Phase III (212) 546-4000
			rheumatoid arthritis (subcutaneous solution)	Phase II (212) 546-4000
Rituxan® rituximab	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAb	rheumatoid arthritis (DMARD inadequate responders), lupus, primary progressive multiple sclerosis, SLE (see also cancer)	Phase III (650) 225-1000 (617) 679-2000
			relapsing-remitting multiple sclerosis	Phase II (650) 225-1000 (617) 679-2000

AUTOIMMUNE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
TACI-Ig	Serono Rockland, MA Zymogenetics Seattle, WA	recombinant protein	SLE, rheumatoid arthritis (see also cancer)	Phase I/II (800) 275-7376 (206) 442-6000
			lupus	Phase I (800) 275-7376 (206) 442-6000
Tauferon™ interferon-tau	Pepgen Alameda, CA	interferon	multiple sclerosis	Phase II (510) 473-0010
T-cell replacement therapy	Targeted Genetics Seattle, WA	cell therapy	multiple sclerosis (see also AIDS, cancer, infectious)	Phase I (206) 623-7612
tgAAC94	Targeted Genetics Seattle, WA	gene therapy	inflammatory arthritis	Phase I (206) 623-7612
TRX 1 (anti-CD4)	TolerRx Cambridge, MA	MAB	cutaneous lupus erythematosus	Phase I (617) 354-8100
Veldona® Lozenges natural human interferon-alpha (Orphan Drug)	Amarillo Biosciences Amarillo, TX	interferon	Behcet's disease (see also other)	Phase II (806) 376-1741

BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
afelimomab	Abbott Laboratories Abbott Park, IL	MAB	sepsis, septic shock	Phase III (847) 937-6100
Aranesp® darbepoetin alfa	Amgen Thousand Oaks, CA	recombinant protein	anemia of cancer in patients not receiving chemotherapy	Phase III (805) 447-1000
			anemia in heart failure	Phase II (805) 447-1000
Dynepo™ epoetin delta	Shire Pharmaceutical Wayne, PA	erythropoietin	anemia	application submitted (484) 595-8800
eculizumab	Alexion Pharmaceuticals Cheshire, CT	MAB	paroxysmal nocturnal hemoglobinuria	Phase III (203) 272-2596
EPO-Fc	Syntonix Pharmaceuticals Waltham, MA	recombinant erythropoietin	anemia	Phase I (781) 547-6000
R744 CERA	Roche Nutley, NJ Nektar Therapeutics San Carlos, CA	continuous erythropoietin receptor activator	renal anemia	Phase III (973) 235-5000
			cancer-related anemia	Phase II (973) 235-5000
Refacto™ AF	Wyeth Collegeville, PA	recombinant clotting factor	hemophilia A	Phase III (610) 902-1200

BLOOD DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
rFX111 (Orphan Drug)	Novo Nordisk <i>Princeton, NJ</i>	recombinant coagulation factor XIII	congenital factor XIII deficiency	Phase III (800) 727-6500
rhThrombin	Zymogenetics <i>Seattle, WA</i>	recombinant human thrombin	surgical hemostasis	Phase III (206) 442-6600
urttoxazumab	Teijin Pharma <i>Tokyo, Japan</i>	MAB	hemolytic uremic syndrome	Phase I

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
1018-ISS	Dynavax Technologies <i>Emeryville, CA</i>	immune-based therapy	non-Hodgkin's lymphoma (see also respiratory)	Phase II (510) 848-5100
1311-huA33	Life Science Pharmaceuticals <i>Greenwich, CT</i>	MAB	colorectal cancer	Phase I (203) 422-6500
1D09C3	GPC Biotech <i>Waltham, MA</i>	MAB	relapsed/refractory B-cell lymphomas	Phase I (781) 890-9007
γ -fowlpox-CEA (6D)/ tricom vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	CEA-expressing tumors	Phase I/II N C I T R I A L (800) 4-CANCER
γ -fowlpox-GM-CSF vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	CEA-expressing cancers	Phase I N C I T R I A L (800) 4-CANCER
γ -fowlpox PSA vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	prostate cancer	Phase II N C I T R I A L (800) 4-CANCER
γ -fowlpox, r-vaccinia-tricom vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	head and neck cancer, melanoma	Phase I N C I T R I A L (800) 4-CANCER
AC vaccine	AVAX Technologies <i>Philadelphia, PA</i>	vaccine	non-small-cell lung cancer (NSCLC)	Phase I/II (215) 241-9760
adenovirus p53	National Cancer Institute <i>Bethesda, MD</i> Introgen Therapeutics <i>Austin, TX</i>	gene therapy	lip and oral cavity carcinoma	Phase I/II N C I T R I A L (800) 4-CANCER
Advexin®	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	head and neck cancer	Phase III (866) 631-4646
			----- esophageal cancer, perioperative (and surgery)	Phase I/II (866) 631-4646
AEG 35156	Aegera Therapeutics <i>Montreal, Quebec</i>	antisense	acute myeloid leukemia (AML)	Phase I (514) 288-5532
AGS-PSCA MAB	Agensys <i>Santa Monica, CA</i> Merck <i>Whitehouse Station, NJ</i>	MAB	prostate cancer	Phase I (310) 820-8029 (800) 672-6372

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Allovectin-7® High Dose DNA/lipid complex encoding HLA-B7 antigen (Orphan Drug)	Vical <i>San Diego, CA</i>	gene therapy/ immunotherapy	advanced metastatic melanoma	Phase II completed (858) 646-1100
ALVAC-CEA/B7.1	sanofi pasteur <i>Swiftwater, PA</i> sanofi-aventis <i>Bridgewater, NJ</i>	vaccine	colorectal cancer	Phase II completed (570) 839-4627
ALVAC gp100	sanofi pasteur <i>Swiftwater, PA</i>	vaccine	melanoma	Phase I/II completed (570) 839-4627
AMG 102	Amgen <i>Thousand Oaks, CA</i>	MAB	cancer	Phase I (805) 447-1000
AMG 386	Amgen <i>Thousand Oaks, CA</i>	recombinant protein	cancer	Phase I (805) 447-1000
AMG 479	Amgen <i>Thousand Oaks, CA</i>	MAB	cancer	Phase I (805) 447-1000
AMG 623	Amgen <i>Thousand Oaks, CA</i>		B-cell chronic lymphocytic leukemia (CLL) (see also autoimmune)	Phase I (805) 447-1000
AMG 655	Amgen <i>Thousand Oaks, CA</i>	MAB	cancer	Phase I (805) 447-1000
AMG 706	Amgen <i>Thousand Oaks, CA</i>		imatinib-resistant GIST, advanced thyroid cancer	Phase II (805) 447-1000
Angiocol™	BioStratum <i>Durham, NC</i>	recombinant protein	cancer	Phase I (919) 433-1000
anti-CD23 MAB	Biogen Idec <i>Cambridge, MA</i>	MAB	CLL	Phase II (617) 679-2000
anti-CD80 MAB	Biogen Idec <i>Cambridge, MA</i>	MAB	non-Hodgkin's B-cell lymphoma	Phase II (617) 679-2000
anti-idiotypic cancer vaccine	Viventia Biotech <i>Toronto, Ontario</i>	MAB	malignant melanoma	Phase II (416) 815-0700
anti-lymphotoxin beta receptor MAB	Biogen Idec <i>Cambridge, MA</i>	MAB	solid tumors	Phase I (617) 679-2000
anti-PEM MAB	Somanta Pharmaceuticals <i>Irvine, CA</i>	MAB	cancer	Phase I (949) 477-8090
anti-Tac(Fv)-PE38 immunotoxin	National Cancer Institute <i>Bethesda, MD</i>	MAB+toxin	leukemia, lymphoma	Phase I/II N C I T R I A L (800) 4-CANCER
Apo2L/TRIAL (AMG 951)	Amgen <i>Thousand Oaks, CA</i> Genentech <i>South San Francisco, CA</i>	soluble human protein	cancer	Phase I (805) 447-1000 (650) 225-1000

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
autologous gp100-reactive PBL and TIL plus RF-gp100P209	National Cancer Institute <i>Bethesda, MD</i>	vaccine	melanoma	Phase I/II N C I T R I A L (800) 4-CANCER
Avastin [®] bevacizumab	Genentech <i>South San Francisco, CA</i>	MAb	relapsed metastatic colorectal cancer	application submitted (650) 225-1000
			first-line metastatic breast, first-line non-squamous NSCLC cancers	Phase III completed (650) 225-1000
AVE 0005 (VEGF trap)	sanofi-aventis <i>Bridgewater, NJ</i> Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	anti-angiogenesis	solid tumors	Phase I/II (800) 633-1610
AVE 9633 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	systemic symptoms associated with advanced cancers	Phase II (914) 376-7383
bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	MAb	solid cancers (see also infectious)	Phase I (800) 694-5334
Bexidem [™] (IDM 2)	IDM Pharma <i>Irvine, CA</i>	cell therapy	bladder cancer	Phase I (949) 470-4751
BIOVAXID [™] FNHLIdl	Accentia Biopharmaceuticals <i>Morrisville, NC</i> Biovest International <i>Minneapolis, MN</i>	cellular therapy	indolent (slow-growing) follicular non-Hodgkin's lymphoma	Phase III (877) 654-6052
bivatuzumab	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	MAb	cancer	Phase II (203) 798-9988
BLX 883	Biolex <i>Pittsboro, NC</i>	interferon	cancer (see also infectious)	Phase I (919) 542-9901
BrevaRex [™] antibody-based immunotherapy	ViRexx <i>Edmonton, Alberta</i>	MAb	breast cancer, multiple myeloma	Phase I completed (780) 433-4411
CA4P	OXIGENE <i>Waltham, MA</i>	vascular targeting agent	stage III/IV NSCLC (see also eye)	Phase III (781) 547-5900
			ovarian cancers, stage III NSCLC	Phase II (781) 547-5900
			head and neck, NSCLC, prostate cancers	Phase I/II (781) 547-5900
Campath [®] alemtuzumab	National Cancer Institute <i>Bethesda, MD</i> Berlex Laboratories <i>Montville, NJ</i>	MAb	leukemia, lymphoma	Phase I/II N C I T R I A L (800) 4-CANCER

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
cancer vaccine	Centocor <i>Horsham, PA</i>	vaccine	colorectal cancer	Phase I (610) 551-6000
carcinoembryonic antigen peptide-1 vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	gastrointestinal tract cancer	Phase II N C I T R I A L (800) 4-CANCER
CAT 3888	Cambridge Antibody Technology <i>Cambridge, England</i>	MAb	hairy cell leukemia	Phase II
CB 001	Via Cell <i>Cambridge, MA</i>	cell therapy	hematological malignancies	Phase I (866) 842-2355
CDP 791 (peg-antibody fragment angiogenesis inhibitor)	Imclone Systems <i>New York, NY</i> Nektar Therapeutics <i>San Carlos, CA</i> UCB Pharma <i>Brussels, Belgium</i>	peg-antibody	cancer	Phase II (212) 645-1405 (650) 631-3100
Cerebro™ EG 009	Ark Therapeutics <i>London, England</i>	gene therapy	glioma	in clinical trials
chimeric MAb 14.18	National Cancer Institute <i>Bethesda, MD</i>	MAb	neuroblastoma	Phase III N C I T R I A L (800) 4-CANCER
CHIR-12.12	Chiron <i>Emeryville, CA</i> XOMA <i>Berkeley, CA</i>	antagonist antibody	CLL, multiple myeloma	Phase I (510) 204-7200
CMC-544	Wyeth <i>Collegeville, PA</i>	antibody-targeted chemotherapy	non-Hodgkin's lymphoma	Phase I (610) 902-1200
CMD-193	Wyeth <i>Collegeville, PA</i>	antibody-targeted chemotherapy	NSCLC	Phase I (610) 902-1200
CNTO 328	Centocor <i>Horsham, PA</i>	MAb	renal cancer	Phase I (610) 651-6000
Collidem™ (IDD-5)	IDM Pharma <i>Irvine, CA</i>	cell therapy	colorectal cancer	Phase I (949) 470-4751
Cotara™ 131-I-chTNT-I/B MAb (Orphan Drug)	Peregrine Pharmaceuticals <i>Tustin, CA</i>	MAb	brain cancer	Phase II (714) 508-6000
CP-547,632	OSI Pharmaceuticals <i>Melville, NY</i> Pfizer <i>New York, NY</i>	growth factor	ovarian cancer	Phase II (800) 572-1932
			NSCLC	Phase I/II (800) 572-1932
CP-751,871	Pfizer <i>New York, NY</i>	MAb	multiple myeloma	Phase I (860) 732-5156

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
CPG 7909	Coley Pharmaceutical Wellesley, MA Pfizer New York, NY	immune-based therapy	NSCLC	Phase III (781) 431-9000
CS 1008	Daiichi Sankyo Tokyo, Japan Sankyo Pharma Development Parsippany, NJ	MAB	cancer	Phase I (877) 4-SANKYO
denosumab (AMG 162)	Amgen Thousand Oaks, CA	MAB	bone loss induced by hormone ablation therapy for breast or prostate cancer, prolonging bone-metastases-free survival (see also autoimmune, other)	Phase III (805) 447-1000
			bone metastases in breast cancer	Phase II (805) 447-1000
ecromeximab (KW-2871)	Kyowa Hakko USA New York, NY	MAB	malignant melanoma	Phase I (212) 319-5353
EGEN-001	Expression Genetics Huntsville, AL	gene therapy	ovarian cancer	Phase I (256) 512-0077
EMD 273063	EMD Lexigen Pharmaceuticals Billerica, MA	MAB	solid tumors	Phase II (978) 294-1100
			malignant melanoma, neuroblastoma, SCLC	Phase I (978) 294-1100
Erbix™ cetuximab (IMC-C225)	Bristol-Myers Squibb Princeton, NJ ImClone Systems New York, NY	MAB	head/neck cancer	application submitted (212) 546-4000
			first-line pancreatic, first-line NSCLC, second-line NSCLC, first line colorectal, second-line colorectal cancers	Phase III (212) 546-4000
ethynylcytidine	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	RNA inhibitor	solid tumors	Phase II (888) 825-5249
FGF-5 peptides	National Cancer Institute Bethesda, MD	peptide	renal cancer	Phase II N C I T R I A L (800) 4-CANCER
Genasense®	Centa Berkeley Heights, NJ	antisense	AML	Phase III (908) 286-9800
GliAtak™	Advantagene Boston, MA San Diego, CA	gene therapy	brain cancer	Phase I (617) 916-5445 (760) 943-8981
GMK	Progenics Pharmaceuticals Tarrytown, NY	MAB	prevention of recurrence following surgery to remove primary melanoma in high-risk patients	Phase III (914) 789-2800

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
gp100 peptide vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	melanoma	Phase II/III N C I T R I A L (800) 4-CANCER
GTI 2040	Lorus Therapeutics <i>Toronto, Ontario</i>	antisense	breast, colorectal, renal cancer, solid tumors	Phase II (416) 798-1200
			AML	Phase I (416) 798-1200
GVAX® Leukemia cancer vaccine	Cell Genesys <i>South San Francisco, CA</i>	vaccine	AML	Phase II (650) 266-3000
GVAX® Pancreatic cancer vaccine	Cell Genesys <i>South San Francisco, CA</i>	vaccine	pancreatic cancer	Phase II (650) 266-3000
GVAX® Prostate cancer vaccine	Cell Genesys <i>South San Francisco, CA</i>	vaccine	hormone refractory prostate cancer	Phase III (650) 266-3000
Her2 recombinant pharmaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant pharmaccine	treatment of breast cancer	Phase I/II (888) 835-5249
Herceptin® trastuzumab	Genentech <i>South San Francisco, CA</i>	MAb	early stage HER2-positive breast cancer	application submitted (650) 225-1000
			first-line metastatic HER2-positive breast cancer in combination with Taxotere®	Phase III completed (650) 225-1000
HGS-ETR1	Human Genome Sciences <i>Rockville, MD</i>	MAB	hematologic and solid tumors	Phase I www.hgsi.com
HGS-ETR2 (mapatumumab)	Human Genome Sciences <i>Rockville, MD</i>	MAB	hematologic and solid tumors	Phase I www.hgsi.com
HGS-TR2J	Human Genome Sciences <i>Rockville, MD</i>	MAB	advanced solid tumors	Phase I www.hgsi.com
HuC242-DM4	ImmunoGen <i>Cambridge, MA</i>	MAB conjugate	colorectal, gastrointestinal, NSCLC, pancreatic cancers	Phase I (617) 995-2500
HuMax-CD4 (zanolimumab)	Genmab <i>Princeton, NJ</i> Serono <i>Rockland, MA</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>	MAB	CLL, non-Hodgkin's lymphoma (see also autoimmune)	Phase II (609) 430-2481
HuMax-EGFr	Genmab <i>Princeton, NJ</i>	MAB	head and neck cancer	Phase I/II (609) 430-2481
huN901-DM1	ImmunoGen <i>Cambridge, MA</i>	MAB conjugate	SCLC	Phase I/II (617) 995-2500
			multiple myeloma	Phase I (617) 995-2500

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
iboctadekin (recombinant human IL-18 immunomodulator)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	interleukin	immunologically-sensitive cancers (melanoma, renal cell)	Phase II (888) 825-5249
IGN101	Aphton Biopharma <i>Miami, FL</i>	MAB vaccine	NSCLC	Phase II/III www.aphton.com
IGN311	Aphton Biopharma <i>Miami, FL</i>	MAB	Lewis Y-positive tumors	Phase I completed www.aphton.com
IL-2/EP (electroporation-enhanced delivery of interleukin-1 DNA)	Vical <i>San Diego, CA</i>	gene therapy/ immunotherapy	advanced metastatic melanoma	Phase I (888) 646-1100
IL13-PE38QQR (Orphan Drug)	NeoPharm <i>Lake Forest, IL</i>	recombinant protein	glioblastoma multiforme	Phase III (847) 295-8678
IL-21	Zymogenetics <i>Seattle, WA</i>	interleukin	metastatic melanoma, metastatic renal cell carcinoma	Phase I (206) 442-6600
IMC-3G3 (PDGFRa)	ImClone Systems <i>New York, NY</i>	MAB	breast, ovarian, prostate	Phase I (212) 645-1405
IMC-11F8 (EGFR)	ImClone Systems <i>New York, NY</i>	MAB	solid tumors	Phase I (212) 645-1405
IMC-18F1 (VEGFR-1)	ImClone Systems <i>New York, NY</i>	MAB	breast	Phase I (212) 645-1405
IMC-1121b (VEGFR-2/KDR)	ImClone Systems <i>New York, NY</i>	MAB	solid and liquid tumors	Phase I (212) 645-1405
IMC-A12 (IGF-1R)	ImClone Systems <i>New York, NY</i>	MAB	solid tumors	Phase I (212) 645-1405
IMMU-100 (labetuzumab)	Immunomedics <i>Morris Plains, NJ</i>	MAB	breast, colorectal cancers, inoperable metastatic solid tumors	Phase I completed (973) 605-8200
IMMU-101 (Y-90 labetuzumab)	Immunomedics <i>Morris Plains, NJ</i>	MAB	inoperable metastatic solid tumors	Phase I completed (973) 605-8200
IMMU-102 (Y-90 epratuzumab)	Immunomedics <i>Morris Plains, NJ</i>	MAB	B-cell lymphoma	Phase I (973) 605-8200
IMMU-105 (Y-90 hAFP)	Immunomedics <i>Morris Plains, NJ</i>	MAB	liver cancer	Phase I (973) 605-8200
IMMU-106 (hCD20)	Immunomedics <i>Morris Plains, NJ</i>	MAB	non-Hodgkin's lymphoma (see also autoimmune)	Phase I/II (973) 605-8200
IMMU-107 (Y-90 hPAM4)	Immunomedics <i>Morris Plains, NJ</i>	MAB	MUC1-expressing tumors	Phase I (973) 605-8200
ING 1	Triton BioSystems <i>Chelmsford, MA</i>	MAB	adenocarcinoma	Phase I (978) 606-2900
INGN 225 (p53 vaccine)	Introgen Therapeutics <i>Austin, TX</i>	vaccine	breast, small-cell lung cancer (SCL)	Phase I/II (866) 631-4646
INGN 234 (p53 topical)	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	oral cancer prevention	Phase I/II (866) 631-4646

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
INGN 241 (mda-7)	Introgen Therapeutics <i>Austin, TX</i>	gene therapy	solid tumors	Phase III (866) 631-4646
			melanoma	Phase I/II (866) 631-4646
INGN 401 (FUS-1)	Introgen Therapeutics <i>Austin, TX</i>	vaccine	lung	Phase I (866) 631-4646
INNO-105 MET-enkephalis	Innovive Pharmaceuticals <i>New York, NY</i>	therapeutic peptide	refractory pancreatic cancer	Phase I (212) 716-1811
INNO-305 WT1 peptides	Innovive Pharmaceuticals <i>New York, NY</i>	immunotherapy	AML	Phase I (212) 716-1811
INNO-406	Innovive Pharmaceuticals <i>New York, NY</i>	kinase inhibitor	Gleevec®-refractory AML	in clinical trials (212) 716-1811
Insegia™ anti-gastrin 17	Aphton Biopharma <i>Miami, FL</i>	vaccine	advanced pancreatic cancer (see also digestive)	Phase III www.aphton.com
			advanced stomach, esophageal cancers	Phase II completed www.aphton.com
interferon alpha-2b inhalation	Aradigm <i>Hayward, CA</i>	interferon	cancer (see also infectious)	Phase I (510) 265-9000
interferon beta gene delivery	Biogen Idec <i>Cambridge, MA</i>	gene therapy	solid tumors with liver metastasis	Phase I (617) 679-2000
interleukin-3	Wyeth <i>Collegeville, PA</i>	interleukin	Hodgkin's disease, non-Hodgkin's lymphoma	Phase III (610) 902-1200
interleukin-12	National Cancer Institute <i>Bethesda, MD</i> Wyeth <i>Collegeville, PA</i>	interleukin	renal cell carcinoma	Phase I N C I T R I A L (800) 4-CANCER
ipilimumab (MDX-010)	Bristol-Myers Squibb <i>Princeton, NJ</i> Medarex <i>Princeton, NJ</i>	MAb	melanoma monotherapy	Phase III (212) 546-4000 (609) 430-2880
			leukemia, lymphoma, ovarian, prostate, renal cell cancers	Phase II (212) 546-4000 (609) 430-2880
			melanoma (MCX-010 +/- DTIC)	Phase III (212) 546-4000 (609) 430-2880
			second-line metastatic melanoma (MDX-010 disomotide/overmotide MDX-1379)	Phase III (212) 546-4000 (609) 430-2880
ISF 154 (Ad-CD-154)	Tragen <i>San Diego, CA</i>	gene therapy	CLL	Phase II (858) 623-2754

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Keplivance™ palifermin	Amgen <i>Thousand Oaks, CA</i>	recombinant growth factor	oral mucositis associated with radiation therapy and chemotherapy for solid tumors	Phase II/III (805) 447-1000
KOS-862 epothilone D	Kosan Biosciences <i>Hayward, CA</i>	polyketide	cancer, including taxane-resistant tumors	Phase I/II (510) 732-8400
KOS-953 (17-AAG)	Kosan Biosciences <i>Hayward, CA</i>	polyketide	cancer	Phase I/II (510) 732-8400
lapuleucel-T	Dendreon <i>Seattle, WA</i>	cellular immunotherapy	breast, colorectal, ovarian cancers	Phase I (206) 256-4545
LEP-ETU	NeoPharm <i>Lake Forest, IL</i>	antisense	solid tumors	Phase I (847) 295-8678
LEP-SN38	NeoPharm <i>Lake Forest, IL</i>	pro-drug	solid tumors	Phase I (847) 295-8678
LErafAON-ETU	NeoPharm <i>Lake Forest, IL</i>	antisense	cancer	Phase I (847) 295-8678
LY 2181308	Eli Lilly <i>Indianapolis, IN</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	cancer	Phase I (317) 276-2000 (800) 679-ISIS
LY 2275796	Eli Lilly <i>Indianapolis, IN</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	cancer	Phase I (317) 276-2000 (800) 679-ISIS
M195-bismuth 213 conjugate	Actinium Pharmaceuticals <i>Florham Park, NJ</i>	MAB	AML	Phase I (973) 377-0713
M200 (volociximab)	PDL BioPharma <i>Fremont, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAB	advanced solid tumors	Phase II (510) 574-1400 (617) 679-2000
MAB HeFi-1	National Cancer Institute <i>Bethesda, MD</i>	MAB	lymphoma, non-Hodgkin's lymphoma	Phase I N C I T R I A L (800) 4-CANCER
MAGE-3	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant pharmaccine	treatment of NSCLC, melanoma	Phase II (888) 825-5249
MART-1 melanoma vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	metastatic melanoma	Phase II N C I T R I A L (800) 4-CANCER
matuzumab	Merck KGaA <i>Darmstadt, Germany</i>	MAB	ovarian cancer	Phase II www.merck.de
MDX-060 (iratimumab)	Medarex <i>Princeton, NJ</i>	MAB	Hodgkin's disease, anaplastic large-cell-lymphoma	Phase II (609) 430-2880
MDX-070	Medarex <i>Princeton, NJ</i>	MAB	prostate cancer	Phase II (609) 430-2880

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
MDX-214	Medarex <i>Princeton, NJ</i>	MAb	EGFR-expressing cancers	Phase I/II (609) 430-2880
MEDI-507 siplizumab	MedImmune <i>Gaithersburg, MD</i>	MAB	T-cell lymphoma infections	Phase I (301) 398-0000
MEDI-522	MedImmune <i>Gaithersburg, MD</i>	MAB	melanoma, prostate cancer	Phase II (301) 398-0000
	National Cancer Institute <i>Bethesda, MD</i> MedImmune <i>Gaithersburg, MD</i>	MAB	solid tumors	Phase I N C I T R I A L (800) 4-CANCER
melanoma tumor-reactive autologous TIL	National Cancer Institute <i>Bethesda, MD</i>	cellular therapy	melanoma	Phase II N C I T R I A L (800) 4-CANCER
MG98	MethylGene <i>Montreal, Quebec</i> MGI Pharma <i>Bloomington, MN</i>	antisense	renal cell cancer	Phase II (514) 337-3333 (952) 346-4700
MORAb 003	Morphotek <i>Exton, PA</i>	MAB	ovarian cancer	Phase II (610) 423-6100
MORAb 009	Morphotek <i>Exton, PA</i>	MAB	mesothelin-expressing tumors	Phase I (610) 423-6100
M-Vax	AVAX Technologies <i>Philadelphia, PA</i>	vaccine	melanoma	Phase I/II (215) 241-9760
myeloma-derived idiotypic antigen vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	multiple myeloma	Phase I/II N C I T R I A L (800) 4-CANCER
neuradiab	Bradmer Pharmaceuticals <i>Louisville, KY</i>	MAB	glioblastoma	Phase II (502) 657-6038
nimotuzumab (Orphan Drug)	YM Biosciences <i>Mississauga, Ontario</i>	MAB	metastatic pancreatic, NSCLC	Phase I/II (905) 629-9761
Norelin™ recombinant GrNH protein	YM Biosciences <i>Mississauga, Ontario</i>	recombinant protein	prostate cancer	Phase I/II completed (905) 629-9761
ocrelizumab (2nd anti-CD20) (R1594)	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i> Roche <i>Nutley, NJ</i>	MAB	hematologic malignancies (see also autoimmune)	Phase I (650) 225-1000 (617) 679-2000 (973) 235-5000
OGX-011	Isis Pharmaceuticals <i>Carlsbad, CA</i> OncoGenex Technologies <i>Vancouver, British Columbia</i>	antisense	cancer	Phase II (760) 931-9200 (604) 736-3678
Omnitarg™ pertuzumab	Genentech <i>South San Francisco, CA</i>	humanized antibody	ovarian cancer	Phase II (650) 225-1000

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Oncophage™ vitespen (Orphan Drug)	Antigenics New York, NY	heat shock protein	metastatic melanoma, kidney cancer	Phase III (781) 674-4400
OncovEX®	BioVex Cambridge, MA	recombinant protein	malignant melanoma	Phase II (617) 444-8445
Ontak® denileukin diftitox	Ligand Pharmaceuticals San Diego, CA	fusion protein	B-cell non-Hodgkin's lymphoma, CLL, NSCLC, T-cell lymphoma	Phase II (858) 550-7500
OvaRex® oregovomab	ViRexx Edmonton, Alberta	MAB	ovarian cancer	Phase III (780) 433-4411
p53 and RAS vaccine	National Cancer Institute Bethesda, MD	vaccine	ovarian cancer	Phase I/II N C I T R I A L (800) 4-CANCER
P501	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	recombinant pharmaccine	prostate cancer	Phase I (888) 825-5249
PAM 4	Merck Whitehouse Station, NJ	MAB	pancreatic cancer	Phase I (800) 672-6372
PancAtak™	Advantagene Boston, MA San Diego, CA	gene therapy	pancreatic cancer	Phase I (617) 916-5445 (760) 943-8981
panitumumab (rHuMAB-EGFr)	Abgenix Fremont, CA Amgen Thousand Oaks, CA	MAB	colorectal cancer	application submitted (510) 608-6500 (805) 447-1000
PANVAC™-VF	Therion Biologics Cambridge, MA	vaccine	refractory pancreatic cancer	Phase III (617) 876-7779
	National Cancer Institute Bethesda, MD Therion Biologics Cambridge, MA	vaccine	CEA- or MUC1- expressing tumors	Phase I/II N C I T R I A L (800) 4-CANCER
Panzem® 2-methoxyestradiol (Orphan Drug)	EntreMed Rockville, MD	angiogenesis inhibitor	cancer	Phase II (240) 864-2600 www.entremed.com
pazopanib (786034)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	growth factor	solid tumors	Phase II (888) 825-5249
PBL and TIL transduced with retroviral vector-expressing anti-gp100 TCR	National Cancer Institute Bethesda, MD	gene therapy	melanoma	Phase II N C I T R I A L (800) 4-CANCER
PBL or TIL transduced with retroviral vector-expressing anti-MART-1 TCR gene	National Cancer Institute Bethesda, MD	gene therapy	melanoma	Phase I N C I T R I A L (800) 4-CANCER

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
PEG-Intron® peginterferon alfa-2b	Schering-Plough <i>Kenilworth, NJ</i>	interferon	malignant melanoma	Phase III (908) 298-4000
PG-CPT (CT-2106)	Cell Therapeutics <i>Seattle, WA</i>		colorectal cancer	Phase II (206) 282-7100
PHP (pyridoxalated hemoglobin polyoxyethylene)	Curacyte <i>Chapel Hill, NC</i>	nitric oxide scavenger	IL-2 treatment of renal cell carcinoma, melanoma (see also other)	Phase II (919) 405-4002
Proleukin® aldesleukin (interleukin-2)	Chiron <i>Emeryville, CA</i>	MAB	non-Hodgkin's lymphoma	Phase II (800) CHIRON-8
ProstAtak™	Advantagene <i>Boston, MA</i> <i>San Diego, CA</i>	gene therapy	prostate cancer	Phase II (617) 916-5445 (760) 943-8981
Prostvac®-VF recombinant vaccinia virus expressing PSA	Therion Biologics <i>Cambridge, MA</i>	vaccine	metastatic, androgen- independent prostate cancer	Phase II (617) 876-7779
	National Cancer Institute <i>Bethesda, MD</i> Therion Biologics <i>Cambridge, MA</i>	vaccine	prostate cancer	Phase I/II N C I T R I A L (800) 4-CANCER
proteinase 3 peptide vaccine	National Cancer Institute <i>Bethesda, MD</i>	vaccine	leukemia	Phase I/II N C I T R I A L (800) 4-CANCER
PSA: 154-163 (155L) Peptide	National Cancer Institute <i>Bethesda, MD</i>	vaccine	prostate cancer	Phase II N C I T R I A L (800) 4-CANCER
PSMA	Progenics Pharmaceuticals <i>Tarrytown, NY</i>	MAB	prostate cancer	Phase I/II (914) 789-2800
R1550	Roche <i>Nutley, NJ</i>	MAB	metastatic breast cancer	Phase I (973) 235-5000
RadioTheraCIM	YM BioSciences <i>Mississauga, Ontario</i>	MAB	glioma	Phase I (905) 629-9761
RAV 12	Raven Biotechnologies <i>South San Francisco, CA</i>	MAB	cancer	Phase I (650) 624-2600
renal tumor- reactive autologous TIL and PBL	National Cancer Institute <i>Bethesda, MD</i>	cellular therapy	renal cell carcinoma	Phase II N C I T R I A L (800) 4-CANCER
Rencarex® G250	Wilex <i>Munich, Germany</i>	MAB	renal cancer	Phase III www.wilex.com
Rexin-G™	Epeius Biotechnologies <i>San Marino, CA</i>	gene therapy	cancer metastases, pancreatic cancer	Phase I (626) 441-6695
rhIGFBP-3	Insmed <i>Glen Allen, VA</i>	recombinant growth factor	cancer	Phase I (804) 565-3000

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Rituxan® rituximab	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAB	indolent non-Hodgkin's lymphoma induction therapy (see also autoimmune)	application submitted (650) 225-1000 (617) 679-2000
			relapsed or refractory CLL	Phase III (650) 225-1000 (617) 679-2000
RX 0201	Rexahn Pharmaceuticals <i>Rockville, MD</i>	antisense	solid tumors	Phase I (240) 268-5300
SBIL-2 transduced autologous TIL	National Cancer Institute <i>Bethesda, MD</i>	gene therapy	melanoma	Phase I/II N C I T R I A L (800) 4-CANCER
SGN-30 (Orphan Drug)	Seattle Genetics <i>Bothell, WA</i>	MAB	cutaneous anaplastic large-cell MAb lymphoma, systemic anaplastic large-cell lymphoma, Hodgkin's disease	Phase II (425) 527-4000
SGN-33 (lintuzumab)	Seattle Genetics <i>Bothell, WA</i>	MAB	AML, myelodysplastic syndromes	Phase I (425) 527-4000
SGN-40	Seattle Genetics <i>Bothell, WA</i>	MAB	CLL	Phase I/II (425) 527-4000
			multiple myeloma, non-Hodgkin's lymphoma	Phase I (425) 527-4000
SGN-00101 (HspE7)	National Cancer Institute <i>Bethesda, MD</i> StressGen Biotechnologies <i>Victoria, British Columbia</i>	vaccine	cervical cancer	Phase I/II N C I T R I A L (800) 4-CANCER
sibrotuzumab	Life Science Pharmaceuticals <i>Greenwich, CT</i>	MAB	colorectal, head and neck, lung cancers	Phase II (203) 422-6500
sipuleucel-T	Dendreon <i>Seattle, WA</i>	cellular immunotherapy	prostate cancer	Phase II/III (206) 256-4545
SS1(dsFv)-PE38	National Cancer Institute <i>Bethesda, MD</i>	immunotoxin	solid tumors	Phase I N C I T R I A L (800) 4-CANCER
TACI-Ig	Serono <i>Rockland, MA</i> Zymogenetics <i>Seattle, WA</i>	recombinant protein	B-cell malignancies, lymphoma, multiple myeloma (see also autoimmune)	Phase I (800) 275-7376 (206) 442-6000
Tarvacin™ bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	MAB	solid tumors (see also infectious)	Phase I (714) 508-6000
T-cell replacement therapy	Targeted Genetics <i>Seattle, WA</i>	cell therapy	glioma (see also AIDS, autoimmune, infectious)	Phase II (206) 623-7612

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
Telcyta [®] TLK286	Telik <i>Palo Alto, CA</i>	tumor-activated prodrug	NSCLC (3rd line), ovarian cancer (2nd and 3rd line)	Phase III (650) 845-7700
Telintra [™] I.V. TLK199	Telik <i>Palo Alto, CA</i>		myelodysplastic syndromes	Phase II (650) 845-7700
Telintra [™] Tablets TLK199	Telik <i>Palo Alto, CA</i>	myelo-stimulant	myelodysplastic syndromes	Phase I (650) 845-7700
TG 1042 (adenovirus IFN gamma)	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene therapy	cutaneous T-cell lymphoma	Phase II (301) 816-5404
TG 4001 (MVA HPV IL2)	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene therapy	cervical dysplasia	Phase II (301) 816-5404
TG 4010 (MVA MUC1 IL2)	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene therapy	lung cancer	Phase II (301) 816-5404
ticilimumab	Pfizer <i>New York, NY</i>	MAb	metastatic melanoma	Phase III (860) 732-5156
			prostate cancer	Phase II (860) 732-5156
TNFerade [™]	GenVec <i>Gaithersburg, MD</i>	gene therapy	melanoma, pancreatic, rectal cancers	Phase II (240) 632-0740
TNX-650	Tanox <i>Houston, TX</i>	MAb	Hodgkin's disease	Phase I (713) 578-4000
TroVax [®]	BioMedica <i>San Diego, CA</i> Oxford BioMedica <i>Oxford, UK</i>	gene therapy	colorectal and renal cancers	Phase II (858) 677-6500
tucotuzumab celmoleukin	EMD Lexigen <i>Billerica, MA</i>	interleukin	colorectal, NSCLC, ovarian, prostate cancers	Phase I (978) 294-1100
tumor necrosis factor alpha	Amarillo Biosciences <i>Amarillo, TX</i>	tumor necrosis factor	malignant melanoma	Phase II (806) 376-1741
Tykerb lapatinib	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	growth factor	breast cancer	Phase III (888) 825-5249
VEGF trap	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	anti-angiogenesis	non-Hodgkin's lymphoma, solid tumors (see also eye)	Phase I (914) 345-7400

CANCER AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
veglin (VEGF antisense)	VasGene Therapeutics <i>Los Angeles, CA</i>	antisense	cancer	Phase I (323) 221-7818
			renal cell cancer with IL-2	Phase I (323) 221-7818
			mesothelioma with Alimta and cisplatin	Phase I (323) 221-7818
			mesothelioma with Genzar and carboplatin	Phase I (323) 221-7818
Voraxaze™ glucarpidase (Orphan Drug)	Protherics <i>Brentwood, TN</i>	recombinant enzyme	methotrexate toxicity	Phase III completed (615) 327-1027
Xyotax™	Cell Therapeutics <i>Seattle, WA</i>		NSCLC, ovarian cancer	Phase I/II/III (206) 282-7100
Zevalin™ ibritumomab tiuxetan	National Cancer Institute <i>Bethesda, MD</i> Biogen Idec <i>Cambridge, MA</i>	MAB	leukemia, lymphoma, non-Hodgkin's lymphoma	Phase I/II N C I T R I A L (800) 4-CANCER
ZYC 101a	MGI Pharma <i>Bloomington, MN</i>		cervical dysplasia	Phase II (952) 346-4700
ZYC 300	MGI Pharma <i>Bloomington, MN</i>	gene therapy	metastatic cancer	Phase I/II (952) 346-4700

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
AC2592 (GLP-1)	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide biologic	congestive heart failure	Phase II (858) 552-2200
BioByPass® therapeutic angiogenesis (VEGF)	GenVec <i>Rockville, MD</i>	gene therapy, growth factor	coronary artery disease	Phase II (240) 632-0740
cell therapy	Genzyme <i>Cambridge, MA</i>	cell therapy	ventricular restoration	Phase II (617) 252-7500
CETi-1 vaccine	AVANT Immunotherapeutics <i>Needham, MA</i>	vaccine	cholesterol management	Phase II (781) 433-0771
Deltavasc™	Valentis <i>Burlingame, CA</i>	gene therapy	intermittent claudication, peripheral arterial disease	Phase II completed (650) 697-1900
DX-88	Dyax <i>Cambridge, MA</i> Genzyme <i>Cambridge, MA</i>	recombinant small protein	on-pump coronary artery bypass grafting procedures (see also genetic)	Phase I/II completed (617) 225-2500 (617) 252-7500

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
FGF-1	Vical San Diego, CA Centelion France	gene therapy	peripheral arterial disease	Phase II (858) 646-1100
fibroblast growth factor 1	CardioVascular Therapeutics Las Vegas, NV	growth factor	angina pectoris (see also diabetes, skin)	Phase I (702) 248-1174
GENERX™	Collateral Therapeutics San Diego, CA	gene therapy	stable exertional angina due to coronary artery disease	Phase II/III (858) 794-3400
gene therapy	Genzyme Cambridge, MA	gene therapy	peripheral arterial disease	Phase II (617) 252-7500
			coronary artery disease	Phase I (617) 252-7500
hepatocyte growth factor gene therapy	Daiichi Sankyo Parsippany, NJ AnGes MG Osaka, Japan Vical San Diego, CA	growth factor	peripheral arterial disease	Phase II (973) 359-2600
			ischemic heart disease	Phase I (973) 359-2600
ISIS 301012	Isis Pharmaceuticals Carlsbad, CA	antisense	high cholesterol	Phase II (800) 679-ISIS
Liprostin™	Endovasc Montgomery, TX		peripheral vascular disease	Phase II (936) 582-5920
MLN 1202	Millennium Pharmaceuticals Cambridge, MA	MAb	atherosclerosis (see also autoimmune)	Phase II (800) 589-9005
pexelizumab	Alexion Pharmaceuticals Cheshire, CT Procter & Gamble Pharmaceuticals Mason, OH	MAb	acute myocardial infarction, cardiopulmonary bypass	Phase III (203) 272-2596
Resten-MP	AVI BioPharma Portland, OR	antisense	cardiovascular restinosis	Phase II (503) 227-0554
Resten-NG	AVI BioPharma Portland, OR	antisense	cardiovascular restinosis	Phase II completed (503) 227-0554
TP10	AVANT Immunotherapeutics Needham, MA	recombinant soluble receptor	adult cardiac surgery	Phase II (781) 433-0771
trafermin	Kaken Pharmaceuticals New York, NY	growth factor	coronary disorders, peripheral vascular disease	Phase II (212) 372-8910
Trinam® EG 004	Ark Therapeutics London, England	gene therapy	vascular restenosis	Phase II
vascular endothelial growth factor 2 (VEGF.2)	Corautus Genetics Atlanta, GA Vical San Diego, CA	gene therapy	severe angina (see also diabetes)	Phase II (404) 526-6200
			critical limb ischemia	Phase I (404) 526-6200

CARDIOVASCULAR DISEASE

Product Name	Sponsor	Product Category	Indication	Development Status
XRP0038 (NV1FGF)	sanofi-aventis <i>Bridgewater, NJ</i>	gene therapy	peripheral arterial disease	Phase II (800) 633-1610

DIABETES AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AMG 221	Amgen <i>Thousand Oaks, CA</i>		type 2 diabetes	Phase I (805) 447-1000
anti-CD3 MAb	MacroGenics <i>Rockville, MD</i>	MAB	type-1 diabetes mellitus	Phase II (301) 251-5172
cellular implant therapy	Sertoli Technologies <i>Tucson, AZ</i>	cell therapy	type-1 diabetes mellitus	in clinical trials (320) 748-4400
exenatide LAR	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide biologic	type 2 diabetes	Phase II (858) 552-2200
fibroblast growth factor 1	CardioVascular Therapeutics <i>Las Vegas, NV</i>	growth factor	diabetic foot ulcers (see also cardiovascular, skin)	Phase I (702) 248-1174
INGAP peptide	GMP Companies <i>Ft. Lauderdale, FL</i>	recombinant protein	type-1 and type-2 diabetes mellitus	Phase I (954) 745-3510
Iplex™ mecasermin rinsatate (Orphan Drug)	Insmed <i>Glen Allen, VA</i>	growth factor	extreme insulin resistance (see also other)	Phase II (804) 565-3000
ISIS 113715	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	type 2 diabetes	Phase II (800) 679-ISIS
liraglutide (NN2211)	Novo Nordisk <i>Princeton, NJ</i>	incretin mimetic	adjunct to diet and exercise to improve glycemic control in type 2 diabetes	Phase III (800) 727-6500
NBI-6024	Neurocrine Biosciences <i>San Diego, CA</i>	peptide therapeutic vaccine	type 1 diabetes	Phase II (858) 617-7600
NovoLog® Mix 30/70 30% insulin aspart protamine suspension and 70% insulin aspart injection (4DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	diabetes mellitus	application submitted (800) 727-6500
NovoLog® Mix 50/50 50% insulin aspart protamine suspension and 50% insulin aspart injection (4DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	diabetes mellitus	application submitted (800) 727-6500

DIABETES AND RELATED CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
OKT3-gamma-1	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	MAB	type-1 diabetes mellitus (see also autoimmune, transplantation)	Phase I (800) 817-5286
topical VEGF	Genentech <i>South San Francisco, CA</i>	growth factor	diabetic foot ulcers	Phase II (650) 225-1000
TRX 4 (anti-CD3)	TolerRx <i>Cambridge, MA</i>	MAB	type-1 diabetes mellitus (see also skin)	Phase I (617) 354-8100
vascular endothelial growth factor 2 (VEGF.2)	Corautus Genetics <i>Atlanta, GA</i> Vical <i>San Diego, CA</i>	gene therapy	diabetic neuropathy (see also cardiovascular)	Phase I (404) 526-6200

DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ABT 874	Abbott Laboratories <i>Abbott Park, IL</i>	MAB	Crohn's disease (see also autoimmune)	Phase II (847) 937-6100
alicaforfen (ISIS 2302)	Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	ulcerative colitis	Phase II (800) 679-ISIS
Cimzia TM certolizumab pegol	Nektar Therapeutics <i>San Carlos, CA</i>	pegylated antibody fragment	Crohn's disease (see also autoimmune)	application submitted (650) 631-3100
CNTO 1275	Centocor <i>Horsham, PA</i>	MAB	Crohn's disease (see also autoimmune, skin)	Phase II (610) 651-6000
Humira [®] adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	MAB	Crohn's disease (see also autoimmune, skin)	Phase III (847) 936-1189
Insegia TM anti-gastrin 17	Aphton <i>Miami, FL</i>	vaccine	gastroesophageal reflux disease (GERD), gastrointestinal ulcerations (see also cancer)	Phase II www.aphton.com
MDX-066 (CDA-1)	Medarex <i>Princeton, NJ</i>	MAB	<i>C. difficile</i> disease	Phase II (609) 430-2880
MDX-1100	Medarex <i>Princeton, NJ</i>	MAB	ulcerative colitis	Phase I (609) 430-2880
MLN-02	Millennium Pharmaceuticals <i>Cambridge, MA</i>	MAB	ulcerative colitis	Phase II (800) 589-9005
Nuvion [®] visilizumab	PDL BioPharma <i>Fremont, CA</i>	MAB	I.V. steroid-refractory ulcerative colitis	Phase II/III (510) 574-1400
			Crohn's disease	Phase I (510) 574-1400

DIGESTIVE DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
Prochymal™ human mesenchymal stem cell therapy	Osiris Therapeutics <i>Baltimore, MD</i>	cell therapy	Crohn's disease (see also transplantation)	Phase II (410) 522-5005
teduglutide (ALX-0600)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	recombinant DNA	short bowel syndrome	Phase III (801) 583-4939
			Crohn's disease	Phase II (801) 583-4939
tolevamer (toxin binder)	Genzyme <i>Cambridge, MA</i>	polymer-based toxin binder	treatment of <i>C. difficile</i> colitis	Phase III (617) 252-7500
Tysarbi® natalizumab	Biogen Idec <i>Cambridge, MA</i>	MAB	Crohn's disease	Phase III (617) 679-2000

EYE CONDITIONS

Product Name	Sponsor	Product Category	Indication	Development Status
AdPEDF	GenVec <i>Gaithersburg, MD</i>	gene therapy	severe wet age-related macular degeneration	Phase I (240) 632-0740
CA4P	OXiGENE <i>Watertown, MA</i>	vascular targeting agent	myopic macular degeneration (see also cancer)	Phase II (617) 673-7800
golimumab	Centocor <i>Horsham, PA</i>	MAB	uveitis (see also autoimmune)	Phase I (610) 651-6000
Lucentis™ ranibizumab	Genentech <i>South San Francisco, CA</i>	antibody fragment	wet age-related macular degeneration	application submitted (650) 225-1000
			diabetic macular edema	Phase II (650) 225-1000
NT 501 ciliary neurotrophic factor	Neurotech <i>Lincoln, RI</i> <i>Paris, France</i>	cell therapy	age-related macular degeneration	Phase II (401) 333-3880
			retinal disorders	Phase I (401) 333-3880
VEGF trap	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	anti-angiogenesis	age-related macular degeneration (see also cancer)	Phase I (914) 345-7400

GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
AGTC 0106	Applied Genetic Technologies <i>Alachua, FL</i>	gene therapy	alpha-1 anti-trypsin deficiency	Phase I (386) 462-2204

GENETIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
DNA nanoparticle gene therapy	Copernicus Therapeutics <i>Cleveland, OH</i>	gene therapy	cystic fibrosis	Phase I (216) 231-0227
DX-88	Dyax <i>Cambridge, MA</i> Genzyme <i>Cambridge, MA</i>	recombinant small protein	treatment of hereditary angioedema (see also cardiovascular)	Phase III (617) 225-2500 (617) 252-7500
DX-890	Dyax <i>Cambridge, MA</i>	recombinant small protein	cystic fibrosis	Phase II (617) 225-2500
elaprase	Shire <i>Wayne, PA</i>	gene therapy	Hunter syndrome	Phase II (484) 595-8800
GA-GCB (gene-activated glucocerebrosidase)	Shire <i>Wayne, PA</i>	gene therapy	Gaucher disease	Phase I (484) 595-8800
HuCNS-SC™	StemCells <i>Palo Alto, CA</i>	cell therapy	infantile and late-infantile neuronal ceroid lipofuscinosis (NCL) – Batten disease	Phase I (650) 475-3100
Soliris™ eculizumab (Orphan Drug)	Alexion Pharmaceuticals <i>Cheshire, CT</i>	MAB	paroxysmal nocturnal hemoglobinuria (PNH)	Phase III (203) 272-2596
TheraCLEC™-Total ALTU-135	Altus Pharmaceuticals <i>Cambridge, MA</i>	enzyme replacement therapy	treatment of malabsorption as a result of pancreatic insufficiency	Phase II (617) 299-2900

GROWTH DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ALTU-238	Altus Pharmaceuticals <i>Cambridge, MA</i>	growth hormone	somatotropin deficiency	Phase II (617) 299-2900
Biosphere® somatropin	SkyePharma <i>San Diego, CA</i>	growth hormone	growth disorders	Phase I (858) 625-2424
oral recombinant human growth hormone (somatropin)	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant human growth hormone	somatropin deficiency	Phase I (914) 347-2220 (888) NOW-NOVA
Valtropin™ somatropin	LG Life Sciences <i>Seoul, South Korea</i>	recombinant human growth hormone	somatropin deficiency	application submitted

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
ABthrax™ raxibacumab	Human Genome Sciences <i>Rockville, MD</i>	MAB	anthrax	Phase I www.hgsi.com

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
AG-707 vaccine	Antigenics New York, NY	recombinant protein	herpes simplex virus type 2 (HSV-2)	Phase I (866) 805-8994
Albuferon™ albumin-interferon alpha	Human Genome Sciences Rockville, MD	interferon	chronic hepatitis C	Phase II www.hgsi.com
Alferon LDO®	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	interferon	antiviral indications	Phase I/II (215) 988-0080
Alferon N Injection® interferon alfa-n3	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	interferon	West Nile virus (see also autoimmune)	Phase II (215) 988-0080
AltaStaph™	Nabi Biopharmaceuticals Rockville, MD	immune globulin	prevention of <i>Staphylococcus aureus</i>	Phase II (301) 770-3099
Anthim™ (ETI-204) (Orphan Drug)	Elusys Therapeutics Pine Brook, NJ	MAb	anthrax	Phase I (973) 808-0222
anti-hsp90 MAb	NeuTec Pharma Manchester, England	MAB	candidiasis	Phase II
anti-staph MAb (pagibaximab)	MedImmune Gaithersburg, MD	MAB	prevention of staphylococcal infections	Phase II (301) 398-0000
Aurexis tefibazumab	Inhibitex Atlanta, GA	MAB	prevention and treatment of <i>S. aureus</i> bacteremia	Phase II (678) 746-1182
AVI-4065	AVI BioPharma Portland, OR	antisense	hepatitis C	Phase II (503) 227-0554
bavituximab	Peregrine Pharmaceuticals Tustin, CA	MAB	chronic hepatitis C (see also cancer)	Phase I (800) 694-5334
BLX 883 (recombinant alfa interferon)	Biolex Pittsboro, NC	interferon	hepatitis C treatment (see also cancer)	Phase I (919) 542-9901
CAIV-T	MedImmune Gaithersburg, MD	vaccine	prevention of influenza	Phase III (301) 398-0000
Cervarix™ HPV vaccine	MedImmune Gaithersburg, MD GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	recombinant vaccine	prevention of human papillomavirus infection	Phase III (301) 398-0000 (888) 825-5249
CholeraGarde® cholera vaccine	AVANT Immunotherapeutics Needham, MA	vaccine	cholera	Phase II (781) 433-0771
Civacir™	Nabi Biopharmaceuticals Rockville, MD	polyclonal antibody	hepatitis C	Phase I (301) 770-3099
DNA vaccine (anthrax)	Vical San Diego, CA	vaccine	anthrax	Phase I (858) 646-1100
DNA vaccine (CMV)	Vical San Diego, CA	vaccine	cytomegalovirus (CMV)	Phase II (858) 646-1100
DNA vaccine (ebola)	Vical San Diego, CA	vaccine	ebola virus	Phase I (858) 646-1100

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
DNA vaccine (West Nile)	Vical <i>San Diego, CA</i>	vaccine	West Nile virus	Phase I (858) 646-1100
Epstein-Barr virus vaccine	MedImmune <i>Gaithersburg, MD</i> GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	Epstein-Barr virus infection prophylaxis	Phase II (301) 398-0000 (888) 825-5249
FluBIOk™ derived from recombinant hemagglutinin (rHA)	Protein Sciences <i>Meriden, CT</i>	recombinant vaccine	influenza	Phase II/III (203) 686-0800
HEPLISAV™	Dynavax Technologies <i>Emeryville, CA</i>	immune-based therapy	hepatitis B prophylaxis	Phase III (510) 848-5100
herpes DNA vaccine	PowderMed <i>Oxford, England</i>	DNA vaccine	herpes simplex virus infections	Phase I
IL-1Ra gene therapy	PowderMed <i>Oxford, England</i>	gene therapy	hepatitis B treatment	Phase I
Immuntin™	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	cellular therapy	infectious disease	Phase II/III (858) 587-9333
INNO 102	Innogenetics <i>Gent, Belgium</i>	DNA vaccine	hepatitis B treatment	Phase I
interferon alpha	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	human papillomavirus infections (see also autoimmune)	Phase II (806) 376-1741
interferon alpha-2b inhalation	Aradigm <i>Hayward, CA</i>	interferon	hepatitis C treatment (see also cancer)	Phase I (510) 265-9000
interferon omega	Intarcia Therapeutics <i>Emeryville, CA</i>	interferon	hepatitis C	Phase II (510) 652-2600
Locteron™ controlled-release alfa interferon	Biolex Therapeutics <i>Pittsboro, NC</i>	interferon	hepatitis C	Phase I (919) 542-9901
MDX-1303	Medarex <i>Princeton, NJ</i> PharmAthene <i>Annapolis, MD</i>	MAB	anthrax	Phase I (609) 430-2880
MEDI-534 RSV/PIV-3 vaccine	MedImmune <i>Gaithersburg, MD</i>	vaccine	prevention of respiratory syncytial virus (RSV) and PIV-3 viruses	Phase I (301) 398-0000
Mosquirix malaria vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	malaria prophylaxis	Phase II (888) 825-5249
Numax™ motavizumab	MedImmune <i>Gaithersburg, MD</i>	MAB	RSV	Phase III (301) 398-0000

INFECTIOUS DISEASES

Product Name	Sponsor	Product Category	Indication	Development Status
recombinant neuraminidase (rNA)	Protein Sciences <i>Meriden, CT</i>	recombinant protein	influenza	Phase II (203) 686-0800
rhMBL (recombinant human mannose-binding lectin [MBL])	Enzon Pharmaceuticals <i>Bridgewater, NJ</i>	recombinant protein	severe infections in MBL-deficient individuals undergoing chemotherapy	Phase I (908) 541-8600
rPA102 (recombinant protective antigen)	VaxGen <i>Brisbane, CA</i>	recombinant vaccine	inhaled anthrax (pre- and post-exposure)	Phase II (650) 624-1000
Simplirix	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	genital herpes prophylaxis	Phase III (888) 825-5249
<i>S. pneumoniae</i> recombinant vaccine (elderly)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of <i>S. pneumoniae</i> in the elderly	Phase I (888) 825-5249
<i>S. pneumoniae</i> recombinant vaccine (PGCvax)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of <i>S. pneumoniae</i> in children	Phase III (888) 825-5249
Tarvacin™ bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	MAB	hepatitis C (see also cancer)	Phase I (714) 508-6000
T-cell replacement therapy	Targeted Genetics <i>Seattle, WA</i>	cell therapy	cytomegalovirus infections, Epstein-Barr virus infection (see also AIDS, autoimmune, cancer)	Phase I (206) 623-7612
tifacogin (TFPI)	Chiron <i>Emeryville, CA</i>	recombinant protein	severe community-acquired pneumonia	Phase III (800) CHIRON-8
tuberculosis recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	tuberculosis	Phase I/II (888) 825-5249
Ty800 typhoid fever vaccine	AVANT Immunotherapeutics <i>Needham, MA</i>	vaccine	typhoid fever	Phase I (781) 433-0771
varicella zoster virus recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	prevention of varicella zoster	Phase I (888) 825-5249
velafermin	CuraGen <i>Branford, CT</i>	growth hormone	stomatitis	Phase II (203) 481-1104
XTL 6865	XTL Biopharmaceuticals <i>New York, NY</i>	MAB	hepatitis C	Phase I (212) 531-5965

NEUROLOGIC DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ACC-001	Wyeth <i>Collegeville, PA</i>	immune-based therapy	Alzheimer's disease (active immunotherapy)	Phase I (800) 934-5556
Altropane® E-IACFT	Boston Life Sciences <i>Hopkinton, MA</i>	molecular imaging agent	diagnosis of Parkinson's disease	Phase III (508) 497-2360
			diagnosis of attention deficit/hyperactivity disorder	Phase II (508) 497-2360
Alzhemed™	Neurochem <i>Laval, Quebec</i>	anti-amyloidotic (AB) agent	Alzheimer's disease	Phase III
AMG 403	Amgen <i>Thousand Oaks, CA</i>	growth factor	neuropathic pain	Phase I (805) 447-1000
AMG 517	Amgen <i>Thousand Oaks, CA</i>		pain	Phase I (805) 447-1000
bapineuzumab (AAB-001)	Elan <i>New York, NY</i> Wyeth <i>Collegeville, PA</i>	immune-based therapy	Alzheimer's disease (passive immunotherapy)	Phase II (610) 902-1200
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 I (858) 458-8800
Cerebril™	Neurochem <i>Laval, Quebec</i>	anti-amyloidotic (AB) agent	hemorrhagic stroke caused by cerebral amyloid angiopathy	Phase II
desmoteplase	Forest Laboratories <i>New York, NY</i>	recombinant plasminogen activator	acute stroke	Phase II/III
IL-1Ra gene therapy	PowderMed <i>Oxford, England</i>	gene therapy	hepatitis B treatment	Phase I www.powdermed.com
MYO-029 (stamulumab)	Wyeth <i>Collegeville, PA</i>	recombinant antibody	muscular dystrophy	Phase I (800) 934-5556
MyoDys®	Transgene <i>Strasbourg, France</i> <i>Kensington, MD</i>	gene therapy	Duchenne/Becker muscular dystrophy	Phase I (301) 816-5404
NLX P101	Neurologix <i>Fort Lee, NJ</i>	gene therapy	Parkinson's disease	Phase I (201) 592-6451
RN624	Rinat Neuroscience <i>South San Francisco, CA</i>	MAb	osteoarthritis pain	Phase II (650) 615-7300
RN1219	Rinat Neuroscience <i>South San Francisco, CA</i>	MAb	Alzheimer's disease	Phase I (650) 615-7300
Spheramine® allogeneic human retinal pigment epithelial cells on gelatin microcarriers (Orphan Drug)	Titan Pharmaceuticals <i>South San Francisco, CA</i>	cellular therapy	Parkinson's disease	Phase II (650) 244-4990

RESPIRATORY DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
1018-ISS	Dynavax Technologies <i>Emeryville, CA</i>	immune-based therapy	asthma (see also cancer)	Phase II (510) 848-5100
ABN 912	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	MAB	asthma, chronic obstructive pulmonary disorders (COPD)	Phase I (888) NOW-NOV
ABX-IL8	Amgen <i>Thousand Oaks, CA</i>	MAB	COPD	Phase II (805) 447-1000
AMG 317	Amgen <i>Thousand Oaks, CA</i>	MAB	asthma	Phase I (805) 447-1000
daclizumab (anti-CD25 MAb)	Protein Design Labs <i>Fremont, CA</i> Roche <i>Nutley, NJ</i>	MAB	asthma (see also autoimmune)	Phase II (510) 574-1400
Enbrel [®] etanercept	Amgen <i>Thousand Oaks, CA</i> Wyeth <i>Collegeville, PA</i>	recombinant soluble receptor	asthma	Phase II (610) 902-1200
IMA-638	Wyeth <i>Collegeville, PA</i>	anti-interleukin-13 antibody	asthma	Phase I (610) 902-1200
MEDI-528 anti-IL-9 MAb	MedImmune <i>Gaithersburg, MD</i>	MAB	asthma	Phase I (301) 398-0000
mepolizumab (anti-IL5 MAb)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	MAB	asthma and nasal polyposis (see also other)	Phase II (888) 825-5249
rhCC10	CC10 Sweden <i>Stockholm, Sweden</i>	recombinant human protein	prevention of broncho-pulmonary dysplasia in preterm infants, viral exacerbation of chronic obstructive pulmonary disorders	Phase I (301) 452-2899
TNX-832	Tanox <i>Houston, TX</i>	MAB	respiratory diseases	Phase I (713) 578-4000
TPI-ASM8	Topigen Pharmaceuticals <i>Randolph, NJ</i>	antisense gene therapy	asthma	Phase II (973) 809-5582
Xolair [®] omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	MAB	pediatric asthma (see also other)	Phase III (650) 225-1000

SKIN DISORDERS

Product Name	Sponsor	Product Category	Indication	Development Status
ATL 1101	Antisense Therapeutics <i>Toorak, Australia</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	psoriasis	Phase I (760) 931-9200
CNTO 1275	Centocor <i>Horsham, PA</i>	MAB	psoriasis (see also autoimmune, digestive)	Phase II/III (610) 651-6000
Dimericine® T4N5 liposome lotion	AGI Dermatics <i>Freeport, NY</i>		xeroderma pigmentosa	Phase III completed (516) 868-9026
			prevention of skin cancer in renal transplant patients	Phase II (516) 868-9026
fibroblast growth factor 1	CardioVascular Therapeutics <i>Las Vegas, NV</i>	growth factor	wounds (see also cardiovascular, diabetes)	Phase I (702) 248-1174
Humira® adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	MAB	psoriasis (see also autoimmune, digestive)	Phase III (847) 937-6100
MM-093 (recombinant human alpha-fetoprotein)	Merrimack Pharmaceuticals <i>Cambridge, MA</i>	recombinant protein	psoriasis (see also autoimmune)	Phase II (617) 441-1000
TRX 4 (anti-CD3)	TolerRx <i>Cambridge, MA</i>	MAB	psoriasis (see also diabetes)	Phase I (617) 354-8100

TRANSPLANTATION

Product Name	Sponsor	Product Category	Indication	Development Status
belatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant soluble receptor	prevention of solid organ transplantation rejection	Phase III (212) 546-4000
OKT3-gamma-1	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	MAB	renal transplant rejection (see also autoimmune, diabetes)	Phase I (800) 817-5286
Prochymal™ human mesenchymal stem cell therapy	Osiris Therapeutics <i>Baltimore, MD</i>	cell therapy	bone marrow transplant rejection, graft-versus-host disease (see also digestive)	Phase II (410) 522-5005
Thymoglobulin® anti-thymocyte globulin (rabbit)	Genzyme <i>Cambridge, MA</i>	polyclonal antibody	living kidney donor	Phase II (617) 252-7500
			liver transplant	Phase II (617) 252-7500

OTHER

Product Name	Sponsor	Product Category	Indication	Development Status
AC162352 (PYY 3-36)	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide biologic	obesity	Phase I (858) 552-2200
CR 0002	CuraGen <i>Branford, CT</i>	MAb	kidney inflammation	Phase I (203) 481-1104
denosumab (AMG 162)	Amgen <i>Thousand Oaks, CA</i>	MAb	postmenopausal osteoporosis (see also autoimmune, cancer)	Phase III (805) 447-1000
Fibrillex™ NC-503 (Orphan Drug)	Neurochem <i>Laval, Quebec</i>	anti-amyloidosis (AA) agent	AA amyloidosis	Phase II/III
GEM OS1™ Bone Graft	BioMimetic Therapeutics <i>Franklin, TN</i>	recombinant growth factor	foot and ankle fusion distal radius fractures	Phase I (615) 844-1280
human liver cell therapy	Vesta Therapeutics <i>Durham, NC</i>	cellular therapy	cirrhosis of the liver, end-stage liver disease	Phase I (919) 433-1900
Iplex™ mecasermin rinsatate	Insmed <i>Richmond, VA</i>	growth factor	AIDS lipodystrophy, myotonic dystrophy (see also diabetes)	Phase II (804) 565-3000
mepolizumab (anti-IL5 MAb)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	MAb	hypereosinophilic syndrome, eosinophilic esophagitis (see also respiratory)	Phase II (888) 825-5249
oral recombinant parathyroid hormone 1-34	Emisphere Technologies <i>Tarrytown, NY</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	recombinant protein	bone-related disease	Phase I (914) 347-2220 (888) NOW-NOVA
PHP pyridoxalated hemoglobin polyoxyethylene	Curacyte <i>Chapel Hill, NC</i>	nitric oxide scavenger	distributive shock (see also cancer)	Phase III (919) 405-4002
pramlintide (AC137)	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide biologic	obesity	Phase II (858) 552-2200
Preos™ recombinant human parathyroid hormone (rhPTH)	NPS Pharmaceuticals <i>Salt Lake City, UT</i>	recombinant human parathyroid hormone	post-menopausal osteoporosis	application submitted (801) 583-4939
Puricase® PEG-uricase (Orphan Drug)	Savient Pharmaceuticals <i>East Brunswick, NJ</i>	recombinant enzyme	symptomatic gout that is unresponsive to conventional treatments	Phase II (800) 284-2480
rhBMP-2 injectable	MedTronic <i>Minneapolis, MN</i> Wyeth <i>Collegeville, PA</i>	recombinant growth factor	closed fracture treatment	Phase I (610) 902-1200
tissue repair cells (adult bone marrow-derived stem cells)	Aastrom Biosciences <i>Ann Arbor, MI</i>	cellular therapy	long bone fractures	Phase I/II (734) 930-5555

OTHER

Product Name	Sponsor	Product Category	Indication	Development Status
Tolamba™	Dynavax Technologies <i>Emeryville, CA</i>	immune-based therapy	ragweed allergy	Phase II/III (510) 848-5100
Valtropin™ somatotropin	LG Life Sciences <i>Seoul, South Korea</i>	recombinant human growth hormone	somatropin deficiency	application submitted
Veldona® Lozenges natural human interferon-alpha (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	interferon	essential thrombocythemia and polycythemia vera (combined trial) (see also autoimmune)	Phase II (806) 376-1741
vertoporfin	QLT <i>Vancouver, British Columbia</i>	photodynamic therapy	benign prostatic hyperplasia	Phase II (604) 707-7472
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)	Phase II (650) 225-1000

The content of this survey has been obtained through government sources, industry sources, and the "Adis R&D Insight" database based on the latest information. **Survey current as of June 1, 2006.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly. The entire series of "Medicines in Development" is available on PhRMA's web site.

A publication of PhRMA's Communications Department. (202) 835-3460

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Approved Biotechnology Products

Product Name	Company	Product Category	Indication
Actimmune® interferon gamma-1b	InterMune <i>Brisbane, CA</i>	interferon	management of chronic granulomatous disease (December 1990); malignant osteopetrosis (February 2000)
Activase® alteplase, recombinant	Genentech <i>South San Francisco, CA</i>	tissue plasminogen activator	acute myocardial infarction (November 1987); acute massive pulmonary embolism (June 1990); acute myocardial infarction (accelerated infusion) (April 1995); ischemic stroke within 3 to 5 hours of symptom onset (June 1996)
Adagen® Injection pegademase bovine	Enzon <i>Bridgewater, NJ</i>	enzyme replacement therapy	treatment of severe combined immunodeficiency disease (SCID) (March 1990)
Advate antihemophilic factor (recombinant) plasma/albumin-free method	Baxter Healthcare <i>Deerfield, IL</i>	recombinant factor VIII	hemophilia A (July 2003)
Aldurazyme® laronidase for injection (Orphan Drug)	BioMarin Pharmaceutical <i>Novato, CA</i> Genzyme <i>Cambridge, MA</i>	enzyme replacement therapy	treatment of mucopolysaccharidosis-I (MPS-I) (April 2003)
Alferon N Injection® Interferon alfa-n2	Hemispherx Biopharma <i>New Brunswick, NJ</i> <i>Philadelphia, PA</i>	interferon	genital warts (October 1989)
Amevive® alefacept	Biogen Idec <i>Cambridge, MA</i>	fusion protein	moderate to severe chronic plaque psoriasis (January 2003)
Apidra® insulin glulisine (rDNA origin) injection	sanofi-aventis <i>Bridgewater, NJ</i>	recombinant insulin	treatment of adults with diabetes mellitus for the control of hyperglycemia (April 2004)
Apligraf™ graftskin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	cell/tissue therapy	treatment of venous leg ulcers (May 1998)
Aranesp® darbepoetin alfa	Amgen <i>Thousand Oaks, CA</i>	recombinant protein	treatment of anemia in chronic renal failure (September 2001); treatment of chemotherapy-induced anemia (July 2002)
Avastin™ bevacizumab	Genentech <i>South San Francisco, CA</i>	MAb	in combination with intravenous 5-fluorouracil-based chemotherapy as a treatment for patients with first-line—or previously untreated—metastatic colorectal cancer (February 2004)
Avonex® interferon beta-1a	Biogen Idec <i>Cambridge, MA</i>	interferon	relapsing multiple sclerosis (May 1996); treatment after initial multiple sclerosis attack if a brain MRI shows abnormalities characteristic of the disease (February 2003)
BeneFIX™ coagulation factor IX	Wyeth <i>Collegeville, PA</i>	clotting factor	hemophilia B (February 1997)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Betaseron [®] recombinant interferon beta-1b	Berlex Laboratories <i>Montville, NJ</i> Chiron <i>Emeryville, CA</i>	interferon	relapsing-remitting multiple sclerosis (July 1993); relapsing forms of multiple sclerosis (March 2003)
Bexxar [®] tositumomab, iodine I 131 tositumomab	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	radio- immunotherapy MAB	CD20-positive, follicular non-Hodgkin's lymphoma (June 2003); CD20 antigen-expressing relapsed or refractory, low-grade, follicular or transformed non-Hodgkin's lymphoma (January 2005)
BioTropin [™] human growth hormone	Bio-Technology General <i>Iselin, NJ</i>	human growth hormone	growth hormone deficiency in children (May 1995)
Byetta [™] exenatide	Amylin Pharmaceuticals <i>San Diego, CA</i> Eli Lilly <i>Indianapolis, IN</i>	peptide biologic	treatment of type 2 diabetes (April 2005)
Campath [®] alemtuzumab	Berlex Laboratories <i>Montville, NJ</i> Genzyme <i>Cambridge, MA</i>	MAB	treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy (May 2001); single-use vial (October 2004)
Carticel [®] autologous cultured chondrocytes	Genzyme <i>Cambridge, MA</i>	autologous cell therapy	repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear) caused by acute or repetitive trauma (August 1997)
CEA-Scan [®] technetium-99m- arctumomab	Immunomedics <i>Morris Plains, NJ</i>	monoclonal antibody (MAB), Fab' fragment	presence, location and detection of recurrent and metastatic colorectal cancer (June 1996)
Cerezyme [®] imiglucerase for injection	Genzyme <i>Cambridge, MA</i>	enzyme replacement therapy	treatment of type 1 Gaucher disease (May 1994)
Comvax [™] Haemophilus b conjugate (meningococcal protein conjugate) and hepatitis b recombinant vaccine	Merck <i>Whitehouse Station, NJ</i>	recombinant vaccine	vaccination of infants beginning at two months of age against both invasive <i>Haemophilus influenzae</i> type b diseases (Hib) and hepatitis B (October 1996)
DACS [™] SC stem cell enrichment device	Dendreon <i>Seattle, WA</i>	cell/tissue therapy	rescue therapy following high-dose chemotherapy (August 1999)
Elitek [®] rasburicase	sanofi-aventis <i>Bridgewater, NJ</i>	recombinant enzyme	prophylaxis for chemotherapy-related hyperuricemia, treatment of cancer-related hyperuricemia (July 2002)
Enbrel [®] etanercept	Amgen <i>Thousand Oaks, CA</i> Wyeth <i>Collegeville, PA</i>	recombinant soluble receptor	moderate to severe active rheumatoid arthritis (November 1998); moderate to severe active juvenile rheumatoid arthritis (May 1999); psoriatic arthritis (January 2002); disease modification of active rheumatoid arthritis, ankylosing spondylitis (July 2003); psoriasis (April 2004); psoriatic arthritis (June 2005)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Engerix-B® hepatitis B vaccine (recombinant)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant vaccine	hepatitis B (September 1989); adult chronic hepatitis C (August 1998)
EPOGEN® Epoetin alfa (rEPO)	Amgen <i>Thousand Oaks, CA</i>	erythropoietin	treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis, and anemia in Retrovir®-treated HIV-infected patients (June 1989); treatment of anemia caused by chemotherapy in patients with non-myeloid malignancies (April 1993); prevention of anemia associated with surgical blood loss, autologous blood donation adjuvant (December 1996); anemia in children with chronic renal failure who are currently undergoing dialysis (November 1999)
Erbix™ cetuximab	Bristol-Myers Squibb <i>Princeton, NJ</i> Medarex <i>Princeton, NJ</i>	MAB	colorectal cancer (February 2004); squamous cell cancer of the head and neck (March 2006)
Exubera® insulin human (rDNA origin) inhalation powder	Nektar Therapeutics <i>San Carlos, CA</i> Pfizer <i>New York, NY</i>	recombinant insulin	treatment of adults with type 1 and type 2 diabetes (January 2006)
Fabrazyme® agalsidase beta (Orphan Drug)	Genzyme <i>Cambridge, MA</i>	enzyme replacement therapy	treatment of Fabry disease (April 2003)
Follistim® recombinant follicle-stimulating hormone	Organon <i>West Orange, NJ</i>	recombinant hormone	infertility (September 1997); induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (February 2002)
Fortéo® teriparatide injection rDNA origin	Eli Lilly <i>Indianapolis, IN</i>	recombinant DNA origin	osteoporosis (November 2002)
Fortical® Nasal Spray calcitonin salmon	Unigene Laboratories <i>Fairfield, NJ</i>	recombinant peptide	postmenopausal osteoporosis in women with low bone mass (August 2005)
Genotropin® somatotropin (rDNA origin) for injection	Pfizer <i>New York, NY</i>	human growth hormone	short stature in children due to growth hormone deficiency (August 1995); adult growth hormone deficiency (November 1997); growth failure due to Prader-Willi syndrome (June 2000); long-term treatment of growth failure in children born small for gestational age (July 2001)
Geret® human growth hormone-releasing factor (Orphan Drug)	Serono <i>Rockland, MA</i>	growth factor	evaluation of the ability of the somatotroph of the pituitary gland to secrete growth hormone (December 1990); pediatric growth hormone deficiency (October 1997)
GlucaGen® glucagon (rDNA origin) for injection	Novo Nordisk <i>Princeton, NJ</i>	recombinant human protein	treatment of hypoglycemia and for use as a diagnostic aid (June 1998)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Gonal-F® recombinant human follicle-stimulating hormone (r-FSH)	Serono <i>Rockland, MA</i>	recombinant fertility hormone	female infertility (September 1997); induction of spermatogenesis in men with hypogonadotropic hypogonadism (June 2000)
Helixate® FS antihemophilic factor (recombinant)	Aventis Behring <i>King of Prussia, PA</i>	clotting factor	treatment of hemophilia A (June 2000)
Herceptin® trastuzumab	Genentech <i>South San Francisco, CA</i>	MAb	treatment of HER2-overexpressing metastatic breast cancer (September 1998)
Humalog® insulin lispro recombinant	Eli Lilly <i>Indianapolis, IN</i>	recombinant insulin	diabetes (June 1996)
Humatrope® somatropin (rDNA origin) for injection	Eli Lilly <i>Indianapolis, IN</i>	human growth hormone	treatment of short stature associated with Turner's syndrome (December 1996); human growth hormone deficiency in children (March 1987); long-term treatment of children with short stature (July 2003)
Humira® adalimumab	Abbott Laboratories <i>Abbott Park, IL</i>	MAb	rheumatoid arthritis (December 2002)
Humulin® human insulin (recombinant DNA origin)	Eli Lilly <i>Indianapolis, IN</i>	recombinant insulin	diabetes (October 1982)
Hylenex™ recombinant human hyaluronidase injection	Baxter Healthcare <i>Deerfield, IL</i> Halozyme <i>San Diego, CA</i>	recombinant enzyme	adjuvant to increase absorption and dispersion of other injected drugs; hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents (December 2005)
Increlex™ mecasermin (rDNA origin) injection	Tercica <i>Brisbane, CA</i>	recombinant hormone	long-term treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone gene deletion (August 2005)
Infergen® interferon alfacon-1	Amgen <i>Thousand Oaks, CA</i>	interferon	treatment of chronic hepatitis C viral infection (October 1997)
Infuse® Bone Graft device utilizing recombinant human bone morphogenetic protein (rhBMP-2)	MedTronic <i>Minneapolis, MN</i> Wyeth <i>Collegeville, PA</i>	recombinant growth factor	for use in spinal fusion surgery to treat certain types of spinal degenerative disease (July 2002); acute open tibia shaft fractures in adults (April 2004)
Intron® A interferon alfa-2b (recombinant)	Schering-Plough <i>Kenilworth, NJ</i>	interferon	hairy cell leukemia (June 1986); genital warts (June 1988); AIDS-related Kaposi's sarcoma (November 1988); hepatitis C (February 1991); hepatitis B (July 1992); malignant melanoma (December 1995); follicular lymphoma in conjunction with chemotherapy (November 1997); treatment of hepatitis B in pediatric patients (August 1998)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
iPlex™ mecasermin rinfabate (rDNA origin) injection	Insmed <i>Richmond, VA</i>	recombinant hormone	long-term treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone gene deletion (December 2005)
Kepivance™ palifermin	Amgen <i>Thousand Oaks, CA</i>	recombinant growth factor	treatment of severe oral mucositis (mouth sores) in patients undergoing chemotherapy (December 2004)
Kineret® anakinra	Amgen <i>Thousand Oaks, CA</i>	recombinant protein	signs and symptoms of rheumatoid arthritis (November 2001)
KoGENate® antihemophiliac factor (recombinant)	Bayer <i>West Haven, CT</i>	clotting factor	treatment of hemophilia A (February 1993)
KoGENate-FS rFVIII	Bayer <i>West Haven, CT</i>	clotting factor	hemophilia A (June 2000)
Lantus® insulin glargine (rDNA origin) injection	sanofi-aventis <i>Bridgewater, NJ</i>	recombinant insulin	adults with type 2 diabetes or adults and children (6 years and older) with type 2 diabetes who require long-acting insulin for the control of high blood sugar (April 2000)
Leukine™ sargramostim (GM-CSF)	Berlex Laboratories <i>Montville, NJ</i>	colony stimulating factor	autologous bone marrow transplantation (March 1991); neutropenia resulting from chemotherapy in acute myelogenous leukemia (September 1995); allogeneic bone marrow transplantation (November 1995); peripheral blood progenitor cell mobilization and transplantation (December 1995)
Levemir® insulin detemir	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus (June 2005)
Luveris® lutropin alfa for injection (Orphan Drug)	Serono <i>Rockland, MA</i>	recombinant protein	follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency (October 2004)
LYMErix™ Lyme disease vaccine (recombinant OspA)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	vaccine	prevention of Lyme disease (December 1998)
Macugen® pegaptanib sodium injection	Pfizer <i>New York, NY</i>	vascular endothelial growth factor	treatment of neovascular (wet) age-related macular degeneration (December 2004)
Mylotarg™ gemtuzumab ozogamicin	Wyeth <i>Collegeville, PA</i>	MAb	treatment of patients 60 years and older in first relapse with CD33-positive acute myeloid leukemia (AML) who are not considered candidates for cytotoxic chemotherapy (May 2000)
Naglazyme™ galsulfase	BioMarin Pharmaceutical <i>Novato, CA</i>	enzyme replacement therapy	treatment of MPS VI (mucopolysaccharidoses VI) (May 2005)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Natrecor® nesiritide	Scios <i>Sunnyvale, CA</i>	recombinant human peptide	acute decompensated congestive heart failure (August 2001)
Neulasta® pegfilgrastim	Amgen <i>Thousand Oaks, CA</i>	colony stimulating factor	chemotherapy-induced neutropenia (January 2002)
Neumega® oprelvekin	Wyeth <i>Collegeville, PA</i>	interleukin	prevention of severe thrombocytopenia, reduction of the need for platelet transfusions following myelosuppressive chemotherapy in adults (November 1997)
NEUPOGEN® filgrastim (rG-CSF)	Amgen <i>Thousand Oaks, CA</i>	colony stimulating factor	chemotherapy-induced neutropenia (February 1991); autologous or allogeneic bone marrow transplantation (June 1994); chronic severe neutropenia (December 1994); support peripheral blood progenitor cell transplantation (December 1995); acute myelogenous leukemia (April 1998)
NeuroSpec™ technetium 99m Tc fanolesomab	Palatin Technologies <i>Cranbury, NJ</i>	MAB	diagnosis of appendicitis in patients with equivocal signs (July 2004)
Norditropin® somatropin (rDNA origin) for injection	Novo Nordisk <i>Princeton, NJ</i>	recombinant human growth hormone	treatment of growth failure in children due to inadequate growth hormone secretion (May 1995); replacement of endogenous growth hormone in adults with adult or childhood onset of growth hormone deficiency (November 2004)
Novolin®	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (October 1982)
Novolin® 70/30 70% NPH human insulin isophane suspension & 30% regular, human insulin injection (recombinant DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (June 1991)
Novolin® L Lente®, human insulin zinc suspension (recombinant DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (June 1991)
Novolin® N NPH, human insulin isophane suspension (recombinant DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (June 1991)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Novolin® R regular, human insulin injection (recombinant DNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (June 1991)
NovoLog® insulin aspart (rDNA origin) injection	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus (May 2000)
NovoLog® Mix 70/30 70% insulin aspart (rDNA origin) protamine suspension and 30% insulin aspart (rDNA origin) injection	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus (November 2001)
NovoSeven® coagulation factor VIIa (recombinant)	Novo Nordisk <i>Princeton, NJ</i>	recombinant human protein	treatment of bleeding episodes in hemophilia A or B patients with inhibitors to factor VIII or factor IX (March 1999); treatment of bleeding episodes in patients with congenital factor VII deficiency (July 2005); prevention of bleeding in surgical interventions or invasive procedures in patients with congenital factor VII deficiency (July 2005); prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B patients with inhibitors to factor VIII or factor IX (August 2005)
Nutropin® somatotropin (rDNA origin) for injection	Genentech <i>South San Francisco, CA</i>	recombinant human growth hormone	growth failure in children due to chronic renal insufficiency, growth hormone inadequacy in children (March 1994); Turner's syndrome (December 1996); growth hormone inadequacy in adults (December 1997); idiopathic short stature (July 2005)
Nutropin AQ™ somatotropin (rDNA origin) (liquid)	Genentech <i>South San Francisco, CA</i>	recombinant human growth hormone	growth failure in children due to chronic renal insufficiency, growth hormone inadequacy in children (December 1995); Turner's syndrome (December 1996); growth hormone inadequacy in adults (December 1997); idiopathic short stature (July 2005)
OncoScint® CR/OV satumomab pendetide	CYTOGEN <i>Princeton, NJ</i>	MAB	detection, staging and follow-up of colorectal and ovarian cancers (December 1992)
Oncospar® PEG-L-asparaginase	Enzon <i>Bridgewater, NJ</i>	pegylated-enzyme	first-line treatment of acute lymphoblastic leukemia (February 1994)
Ontak® denileukin diftitox	Ligand Pharmaceuticals <i>San Diego, CA</i>	fusion protein	persistant or recurrent cutaneous T-cell lymphoma (February 1999)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Orencia™ abatacept	Bristol-Myers Squibb <i>Princeton, NJ</i>	recombinant soluble receptor	rheumatoid arthritis (December 2005)
ORTHOCLONE OKT®3 muromonab-CD3	Ortho Biotech <i>Raritan, NJ</i>	MAB	reversal of acute kidney transplant rejection (June 1991); reversal of heart and liver transplant rejection (June 1993)
Ovidrel® choriogonadotropin alfa injection	Serono <i>Rockland, MA</i>	recombinant protein	induction of final follicular maturation and early luteinization (October 2003)
Pediarix™ diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B (recombinant) and inactivated poliovirus vaccine combined	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant antigen	immunization of infants at 2, 4 and 6 months of age against diphtheria, tetanus, pertussis (whooping cough), hepatitis B and polio (December 2002)
Pegasys® peginterferon alfa-2a	Roche <i>Nutley, NJ</i>	interferon	chronic hepatitis C (December 2002); chronic hepatitis B (May 2005)
Pegasys® pegylated interferon alfa-2a and ribivirin combination	Roche <i>Nutley, NJ</i>	interferon	chronic hepatitis C (December 2002)
PEG-Intron® peginterferon alfa-2b	Schering-Plough <i>Kenilworth, NJ</i>	interferon	hepatitis C (August 2001)
Prevnar® pneumococcal 7-valent conjugate vaccine (diphtheria CRM197 protein)	Wyeth <i>Collegeville, PA</i>	recombinant vaccine	active immunization of infants and toddlers against invasive disease caused by <i>S. pneumoniae</i> due to capsular serotypes included in the vaccine (4, 6B, 9V, 14, 19F and 23F) (February 2000)
PROCRIT® epoetin alfa (rEPO)	Ortho Biotech <i>Raritan, NJ</i>	erythropoietin	treatment of anemia associated with chronic renal failure, including patients on dialysis and not on dialysis, and anemia in Retrovir®-treated HIV-infected patients (December 1990); treatment of anemia caused by chemotherapy in patients with non-myeloid malignancies (April 1993); prevention of anemia associated with surgical blood loss, autologous blood donation adjuvant (December 1996); anemia in children with chronic renal failure who are currently undergoing dialysis (July 1999)
<p><i>[PROCRIT® was approved for marketing under Amgen's epoetin alfa PLA. Amgen manufactures the product for Ortho Biotech.] Under an agreement between the two companies, Amgen licensed to Ortho Pharmaceutical the U.S. rights to epoetin alfa for indications for human use excluding dialysis and diagnostics.</i></p>			
Proleukin® aldesleukin (interleukin-2)	Chiron <i>Emeryville, CA</i>	interleukin	renal cell carcinoma (May 1992); metastatic melanoma (January 1998)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
ProstaScint® capromab pentetate	CYTOGEN <i>Princeton, NJ</i>	MAB	detection, staging and follow-up of prostate adenocarcinoma (October 1996)
Protropin® somatrem for injection	Genentech <i>South San Francisco, CA</i>	human growth hormone	human growth hormone deficiency in children (October 1985)
Pulmozyme® dornase alpha, recombinant	Genentech <i>South San Francisco, CA</i>	recombinant DNase	cystic fibrosis (December 1993); management of advanced cystic fibrosis (December 1996)
Raptiva® efalizumab	Genentech <i>South San Francisco, CA</i> XOMA <i>Berkeley, CA</i>	MAB	chronic moderate to severe plaque psoriasis (October 2003)
Rebetron™ ribavirin/interferon alfa-2b, combination therapy	Schering-Plough <i>Kenilworth, NJ</i>	interferon	treatment of chronic hepatitis C in patients who have relapsed following alpha interferon therapy (June 1998); treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha interferon therapy (December 1999)
Rebif® interferon beta-1a	Serono <i>Rockland, MA</i>	interferon	relapsing forms of multiple sclerosis (March 2002)
recombinant human bone morphogenetic protein-2/ Absorbable Collagen Sponge (rhBMP-2/ACS)	Wyeth <i>Philadelphia, PA</i>	growth factor	bone and tissue repair
Recombinate™ antihemophilic factor recombinant (rAHF)	Baxter Healthcare <i>Deerfield, IL</i> Wyeth <i>Philadelphia, PA</i>	clotting factor	prevention and control of bleeding episodes in patients with hemophilia A (December 1992)
RECOMBIVAX HB® hepatitis B vaccine (recombinant)	Merck <i>Whitehouse Station, NJ</i>	recombinant vaccine	hepatitis B prevention (July 1986)
ReFacto® antihemophilic factor, recombinant (factor VIII)	Wyeth <i>Collegeville, PA</i>	clotting factor	hemophilia A (March 2000)
Refludan™ lepirudin [rDNA] for injection	Berlex Laboratories <i>Montville, NJ</i>	recombinant anticoagulant	heparin-induced thrombocytopenia type II (March 1998)
Regranex® becaplermin (recombinant human platelet- derived growth factor-BB)	Ortho-McNeil Pharmaceuticals <i>Raritan, NJ</i>	growth factor	chronic diabetic ulcers (December 1997)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Remicade™ infliximab	Centocor <i>Malvern, PA</i>	MAB	short-term use in Crohn's disease (August 1998); reduction of signs and symptoms in rheumatoid arthritis (November 1999); inhibit the progression of structural damage in patients with rheumatoid arthritis (January 2001); improve physical function in patients with rheumatoid arthritis (February 2002); long-term remission-level control of Crohn's disease (July 2002)
ReoPro® abciximab	Centocor <i>Malvern, PA</i> Eli Lilly <i>Indianapolis, IN</i>	MAB	anti-platelet prevention of blood clots in the setting of high-risk percutaneous transluminal coronary angioplasty (December 1994); refractory unstable angina when percutaneous coronary intervention is planned (November 1997)
Retavase® reteplase	Centocor <i>Malvern, PA</i>	tissue plasminogen factor	treatment of acute myocardial infarction (October 1996)
Rituxan® rituximab	Genentech <i>South San Francisco, CA</i> Biogen Idec <i>Cambridge, MA</i>	MAB	treatment of relapsed or refractory low-grade or follicular CD20-positive B-cell non-Hodgkin's lymphoma (November 1997); retreatment of patients who have relapsed following initial Rituxan treatment, eight week doses (compared to original four), and treatment of bulky disease (April 2001); first-line treatment of diffuse large B0-cell, CD20-positive, non-Hodgkin's lymphoma in combination with other chemotherapy regimens (February 2006); reduction of signs and symptoms of adult moderate to severe active rheumatoid arthritis in combination with methotrexate (February 2006)
Roferon®-A interferon alfa-2a, recombinant	Roche <i>Nutley, NJ</i>	interferon	hairy cell leukemia (June 1986); AIDS-related Kaposi's sarcoma (November 1988); chronic myelogenous leukemia (November 1995); hepatitis C (November 1996)
Saizen® somatropin (rDNA origin) for injection	Serono <i>Rockland, MA</i>	human growth hormone	pediatric growth hormone deficiency (October 1996)
Serostim™ somatropin (rDNA origin) for injection (Orphan Drug)	Serono <i>Rockland, MA</i>	human growth hormone	treatment of AIDS-associated catabolism/wasting (August 1996); pediatric HIV failure to thrive (February 1998)
Simulect® basiliximab	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	MAB	prevention of renal transplant rejection (May 1998)
Somavert® pegvisomant for injection	Pfizer <i>New York, NY</i>	growth hormone receptor antagonist	treatment of acromegaly (March 2003)
Symlin® pramlintide acetate	Amylin Pharmaceuticals <i>San Diego, CA</i>	peptide biologic	treatment of type 1 and insulin-using type 2 diabetes in conjunction with insulin (March 2005)
Synagis® palivizumab	MedImmune <i>Gaithersburg, MD</i>	MAB	prevention of respiratory syncytial virus (RSV) (June 1998)

APPROVED BIOTECHNOLOGY PRODUCTS

Product Name	Company	Product Category	Indication
Thymoglobulin® thymocyte globulin (rabbit)	Genzyme <i>Cambridge, MA</i>	polyclonal antibody	prevention of kidney transplant rejection (December 1998)
Thyrogen® thyrotropin alfa for injection	Genzyme <i>Cambridge, MA</i>	recombinant hormone (diagnostic)	thyroid cancer follow-up (November 1998)
TNKase™ tenecteplase	Genentech <i>South San Francisco, CA</i>	thrombolytic	acute myocardial infarction (June 2000)
Twinrix® hepatitis A inactivated and hepatitis B (recombinant) vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	recombinant antigen	immunization against hepatitis A and B viruses (May 2001)
Tysarbi® natalizumab	Biogen Idec <i>Cambridge, MA</i>	MAb	treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical relapses (November 2004)
Velosulin® BR buffered regular human insulin injection (rDNA origin)	Novo Nordisk <i>Princeton, NJ</i>	recombinant insulin	treatment of diabetes mellitus for the control of hyperglycemia (July 1999)
Verluma® nofetumomab	DuPont Pharmaceuticals <i>Billerica, MA</i>	MAb	detection of small-cell lung cancer (August 1996)
Visudyne® verteporfin	QLT <i>Vancouver, British Columbia</i>	photodynamic therapy	age-related macular degeneration, ocular histoplasmosis, pathologic myopia (April 2000)
Vitravene® fomiviren sodium injectable	Ciba Vision <i>Duluth, GA</i> Isis Pharmaceuticals <i>Carlsbad, CA</i>	antisense	treatment of cytomegalovirus retinitis in patients with AIDS (August 1998)
Xigris™ drotrecogin alfa (activated)	Eli Lilly <i>Indianapolis, IN</i>	recombinant activated protein C	severe sepsis (November 2001)
Xolair® omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	MAb	treatment of moderate to severe allergy-related asthma (12 years and older) (June 2003)
Zenapax® daclizumab	Roche <i>Nutley, NJ</i> Protein Design Labs <i>Fremont, CA</i>	MAb	prophylaxis of acute kidney transplant rejection (December 1997)
Zevalin™ ibritumomab tiuxetan	IDEC Pharmaceuticals <i>San Diego, CA</i>	MAb	treatment of relapsed or refractory low grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (February 2002)
Zorbitive™ somatropin [rDNA origin] for injection	Serono <i>Rockland, MA</i>	recombinant protein	for patients with short bowel syndrome requiring specialized nutritional support (December 2003)

acromegaly—Chronic hyperpituitarism characterized by a gradual and permanent enlargement of the flat bones and of the hands and feet, abdominal organs, nose, lips and tongue.

adenocarcinoma—Malignant tumor derived from a gland or glandular tissue.

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

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

AIDS—Acquired immune deficiency syndrome.

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

amyloidosis—A disease in which amyloid, an unusual protein that normally isn't present in the body, accumulates in various tissues. There are many forms of the disease. In primary amyloidosis, the cause isn't known, but it is associated with abnormalities of plasma cells. In secondary amyloidosis, the disease is secondary to another disease, such as tuberculosis. A third form is hereditary and affects nerves and certain organs.

ANCA—antineutrophil cytoplasmic antibodies.

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

angiogenesis—The formation of new blood vessels, which is a process controlled by certain chemicals produced in the body. A chemical that signals this process to stop is referred to as an **angiogenesis**

inhibitor. Cancer spreads by the formation of new blood vessels, which supply the cancer cells with oxygen and nutrients, helping the cells to grow, invade nearby tissue, and spread to other areas of the body. Scientists are studying ways to stop angiogenesis, in the hope that angiogenesis inhibitors will be able to prevent the growth of cancer by blocking the formation of new blood vessels.

angioplasty—A technique to open up blocked coronary arteries with a catheter tube.

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. The arthritis may involve large joints, such as the hip.

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).

autoimmune disorders—Diseases, such as type 1 diabetes, rheumatoid arthritis, and multiple sclerosis, caused by the body producing an immune response against its own tissues. The cause of autoimmune diseases is unknown, but it appears

that there is an inherited predisposition to develop them in many cases.

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

B- and T-cell lymphomas—Cancers caused by proliferation of the two principal types of white blood cells—B- and T-lymphocytes.

bacteremia—Presence of bacteria in the bloodstream.

biotechnology—The collection of industrial 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 chart, only those products that involve recombinant DNA, monoclonal antibody/hybridoma, continuous cell lines, cellular therapy and gene therapy technology are included.

CEA—Carcinoembryonic antigen found in the blood of patients suffering from cancer of the colon and some other diseases that is otherwise found in fetal gut tissue.

cerebral amyloid angiopathy—A condition in which there is a deposition of amyloid (insoluble protein) in the walls of the arteries supplying the brain, resulting in an increased risk of dementia or intracerebral hemorrhage. This condition is a complication of primary **amyloidosis**.

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.

clotting factors—Proteins involved in the normal clotting of blood.

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.

cystic fibrosis—A genetic disorder of the exocrine glands causing abnormal mucous secretions that obstruct glands and ducts in various organs, particularly the lungs.

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. As an opportunistic infection in AIDS patients, it can cause **CMV retinitis**, an inflammation of the retina that can lead to blindness if left untreated.

demyelinating polyneuropathy, chronic inflammatory—CIDP 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. Although it can occur at any age and in both genders, CIDP is more common in young adults and in men more so than women.

DMARD—disease modifying antirheumatic drug.

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

Fabry disease—A rare hereditary disorder that leads to an accumulation of glycolipid, a product of fat metabolism.

gastroesophageal reflux disease (GERD)—A backflow of stomach contents upward into the esophagus caused by poorly functioning muscles in the lower esophagus. Because the esophagus lacks a protective lining, stomach acid that refluxes into it causes pain, inflammation (esophagitis), and damage.

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.

genital warts—Soft warts that grow in and around the entrance of the vagina and the anus and on the penis. They are transmitted by sexual contact and are caused by a **human papillomavirus**.

GIST—Gastrointestinal stromal tumors.

glioblastoma multiforme—A rare, fast growing, highly malignant type of brain tumor arising from glial (supporting) cells within the brain.

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**.

histoplasmosis—A disease caused by a fungal infection that can affect all organs of the body.

HIV—Human immunodeficiency virus (the virus that causes AIDS).

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.

Hunter syndrome—see **mucopolysaccharidoses**.

hyperuricemia—An abnormally high uric acid level in the blood.

hypodermoclysis—The subcutaneous (under the skin) infusion of fluids.

hypogonadism—Underactivity of the gonads (ovaries and testes), which may be caused by disorders of these sex glands or by a pituitary gland disorder.

immune globulin—A class of proteins produced in lymph tissue in vertebrates that function as antibodies in the immune system's response.

immune/idiopathic thrombocytopenia purpura—A condition that may follow a viral infection, which can trigger destruction of blood platelets by the immune system. The reduced number of platelets may result in abnormal bleeding into the skin and from other parts of the body (purpura).

immune modulator—A substance that changes an aspect of the way the immune system is working.

immunotoxin—A *hybrid molecule* created by coupling an *antibody* or *antigen* with part or all of a *toxin*. The hybrid molecule combines the specificity of the antibody or antigen with the toxicity of the toxin. The possible targets of immunotoxins include cancer cells and cells containing **HIV**.

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.

intermittent claudication—The most prominent symptom of **peripheral arterial disease** (PAD). It occurs in one-third to one-half of PAD patients. Claudication refers to the pain that occurs in PAD patients when they exercise, particularly during walking, which is relieved only by rest. Leg pain occurs in one leg in 40 percent of patients and in both legs in 60 percent of patients.

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

leukemia—Form of cancer in which the white blood cells grow abnormally.

lipodystrophy—A disturbance in the way the body produces, uses and distributes fat. In HIV disease, it refers to a group of symptoms: the loss of the thin layer of fat under the skin, making veins seem to protrude; wasting of the face and limbs; and the accumulation of fat on the abdomen (both under the skin and within the abdominal cavity) or between the shoulder blades.

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.

melanoma—Cancer made up of pigmented skin cells.

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

mucopolysaccharidoses—Hereditary disorders that result in a characteristic facial appearance and abnormalities of the bones, eyes, liver, and spleen, sometimes accompanied by mental retardation. The cause of these disorders is an inability to break down and store mucopolysaccharides, which are major components of connective tissue. **Hunter syndrome** is one of these disorders.

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. The condition is rare and affects those of middle to older age groups.

multiple sclerosis—Progressive disease of the central nervous system in which scattered patches of the covering of nerve fibers (myelin)

in the brain and spinal cord are destroyed. Symptoms range from numbness and tingling to paralysis and incontinence.

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.

myelosuppression—Bone marrow decrease in activity or number of bone marrow cells, which is a common side effect of radiation therapy and chemotherapy.

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”). Neuroblastomas are the most common extracranial (outside the skull) solid tumor of childhood.

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

non-small-cell lung cancer

(NSCLC)—One of the two types of lung cancer. There are five types of NSCLC, each of which has different kinds of cancer cells that grow and spread in different ways. NSCLC

accounts for about 75 percent of all lung cancers.

Orphan Drug—A drug to treat a disease that has a patient population of 200,000 or less, 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.

Parkinson’s disease—Chronic neurologic disease of unknown cause, characterized by tremors, rigidity and an abnormal gait. Some patients with advanced disease develop dementia. It is a common chronic disease of later life.

peptide—A compound containing two or more amino acids.

peripheral vascular disease—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.

Photodynamic therapy (PDT)—A treatment that uses a *drug*, called a *photosensitizer* or photosensitizing agent, and a particular type of light. When photosensitizers are exposed to a specific wavelength of light, they produce a form of oxygen that kills nearby cancer **cells**.

Prader-Willi syndrome—A genetic disorder characterized by short stature, mental retardation, abnormally small hands and feet, hypogonadism, and uncontrolled appetite leading to extreme obesity.

prodrug—A precursor (forerunner) of a drug. A prodrug must undergo

chemical conversion by metabolic processes before becoming an active pharmacological agent. For example, sulfasalazine is a prodrug. It is not active in its ingested form. It has to be broken down by bacteria in the colon into two products--5-aminosalicylic acid and sulfapyridine—before becoming active as a drug.

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

pulmonary embolism (embolus)—Obstruction of the pulmonary artery (the blood vessel that carries blood from the heart to the lungs) or one of its branches in the lung by an embolus, usually a portion of a blood clot that originated in a vein in the leg or pelvis, that breaks off and travels in the circulation to the lung. It can be life-threatening.

pulmonary fibrosis, idiopathic—Scarring and thickening of lung tissue of unknown cause.

recombinant DNA—DNA produced by joining pieces of DNA from different sources. Usually designated as rDNA.

recombinant soluble receptors—Synthetic versions of cellular receptors manufactured with recombinant DNA technology, used as decoys to attract pathogens that otherwise would bind to cellular receptors and cause disease. They are “soluble” because they are free-standing and not attached to (insoluble) cells.

respiratory syncytial virus 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. Some of the most common causes in adults are Crohn's disease, radiation enteritis and trauma.

Staphylococcus aureus—A common bacterium that is a frequent cause of hospital infections, including pneumonia, surgical wounds and systemic blood infections.

Streptococcus pneumoniae—A gram-positive bacterium that causes pneumococcal infections in the brain, ear and other organs.

systemic lupus erythematosus (SLE)—The most serious form of

lupus, a chronic autoimmune disorder causing inflammation and damage to multiple organs. SLE affects many systems of the body, including the joints, kidneys and brain.

taxane—A drug that inhibits cell growth by stopping cell division. Taxanes, such as docetaxel and paclitaxel, are used as treatments for cancer.

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

thrombolytic—A kind of pharmaceutical that can break up clots blocking the flow of blood to the heart muscle.

tissue plasminogen activator (t-PA)—TPA is a substance produced in small amounts by the inner lining of blood vessels that prevents abnormal blood clotting by convert-

ing plasminogen—a chemical in the blood—to the enzyme plasmin.

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.

varicella zoster—Chicken pox and herpes zoster are caused by the varicella zoster virus, chicken pox being the acute invasive phase of the virus and zoster (shingles) being the reactivation of the latent stage.

Vascular endothelial growth factor (VEGF)—Responsible for the growth of blood vessels.

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 \$802 million to get one new medicine from the laboratory to U.S. patients, according to a November 2001 report 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 28 new therapeutics approved by the FDA in 2005 was 12.5 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. PhRMA member companies invested an estimated \$39.4 billion in research and development in 2005.

Genomics, Proteomics and Biotechnology— What’s in it for Patients?

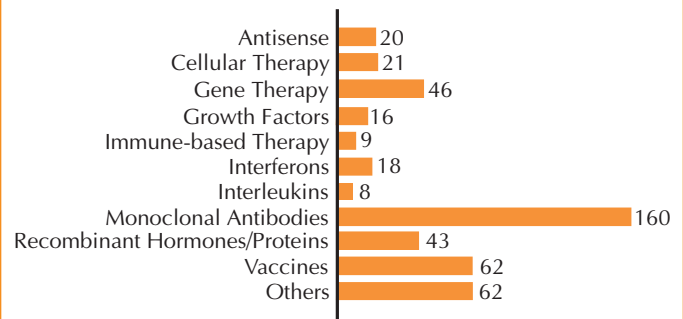
The complete set of genes of an organism is called its genome and is made up of DNA, or deoxyribonucleic acid. Completed in 2003, scientists—both in the government and in private industry—worked together to “map” the human genome. The goals of the 13-year project were to identify the nearly 25,000 genes in human DNA and determine the sequences of the 3 billion chemical base pairs that make up human DNA.

DNA is found tightly coiled in every nucleus of a person’s many trillion cells. These slender threads of DNA have four different chemical building blocks or bases, abbreviated as A, T, C and G. The human genome contains about 3 billion pairs of these bases. Genes are specific pieces of DNA. They vary in length—with the average gene consisting of about 2,000 base pairs—and they differ from one another in the order, or sequence, of the base pairs. This order determines which proteins the genes encode.

Now that we know the sequence of the entire genome, we can compare that data with known sequences, and work out what protein each gene produces and what that protein does in the body. This will allow us to understand the molecular basis of many diseases, and determine who is most likely to get which illnesses, and why. Ultimately, this will enable us to develop medicines that prevent or at least slow down those diseases before symptoms become debilitating, as opposed to many medicines today which treat the symptoms rather than the causes of disease.

Pharmaceutical researchers are now pursuing the discovered genes for intervention with medicines. More targets and an understanding of how they are involved in the development of human disease allows more

BIOTECHNOLOGY MEDICINES IN DEVELOPMENT—BY PRODUCT CATEGORY



precise treatments and the prevention of more diseases by both conventional and biotechnology-based medicines. The completion of the human genome “map” means there will be more opportunities for pharmaceutical breakthroughs and, eventually, more and better medicines.

Already many medicines are based on biotechnology, but the study of gene sequences (genomics) and the arrays of proteins produced by different cells (proteomics) is allowing much better understanding of what makes one person healthy and another suffer from disease. Both genomics and proteomics are contributing to the development of therapeutic and preventive medicines, both biotechnological and chemical. Ultimately, we hope to be able to fix the gene in the person afflicted (gene therapy) and choose the right drug for each patient the first time (pharmacogenomics), but in the meantime we will make many more therapies available to patients as the cumulative experience in biotechnology expands our knowledge and understanding of the human body.



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