

Hispanic Americans

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES, INTERAMERICAN COLLEGE OF PHYSICIANS AND SURGEONS, THE NATIONAL ALLIANCE FOR HISPANIC HEALTH, AND THE NATIONAL PUERTO RICAN COALITION

Survey Finds 581 Medicines in Development for Major Diseases That Disproportionately Afflict Hispanic Americans

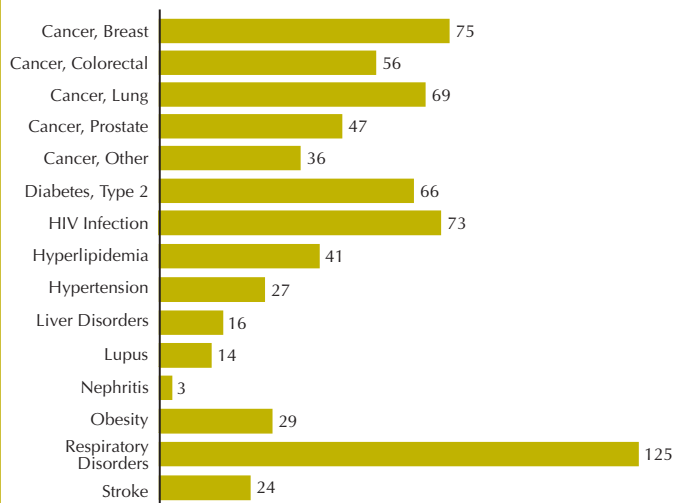
Pharmaceutical researchers are developing 581 new medicines for diseases that disproportionately affect the nation's 42.7 million Hispanic Americans, according to this report by the Pharmaceutical Research and Manufacturers of America (PhRMA). The report was compiled in cooperation with the Interamerican College of Physicians and Surgeons, the National Alliance for Hispanic Health, and the National Puerto Rican Coalition. Here are some highlights:

- Although Hispanic Americans make up only 14.4 percent of the U.S. population, they account for nearly 20 percent of new AIDS cases. Pharmaceutical companies are currently developing 73 new medicines to fight HIV and AIDS.
- Hispanic Americans have disproportionately high rates of cervical, gall bladder, gastric and liver cancers. In 2003, breast, colorectal, lung and prostate cancers were the leading cancer killers of Hispanic Americans. Pharmaceutical researchers are working on 178 potential medicines for these types of cancer.
- Hispanic Americans are nearly twice as likely to develop type 2 diabetes as non-Hispanic whites. There are 66 medicines in the pipeline to combat this disease.
- Between the ages of 35 and 64, Hispanic Americans have a higher risk of having a stroke than non-Hispanic whites. Companies have 24 medicines for stroke in the pipeline.

In addition, companies are developing 125 medicines for respiratory disorders, 41 for high cholesterol, 27 for hypertension, and 29 for obesity—all of which affect Hispanic Americans disproportionately. All of the medicines included in the report are either in clinical trials or awaiting approval by the Food and Drug Administration.

For a host of reasons, Hispanic Americans suffer from a health deficit. Lack of access to health care is an important contributing factor. According to a survey by the Pew Hispanic Center/Kaiser Family Foundation,

MEDICINES IN DEVELOPMENT FOR MAJOR DISEASES AFFECTING HISPANIC AMERICANS*



*Some medicines are listed in more than one category.

73 percent of Hispanic Americans either lack insurance coverage themselves or know someone who is uninsured, 15 percent of Hispanics did not get medical treatment they needed, and another 20 percent postponed treatment they could not afford. These quality and access problems must be addressed. PhRMA member companies are helping needy Americans get the medicines they need through the Partnership for Prescription Assistance (PPA). Since April 2005, PPA has matched more than 2.5 million qualified patients to one or more of over 475 national, state and industry-sponsored patient assistance programs that provide eligible patients their medicines for free or nearly free. Pharmaceutical research on diseases that disproportionately affect Hispanic Americans can also help close the health care gap.

Billy Tauzin
President and CEO
PhRMA

Medicines in Development for Major Diseases Affecting Hispanic Americans

CANCER

Product Name	Sponsor	Indication	Development Status*
4-OHT	ASCEND Therapeutics <i>Herndon, VA</i>	breast cancer	Phase II (703) 471-4744
1311huA33	Life Science Pharmaceuticals <i>Greenwich, CT</i>	colorectal cancer	Phase I (203) 422-6500
A-007	Tigris Pharmaceuticals <i>Bonita Springs, FL</i>	cervical intraepithelial neoplasia	Phase II (239) 444-5400
Abraxane™ (ABI 007)	Abraxis Pharmaceutical <i>Schaumburg, IL</i>	non-small-cell lung cancer (NSCLC)	Phase II (847) 413-2075
		----- cervical cancer	Phase II (847) 413-2075
ABT 510	Abbott Laboratories <i>Abbott Park, IL</i>	lung cancer	Phase II (847) 937-6100
AC vaccine	AVAX Technologies <i>Philadelphia, PA</i>	NSCLC	Phase I/II (215) 241-9760
Advexin® (p53)	Introgen Therapeutics <i>Austin, TX</i>	breast, NSCLC cancers	Phase II (512) 708-9310
AGS-PSCA MAb	Agensys <i>Santa Monica, CA</i> Merck <i>Whitehouse Station, NJ</i>	prostate cancer	Phase I (310) 820-8029 (800) 672-6372
Alimta® pemetrexed	Eli Lilly <i>Indianapolis, IN</i>	colorectal, lung cancers	Phase III (317) 276-2000
		----- breast, liver cancers	Phase II (317) 276-2000
AMG 706	Amgen <i>Thousand Oaks, CA</i>	colorectal, NSCLC cancers	Phase I (805) 447-1000
amolmogene (ZYC101a)	MGI Pharma Biologics <i>Bloomington, MN</i>	cervical dysplasia	Phase II (952) 346-4700
amrubicin	Cabrellis Pharmaceuticals <i>San Diego, CA</i>	NSCLC, small-cell lung cancer (SCLC)	Phase II (858) 404-7111
anti-KSA cancer vaccine	IDM Pharma <i>Irvine, CA</i>	colorectal cancer	Phase I (949) 470-4751
ANX-510	Adventrx Pharmaceuticals <i>San Diego, CA</i>	colorectal cancer	Phase III (858) 552-0866

* For more information about a specific medicine in this report, please call the telephone number listed.

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Product Name	Sponsor	Indication	Development Status
AP 23573	ARIAD Pharmaceuticals Cambridge, MA	prostate cancer	Phase II (617) 494-0400
		breast cancer	Phase I (617) 494-0400
Aromasin® exemestane	Pfizer New York, NY	breast cancer prevention	Phase III (860) 732-5156
Aroplatin™	Antigenics New York, NY	colorectal cancer	Phase II (212) 994-8200
arzoxifene	Eli Lilly Indianapolis, IN	breast cancer	Phase III (317) 276-2000
atamestane	Intarcia Therapeutics Emeryville, CA	breast cancer	Phase III (510) 652-2600
Avastin® bevacizumab	Genentech South San Francisco, CA	first-line metastatic breast cancer, first-line NSCLC other than predominant squamous histology	application submitted (650) 225-1000
		adjuvant breast, adjuvant colon, adjuvant NSCLC, extensive SCLC, first-line metastatic breast, second-line metastatic breast, hormone refractory prostate cancers	Phase III (650) 225-1000
		HER2 metastatic breast cancer (with Herceptin®)	Phase III (650) 225-1000
		adjuvant HER2 breast cancer	Phase II (650) 225-1000
Avicine® cancer vaccine	SuperGen Dublin, CA	colorectal cancer	Phase III (925) 560-0100
Avodart® dutasteride	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	reduction in the risk of prostate cancer	Phase III (888) 825-5249
axitinib	Pfizer New York, NY	breast cancer	Phase I (860) 732-5156
BrevaRex® antibody-based immunotherapy	ViRexx Medical Edmonton, Alberta	breast cancer	Phase I (780) 433-4411
BZL 101	Bionovo Emeryville, CA	breast cancer	Phase I (510) 601-2000
CA4P	OXiGENE Waltham, MA	breast, lung cancers	Phase II (781) 547-5900
Camptosar® irinotecan	Pfizer New York, NY	cervical, lung cancers	application submitted (860) 732-5156
		prostate cancer	Phase II (860) 732-5156

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Product Name	Sponsor	Indication	Development Status
cancer vaccine	Centocor <i>Horsham, PA</i>	colorectal cancer	Phase I (610) 551-6000
Celebrex® celecoxib	Pfizer <i>New York, NY</i>	colorectal cancer	Phase III (860) 732-5156
		NSCLC, prostate cancer	Phase II (860) 732-5156
		cervical dysplasia	in clinical trials (860) 732-5156
cisplatin (controlled-release)	Transave <i>Monmouth Junction, NJ</i>	lung cancer	Phase II (732) 438-9434
CMD-193	Wyeth <i>Collegeville, PA</i>	NSCLC	Phase I (610) 902-1200
Collidem™ IDD-5	IDM Pharma <i>Irvine, CA</i>	colorectal cancer	Phase I (949) 470-4751
Coprexa™ tetrathiomolybdate	Attenuon <i>San Diego, CA</i> Pipex Therapeutics <i>Ann Arbor, MI</i>	breast cancer	Phase II (858) 720-8797
Corlux™	Corcept Therapeutics <i>Menlo Park, CA</i>	uterine cancer	in clinical trials (650) 327-3270
Davanat™ fluorouracil/ carbohydrate complex	Pro-Pharmaceuticals <i>Newton, MA</i>	colorectal cancer	Phase II (617) 559-0033
docosahexaenoic acid	Martek Biosciences <i>Columbia, MD</i>	breast cancer prevention (see also hyperlipidemia)	in clinical trials (410) 740-0081
doxorubicin liposomal	Sopherion Therapeutics <i>Princeton, NJ</i>	breast cancer	Phase III (609) 986-2021
E7389	Eisai <i>Ridgefield Park, NJ</i>	breast, NSCLC, prostate cancers	Phase II (888) 274-2378
edotecarin	Pfizer <i>New York, NY</i>	colorectal cancer	Phase III (860) 732-5156
EM 1421	Erimos Pharmaceuticals <i>Houston, TX</i>	cervical intraepithelial neoplasia	Phase II (713) 541-2000
EMD 273063	EMD Lexigen Pharmaceuticals <i>Billerica, MA</i>	SCLC	Phase I (978) 294-1100
EP 2101	IDM Pharma <i>Irvine, CA</i>	NSCLC	Phase II (949) 470-4751
		colorectal cancer	Phase I (949) 470-4751

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Product Name	Sponsor	Indication	Development Status
Erbix™ cetuximab	Bristol-Myers Squibb <i>Princeton, NJ</i> ImClone Systems <i>New York, NY</i>	colorectal (first-line, second-line, adjuvant), NSCLC cancers	in clinical trials (212) 546-4000 (877) 925-6631
exisulind	OSI Pharmaceuticals <i>Melville, NY</i>	breast, NSCLC, prostate cancers	Phase III (800) 572-1932
		SCLC	Phase II (800) 572-1932
GCS-100	GlycoGenesys <i>Boston, MA</i>	colorectal, prostate cancers	Phase II (617) 422-0674
Gemzar® gemcitabine	Eli Lilly <i>Indianapolis, IN</i>	colorectal, gastric cancers	Phase II (317) 276-2000
		SCLC	Phase I (317) 276-2000
Genasense® oblimersen	Genta <i>Berkeley Heights, NJ</i>	breast, colorectal, NSCLC, prostate, SCLC cancers	Phase II (908) 286-9800
glufosfamide	Threshold Pharmaceuticals <i>Redwood City, CA</i>	breast cancer	Phase II (650) 474-8200
GTI-2040	Lorus Therapeutics <i>Toronto, Ontario</i>	breast, colorectal cancers	Phase II (416) 798-1200
GVAX® Prostate	Cell Genesys <i>South San Francisco, CA</i>	prostate cancer	Phase III (650) 266-3000
Her2 recombinant pharmaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	treatment of breast cancer	Phase I/II (888) 825-5249
Herceptin® trastuzumab	Genentech <i>South San Francisco, CA</i>	adjuvant HER2 breast cancer	application submitted (650) 225-1000
		first-line metastatic HER2 breast cancer (with Taxotere®)	Phase III (650) 225-1000
HKI 272	Wyeth <i>Collegeville, PA</i>	breast, NSCLC cancers	Phase II (610) 902-1200
HuC242-DM4	ImmunoGen <i>Cambridge, MA</i>	colorectal, NSCLC cancers	Phase I (617) 995-2500
huN901-DM1	ImmunoGen <i>Cambridge, MA</i>	SCLC	Phase II (617) 995-2500
Hycamtin® topotecan	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	cervical cancer (2nd-line therapy)	application submitted (888) 825-5249
		SCLC (2nd-line therapy) (oral formulation)	Phase III (888) 825-5249
idronoxil	Novogen <i>Stamford, CT</i>	cervical, vulvovaginal cancers	Phase II (203) 327-1188

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Product Name	Sponsor	Indication	Development Status
IMC-3G3 (PDGFRa)	ImClone Systems New York, NY	breast, prostate cancers	Phase I (877) 925-6631
IMC-18F1 (VEGFR-1)	ImClone Systems New York, NY	breast cancer	Phase I (877) 925-6631
imexon	AmpliMed Tucson, AZ	breast, lung, prostate cancers	Phase I (520) 529-1000
IMMU-100 (labetuzumab)	Immunomedics Morris Plains, NJ	breast, colorectal, lung cancers	Phase I completed (973) 605-8200
IMMU-101 (Y-90 labetuzumab)	Immunomedics Morris Plains, NJ	breast, colorectal, lung cancers	Phase I completed (973) 605-8200
IMMU-105 (Y-90 hAFP)	Immunomedics Morris Plains, NJ	liver cancer	Phase I (973) 605-8200
ING 225	Introgen Therapeutics Austin, TX	breast, NSCLC cancers	Phase I/II (512) 708-9310
INGN 401 (FUS-1)	Introgen Therapeutics Austin, TX	lung cancer	Phase I (512) 708-9310
INOC-002	Avantogen Oncology San Diego, CA	colorectal cancer	Phase II (858) 458-6807
Insegia™ anti-gastrin 17 therapeutic vaccine	Aphton Biopharma Miami, FL	advanced stomach, esophageal cancers	Phase II completed www.aphton.com
Iressa® gefitinib	AstraZeneca Wilmington, DE	breast cancer	Phase II (800) 236-9933
ispenesib (kinesin spindle protein inhibitor)	Cytokinetics South San Francisco, CA GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	NSCLC	Phase II (650) 624-3000 (888) 825-5249
ixabepilone	Bristol-Myers Squibb Princeton, NJ	metastatic breast cancer	Phase III (212) 546-4000
KOS 862	Kosan Biosciences Hayward, CA	breast cancer	Phase II (510) 732-8400
KOS 953	Kosan Biosciences Hayward, CA	breast cancer	Phase II (510) 732-8400
KRN 5500	DARA BioSciences Raleigh, NC	colorectal cancer	Phase I (919) 872-5578
lapuleucel-T	Dendreon Seattle, WA	breast, colorectal cancers	Phase I (206) 256-4545
lasofoxifene	Ligand Pharmaceuticals San Diego, CA	breast cancer prevention	Phase III (858) 550-7500
LEP-ETU	NeoPharm Waukegan, IL	breast, NSCLC cancers	Phase III (847) 887-0800
LE-SN38	NeoPharm Waukegan, IL	colorectal cancer	Phase II (847) 887-0800

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Product Name	Sponsor	Indication	Development Status
Levulan®	DUSA Pharmaceuticals <i>Wilmington, MA</i>	cervical intraepithelial neoplasia	Phase II (978) 657-7500
		colorectal, lung cancers	in clinical trials (978) 657-7500
LMB-9	IVAX <i>Miami, FL</i>	stomach cancer	Phase II (305) 575-6000
LTSDEL	Celsion <i>Columbia, MD</i>	breast, liver, prostate cancers	Phase I (410) 290-5390
lung cancer vaccine	PowderMed <i>Oxford, England</i>	lung cancer	Phase I www.powdermed.com
mage3 recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	NSCLC	Phase II (888) 825-5249
Marqibo™ vincristine liposomal	Hana Biosciences <i>South San Francisco, CA</i>	SCLC	Phase II (650) 588-6404
matuzumab	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	colorectal, gastric, NSCLC cancers	Phase II (847) 383-3000
MB 7133	Metabasis Therapeutics <i>La Jolla, CA</i>	liver cancer	Phase I (858) 587-2770
MDX-010 (ipilimumab)	Bristol-Myers Squibb <i>San Diego, CA</i> Medarex <i>Princeton, NJ</i>	breast, prostate cancers	in clinical trials (212) 546-5000 (609) 430-2880
MDX-070	Medarex <i>Princeton, NJ</i>	prostate cancer	Phase II (609) 430-2880
MEDI-522	MedImmune <i>Gaithersburg, MD</i>	prostate cancer	Phase II (301) 398-0000
mitataxel	Taxolog <i>Fairfield, NJ</i>	breast, colorectal, NSCLC cancers	Phase II (877) TAX-OLOG
MK 0752	Merck <i>Whitehouse Station, NJ</i>	advanced breast cancer	Phase I (800) 672-6372
MKC-1	EntreMed <i>Rockville, MD</i>	breast cancer, NSCLC	Phase II (240) 864-2600
Multikine®	CEL-SCI <i>Vienna, VA</i>	cervical cancer, cervical dysplasia	Phase II (703) 506-9460
NBI 42902	Neurocrine Biosciences <i>San Diego, CA</i>	breast, prostate cancers	Phase I (858) 617-7600
Nexavar® sorafenib	Bayer <i>West Haven, CT</i> Onyx Pharmaceuticals <i>Emeryville, CA</i>	liver cancer	Phase III (203) 812-2000 (510) 597-6500
nimotuzumab (Orphan Drug)	YM Biosciences <i>Mississauga, Ontario</i>	NSCLC	Phase I/II (905) 629-9761

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Product Name	Sponsor	Indication	Development Status
NS 9	NS Pharma <i>Parsippany, NJ</i>	liver cancer	Phase I (973) 285-7010
OCX 0191	Vion Pharmaceuticals <i>New Haven, CT</i>	breast, NSCLC, prostate cancers	Phase II (203) 498-4210
OncoVAX® autologous vaccine	Intracel <i>Frederick, MD</i>	colon cancer	Phase III (301) 668-8400
Ontak®	Ligand Pharmaceuticals <i>San Diego, CA</i>	NSCLC	Phase II (858) 550-7500
OPT 22	Optimer Pharmaceuticals <i>San Diego, CA</i>	breast cancer	Phase I (858) 909-0736
oral taxane	Bristol-Myers Squibb <i>Princeton, NJ</i>	NSCLC	Phase II (212) 546-4000
Orathecin® rubitecan	SuperGen <i>Dublin, CA</i>	breast, lung cancers	Phase II (925) 560-0100
		colorectal, prostate cancers	Phase I (925) 560-0100
OSI 7904L	OSI Pharmaceuticals <i>Melville, NY</i>	biliary cancer	Phase II (631) 962-2000
P501 recombinant pharmacine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	treatment of prostate cancer	Phase I (888) 825-5249
panitumumab	Amgen <i>Thousand Oaks, CA</i>	colorectal cancer	application submitted (805) 447-1000
		NSCLC, prostate cancer	Phase II (805) 447-1000
Panzem®	EntreMed <i>Rockville, MD</i>	prostate cancer	Phase II (240) 864-2600
		breast cancer	Phase I (240) 864-2600
pegylated arginine deiminase	Phoenix Pharmacologics <i>San Diego, CA</i>	liver cancer	Phase II (858) 452-6688
perifosine	AEterna Zentaris <i>Quebec, Quebec</i>	breast, NSCLC, prostate cancers	Phase II (418) 652-8525
Photofrin®	QLT USA <i>Fort Collins, CO</i>	cholangiocarcinoma	Phase II (800) 663-5486
picoplatin	Poniard Pharmaceuticals <i>Seattle, WA</i>	prostate, SCLC cancers	Phase II (206) 281-7001
		colorectal cancer	Phase I (206) 281-7001
plitidepsin	PharmaMar USA <i>Cambridge, MA</i>	prostate, SCLC cancers	Phase II (617) 868-3797

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Product Name	Sponsor	Indication	Development Status
PN401	Wellstat Therapeutics <i>Gaithersburg, MD</i>	gastric cancer	Phase II (240) 631-2500
		colorectal cancer	Phase I (240) 631-2500
ProstAtak™	Advantagene <i>Boston, MA</i> <i>San Diego, CA</i>	prostate cancer	Phase II (617) 916-5445 (760) 943-8981
Prostvac®-VF	Therion Biologics <i>Cambridge, MA</i>	prostate cancer	Phase I/II (617) 475-7500
PSMA	Progenics Pharmaceuticals <i>Tarrytown, NY</i>	prostate cancer	Phase I/II (914) 789-2800
PX 1041	Pharmexa-Epimmune <i>San Diego, CA</i>	breast cancer	Phase I (858) 860-2500
PXD 101	CuraGen <i>Branford, CT</i>	colorectal cancer	Phase I (203) 481-1104
Quinamed® amonafile dihydrochloride	ChemGenex <i>Menlo Park, CA</i>	breast cancer	Phase II (650) 474-9800
		prostate cancer	Phase I (650) 474-9800
R851	3M Pharmaceuticals <i>St. Paul, MN</i>	cervical dysplasia	Phase I (888) 364-3577
R1550	Roche <i>Nutley, NJ</i>	metastatic breast cancer	Phase I (973) 235-5000
Rexin-G™	Epeius Biotechnologies <i>San Marino, CA</i>	breast cancer	Phase I (626) 441-6695
S-1	Taiho Pharma USA <i>Princeton, NJ</i>	gastric cancer	Phase III (609) 750-5300
		NSCLC	Phase II (609) 750-5300
S-8184	Sonus Pharmaceuticals <i>Bothell, WA</i>	breast cancer	Phase III (425) 487-9500
		colorectal cancer, NSCLC	Phase II (425) 487-9500
Sandostatin® octretide	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	breast cancer	Phase II (888) NOW-NOVA
Sarasar™ lonafarnib	Schering-Plough <i>Kenilworth, NJ</i>	breast cancer	Phase II (908) 298-4000
sibrotuzumab	Life Science Pharmaceuticals <i>Greenwich, CT</i>	colorectal, lung cancers	Phase II (203) 422-6500
sipuleucel-T	Dendreon <i>Seattle, WA</i>	prostate cancer	Phase II/III (206) 256-4545

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Product Name	Sponsor	Indication	Development Status
SNS 595	Sunesis Pharmaceuticals <i>South San Francisco, CA</i>	NSCLC, SCLC	Phase II (650) 266-3500
squalamine	Genaera <i>Plymouth Meeting, PA</i>	NSCLC, prostate cancer	Phase II (610) 941-4020
SR 31747	sanofi-aventis <i>Bridgewater, NJ</i>	prostate cancer	Phase II (800) 633-1610
SSR 125329	sanofi-aventis <i>Bridgewater, NJ</i>	prostate cancer	Phase I (800) 633-1610
Sutent® sunitinib	Pfizer <i>New York, NY</i>	breast, colorectal cancers	Phase II (860) 732-5156
talaporfin sodium	Light Sciences <i>Snoqualmine, WA</i>	liver cancer	Phase II (425) 369-2800
Tarceva® erlotinib HCl	Genentech <i>South San Francisco, CA</i> Roche <i>Nutley, NJ</i> OSI Pharmaceuticals <i>Melville, NY</i>	first-line NSCLC, second-line NSCLC (with Avastin®), NSCLC adjuvant	Phase III (650) 225-6455 (973) 235-5000 (516) 222-0023
Targretin® Capsules bexarotene oral	Ligand Pharmaceuticals <i>San Diego, CA</i>	NSCLC ----- breast, colon, prostate cancers	Phase III (858) 550-7500 Phase II (858) 550-7500
tariquidar	QLT USA <i>Fort Collins, CO</i>	breast, cervical, NSCLC cancers	Phase II (604) 707-7000
TAS-108	Taiho Pharma USA <i>Princeton, NJ</i>	breast cancer	Phase II (609) 750-5300
Taxoprexin®	Luitpold Pharmaceuticals <i>Shirley, NY</i>	colorectal, prostate cancers	Phase II (631) 924-4000
Taxotere® docetaxel	sanofi-aventis <i>Bridgewater, NJ</i>	gastric cancer	application submitted (800) 633-1610
T-cell gene therapy	Cell Genesys <i>South San Francisco, CA</i>	colorectal cancer	Phase II (650) 266-3000
tegafur/uracil combination	Merck KGaA <i>Darmstadt, Germany</i>	colorectal cancer	Phase III www.merck.de
Telcyta™ canfosfamide	Telik <i>Palo Alto, CA</i>	NSCLC ----- breast, colorectal cancers	Phase III (866) 485-5286 Phase II (866) 485-5286
temsirolimus	Wyeth <i>Collegeville, PA</i>	colorectal, NSCLC, prostate cancers	Phase II (610) 902-1200
TG 4001 (human papillomavirus vaccine)	Transgene <i>Cedex, France</i> <i>Kensington, MD</i>	cervical intraepithelial neoplasia	Phase I (301) 816-5404

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Product Name	Sponsor	Indication	Development Status
TG 4010 (cancer vaccine)	Transgene <i>Cedex, France</i> <i>Kensington, MD</i>	lung cancer	Phase I (301) 816-5404
Thalomid® thalidomide	Celgene <i>Summit, NJ</i>	colorectal, NSCLC cancers (see also HIV infection, lupus, respiratory)	Phase III (908) 673-9000
		breast, prostate cancers	Phase II (908) 673-9000
ticilimumab	Pfizer <i>New York, NY</i>	prostate cancer	Phase II (860) 732-5156
TNFrade™	GenVec <i>Gaithersburg, MD</i>	colorectal cancer	Phase II (240) 632-0740
tranex 18 (tetrandrine)	Millenia Hope <i>Montreal, Quebec</i>	colorectal cancer	Phase III (514) 846-5757
trastuzumab-DM1	Genentech <i>South San Francisco, CA</i>	HER2 metastatic breast cancer	Phase I (650) 225-1000
trilostane	Stegram Pharmaceuticals <i>Sussex, United Kingdom</i>	breast, prostate cancers	Phase II
Trisenox® arsenic trioxide	Cephalon <i>Frazer, PA</i>	breast, cervical, colorectal, NSCLC, prostate cancers	Phase II (610) 344-0200
		liver cancer	Phase I (610) 344-0200
TroVax®	BioMedica <i>San Diego, CA</i> Oxford BioMedica <i>Oxford, UK</i>	colorectal cancer	Phase II (858) 677-6500
tucotuzumab celmoleukin	EMD Lexigen <i>Billerica, MA</i>	colorectal, NSCLC, prostate cancers	Phase I (978) 294-1100
Tykerb lapatinib	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	breast cancer	Phase III (888) 825-5249
vatalanib (PKT 787)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	colorectal cancer	Phase III (888) NOW-NOVA
verpasep caltespen	Nventa Biopharmaceuticals <i>San Diego, CA</i>	cervical cancer, cervical dysplasia	Phase II (858) 202-4900
vinflunine	Bristol-Myers Squibb <i>Princeton, NJ</i>	breast cancer, NSCLC	in clinical trials (212) 546-4000
VNP 4010M	Vion Pharmaceuticals <i>New Haven, CT</i>	SCLC	Phase II (203) 498-4210
vorinostat	Aton Pharma <i>Tarrytown, NY</i>	colorectal cancer	Phase I (914) 347-2900
VP 101	Virium Pharmaceuticals <i>Princeton, NJ</i>	colorectal, prostate cancers	Phase II (609) 951-2270

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Product Name	Sponsor	Indication	Development Status
VX 680	Merck <i>Whitehouse Station, NJ</i> Vertex Pharmaceuticals <i>Cambridge, MA</i>	colorectal cancer	Phase II (800) 672-6372 (617) 444-6100
WX UK1	Wilex <i>Munich, Germany</i>	breast cancer	Phase I www.wilex.com
Xanafide	Xanthus Pharmaceuticals <i>Cambridge, MA</i>	breast cancer	Phase II (617) 225-0522
		prostate cancer	Phase I (617) 225-0522
Xcytrin [®] motexafin gadolinium	Pharmacyclics <i>Sunnyvale, CA</i>	lung cancer	Phase II (408) 774-0330
Xeloda [®] capecitabine	Roche <i>Nutley, NJ</i>	adjuvant breast, adjuvant colorectal, gastric cancers	Phase III (973) 546-4000
Xinlay [™] atrasentan	Abbott Laboratories <i>Abbott Park, IL</i>	prostate cancer	application submitted (847) 937-6100
		lung cancer	Phase II (847) 937-6100
XL 999	Exelixis <i>South San Francisco, CA</i>	colorectal cancer, NSCLC	Phase II (650) 837-7000
Xorane [™] oral paclitaxel	IVAX <i>Miami, FL</i>	breast, lung, stomach cancers	Phase II (305) 575-6000
XRP 6258	sanofi-aventis <i>Bridgewater, NJ</i>	breast cancer	Phase II (800) 633-1610
XRP 9881	sanofi-aventis <i>Bridgewater, NJ</i>	breast cancer	Phase III (800) 633-1610
Xyotax [™]	Cell Therapeutics <i>Seattle, WA</i>	NSCLC	Phase III (800) 215-CELL
		colorectal, prostate cancers	Phase II (800) 215-CELL
		gastric cancer	Phase I (800) 215-CELL
YMB-1002	YM Biosciences <i>Mississauga, Ontario</i>	breast cancer	Phase III (905) 629-9761
		prostate cancer	Phase II (905) 629-9761
Yondelis [®] trabectedin	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	breast, prostate cancers	Phase II (800) 817-5286

CANCER

Product Name	Sponsor	Indication	Development Status
Zactima™ vandetanib	AstraZeneca <i>Wilmington, DE</i>	NSCLC	Phase III (800) 236-9933
		breast cancer	Phase II (800) 236-9933
Zadaxin® thymalfasin	SciClone Pharmaceuticals <i>San Mateo, CA</i>	liver cancer	Phase II (650) 358-3456
Zarnestra® tipifarnib	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	breast cancer	Phase II (800) 817-5286
ZK epothilone	Schering AG <i>Berlin, Germany</i>	breast cancer	Phase II www.schering.de

DIABETES, TYPE 2

Product Name	Sponsor	Indication	Development Status
189075 (sodium-dependent glucose transport [SGLT2] inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
625019 (PPAR pan agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase I (888) 825-5249
677954 (PPAR pan agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
716155 (glucagon-like peptide 1 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase I (888) 825-5249
Accompia® rimonabant	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes (see also hyperlipidemia, obesity)	Phase III (800) 633-1610
AERx® iDMS insulin inhalation (NN1998)	Aradigm <i>Hayward, CA</i> Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase III (510) 265-9000 (800) 727-6500
AMG 221	Amgen <i>Thousand Oaks, CA</i>	type 2 diabetes	Phase II (805) 447-1000
APD 668	Arena Pharmaceuticals <i>San Diego, CA</i>	type 2 diabetes	Phase I (858) 453-7200
Apidra® insulin glulisine (opticlick pen)	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	application submitted (800) 633-1610

DIABETES, TYPE 2

Product Name	Sponsor	Indication	Development Status
AT 1391 (basal insulin skin patch)	Altea Therapeutics <i>Tucker, GA</i>	type 2 diabetes	Phase I (678) 495-3100
Avandamet™ XR rosiglitazone maleate/metformin (extended release)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase III (888) 825-5249
Avandia® rosiglitazone maleate/ simvastatin	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
AVE0010	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase II (800) 633-1610
AVE0847	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes (see also hyperlipidemia)	Phase II (800) 633-1610
AVE2268	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase II (800) 633-1610
AVE5376	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase I (800) 633-1610
AVE8134	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes (see also hyperlipidemia)	Phase I (800) 633-1610
AVR118	Advanced Viral Research <i>Yonkers, NY</i>	type 2 diabetes (see also HIV infection)	Phase I (914) 376-7383
colesevelam	Daiichi Sankyo <i>Parsippany, NJ</i>	type 2 diabetes	Phase III (973) 359-2600
CS-917	Daiichi Sankyo <i>Parsippany, NJ</i> Metabasis Therapeutics <i>San Diego, CA</i>	type 2 diabetes	Phase II (973) 359-2600 (858) 587-2770
Cycloset® bromocriptine	Wythe Therapeutics <i>Bristol, TN</i> <i>Wytheville, VA</i>	type 2 diabetes	Phase III
denagliptin (DPP IV inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
DIO 902	DIObex <i>San Francisco, CA</i>	type 2 diabetes	Phase II (415) 551-0400
exenatide LAR (long-acting release)	Amylin Pharmaceuticals <i>San Diego, CA</i> Alkermes <i>Cambridge, MA</i>	type 2 diabetes	Phase II (858) 552-2200
FK 614	Astellas Pharma US <i>Deerfield, IL</i>	type 2 diabetes	Phase II (800) 727-7003
Galvus® vildagliptin	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	type 2 diabetes	application submitted (888) NOW-NOVA

DIABETES, TYPE 2

Product Name	Sponsor	Indication	Development Status
INCB 13739	Incyte <i>Wilmington, DE</i>	type 2 diabetes	Phase I (302) 498-6700
INGAP peptide	GMP Companies <i>Ft. Lauderdale, FL</i> Procter & Gamble Pharmaceuticals <i>Cincinnati, OH</i>	type 2 diabetes	Phase I (888) 723-3310 (513) 983-1100
Iplex™	Insmed <i>Glen Allen, VA</i>	type 2 diabetes	Phase II (804) 565-3000
ISIS 113715	Isis Pharmaceuticals <i>Carlsbad, CA</i>	type 2 diabetes	Phase II (760) 931-9200
Januvia™ sitagliptin	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	application submitted (800) 672-6372
K 111	Kowa Pharmaceuticals <i>Morrisville, NC</i>	type 2 diabetes	Phase I
KRP 104	ActivX Biosciences <i>La Jolla, CA</i>	type 2 diabetes	Phase I (858) 558-5558
L 410198	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	in clinical trials (800) 672-6372
liraglutide (NN2211)	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase III (800) 727-6500
LY929	Ligand Pharmaceuticals <i>San Diego, CA</i>	type 2 diabetes (see also hyperlipidemia)	Phase I (858) 550-7500
MB 07803	Metabasis Therapeutics <i>San Diego, CA</i>	type 2 diabetes	Phase I (858) 587-2770
MBX 2044	Metabolex <i>Hayward, CA</i>	type 2 diabetes	Phase I (510) 293-8800
metaglidasen MBX-102	Metabolex <i>Hayward, CA</i>	type 2 diabetes	Phase II (510) 293-8800
metformin buccal	Generex Biotechnology <i>Toronto, Ontario</i>	type 2 diabetes	in clinical trials (416) 364-2551
mitiglinide	Elixir Pharmaceuticals <i>Cambridge, MA</i>	type 2 diabetes	Phase II (617) 995-7000
naveglitazar (LY 818)	Eli Lilly <i>Indianapolis, IN</i> Ligand Pharmaceuticals <i>San Diego, CA</i>	type 2 diabetes	Phase II (317) 276-2000 (858) 550-7500
NN344	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase I (800) 727-6500
NN0606	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase I (800) 727-6500
NN5401	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase I (800) 727-6500
NN9101	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	Phase I (800) 727-6500

DIABETES, TYPE 2

Product Name	Sponsor	Indication	Development Status
NovoMix® 50 and 70	Novo Nordisk <i>Princeton, NJ</i>	type 2 diabetes	application submitted (800) 727-6500
oral insulin	Emisphere Technologies <i>Tarrytown, NY</i>	type 2 diabetes	Phase I (914) 347-2220
oral insulin	Biocon <i>Bangalore, India</i>	type 2 diabetes	Phase I www.biocon.com
Oral-lyn™ insulin oral	Generex Biotechnology <i>Toronto, Ontario</i>	type 2 diabetes	Phase II (416) 364-2551
PHX 1149	Phenomix <i>San Diego, CA</i>	type 2 diabetes	Phase II (858) 731-5200
pioglitazone/ glimepiride	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	type 2 diabetes	application submitted (847) 383-3000
PLX 204	Plexxikon <i>Berkeley, CA</i> Wyeth Pharmaceuticals <i>Collegeville, PA</i>	type 2 diabetes	Phase I (510) 647-4000 (610) 902-1200
R1438	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II (973) 235-5000
R1439	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase I (973) 235-5000
R1440	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II (973) 235-5000
R1583	Roche <i>Nutley, NJ</i>	type 2 diabetes	Phase II (973) 235-5000
rivoglitazone (CS-011)	Daiichi Sankyo <i>Parsippany, NJ</i>	type 2 diabetes	Phase II/III (973) 359-2600
saxagliptin	Bristol-Myers Squibb <i>Princeton, NJ</i>	type 2 diabetes	Phase III (212) 546-4000
SGLT2 inhibitor lead	Bristol-Myers Squibb <i>Princeton, NJ</i>	type 2 diabetes	Phase II (212) 546-4000
sitagliptin/ metformin combination	Merck <i>Whitehouse Station, NJ</i>	type 2 diabetes	Phase III (800) 672-6372
solabegron (beta3 adrenergic agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	type 2 diabetes	Phase II (888) 825-5249
SSR 162369	sanofi-aventis <i>Bridgewater, NJ</i>	type 2 diabetes	Phase I (800) 633-1610
SYR 322	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	type 2 diabetes	Phase III (847) 383-3000
SYR 619	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	type 2 diabetes	Phase I (847) 383-3000

DIABETES, TYPE 2

Product Name	Sponsor	Indication	Development Status
Technosphere® Insulin System insulin inhalation	MannKind Valencia, CA	type 2 diabetes	Phase III (661) 775-5300

HIV INFECTION

Product Name	Sponsor	Indication	Development Status
825780 (DNA antiviral vaccine)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	HIV infection	Phase I (888) 825-5249
Alferon LDO® interferon alfa-n3	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	HIV infection	Phase II (888) 253-3766
ALVAC E120 TMG	sanofi pasteur Swiftwater, PA	HIV infection (Thailand)	Phase III (570) 839-4267
AMD070	AnorMed Langley, British Columbia	HIV infection	Phase II (604) 530-1057
Ampligen®	Hemispherx Biopharma New Brunswick, NJ Philadelphia, PA	HIV infection (strategic treatment intervention)	Phase II/III (215) 988-0080
AMZ0026	Amazon Biotech New York, NY	HIV infection	Phase I/II (212) 947-3363
anti-HIV-1 mAb	Polymun Scientific Vienna, Austria	HIV infection	Phase II www.polymun.com
AVR118	Advanced Viral Research Yonkers, NY	HIV infection (see also diabetes)	Phase I (914) 376-7383
AVX101 (single gene vaccine)	AlphaVax Rsch. Triangle Park, NC	HIV infection	Phase I (919) 595-0400
AVX754	Avexa Richmond, Australia	HIV infection	Phase II www.avexa.com
BAY 50-4798	Bayer West Haven, CT	HIV infection	Phase II (800) 468-0894
brecanavir (640385, aspartyl protease inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	HIV infection	Phase II (888) 825-5249
BufferGel™ (microbicide)	ReProtect Baltimore, MD	prevention of sexual transmission of HIV infection	Phase II (410) 516-7260
calanolide A (NNRTI)	Advanced Life Sciences Woodridge, IL Sarawak MediChem Pharmaceuticals Woodridge, IL	HIV infection (see also respiratory)	Phase II (630) 739-6744
CCR5 mAB	Human Genome Sciences Rockville, MD	HIV infection	Phase I (301) 309-8504

HIV INFECTION

Product Name	Sponsor	Indication	Development Status
CYT 99007	Cytheris <i>Rockville, MD</i>	HIV infection	Phase I www.cytheris.com
Cytolin®	CytoDyn <i>Santa Fe, NM</i>	HIV infection	Phase II (877) 988-5520
dexelvucitabine (DFC)	Incyte <i>Wilmington, DE</i> Pharmasset <i>Princeton, NJ</i>	HIV infection	Phase II (302) 498-6700 (609) 613-4100
elvucitabine (Beta-L-Fd4C)	Achillion Pharmaceuticals <i>West Haven, CT</i>	HIV infection	Phase II (203) 624-7000
EP 1043	Pharmexa-Epimmune <i>San Diego, CA</i>	HIV infection	Phase I (858) 860-2500
EP 1090	Pharmexa-Epimmune <i>San Diego, CA</i>	HIV-1 treatment	Phase I (858) 860-2500
fozivudine tidoxil	Heidelberg Pharma <i>Ladenburg, Germany</i>	HIV infection	Phase II/III
FP-21339	EMD Lexigen <i>Billerica, MA</i>	HIV infection	Phase I completed (978) 294-1100
GS 9137	Gilead Sciences <i>Foster City, CA</i>	HIV infection, AIDS	Phase I/II (650) 574-3000
GS 9160	Gilead Sciences <i>Foster City, CA</i>	HIV infection	Phase I (650) 574-3000
HDP 99.0003	Heidelberg Pharma <i>Ladenburg, Germany</i>	HIV infection	Phase I/II
HGTV43 gene medicine	Enzo Biochem <i>Farmingdale, NY</i>	HIV infection	Phase I/II (631) 755-5500
HIV-1 DNA vaccine	CytRx <i>Los Angeles, CA</i>	HIV-1 DNA vaccine with protein vaccine boost	Phase I (310) 826-5648
HIV attachment inhibitor	Bristol-Myers Squibb <i>Princeton, NJ</i>	HIV-1 viral infection	Phase I (212) 546-4000
HIV DNA vaccine-VRC	Dale and Betty Bumpers Vaccine Research Center at NIH <i>Bethesda, MD</i>	HIV infection	Phase II www.vrc.nih.gov
HIV peptide vaccine	Wyeth <i>Collegeville, PA</i>	prevention of HIV disease	Phase I (610) 902-1200
HIV recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	HIV infection prophylaxis	Phase I (888) 825-5249
HIV therapeutic	sanofi pasteur <i>Swiftwater, PA</i>	HIV infection	Phase II (570) 839-4267
HIV vaccine	NIAID <i>Bethesda, MD</i> Therion Biologics <i>Cambridge, MA</i>	HIV infection	Phase I www.clinicaltrials.gov

HIV INFECTION

Product Name	Sponsor	Indication	Development Status
HIV vaccine	Novartis Vaccines <i>Emeryville, CA</i>	HIV infection	Phase I (510) 655-8730
HIV vaccine (multiple gene)	AlphaVax <i>Rsch. Triangle Park, NC</i>	HIV infection prevention	Phase I (919) 595-0400
		HIV infection treatment	Phase I (919) 595-0400
HIV vaccine (V520)	Merck <i>Whitehouse Station, NJ</i>	HIV infection, AIDS	Phase II/III (800) 672-6372
HIV vaccine (VRC-HIVADV-009)	NIAID, Vaccine Research Center <i>Bethesda, MD</i>	HIV infection	Phase I www.clinicaltrials.gov
HIV vaccine (VRC-HIVADV-014)	GenVec <i>Gaithersburg, MD</i> NIAID, Vaccine Research Center <i>Bethesda, MD</i>	HIV infection	Phase I (240) 632-0740
HIV vaccine (VRC-HIVDNA-016)	NIAID, Vaccine Research Center <i>Bethesda, MD</i>	HIV infection	Phase II www.clinicaltrials.gov
IFN-alpha lozenge (natural human interferon-alpha) (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	treatment of oral warts in HIV-seropositive patients	Phase III (806) 376-1741
IMMUNITIN™ (HE2000)	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	HIV infection/AIDS	Phase II (858) 587-9333
INCB 9471	Incyte <i>Wilmington, DE</i>	HIV infection	Phase I (302) 498-6700
IR103 (HIV-1 immunogen w/ Amplivax™)	Hybridon <i>Cambridge, MA</i> Immune Response <i>Carlsbad, CA</i>	HIV infection	Phase I/II (760) 431-7080
JTK-303	Gilead Sciences <i>Foster City, CA</i>	HIV infection	Phase II (650) 574-3000
KP-1461	Koronis Pharmaceuticals <i>Redmond, WA</i>	HIV infection, AIDS	Phase I (425) 825-0240
MIV-150	Medivir <i>Huddinge, Sweden</i>	HIV infection	Phase I www.medivir.com
MIV-210	Medivir <i>Huddinge, Sweden</i>	HIV infection	Phase II www.medivir.com
MK0518	Merck <i>Whitehouse Station, NJ</i>	HIV infection, AIDS	Phase II/III (800) 672-6372
MVA-nef	Bavarian Nordic <i>Kvistgard, Denmark</i>	HIV infection	Phase II www.bavarian-nordic.com

HIV INFECTION

Product Name	Sponsor	Indication	Development Status
NM01	SRD Pharmaceuticals <i>Los Angeles, CA</i>	HIV infection	Phase I
nonakine	Gryphon Therapeutics <i>South San Francisco, CA</i>	HIV infection	in clinical trials (650) 952-7714
PA-457	Panacos Pharmaceuticals <i>Watertown, MA</i>	HIV infection	Phase II (617) 926-1551
PEHRG214	Virionyx <i>Auckland, New Zealand</i>	HIV infection	Phase I www.virionyx.com
PRO 140	Progenics Pharmaceuticals <i>Tarrytown, NY</i>	HIV infection	Phase I (914) 789-2800
PRO 2000	Indevus Pharmaceuticals <i>Lexington, MA</i>	prevention of HIV infection transmission (intravaginal gel)	Phase III (781) 861-8444
Racivir [®] (PSI 5004)	Pharmasset <i>Princeton, NJ</i>	HIV infection	Phase II (609) 613-4100
Savvy [®] 1% C31G vaginal gel (microbicide)	Biosyn <i>Huntingdon Valley, PA</i> Cellegy Pharmaceuticals <i>Huntingdon Valley, PA</i>	HIV infection prevention	Phase III (215) 914-0900
SP-01A procaine HCl	Samaritan Pharmaceuticals <i>Las Vegas, NV</i>	HIV infection	Phase II (702) 735-7001
tgAAC09	Targeted Genetics <i>Seattle, WA</i> International AIDS Vaccine Initiative <i>New York, NY</i>	HIV infection	Phase II (206) 623-7612
Thalomid [®] thalidomide	Celgene <i>Summit, NJ</i>	HIV infection (see also cancer, lupus, respiratory)	Phase II (908) 673-9000
Therapore [®] HIV vaccine	Avant Immunotherapeutics <i>Needham, MA</i>	HIV infection	Phase I (781) 433-0771
TMC114 (PI)	Tibotec <i>Yardley, PA</i>	HIV infection	Phase II/III (609) 730-7500
TMC125 (NNRTI)	Tibotec <i>Yardley, PA</i>	HIV infection	Phase II (609) 730-7500
TMC278 (NNRTI)	Tibotec <i>Yardley, PA</i>	HIV infection	Phase II (609) 730-7500
TNX-355	Tanox <i>Houston, TX</i>	HIV infection, AIDS	Phase II (713) 578-4000
UC-781 (microbicide gel)	Biosyn <i>Huntingdon Valley, PA</i> Cellegy Pharmaceuticals <i>Huntingdon Valley, PA</i>	HIV infection	Phase I (215) 914-0900
UK-427,857 (maraviroc, CCR5 coreceptor antagonist)	Pfizer <i>New York, NY</i>	HIV-1 infection	Phase III (860) 732-5156

HIV INFECTION

Product Name	Sponsor	Indication	Development Status
Ushercell cellulose sulfate	Polydex Pharmaceuticals <i>Toronto, Ontario</i>	prevention of HIV infection and other sexually-transmitted diseases	Phase III (416) 755-2231
VGX 410	VGX Pharmaceuticals <i>Blue Bell, PA</i>	HIV infection	Phase II (267) 440-4200
vicriviroc (CCR5 receptor antagonist)	Schering-Plough <i>Kenilworth, NJ</i>	HIV infection	Phase II/III (908) 298-4000
Viramune [®] (nevirapine) and Combivir [®] (lamivudine/ zidovudine) combination	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	mother-to-child transmission of HIV infection	Phase IV (203) 798-4700
VRX 496 (modified autologous T cells)	VIRxSYS <i>Gaithersburg, MD</i>	HIV infection	Phase II (301) 987-0480

HYPERLIPIDEMIA

Product Name	Sponsor	Indication	Development Status
256073 (high affinity nicotinic acid receptor [HM74A] agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	dyslipidemia	Phase I (888) 825-5249
501516 (peroxisome proliferator-activator receptor [PPAR] delta agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	dyslipidemia	Phase II (888) 825-5249
590735 (PPAR alpha agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	dyslipidemia	Phase II (888) 825-5249
681323 (p38 kinase inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	atherosclerosis (see also respiratory)	Phase I (888) 825-5249
856553 (p 38 kinase inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	atherosclerosis (see also respiratory)	Phase I (888) 825-5249
Accomplia [®] rimonabant	sanofi-aventis <i>Bridgewater, NJ</i>	atherosclerosis, dyslipidemia (see also diabetes, obesity)	Phase III (800) 633-1610
AGI-1067	AtheroGenics <i>Alpharetta, GA</i>	atherosclerosis	Phase III
Antrin [®] motexafin lutetium	Pharmacyclics <i>Sunnyvale, CA</i>	vulnerable plaque	Phase I (408) 774-0330

HYPERLIPIDEMIA

Product Name	Sponsor	Indication	Development Status
APP018	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	atherosclerosis	in clinical trials (888) NOW-NOVA
AVE0847	sanofi-aventis <i>Bridgewater, NJ</i>	mixed dyslipidemia (see also diabetes)	Phase II (800) 633-1610
AVE5530	sanofi-aventis <i>Bridgewater, NJ</i>	hypercholesterolemia	Phase I (800) 633-1610
AVE8134	sanofi-aventis <i>Bridgewater, NJ</i>	mixed dyslipidemia (see also diabetes)	Phase I (800) 633-1610
BTG 511	BTG International <i>West Conshohocken, PA</i>	hypercholesterolemia	Phase II (610) 278-1660
CETi-1 vaccine	Avant Immunotherapeutics <i>Needham, MA</i>	cholesterol management	Phase II (781) 433-0771
darapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	atherosclerosis	Phase II/III (888) 825-5249
DITPA	Titan Pharmaceuticals <i>South San Francisco, CA</i>	hypercholesterolemia	Phase II (650) 244-4990
docosahexaenoic acid	Martek Biosciences <i>Columbia, MD</i>	hyperlipidemia (see also cancer)	in clinical trials (410) 740-0081
Evista [®] raloxifene	Eli Lilly <i>Indianapolis, IN</i>	hypercholesterolemia	in clinical trials (317) 276-2000
FM-VP4	Forbes Medi-Tech <i>Vancouver, British Columbia</i>	hypercholesterolemia	Phase II (604) 689-5899
gemcabene	Pfizer <i>New York, NY</i>	hyperlipoproteinemia	Phase II (860) 732-5156
GW516	Ligand Pharmaceuticals <i>San Diego, CA</i>	dyslipidemia	Phase II (858) 550-7500
icatibant	KOS Pharmaceuticals <i>Cranbury, NJ</i>	dyslipidemia (see also liver)	Phase I/II (609) 495-0500
implitapide	Bayer <i>West Haven, CT</i>	familial hypercholesterolemia	Phase II (800) 468-0894
ISIS 301012	Isis Pharmaceuticals <i>Carlsbad, CA</i>	hypercholesterolemia	Phase II (760) 931-9200
		hyperlipidemia	Phase I (760) 931-9200
L 410198	Merck <i>Whitehouse Station, NJ</i>	hyperlipidemia (see also diabetes)	Phase II (800) 672-6372
LBM642	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	dyslipidemia	in clinical trials (888) NOW-NOVA
LY674	Ligand Pharmaceuticals <i>San Diego, CA</i>	atherosclerosis, dyslipidemia	Phase II (858) 550-7500
LY929	Ligand Pharmaceuticals <i>San Diego, CA</i>	dyslipidemia (see also diabetes)	Phase I (858) 550-7500

HYPERLIPIDEMIA

Product Name	Sponsor	Indication	Development Status
MD 0727	Microbia <i>Cambridge, MA</i>	hypercholesterolemia	Phase I (617) 621-7722
MK 0859	Merck <i>Whitehouse Station, NJ</i>	hyperlipidemia	Phase II (800) 672-6372
pitavastatin (NK-104)	Daiichi Sankyo Pharma <i>Parsippany, NJ</i>	hypercholesterolemia, hyperlipidemia	Phase III (973) 359-2600
PLT 732	Pilot Therapeutics <i>Winston-Salem, NC</i>	hypertriglyceridemia	in clinical trials (919) 991-5429
QC-BT16	Quark Biotech <i>Fremont, CA</i>	hyperlipidemia	Phase II (510) 402-4020
R1593	Roche <i>Nutley, NJ</i>	dyslipidemia	Phase I (973) 235-5000
R1658	Roche <i>Nutley, NJ</i>	dyslipidemia	Phase II (973) 235-5000
R1664	Roche <i>Nutley, NJ</i>	dyslipidemia	Phase I (973) 235-5000
Reversionex™ (HE2200)	Hollis-Eden Pharmaceuticals <i>San Diego, CA</i>	hypercholesterolemia	Phase II completed (858) 587-9333
rilapladib (Lp-PLA2 inhibitor)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	atherosclerosis	Phase I (888) 825-5249
RWJ-800025	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	hyperlipidemia	Phase I (800) 817-5286
TAK 475	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	hypercholesterolemia, hyperlipidemia	Phase III (847) 383-3000
torcetrapib/ atorvastatin combination	Pfizer <i>New York, NY</i>	hypercholesterolemia, low HDL cholesterol	Phase III (860) 732-5156

HYPERTENSION (HIGH BLOOD PRESSURE)

Product Name	Sponsor	Indication	Development Status
alagebrium chloride (ALT-711)	Alteon <i>Parsippany, NJ</i>	hypertension	Phase II (201) 934-5000
ambrisentan	Myogen <i>Westminster, CO</i>	pulmonary hypertension	Phase III (303) 410-6666
AVE7688	sanofi-aventis <i>Bridgewater, NJ</i>	hypertension	Phase II (800) 633-1610
Cialis® tadalafil	Eli Lilly <i>Indianapolis, IN</i> ICOS <i>Bothell, WA</i>	hypertension	Phase II (317) 276-2000 (425) 485-1900

HYPERTENSION (HIGH BLOOD PRESSURE)

Product Name	Sponsor	Indication	Development Status
Cleavelox® clevidipine	The Medicines Company <i>Parsippany, NJ</i>	perioperative hypertension	Phase II (973) 656-1616
Coreg® CR carvedilol (once daily)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	hypertension	application submitted (888) 825-5249
CS-8663	Daiichi Sankyo <i>Parsippany, NJ</i>	hypertension	Phase III (973) 359-2600
CYT 006	Cytos Biotechnology <i>Zurich, Switzerland</i>	hypertension	Phase I www.cytos.com
daglutril (SLV 306)	Solvay Pharmaceuticals <i>Marietta, GA</i>	hypertension	Phase II (770) 578-5000
darusentan	Myogen <i>Westminster, CO</i>	resistant hypertension	Phase III (303) 410-6666
diltiazem-DOV	DOV Pharmaceutical <i>Somerset, NJ</i>	hypertension	Phase I (732) 907-3600
estradiol/ drospirenone combination	Schering AG <i>Berlin, Germany</i>	hypertension	Phase III www.schering.de
Exforge® amlodipine/ valsartan combination	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hypertension	application submitted (888) NOW-NOVA
imidapril	Xanodyne Pharmaceuticals <i>Newport, KY</i>	hypertension	Phase II (859) 371-6383
J 104132	Merck <i>Whitehouse Station, NJ</i>	hypertension	Phase II (800) 672-6372
levamiodipine	Sepracor <i>Marlborough, MA</i>	hypertension	Phase II (508) 481-9000
MK-0736	Merck <i>Whitehouse Station, NJ</i>	hypertension	Phase II (800) 672-6372
moxonidine	Eli Lilly <i>Indianapolis, IN</i>	hypertension	Phase III (317) 276-2000
nebivolol	Forest Laboratories <i>New York, NY</i>	hypertension	application submitted (212) 421-7850
PRX 08066	Predix Pharmaceuticals <i>Lexington, MA</i>	pulmonary hypertension	Phase I (781) 372-3260
PulmoLAR™ 2-ME	PR Pharmaceuticals <i>Fort Collins, CO</i>	pulmonary hypertension	Phase I (970) 484-5560
Rasilez® aliskiren	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hypertension	application submitted (888) NOW-NOVA
TAK 536	Takeda Pharmaceuticals North America <i>Lincolnshire, IL</i>	hypertension	Phase II (847) 383-3000
Thelin™ sitaxsentan sodium	Encysive Pharmaceuticals <i>Houston, TX</i>	pulmonary hypertension	application submitted (713) 796-8822

HYPERTENSION (HIGH BLOOD PRESSURE)

Product Name	Sponsor	Indication	Development Status
trimazosin	Pfizer New York, NY	hypertension	application submitted (860) 732-5156
UK-369,003	Pfizer New York, NY	pulmonary hypertension	Phase II (860) 732-5156
VNP 489	Novartis Pharmaceuticals East Hanover, NJ	hypertension	Phase I (888) NOW-NOVA

LIVER DISORDERS

Product Name	Sponsor	Indication	Development Status
balsalazide	Salix Pharmaceuticals Morrisville, NC	hepatic encephalopathy	Phase III (919) 862-1000
extracorporeal liver assist device (C3A human hepatocyte cell line)	Vital Therapies San Diego, CA	liver failure	Phase II (858) 673-6840
farglitazar (PPAR gamma agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	hepatic fibrosis	Phase II (888) 825-5249
gene therapy	Bioenvision New York, NY	cirrhosis	Phase I (212) 750-6700
histamine dihydrochloride (oral)	EpiCept Englewood Cliffs, NJ	cirrhosis	Phase I (201) 894-8980
icatibant	KOS Pharmaceuticals Cranbury, NJ	liver cirrhosis (see also hyperlipidemia)	Phase I/II (609) 495-0500
IDN 6556	Pfizer New York, NY	alcoholic hepatitis	Phase II (860) 732-5156
INT 747	Intercept Pharmaceuticals New York, NY	hepatic fibrosis	Phase I (212) 727-8565
liver cell transplant therapy	Vesta Therapeutics Durham, NC	liver disorders	Phase I (919) 433-1900
NCX 1000	Axcan Pharma Birmingham, AL NicOx Cedex, France	portal hypertension	Phase I (205) 991-8085
Prograf [®] tacrolimus	Astellas Pharma US Deerfield, IL	primary biliary cirrhosis (see also respiratory)	Phase II (847) 727-7003
SPI-8811	Sucampo Pharmaceuticals Bethesda, MD	primary biliary cirrhosis	Phase II (301) 961-3400
SR 121463	sanofi-aventis Bridgewater, NJ	cirrhotic ascites	Phase III (800) 633-1610

LIVER DISORDERS

Product Name	Sponsor	Indication	Development Status
terilpressin intravenous	Orphan Therapeutics <i>Lebanon, NJ</i> PDL BioPharma <i>Fremont, CA</i>	hepatorenal syndrome	Phase III (908) 849-4805 (510) 574-1400
ursodeoxycholic acid	Axcan Pharma <i>Mont-Saint-Hilaire, Quebec</i>	primary sclerosing cholangitis	Phase III (450) 467-5138
Xifaxan™ rifaximin	Salix Pharmaceuticals <i>Morrisville, NC</i>	hepatic encephalopathy	Phase III (919) 862-1000

LUPUS

Product Name	Sponsor	Indication	Development Status
Acterna™ tocilizumab	Roche <i>Nutley, NJ</i>	systemic lupus erythematosus (SLE)	Phase I (973) 235-5000
AMG 623	Amgen <i>Thousand Oaks, CA</i>	SLE	Phase I (804) 447-1000
Aslera™ prasterone	Genelabs Technologies <i>Redwood City, CA</i>	SLE	application submitted (650) 369-9500
Cellcept® mycophenolate mofetil	Aspreva Pharmaceuticals <i>Victoria, British Columbia</i> Roche <i>Nutley, NJ</i>	lupus nephritis	Phase III (250) 744-2488 (973) 235-5000
edratide (TV 4710)	Teva Pharmaceuticals USA <i>North Wales, PA</i>	SLE	Phase II (215) 591-3000
epratuzumab	Immunomedics <i>Morris Plains, NJ</i>	SLE	Phase I (973) 605-8200
ETI-201	Elusys Therapeutics <i>Pine Brook, NJ</i>	SLE	Phase I (973) 808-0222
LymphoStat™ belimumab	Human Genome Sciences <i>Rockville, MD</i>	SLE	Phase II (301) 309-8504
MEDI-545	Medarex <i>Princeton, NJ</i> MedImmune <i>Gaithersburg, MD</i>	SLE	Phase I (609) 430-2880 (301) 398-0000
Orencia	Bristol-Myers Squibb <i>Princeton, NJ</i>	lupus	in clinical trials (212) 546-4000
Riquent® abetimus sodium (Orphan Drug)	La Jolla Pharmaceutical <i>San Diego, CA</i>	lupus nephritis	application submitted (888) 452-6600
Rituxan® rituximab	Biogen Idec <i>Cambridge, MA</i> Genentech <i>South San Francisco, CA</i>	lupus nephritis, SLE	Phase III (617) 679-2000 (650) 225-1000

LUPUS

Product Name	Sponsor	Indication	Development Status
TACI-Ig	Serono Rockland, MA Zymogenetics Seattle, WA	SLE	Phase I/II (800) 275-7376 (206) 442-6000
		lupus	Phase I (800) 275-7376 (206) 442-6000
Thalomid® thalidomide	Celgene Summit, NJ	SLE (see also cancer, HIV infection, respiratory)	in clinical trials (908) 673-9000

NEPHRITIS

Product Name	Sponsor	Indication	Development Status
CR 002	CuraGen Branford, CT	IgA nephropathy	Phase I (203) 481-1104
pirfenidone	InterMune Brisbane, CA	glomerulonephritis	Phase II (415) 466-2200
PL 56	Pharmalink Stockholm, Sweden	IgA nephropathy	Phase II www.pharmalink.se

OBESITY

Product Name	Sponsor	Indication	Development Status
856464 (melanin concentrating hormone antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	obesity	Phase I (888) 825-5249
869682 (SGLT2 inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	obesity	Phase II (888) 825-5249
AC 162352	Amylin Pharmaceuticals San Diego, CA	obesity	Phase I (858) 552-2200
Accomplia® rimonabant	sanofi-aventis Bridgewater, NJ	obesity (see also diabetes, hyperlipidemia)	application submitted (800) 633-1610
ALT-962 cetlistat	Alizyme Cambridge, United Kingdom	obesity	Phase II www.alizyme.com
AMG 076	Amgen Thousand Oaks, CA	obesity	Phase I (805) 447-1000
AVE1625	sanofi-aventis Bridgewater, NJ	obesity	Phase II (800) 633-1610
Byetta® exenatide	Amylin Pharmaceuticals San Diego, CA Eli Lilly Indianapolis, IN	obesity	in clinical trials (858) 552-2200 (317) 276-2000

OBESITY

Product Name	Sponsor	Indication	Development Status
cannabinoid antagonist	Bristol-Myers Squibb <i>Princeton, NJ</i>	obesity	Phase I (212) 546-4000
CP-945,598	Pfizer <i>New York, NY</i>	obesity	Phase I (860) 732-5156
Excalia™	Orexigen Therapeutics <i>San Diego, CA</i>	obesity	Phase II (858) 480-2420
GT 389255	Peptimmune <i>Cambridge, MA</i>	obesity	Phase II (617) 715-8000
lorcaserin (APD356)	Arena Pharmaceuticals <i>San Diego, CA</i>	obesity	Phase II (858) 453-7200
mifepristone	Corcept Therapeutics <i>Menlo Park, CA</i>	obesity	Phase II (650) 327-3270
miglitol	Pfizer <i>New York, NY</i>	obesity	Phase II (860) 732-5156
MK-0364	Merck <i>Whitehouse Station, NJ</i>	obesity	Phase II (800) 672-6372
MK-0493	Merck <i>Whitehouse Station, NJ</i>	obesity	Phase II (800) 672-6372
naltrexone/ bupropion combination	Orexigen Therapeutics <i>San Diego, CA</i>	obesity	Phase III (858) 480-2420
NBI 69734	Neurocrine Biosciences <i>San Diego, CA</i>	obesity	Phase I (858) 617-7600
peptide YY (3-36)	Nastech Pharmaceutical <i>Bothell, WA</i>	obesity	Phase II (425) 908-3600
PRX 07034	Predix Pharmaceuticals <i>Lexington, MA</i>	obesity	Phase I (781) 372-3260
Qnexa™ phentermine/ topiramate combination	VIVUS <i>Mountain View, CA</i>	obesity	Phase II (650) 934-5200
radafaxine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	obesity	Phase I (888) 825-5249
S-2367	Shionogi USA <i>Florham Park, NJ</i>	obesity	Phase I (973) 966-6900
SLx 4090	Surface Logix <i>Brighton, MA</i>	obesity	Phase I (617) 746-8500
SR 147778	sanofi-aventis <i>Bridgewater, NJ</i>	obesity	Phase II (800) 633-1610
Symlin® pramlintide	Amylin Pharmaceuticals <i>San Diego, CA</i>	obesity	Phase II (858) 552-2200
Zoloft® sertraline	Pfizer <i>New York, NY</i>	obesity	in clinical trials (860) 732-5156

OBESITY

Product Name	Sponsor	Indication	Development Status
Zonegran® zonisamide	Eisai <i>Ridgefield Park, NJ</i>	obesity	Phase II (888) 274-2378

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
13-valent pneumococcal conjugate vaccine	Wyeth <i>Collegeville, PA</i>	pneumococcal disease in high-risk individuals and adults older than 50	Phase II (610) 902-1200
		pneumococcal disease in infants and children 6 months to 2 years	Phase II (610) 902-1200
159797 (long-acting beta2 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	chronic obstructive pulmonary disease (COPD)	Phase II (888) 825-5249
		asthma, COPD in combination with a glucocorticoid agonist	Phase II (888) 825-5249
159802 (long-acting beta2 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
		asthma, COPD in conjunction with a glucocorticoid agonist	Phase II (888) 825-5249
233705 (muscarinic acetylcholine antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
256066 (PDE IV inhibitor, inhaled)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	asthma, COPD	Phase I (888) 825-5249
597901 (long-acting beta2 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
		asthma, COPD in combination with a glucocorticoid agonist	Phase II (888) 825-5249
642444 (long-acting beta2 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
		asthma, COPD in conjunction with a glucocorticoid agonist	Phase II (888) 825-5249
656398 (muscarinic acetylcholine antagonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase I (888) 825-5249
678007 (long-acting beta2 agonist)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	COPD	Phase II (888) 825-5249
		asthma, COPD in combination with a glucocorticoid agonist	Phase II (888) 825-5249

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
681323 (p38 kinase inhibitor, oral)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	COPD (see also hyperlipidemia)	Phase II (888) 825-5249
685698 (glucocorticoid agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	asthma, COPD in combination with a long-acting beta2 agonist	Phase II (888) 825-5249
799943 (glucocorticoid agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	asthma, COPD in combination with a long-acting beta2 agonist	Phase II (888) 825-5249
856553 (p38 kinase inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	COPD	Phase I (888) 825-5249
870086 (novel glucocorticoid agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	asthma	Phase I (888) 825-5249
961081 (muscarinic antagonist, beta2 agonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	COPD	Phase I (888) 825-5249
ABN 912	Novartis Pharmaceuticals East Hanover, NJ	asthma, COPD	Phase I (888) NOW-NOVA
ABX-IL8	Amgen Thousand Oaks, CA	COPD	Phase II (805) 447-1000
Advair®	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	asthma (non-CFC inhaler)	application submitted (888) 825-5249
		----- COPD (mortality claim)	Phase III (888) 825-5249
AER 001	Aerovance Berkeley, CA	acute asthma	Phase II (510) 549-5500
Alvesco® ciclesonide (XRP 1526)	sanofi-aventis Bridgewater, NJ	asthma (metered-dose inhaler)	application submitted (800) 633-1610
Alvesco® Combo ciclesonide/ formoterol	sanofi-aventis Bridgewater, NJ	asthma	Phase II (800) 633-1610
AMG 317	Amgen Thousand Oaks, CA	asthma	Phase I (805) 447-1000
amikacin inhalation	Nektar Therapeutics San Carlos, CA	nosocomial pneumonia	Phase II (650) 631-3100
arformoterol (PDE IV inhibitor, inhaled)	Sepracor Marlborough, MA	COPD	application submitted (508) 357-7300

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
Ariflo® cilomilast	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	COPD	application submitted (888) 825-5249
AVP 13358	Avanir Pharmaceuticals San Diego, CA	allergic asthma	Phase I (858) 622-5200
azithromycin	Pfizer New York, NY	acute exacerbations of chronic bronchitis	application submitted (860) 732-5156
beclometasone	3M Pharmaceuticals St. Paul, MN	asthma	Phase III (888) 364-3577
bikunin (AER 002)	Aerovance Berkeley, CA	COPD	Phase II (510) 549-5500
budesonide/ formoterol combination	AstraZeneca Wilmington, DE	asthma ----- COPD	application submitted (302) 886-3000 Phase III (302) 886-3000
budesonide inhalation	MAP Pharmaceuticals Mountain View, CA	asthma	Phase I (650) 386-3100
calanolide A	Advanced Life Sciences Woodridge, IL Sarawak MediChem Pharmaceuticals Woodridge, IL	tuberculosis (see also HIV infection)	Phase I (630) 739-6744
CC 10004	Celgene Summit, NJ	asthma	Phase II (908) 673-9000
ceftobiprole medocaril	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	nosocomial pneumonia	Phase III (800) 817-5286
CJ 13610	Pfizer New York, NY	asthma, COPD	Phase II (860) 732-5156
CP 325366 (tofimilast)	Pfizer New York, NY	asthma, COPD	Phase II (860) 732-5156
CRX 170	CombinatoRx Cambridge, MA	asthma	Phase II (617) 301-7000
CS 003	Daiichi Sankyo Parsippany, NJ	asthma, COPD	Phase II (973) 359-2600
CS 615	Daiichi Sankyo Parsippany, NJ	asthma	Phase II (973) 359-2600
CS 8958	Daiichi Sankyo Parsippany, NJ	influenza	Phase I (973) 359-2600
CVT 6883	CV Therapeutics Palo Alto, CA	asthma	Phase I (650) 384-8500
CVT E002	CV Technologies Chicago, IL	influenza	Phase II (888) 843-7239

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
daclizumab	PDL BioPharma <i>Fremont, CA</i>	chronic and persistent asthma	Phase II (510) 574-1400
desloratadine	Sepracor <i>Marlborough, MA</i>	asthma	in clinical trials (508) 357-7300
doripenem	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	nosocomial pneumonia	Phase III (800) 817-5286
DW 908e	Daiichi Sankyo <i>Parsippany, NJ</i>	asthma	Phase I (973) 359-2600
Enbrel® etanercept	Wyeth <i>Collegeville, PA</i>	asthma	Phase II (610) 902-1200
EPI 12323	EpiGenesis Pharmaceuticals <i>Cranbury, NJ</i>	asthma, COPD	Phase II (609) 409-6080
epinastine	Boehringer Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	asthma	Phase I (203) 798-9988
etiprednol	IVAX <i>Miami, FL</i> Teva Pharmaceuticals USA <i>North Wales, PA</i>	asthma	Phase II (305) 575-6000 (215) 591-3000
fandosentan	Pfizer <i>New York, NY</i>	COPD	Phase I (860) 732-5156
faropenem medoxomil	Forest Laboratories <i>New York, NY</i>	community-acquired pneumonia	application submitted (212) 421-7850
FluBIOk™ trivalent recombinant hemagglutinin influenza vaccine	Protein Sciences <i>Meriden, CT</i>	influenza	Phase III (800) 488-7099
flu-improved inactivated split-adjuvanted vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	influenza prophylaxis	Phase II (888) 825-5249
FluINsure (inactivated split-adjuvanted vaccine)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	influenza prophylaxis	Phase II (888) 825-5249
flu micro-injection (new delivery)	sanofi pasteur <i>Swiftwater, PA</i>	influenza	Phase II (570) 839-4267
flu pandemic inactivated whole-aluminum salt adjuvant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	influenza prophylaxis	application submitted (888) 825-5249

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
Fluviral (inactivated split vaccine)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	influenza prophylaxis	Phase III (888) 825-5249
Foradil® formoterol fumarate (dry powder inhalation)	Novartis Pharmaceuticals <i>East Hanover, NJ</i> SkyePharma <i>San Diego, CA</i>	asthma	application submitted (888) NOW-NOVA (858) 625-2424
formoterol/ fluticasone propionate fixed combination	SkyePharma <i>San Diego, CA</i>	asthma	Phase III (858) 625-2424
formoterol hydrofluoroalkane	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma	Phase II (888) NOW-NOVA
GRC-3886	Forest Laboratories <i>New York, NY</i>	COPD	Phase I (212) 421-7850
H5N1 avian influenza intranasal vaccine	MedImmune <i>Gaithersburg, MD</i>	influenza	Phase I (301) 398-0000
hydroxychloroquine inhalation	APT Pharmaceuticals <i>Tucson, AZ</i> Aradigm <i>Hayward, CA</i>	asthma, COPD	Phase II (510) 265-9000
IL-4/13 trap	Regeneron Pharmaceuticals <i>Tarrytown, NY</i>	asthma	Phase I (914) 345-7400
indacaterol (QAB149)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	asthma, COPD	Phase III (888) NOW-NOVA
influenza vaccine	CSL Biotherapies <i>King of Prussia, PA</i>	influenza	Phase III (888) 4FLU-OFF
influenza vaccine	ID Biomedical <i>Burnaby, British Columbia</i>	influenza	application submitted (604) 431-9314
influenza vaccine	Merck <i>Whitehouse Station, NJ</i>	influenza	Phase I (800) 672-6372
influenza vaccine	Novartis Vaccines <i>Emeryville, CA</i>	influenza	Phase I (510) 655-8730
influenza vaccine (new formulation)	sanofi pasteur <i>Swiftwater, PA</i>	influenza	Phase II (570) 839-4267
influenza vaccine (pediatric)	sanofi pasteur <i>Swiftwater, PA</i>	influenza in infants 6 weeks to 6 months of age	Phase II (570) 839-4267
influenza virus vaccine	Baxter Healthcare <i>Deerfield, IL</i>	influenza	Phase I (800) 422-9837
influenza virus vaccine intranasal	ID Biomedical <i>Burnaby, British Columbia</i>	influenza	Phase I (604) 431-9314
influenza virus vaccine intranasal	Vaxin <i>Birmingham, AL</i>	influenza	Phase I (205) 943-6655

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
influenza virus vaccine nasal	DelSite Biotechnologies <i>Irving, TX</i>	influenza	Phase I (972) 717-5009
influenza virus vaccine transdermal	Iomai <i>Gaithersburg, MD</i>	influenza	Phase II (301) 556-4500
INV 102	Inverseon <i>Lenexa, KS</i>	asthma	Phase II (415) 440-7400
IPL-512,602	Inflazyme Pharmaceuticals <i>Richmond, British Columbia</i>	asthma	Phase II (800) 315-3660
Ketek® telithromycin	sanofi-aventis <i>Bridgewater, NJ</i>	acute exacerbations of asthma	Phase I (800) 633-1610
KUR 1246	MediciNova <i>San Diego, CA</i>	status asthmaticus	Phase I (858) 373-1500
Levaquin® levofloxacin	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i>	acute exacerbations of chronic bronchitis	application submitted (800) 817-5286
lumiliximab	Biogen Idec <i>Cambridge, MA</i>	allergic asthma	Phase II (617) 679-2000
MEDI 528	MedImmune <i>Gaithersburg, MD</i>	asthma	Phase I (301) 398-0000
mepolizumab (anti-IL5 MAb)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	asthma	Phase II (888) 825-5249
MN 001	MediciNova <i>San Diego, CA</i>	asthma	Phase II (858) 373-1500
mometasone/ formoterol combination	Schering-Plough <i>Kenilworth, NJ</i>	asthma	Phase II (908) 298-4000
moxifloxacin	Bayer, Pharmaceutical Division <i>West Haven, CT</i> Global Alliance for TB Drug Development <i>New York, NY</i>	tuberculosis	Phase II (203) 812-2000 (212) 227-7540
oglemilast	Glenmark Pharmaceuticals <i>New York, NY</i>	asthma, COPD	Phase II
olopatadine	Alcon <i>Fort Worth, TX</i>	asthma	Phase II
oral cromolyn sodium	Emisphere Technologies <i>Tarrytown, NY</i>	asthma	Phase I (914) 347-2220
oritavancin	Targanta Therapeutics <i>Indianapolis, IN</i>	nosocomial pneumonia	Phase II (317) 536-7707

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
PA 824	Novartis Pharmaceuticals <i>East Hanover, NJ</i> Global Alliance for TB Drug Development <i>New York, NY</i>	tuberculosis	Phase I (800) NOW-NOVA (212) 227-7540
pandemic influenza virus vaccine	sanofi pasteur <i>Swiftwater, PA</i>	influenza	Phase I (570) 839-4267
PB-008	Inflabloc Pharmaceuticals <i>Salt Lake City, UT</i>	asthma	Phase II (801) 464-6100
PDE4 inhibitor	Merck <i>Whitehouse Station, NJ</i>	asthma, COPD	Phase I (800) 672-6372
peramivir	BioCryst Pharmaceuticals <i>Birmingham, AL</i>	influenza	Phase I (205) 444-4600
pleconaril	Schering-Plough <i>Kenilworth, NJ</i>	asthma exacerbations	Phase II (908) 298-4000
Prograf® tacrolimus	Astellas Pharma US <i>Deerfield, IL</i>	asthma (see also liver disorders)	Phase II (847) 727-7003
R411	Roche <i>Nutley, NJ</i>	asthma	Phase II (973) 235-5000
R667	Roche <i>Nutley, NJ</i>	emphysema	in clinical trials (973) 235-5000
rBCG30 recombinant tuberculosis vaccine	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i>	tuberculosis	Phase I (301) 547-2900
recombinant neuraminidase	Protein Sciences <i>Meriden, CT</i>	influenza	Phase II (800) 488-7099
recombinant tuberculosis vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	tuberculosis	Phase I (888) 825-5249
Relenza® zanamivir	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	influenza prevention	application submitted (888) 825-5249
Remicade® infliximab	Centocor <i>Horsham, PA</i>	asthma, COPD	Phase II (610) 651-6000
roflumilast	Altana Pharma <i>Florham Park, NJ</i>	COPD	Phase III (973) 514-4240
S 5751	Shionogi USA <i>Florham Park, NJ</i>	asthma	Phase II (973) 966-6900
SCV 07	SciClone Pharmaceuticals <i>San Mateo, CA</i>	tuberculosis	Phase I (650) 358-3456
sinapultide	Discovery Laboratories <i>Warrington, PA</i>	asthma	Phase I (215) 488-9300

RESPIRATORY DISORDERS

Product Name	Sponsor	Indication	Development Status
Singulair® montelukast	Merck <i>Whitehouse Station, NJ</i>	bronchitis	in clinical trials (800) 672-6372
SMP 028	Dainippon Sumitomo Pharma <i>Osaka, Japan</i>	asthma	Phase I
<i>S. pneumoniae</i> recombinant vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	<i>S. pneumoniae</i> disease prophylaxis (elderly)	Phase I (888) 825-5249
<i>S. pneumoniae</i> recombinant vaccine (PGCvax)	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	<i>S. pneumoniae</i> disease prophylaxis (pediatric)	Phase I (888) 825-5249
Streptorix conjugated vaccine	GlaxoSmithKline <i>Philadelphia, PA</i> <i>Rsch. Triangle Park, NC</i>	<i>S. pneumoniae</i> disease prophylaxis for children	Phase III (888) 825-5249
TBC-4746	Encysive Pharmaceuticals <i>Houston, TX</i>	asthma	Phase I (713) 796-8822
telavancin	Astellas Pharma US <i>Deerfield, IL</i> Theravance <i>South San Francisco, CA</i>	nosocomial pneumonia	Phase III (847) 727-7003 (650) 808-6000
tetomilast	Otsuka America Pharmaceutical <i>Rockville, MD</i>	COPD	Phase II (800) 562-3974
Thalomid® thalidomide	Celgene <i>Summit, NJ</i>	tuberculosis (see also cancer, HIV infection, lupus)	in clinical trials (908) 673-9000
tifacogin	Novartis Pharmaceuticals <i>Emeryville, CA</i>	severe community-acquired pneumonia	Phase III (510) 655-8730
triamcinolone acetone hydrofluoroalkane inhalation	Kos Pharmaceuticals <i>Cranbury, NJ</i>	asthma	Phase III (609) 495-0500
Tygacil® tigecycline	Wyeth <i>Collegeville, PA</i>	community-acquired pneumonia, hospital-acquired pneumonia	Phase III (610) 902-1200
Xolair® omalizumab	Genentech <i>South San Francisco, CA</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i> Tanox <i>Houston, TX</i>	pediatric asthma	Phase III (650) 225-1000 (888) NOW-NOVA
Xopenex® levosalbutamol	Sepracor <i>Marlborough, MA</i>	acute asthma	in clinical trials (508) 357-7300
zileuton controlled-release	Critical Therapeutics <i>Lexington, MA</i>	asthma	Phase III (781) 402-5700
		----- COPD	in clinical trials (781) 402-5700

STROKE

Product Name	Sponsor	Indication	Development Status
234551 (endothelin A antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC Shionogi USA Florham Park, NJ	stroke	Phase I (888) 825-5249
737004 (endothelin A antagonist)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC Shionogi USA Florham Park, NJ	stroke	Phase I (888) 825-5249 (973) 966-6900
813893 (factor Xa inhibitor)	GlaxoSmithKline Philadelphia, PA Rsch. Triangle Park, NC	prevention of stroke due to atrial fibrillation	Phase I (888) 825-5249
apixaban	Bristol-Myers Squibb Princeton, NJ	thrombosis	Phase II (212) 546-4000
Arvin [®] ancrod	Neurobiological Technologies Emeryville, CA	stroke	Phase III (510) 595-6000
BAY 59-7939 rivaroxaban	Bayer West Haven, CT	stroke	Phase II (203) 624-0894
Cerebril [™] tramiprosate	Neurochem Laval, Quebec	hemorrhagic stroke due to cerebral amyloid angiopathy	Phase II (450) 680-4500
clazosentan	Actelion Pharmaceuticals US South San Francisco, CA	cerebral vasospasm	Phase II (650) 624-6900
desmoteplase	Forest Laboratories New York, NY	stroke	Phase III (212) 421-7850
fosphenytoin	Eisai Ridgefield Park, NJ	stroke	Phase III (888) 274-2378
INO 1001	Inotek Pharmaceuticals Beverly, MA	stroke	Phase I (978) 232-9660
MC 1	Medicure Winnipeg, Manitoba	stroke	Phase I (204) 487-7412
MRX 515	ImaRx Therapeutics Tucson, AZ	stroke	Phase III (520) 770-1259
MRX 815	ImaRx Therapeutics Tucson, AZ	stroke	Phase III (520) 770-1259
nalmefene	Somaxon Pharmaceuticals San Diego, CA	stroke	Phase III (858) 480-0400
Novastan [®] argtroban	Encysive Pharmaceuticals Houston, TX	stroke	Phase II (713) 796-8822
NXY 059	Renovis South San Francisco, CA	stroke	Phase III (650) 266-1400
piclozotan	Daiichi Asubio Pharma Rochelle Park, NJ	stroke	Phase II (201) 368-5020

STROKE

Product Name	Sponsor	Indication	Development Status
reteplase	PDL BioPharma <i>Fremont, CA</i>	stroke	Phase II (510) 574-1400
SUN N8075	Daiichi Asubio Pharma <i>Rochelle Park, NJ</i>	stroke	Phase I (201) 368-5020
traxoprodil (CP-101,606)	Pfizer <i>New York, NY</i>	stroke	Phase II (860) 732-5156
TS 011	Taisho Pharmaceutical <i>Tokyo, Japan</i>	stroke	Phase I
V 10153	Vernalis Pharmaceuticals <i>Morristown, NJ</i>	stroke	Phase II (973) 867-5555
zonampanel (YM872)	Astellas Pharma US <i>Deerfield, IL</i>	acute ischemic stroke	Phase II (847) 727-7003

OTHER

Product Name	Sponsor	Indication	Development Status
Aranesp® darbepoetin alfa	Amgen <i>Thousand Oaks, CA</i>	cardiovascular disease in patients with chronic kidney disease and type 2 diabetes	Phase III (805) 447-1000

The content of this report has been obtained through industry sources and the Adis "R&D Insight" database based on the latest information. **Report current as of July 6, 2006.** The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's web site.

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GLOSSARY

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

asthma—Recurrent attacks of breathlessness and wheezing caused by narrowing of the airways (bronchioles) leading to the lungs.

cervical—Relating to the neck of the uterus.

chronic obstructive pulmonary disease (COPD)—The combination of chronic bronchitis and emphysema, in which there is a persistent disruption of airflow out of the lungs and eventual hypoxemia (low level of oxygen in the blood).

diabetes, type 2—A chronic disease due to abnormal insulin secretion from the pancreas, thereby causing problems in metabolizing sugar. Type 2, in most cases, can be controlled by a combination of dietary measures, weight loss, and oral medication.

FDA—The U.S. Food and Drug Administration.

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

hypercholesterolemia—An inherited metabolic disorder resulting in an abnormal amount of cholesterol in the blood. It can lead to accelerated atherosclerosis and early heart attack. Dietary treatment seldom helps in these cases.

hyperlipidemia—A group of metabolic disorders characterized by high levels of lipids (fatty substances, including cholesterol) in the blood. Hyperlipidemia is a risk factor for accelerated atherosclerosis and premature heart attacks.

hypertension (high blood pressure)—Persistent elevation of

blood pressure above the normal range while the heart is in systolic (contracting) or diastolic (relaxed) mode. Uncontrolled, chronic hypertension strains the heart, damages arteries and creates a greater risk of heart attack, stroke and kidney problems. In about 95 percent of cases, the cause is unknown.

influenza—A viral infection of the respiratory tract that causes fever, headache, muscle ache and weakness. There are three main types of influenza virus: A, B and C. A person who has had an attack with the type C virus acquires antibodies that provide immunity against that type for life. Anyone who has been infected with a certain strain of the type A or B viruses acquires immunity to that strain. Both the A- and B-type viruses occasionally alter to produce new strains that may be able to overcome immunity. Type B is fairly stable, but type A is highly unstable, and new strains of it arise constantly throughout the world.

lupus—A chronic autoimmune disorder (which means that the immune system attacks the body's own tissues) causing inflammation and damage to multiple organs.

NNRTI—Non-nucleoside reverse transcriptase inhibitor.

NRTI—Nucleoside reverse transcriptase inhibitor.

obesity—The accumulation of excessive body fat. Generally, people whose weight is 20 percent or more over the midpoint of their weight range on a standard height-weight table are considered obese.

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. Orphan drug designation is issued by FDA's Office of Orphan Products Development. The designation makes the sponsor of the drug eligible for entitlements under the Orphan Drug Act of 1983. The entitlements include seven years of marketing exclusivity upon FDA approval for the designated use.

Phase I—Safety testing and pharmacological profiling in humans.

Phase II—Effectiveness testing in humans.

Phase III—Extensive clinical trials in humans.

PI—Protease inhibitor.

pneumonia—Inflammation of the lungs due to infection, usually by viruses or bacteria. It is the sixth most common cause of death in the United States, primarily because it is a common complication of any serious illness.

pneumonia, community-acquired—Inflammation of the lungs due to infection spread among the general population, as opposed to infection acquired in a hospital or long-term care facility.

stroke—Usually caused by atherosclerosis. It results in death or serious brain damage, such as paralysis or loss of speech. An **ischemic stroke** is caused by blocked or narrowed arteries that prevent sufficient blood and oxygen from reaching the brain.

tuberculosis—An infectious disease caused by the organism *Mycobacterium tuberculosis*, which is passed from person to person by breathing in airborne droplets (from coughing or sneezing). The bacteria multiply in the lungs and in some cases can spread to the lymph nodes. A person's immune system most frequently will attack and heal the infection, causing a scar on the lung.

SELECTED FACTS ABOUT DISEASE AND HISPANIC AMERICANS

10 Leading Causes of Death in Hispanic Americans, 2003 (Both sexes, all ages)

1. Heart disease (28,298)
2. Cancer (24,070)
3. Accidents (unintentional injuries) (10,418)
4. Cerebrovascular diseases (6,658)
5. Diabetes mellitus (6,179)
6. Chronic liver disease and cirrhosis (3,382)
7. Assault (homicide) (3,355)
8. Chronic lower respiratory diseases (3,174)
9. Influenza and pneumonia (2,948)
10. Perinatal conditions (2,628)

Source: National Center for Health Statistics, *Deaths: Final Data for 2003*. National Vital Statistics Report, Vol. 54, No. 13, April 19, 2006. (Number in parentheses is the number of deaths in 2003.)

Overview

- Hispanics are the largest minority group at 42.7 million. They account for almost half (49 percent) of the national population growth of 2.8 million between July 1, 2004 and July 1, 2005.¹
 - In 2001, Hispanics of all races experienced more age-adjusted years of potential life lost before age 75 per 100,000 population than non-Hispanic whites for the following causes of death: **stroke** (18 percent more), **chronic liver disease and cirrhosis** (62 percent), **diabetes** (41 percent), **HIV** disease (168 percent), and homicide (128 percent).²
-

Cancer³

- About 67,400 new cancer cases were diagnosed among Hispanics in 2003.
 - Hispanic women residing in the United States have twice the **cervical** cancer incidence rate of non-Hispanic whites. In 2003, about 2,100 Hispanic women were diagnosed with cervical cancer, and about 200 Hispanic women died of the disease. The death rate from cervical cancer is 40 percent higher among Hispanic women than among other groups.
 - Some 7,000 Hispanic men and women were diagnosed with cancers of the **colon** and **rectum** in 2003. **Colorectal** cancer is the third most commonly diagnosed cancer in Hispanics. Also that year, an estimated 2,300 Hispanics died from colorectal cancer, which is the third leading cause of cancer death among Hispanic women. It ties with prostate as the second deadliest cancer among Hispanic men.
 - In 2003, about 4,500 Hispanics were diagnosed with **lung** cancer, the fourth most commonly diagnosed cancer among both Hispanic men and women. That year, 3,900 Hispanics died from lung cancer, which is the leading cause of cancer death among Hispanic men. It ranks second among Hispanic women.
 - In the United States, the rates of **stomach** cancer incidence are at least 75 percent higher in Hispanics than in non-Hispanic whites. In 2003, some 2,300 Hispanics were diagnosed with stomach cancer, and about 1,300 Hispanics died from the disease.
-

Diabetes

- On average, about 2.5 million, or 9.5 percent, of Hispanic and Latino Americans age 20 or older have been diagnosed with diabetes. Mexican Americans are 1.7 times as likely to have diabetes as non-Hispanic whites of similar age. Residents of Puerto Rico are 1.8 times as likely to have diagnosed diabetes as U.S. non-Hispanic whites.⁴
- Within the Hispanic American population, diabetes is more prevalent in women than in men. Hispanic American women with diabetes are 7.6 times more likely to develop peripheral vascular disease than non-diabetic women, and up to four times more likely to have heart disease or a **stroke**.⁵
- In 2002, 44,400 Hispanics with diabetes began treatment for end-stage kidney disease in the United States and Puerto Rico. That year, 153,730 Hispanics with end-stage kidney disease due to diabetes were living on chronic dialysis or with a kidney transplant in the United States and Puerto Rico.⁴
- In 2002, Hispanics were 1.6 times as likely as non-Hispanic whites to die from diabetes.⁵

SELECTED FACTS ABOUT DISEASE AND HISPANIC AMERICANS

HIV Infection²

- In 2002, Hispanics accounted for 20 percent (8,672) of the 42,514 new HIV/AIDS diagnoses in the United States. The diagnosis rates for adults and adolescents was highest for African Americans (72.1 cases per 100,000 people) followed by the rates for Hispanics (25 cases per 100,000).
 - The 84,001 Hispanic Americans living with AIDS in 2002 accounted for 20 percent of all people in the United States living with AIDS. Hispanics accounted for 19 percent (177,164) of the estimated 944,306 cases of HIV/AIDS diagnosed since the beginning of the epidemic.
 - In 2002, HIV/AIDS was the third leading cause of death among Hispanic men ages 35 to 44 and the fourth leading cause of death among Hispanic women in the same age group. By the end of 2004, an estimated 93,163 Hispanic Americans with AIDS had died.
-

Hyperlipidemia⁶

- A common cause of heart disease is the blockage of the coronary arteries (**atherosclerosis**) due to the accumulation of **cholesterol**. Between 43 percent and 52 percent of Hispanic women have blood cholesterol above the desirable level.
-

Hypertension⁶

- Among Hispanics ages 20-74, the prevalence of hypertension is 24.2 percent for men and 22.4 percent for women.
-

Liver Disorders⁷

- Hispanics are about twice as likely as whites to die from **cirrhosis**, despite a lower prevalence of drinking and heavy drinking.
-

Lupus⁸

- An estimated 1.5 million Americans have a form of lupus, 90 percent of whom are women. Lupus is two to three times more prevalent among people of color, including Hispanics, African Americans, Asians, and Native Americans.
-

Obesity²

- Thirty-eight percent of non-Hispanic African American women are obese compared with 27 percent of Hispanic women and 21 percent of non-Hispanic white women.
 - From 1999-2000, Mexican Americans ages 20-74 reported higher rates of overweight (11 percent higher for males and 26 percent higher for females) and obesity (7 percent for males and 32 percent higher for females) than non-Hispanic whites.
 - Mexican American youths ages 12-19 report higher rates of overweight (112 percent higher for males and 59 percent higher for females) than non-Hispanic whites.
-

Respiratory Disorders

- Nearly 3 million Hispanics have been diagnosed with **asthma** in their lifetime, and about 2 million of them currently have asthma. More than 1 million Hispanics had an asthma attack in the past year.⁹
- Among all racial and ethnic groups, Puerto Ricans have the highest rate of lifetime **asthma** (196 per 1,000 people) and Mexicans the lowest (61 per 1,000). Grouping all Hispanics together masks that difference. Puerto Ricans are almost 80 percent more likely to have ever been diagnosed with asthma than non-Hispanic whites. Puerto Ricans also have the highest asthma attack prevalence—100 percent higher than non-Hispanic whites. Mexican Americans have the lowest asthma attack prevalence.²
- Puerto Ricans may also have higher **asthma** death rates compared with other Hispanic groups and other racial and ethnic groups. According to a recent study, Puerto Ricans had an age-adjusted death rate of 40.9 per million population, followed by Cuban Americans (15.8 per million) and Mexican Americans (9.2 per million). Death rates among non-Hispanic whites and non-Hispanic African Americans were 14.7 per million and 38.1 per million, respectively. In 2001, 274 Hispanics died of asthma.⁹

SELECTED FACTS ABOUT DISEASE AND HISPANIC AMERICANS

Respiratory Disorders (continued)

- Emphysema and chronic bronchitis are the most important conditions that compose **chronic obstructive pulmonary disease (COPD)**. Approximately 80,000 Hispanic Americans (3.0 per 1,000 people) have been diagnosed with emphysema in their lifetime. More than 603,000 Hispanic Americans (23.0 per 1,000 people) were diagnosed with chronic bronchitis in 2003. The prevalence rates seen in Hispanics for both emphysema and chronic bronchitis are significantly lower than in non-Hispanic groups. In 2002, 2,771 Hispanics died of COPD.⁹
- In 2004, the annual estimated cost in the United States for **COPD** was \$37.2 billion.⁹
- Hispanic Americans have the lowest age-adjusted mortality rates due to **influenza** or **pneumonia** among all races and ethnicities. They were almost 6 percent less likely to die from influenza or pneumonia than non-Hispanic whites in 2001. However, influenza and pneumonia ranked as the ninth leading cause of death in Hispanics and sixth in the Hispanic population over age 65. Some 82 percent of all those deaths in Hispanics occurred in that older age group.⁹
- In 2003, Hispanics accounted for 28 percent of new **tuberculosis (TB)** cases (4,108) in the United States—15 percent of cases among people born in the States and 39 percent among foreign-born people. More than one-fourth of foreign-born TB cases came from Mexico. The TB case rate in Hispanics (10.5 per 100,000 people) was about eight times higher than in non-Hispanic whites (1.4 per 100,000). Since 1992, the TB case rate among Hispanics has decreased by 53 percent.⁹

Stroke

- The average age for stroke in Hispanics is 67 compared to 80 for non-Hispanic whites.¹⁰ Among Hispanic Americans, the risk of stroke is 1.3 times higher at ages 35-64 than for non-Hispanics.⁵
- **Hypertension** has been found in 72 percent of Hispanics with stroke compared with 66 percent in non-Hispanic whites.¹⁰
- Stroke causes the deaths of one in four Hispanic men and one in three Hispanic women.¹⁰ In 2002, Hispanic men were 20 percent less likely to die from a stroke than non-Hispanic white men, and Hispanic women were 30 percent less likely to die from a stroke than non-Hispanic white women.⁵

Sources:

1. U.S. Census Bureau, www.census.gov
2. U.S. Centers for Disease Control and Prevention, www.cdc.gov
3. American Cancer Society, www.cancer.org
4. National Diabetes Education Program, www.ndep.nih.gov
5. The Office of Minority Health, U.S. Department of Health & Human Services, www.omhrc.gov
6. International Society on Hypertension in Blacks, www.ishib.org
7. National Institute on Alcohol Abuse and Alcoholism, www.niaaa.nih.gov
8. The Lupus Foundation of America, www.lupus.org
9. American Lung Association, www.lungusa.org
10. American Stroke Association, a Division of the American Heart Association, www.strokeassociation.org

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.

Ethnic and Environmental Differences Affect Therapeutic Response and Access to Medicines

By Rene Rodriquez, M.D., President, Interamerican College of Physicians and Surgeons; Jane L. Delgado, Ph.D., President and CEO, National Alliance for Hispanic Health and Manuel Mirabal, President and CEO, National Puerto Rican Coalition

Over the past 20 years, advances in pharmacogenetics—the study of genetically determined variants in drug response—have revealed significant differences in how different racial and ethnic groups metabolize and respond to medications. A new report* released this year brings together a growing body of scientific research demonstrating how genetic and environmental factors can substantially impact the effectiveness of medicines used by Hispanic patients. For individual patients, this can mean an increase or decrease in the intensity and duration of a medication's expected effect, or even, therapeutic failure, increased side effects or toxicity. In short, the emerging research demonstrates that, among Hispanic Americans, dosage adjustments to achieve an optimal therapeutic effect may be required as a result of genetic variations.

In addition to genetic differences among patients, environmental factors can also affect a patient's response to prescription medicines. Variations in response to medications exist not only between Hispanic and non-Hispanic populations, but also among Hispanic subpopulations as well. These variations may not be easily recognized. For instance, Hispanics have an increased risk for certain conditions and may have coexisting illnesses requiring multiple medications. As health care disparities and improved access and the quality of care for Hispanic patients is addressed by health care policy makers, it is important that the increasing role pharmaceuticals play in medical treatment today be recognized.

Modern medicines can extend life, assure a better quality of life and reduce the use of health care services. Medicines are playing a growing and important role in the treatment and management of chronic conditions common in Hispanic Americans, including diabetes, depression, asthma, and cardiovascular disease. The timely and appropriate use of pharmaceuticals by working persons, for instance, has been shown to improve job productivity and facilitated a return to work after illness.

The appropriate use of medicines also contributes substantially to the large reduction in disability and institu-

tionalization of elderly persons with such diseases as osteoporosis, stroke, Parkinson's disease and congestive heart failure.

These findings underscore the value of medications to the quality of life of Hispanic Americans suffering from these conditions. Unfortunately, compared with the majority population, Hispanic Americans frequently have more limited access to pharmaceuticals and health care. For instance, access to pharmaceutical care is more difficult without health insurance, and Hispanic Americans are less likely to be insured compared with other population groups. Even when Hispanic Americans have fuller access to pharmaceuticals and appropriate health care, they may be less likely to receive or use prescriptions. Unfortunately, as a result, even minimal use of medicines to manage otherwise treatable conditions is often not achieved.

Disparities in health between Hispanic Americans and other populations may be further exacerbated without access to individualized care with appropriate pharmaceuticals. The report also found that language barriers and differences in cultural values can have an impact on the quality of care delivered and can negatively influence medication compliance, self-management of chronic disease, and overall health outcomes for many Hispanic-American patients. As drug coverage policies evolve and expand to encompass more Hispanic-American patients, they must expand to better account for the specific pharmaceutical needs of these patients.

It is increasingly important that those involved in health care delivery and policy better understand how all these factors affect the delivery of quality medical care, and pharmaceutical care specifically, to Hispanic-American populations. Prescribing should be tailored to individual patient needs based on age, coexisting conditions, environment and responsiveness to medications. The choice of medications available must be broad enough to accommodate this range of factors and ensure access to advances in pharmaceutical therapy for all.

**Genes, Culture, and Medicines: Bridging Gaps in Treatment for Hispanic Americans, by Carolina Reyes, M.D., Leticia Van de Putte, R.Ph., Adolph P. Falcon, M.P.P., and Richard A. Levy, Ph.D.*



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