

Infectious Diseases

PRESENTED BY AMERICA'S BIOPHARMACEUTICAL RESEARCH COMPANIES

Biopharmaceutical Research Continues Against Infectious Diseases with 395 Medicines and Vaccines in Testing

Throughout history, infectious diseases have taken a devastating toll on the lives and well-being of people around the world. Caused when pathogens such as bacteria or viruses enter a body and multiply, infectious diseases were the leading cause of death in the United States until the 1920s. Today, vaccines and antibiotics have proven to be effective treatments in many cases, but infectious diseases still pose a very serious threat to patients. Recently, some infectious pathogens, such as staphylococcal bacteria, have become resistant to available treatments. Diseases once considered conquered, such as tuberculosis, have reemerged as a growing health threat. And, alarmingly, some infectious agents have been manipulated for use in bioterrorist attacks.

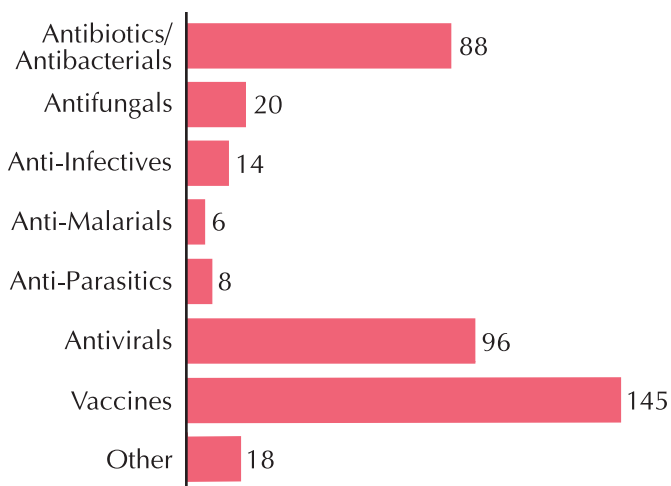
America's biopharmaceutical research companies are developing 395 medicines and vaccines to combat the many threats posed by infectious diseases. Each of these medicines in development is either in clinical trials or under review by the Food and Drug Administration.

Among the medicines now being tested are 88 antibiotics/antibacterials for treating bacterial infections such as pneumonia and tuberculosis; 96 antivirals for treating such viruses as hepatitis, herpes and influenza; and 145 vaccines to prevent or treat diseases such as staph infections and pneumococcal infections. Not included in this report are medicines in development for HIV infection. A 2009 survey by PhRMA found 97 medicines and vaccines are in testing for HIV/AIDS and AIDS-related conditions.

Some examples of the potential medicines for fighting infectious diseases include:

- Two combined monoclonal antibodies that bind to, neutralize, and destroy toxins caused by *Escherichia coli* infections.
- A medicine for the most common and difficult-to-treat form of hepatitis C that inhibits the enzyme essential for viral replication.
- An anti-malarial drug that has shown activity against *Plasmodium falciparum* malaria that is resistant to current treatments.

MEDICINES IN DEVELOPMENT FOR INFECTIOUS DISEASES



- A potential new class of antibiotics to treat methicillin-resistant *Staphylococcus aureus* (MRSA).
- A novel treatment that works by blocking the ability of the smallpox virus to spread to other cells, thus preventing it from causing disease.

Biopharmaceutical researchers also are focusing their efforts on new treatments for fungal infections, herpes, influenza, meningitis, pneumonia, respiratory infections, rotavirus, sepsis, smallpox, and urinary tract infections, among others.

Infectious diseases may never be eradicated. However, new knowledge, new technologies, and a huge commitment of resources by America's biopharmaceutical research companies and the government can help meet the continuing—and ever-changing—threat from infectious diseases.

John J. Castellani
President and CEO
PhRMA

Medicines in Development for Infectious Diseases

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status*
ABthrax™ raxibacumab (Orphan Drug)	Human Genome Sciences <i>Rockville, MD</i>	anthrax (Fast Track)	application submitted (301) 309-8504
ACHN-490	Achaogen <i>South San Francisco, CA</i>	pyelonephritis, urinary tract infections	Phase II (650) 266-1120
AFN-1252	Affinium Pharmaceuticals <i>Austin, TX</i>	bacterial infections	Phase I (416) 645-6614
amikacin inhalation (NKTR-061)	Bayer HealthCare Pharmaceuticals <i>Wayne, NJ</i> Nektar Therapeutics <i>San Carlos, CA</i>	nosocomial pneumonia (Fast Track)	Phase II (888) 842-2937 (650) 631-3100
AN0128	Anacor Pharmaceuticals <i>Palo Alto, CA</i>	acne	Phase II (650) 543-7500
anthrax immune globulin	Cangene <i>Winnipeg, Canada</i>	anthrax	Phase II completed (204) 275-4200
anthrax immune globulin	Emergent BioSolutions <i>Rockville, MD</i>	anthrax (Fast Track)	Phase I/II (301) 795-1800
ARD-3100 (liposomal ciprofloxacin) (Orphan Drug)	Aradigm <i>Hayward, CA</i>	cystic fibrosis-associated respiratory tract infections, non-cystic fibrosis bronchiectasis	Phase II (510) 265-9000
ARD-3150 (liposomal ciprofloxacin) (Orphan Drug)	Aradigm <i>Hayward, CA</i>	non-cystic fibrosis bronchiectasis, cystic fibrosis-associated respiratory tract infections	Phase II (510) 265-9000
Arikace™ amikacin sustained release (Orphan Drug)	Transave <i>Monmouth Junction, NJ</i>	bronchiectasis ----- cystic fibrosis-associated respiratory tract infections ----- mycobacterial infections	Phase II completed (732) 438-9434 Phase I/II completed (732) 438-9434 Phase I (732) 438-9434
AZD5847	AstraZeneca <i>Wilmington, DE</i>	tuberculosis	Phase I (800) 236-9933
AZD9742	AstraZeneca <i>Wilmington, DE</i>	methicillin-resistant <i>Staphylococcus aureus</i> infections	Phase I (800) 236-9933
BC-3781	Nabriva Therapeutics <i>Vienna, Austria</i>	skin and soft tissue infections	Phase II www.nabriva.com

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

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
BLI-489	Pfizer New York, NY	bacterial infections	Phase I (860) 732-5156
Cayston® aztreonam for inhalation (Orphan Drug)	Gilead Sciences Foster City, CA	<i>Burkholderia</i> infections	Phase III (800) 445-3235
CB-182,804	Cubist Pharmaceuticals Lexington, MA	gram-negative infections	Phase I (781) 860-8660
CB-183,315	Cubist Pharmaceuticals Lexington, MA	<i>Clostridium difficile</i> -associated diarrhea	Phase II (781) 860-8660
ceftaroline	Forest Laboratories New York, NY	community-acquired pneumonia, gram-negative infections, gram-positive infections, skin and soft tissue infections (Fast Track)	application submitted (800) 678-1605
ceftaroline/ NXL-104 (CEF104)	AstraZeneca Wilmington, DE Forest Laboratories New York, NY	hepatitis C	Phase II (800) 236-9933 (800) 678-1605
ceftobiprole medocaril	Basilea Pharmaceutica Basel, Switzerland	skin and soft tissue infections	Phase III www.basilea.com
CEM-101	Cempra Pharmaceuticals Chapel Hill, NC Optimer Pharmaceuticals San Diego, CA	community-acquired pneumonia	Phase I completed (919) 467-1716 (858) 909-0730
CEM-102	Cempra Pharmaceuticals Chapel Hill, NC	skin and soft tissue infections	Phase II/III (919) 467-1716
ciprofloxacin inhalation (Orphan Drug)	Bayer HealthCare Pharmaceuticals Wayne, NJ Nektar Therapeutics San Carlos, CA	bronchiectasis, cystic fibrosis-associated respiratory tract infections	Phase II (888) 842-2937 (650) 631-3100
clindamycin/ retinoic acid	Skinvisible Pharmaceuticals Las Vegas, NV	acne	in clinical trials (702) 433-7154
CollaRx® gentamicin surgical implant	Innocoll Ashburn, VA	postoperative infections (Fast Track)	Phase III www.innocollinc.com
		moderately infected foot ulcers	Phase II www.innocollinc.com
CXA-201 (CXA-101/ tazobactam)	Cubist Pharmaceuticals Lexington, MA	gram-negative infections in the hospital, including multi-drug- resistant <i>Pseudomonas aeruginosa</i> infections	Phase II (781) 860-8660
dalbavancin	Durata Therapeutics New York, NY	skin and soft tissue infections	Phase III (646) 871-6400
		bacterial infections in adolescents	Phase I (646) 871-6400

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
delafloxacin	Rib-X Pharmaceuticals New Haven, CT	methicillin-resistant <i>Staphylococcus aureus</i> infections, skin and soft tissue infections	Phase II completed (203) 624-5606
Doribax® doripenem	Shionogi USA Florham Park, NJ Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	nosocomial pneumonia (Fast Track)	application submitted (973) 966-6900 (800) 817-5286
DX-619	Daiichi Sankyo Parsippany, NJ	bacterial infections	Phase I (973) 359-2600
EDP-322	Enanta Pharmaceuticals Watertown, MA	bacterial infections, methicillin-resistant <i>Staphylococcus aureus</i> infections	Phase I (617) 607-0800
EDP-420	Enanta Pharmaceuticals Watertown, MA	community-acquired pneumonia	Phase II (617) 607-0800
ETI-204 (Orphan Drug)	Elusys Therapeutics Pine Brook, NJ	prevention and treatment of anthrax (Fast Track)	Phase I (973) 808-0222
GS 9310/11 (tobramycin/ fosfomycin inhalation)	Gilead Sciences Foster City, CA	bronchiectasis, cystic fibrosis-associated respiratory tract infections	Phase II (800) 445-3235
GSK580416	GlaxoSmithKline Rsch. Triangle Park, NC	bacterial infections	Phase I (888) 825-5249
GSK945237	GlaxoSmithKline Rsch. Triangle Park, NC	bacterial infections	Phase I (888) 825-5249
GSK1322322	GlaxoSmithKline Rsch. Triangle Park, NC	bacterial infections	Phase I (888) 825-5249
GSK2251052	Anacor Pharmaceuticals Palo Alto, CA GlaxoSmithKline Rsch. Triangle Park, NC	gram-negative infections	Phase I completed (650) 543-7500 (888) 825-5249
GW05 (metronidazole vaginal gel)	Graceway Pharmaceuticals Bristol, TN	bacterial vaginosis	Phase II completed (800) 328-0255
H-100	Humanetics Eden Prairie, MN	prevention of drug-resistant bacterial infections	Phase I (952) 937-7660
heptavalent botulinum antitoxin	Cangene Winnipeg, Canada	botulism	Phase II (204) 275-4200
IDP-107	Valeant Pharmaceuticals Aliso Viejo, CA	acne vulgaris	Phase II completed (800) 548-5100
JNJ-32729463	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	skin and soft tissue infections	Phase II (800) 817-5286

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
lysostaphin cream (BSYX-L310)	Biosynexus Gaithersburg, MD	staphylococcal infections	Phase I/II (301) 330-5800
MK-1682	Merck Whitehouse Station, NJ	bacterial infections	Phase I (800) 672-6372
MK-3415A	Merck Whitehouse Station, NJ	<i>Clostridium difficile</i> -associated diarrhea	Phase II (800) 672-6372
MP-376 (levofloxacin inhalation) (Orphan Drug)	Mpex Pharmaceuticals San Diego, CA	cystic fibrosis or chronic obstructive pulmonary disease-associated respiratory tract infections	Phase II (858) 875-2840
		cystic fibrosis-associated respiratory tract infections in children ages 6-16	Phase I (858) 875-2840
MP-601205	Mpex Pharmaceuticals San Diego, CA	cystic fibrosis-associated respiratory tract infections	Phase I (858) 875-2840
NB-003	NanoBio Ann Arbor, MI	acne (<i>Propionibacterium acnes</i> infections)	Phase I (734) 302-4000
nemonoxacin	Warner Chilcott Rockaway, NJ TaiGen Biotechnology Taipei, Taiwan	diabetic foot ulcers	Phase I completed (973) 442-3200
NXL103	AstraZeneca Wilmington, DE	community-acquired infections, skin and soft tissue infections	Phase II (800) 236-9933
NXL104/ ceftazidime (CAZ104)	AstraZeneca Wilmington, DE	gram-negative infections, intra-abdominal infections, urinary tract infections	Phase II (800) 236-9933
omadacycline	Novartis Pharmaceuticals East Hanover, NJ Paratek Pharmaceuticals Boston, MA	skin and soft tissue infections	Phase III (888) 669-6682 (617) 275-0040
		nosocomial infections	Phase I completed (888) 669-6682 (617) 275-0040
		community-acquired pneumonia	Phase I (888) 669-6682 (617) 275-0040
OPT-80	Optimer Pharmaceuticals San Diego, CA	<i>Clostridium</i> infections (Fast Track)	Phase III completed (858) 909-0736
		prevention of vancomycin-resistant enterococcal infections	Phase I (858) 909-0736
oritavancin	Targanta Therapeutics Cambridge, MA	gram-positive infections, skin and soft tissue infections	Phase III (617) 577-9020
		bacteremia	Phase II completed (617) 577-9020

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
PA-824 (Orphan Drug)	Global Alliance for TB Drug Development New York, NY Novartis Pharmaceuticals East Hanover, NJ	tuberculosis	Phase II (212) 227-7540 (888) 669-6682
pagibaximab (Orphan Drug)	Biosynexus Gaithersburg, MD	prevention of staphylococcal infections	Phase II/III (301) 330-5800
PF-2341272	Pfizer New York, NY	tuberculosis	Phase I completed (860) 732-5156
PF-5230894	Pfizer New York, NY	staphylococcal infections	Phase I (860) 732-5156
prulifloxacin	Optimer Pharmaceuticals San Diego, CA	gram-negative infections, gram-positive infections, traveler's diarrhea	Phase III (858) 909-0736
radezolid	Rib-X Pharmaceuticals New Haven, CT	community-acquired pneumonia, gram-positive infections, skin and soft tissue infections	Phase II (203) 624-5606
ramoplanin oral	Nanotherapeutics Alachua, FL	<i>Clostridium</i> infections (Fast Track)	Phase II (386) 462-9663
Restanza™ cethromycin	Advanced Life Sciences Woodridge, IL	community-acquired pneumonia	application submitted (630) 739-6744
SAR279356	Alopexx Pharmaceuticals Cambridge, MA sanofi-aventis Bridgewater, NJ	bacterial infections	Phase I (617) 945-2510 (800) 633-1610
ShigamAbs™ anti-Shiga toxin mAb (Orphan Drug)	Thallion Pharmaceuticals Montreal, Canada	shiga-toxigenic <i>Escherichia coli</i> infections (Fast Track)	Phase I (514) 940-3600
SPRC-AB01	Naryx Pharma Carpinteria, CA	sinusitis (Fast Track)	Phase II (805) 684-2539
SQ-109 (Orphan Drug)	Sequella Rockville, MD	tuberculosis (Fast Track)	Phase I (301) 762-7776
sulopenem intravenous (CP-70429)	Pfizer New York, NY	bacterial infections	Phase II (860) 732-5156
sulopenem oral prodrug (PF-3709270)	Pfizer New York, NY	bacterial infections	Phase II (860) 732-5156
talactoferrin alfa	Agennix Princeton, NJ	severe sepsis	Phase II (609) 524-1000
		nosocomial infections in infants	Phase I/II (609) 524-1000
TD-1792	Theravance South San Francisco, CA	gram-positive infections, skin and soft tissue infections	Phase II (877) 275-8479

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
TIP™ tobramycin dry-powder inhalation	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	cystic fibrosis-associated respiratory tract infections	Phase III completed (888) 669-6682
TMC207	Global Alliance of TB Drug Development <i>New York, NY</i> Tibotech <i>Yardley, PA</i>	tuberculosis	Phase II (609) 730-7500
torezolid phosphate (TR-701 oral)	Trius Therapeutics <i>San Diego, CA</i>	gram-positive infections, skin and soft tissue infections	Phase II (858) 452-0370
		----- bacteremia in adolescents	Phase I (858) 452-0370
torezolid phosphate (TR-701 intravenous)	Trius Therapeutics <i>San Diego, CA</i>	bacteremia in adolescents, gram-positive infections	Phase I (858) 452-0370
TP-434	Tetraphase Pharmaceuticals <i>Watertown, MA</i>	gram-negative infections	Phase I completed (617) 715-3600
Tygacil™ tigecycline	Pfizer <i>New York, NY</i>	skin and soft tissue infections in children	Phase II (860) 732-5156
Ushercell® cellulose sulfate	Polydex Pharmaceuticals <i>Toronto, Canada</i>	bacterial vaginosis	Phase II (416) 755-2231
Valortim® anthrax mAb (intramuscular) (Orphan Drug)	PharmAthene <i>Annapolis, MD</i>	prevention and treatment of anthrax (Fast Track)	Phase I (410) 269-2600
Vibativ™ telavancin	Astellas Pharma US <i>Deerfield, IL</i> Theravance <i>South San Francisco, CA</i>	nosocomial pneumonia (Fast Track)	application submitted (800) 727-7003 (877) 275-8479
WAP-8294A (gel)	aRigen Pharmaceuticals <i>Tokyo, Japan</i>	methicillin-resistant <i>Staphylococcus aureus</i> infections	Phase I/II www.arigen.jp
WAP-8294A (cream)	aRigen Pharmaceuticals <i>Tokyo, Japan</i>	acne	Phase I/II www.arigen.jp
WAP-8294A2 (injectable)	aRigen Pharmaceuticals <i>Tokyo, Japan</i>	methicillin-resistant <i>Staphylococcus aureus</i> infections	Phase I www.arigen.jp
WC2031	Warner Chilcott <i>Rockaway, NJ</i>	chlamydial infections	Phase III (973) 442-3200
WC2055	Warner Chilcott <i>Rockaway, NJ</i>	acne vulgaris	Phase II completed (973) 442-3200
WC3018	Warner Chilcott <i>Rockaway, NJ</i>	acne, skin and soft tissue infections	Phase II (973) 442-3200
Xifaxan® rifaximin	Salix Pharmaceuticals <i>Morrisville, NC</i>	<i>Clostridium</i> infections	Phase III (919) 862-1000

ANTIBIOTICS / ANTIBACTERIALS

Product Name	Sponsor	Indication	Development Status
Zmax [®] azithromycin controlled-release microspheres	Pfizer New York, NY	acute sinusitis and otitis media in children and infants	application submitted (860) 732-5156

ANTIFUNGALS

Product Name	Company	Indication	Development Status
albaconazole	Stiefel Laboratories Rsch. Triangle Park, NC	onychomycosis	Phase II (919) 990-6000
		mycoses	Phase I completed (919) 990-6000
AN2690	Anacor Pharmaceuticals Palo Alto, CA	onychomycosis	Phase II completed (650) 543-7500
AN2718	Anacor Pharmaceuticals Palo Alto, CA	onychomycosis, skin fungal infections	Phase I (650) 543-7500
Bioral [®] amphotericin B	BioDelivery Sciences Raleigh, NC	mycoses	Phase I completed (919) 582-7050
embeconazole	Daiichi Sankyo Parsippany, NJ	mycoses	Phase I (973) 359-2600
Eraxis [™] anidulafungin	Pfizer New York, NY	aspergillosis, candidemia in children, candidiasis in children	Phase III (860) 732-5156
Eraxis [™] anidulafungin	Pfizer New York, NY	aspergillosis	Phase III (860) 732-5156
Vfend [®] voriconazole combination			
Ertaczo [™] sertaconazole (new delivery system)	Johnson & Johnson Pharmaceutical Research & Development Raritan, NJ	tinea pedis	Phase III (800) 817-5286
Hyphanox [™] itraconazole	Stiefel Laboratories Rsch. Triangle Park, NC	onychomycosis	application submitted (919) 990-6000
IDP-108	Valeant Pharmaceuticals Aliso Viejo, CA	onychomycosis	Phase III (800) 548-5100
IDP-113	Valeant Pharmaceuticals Aliso Viejo, CA	tinea capitis	Phase II (800) 548-5100
InnoNyx [™] terbinafine lacquer	NexMed East Windsor, NJ	onychomycosis	Phase III completed (609) 371-8123
isavuconazole	Basilea Pharmaceutica Basel, Switzerland Astellas Pharma US Deerfield, IL	aspergillosis, candidiasis, mycoses	Phase III www.basilea.com (800) 727-7003
luliconazole	Topica Pharmaceuticals Palo Alto, CA	tinea pedis	Phase II completed (650) 473-3800

ANTIFUNGALS

Product Name	Company	Indication	Development Status
Mycamine™ micafungin	Astellas Pharma US <i>Deerfield, IL</i>	<i>Candida</i> infections in infants	Phase I (800) 727-7003
Mycograb® efungumab (Orphan Drug)	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	candidiasis	Phase III (888) 669-6682
NB-002	NanoBio <i>Ann Arbor, MI</i>	onychomycosis	Phase II (734) 302-4000
PAC-113	Pacgen Biopharmaceuticals <i>Vancouver, Canada</i>	candidiasis	Phase II completed (604) 436-4388
SinuNase™ topical amphotericin B (intranasal)	Accentia Biopharmaceuticals <i>Tampa, FL</i>	chronic sinusitis (Fast Track)	Phase III completed (813) 864-2554
terbinafine topical (TDT067)	Celtic Pharma <i>New York, NY</i>	onychomycosis	Phase III (212) 616-4000

ANTI-INFECTIVES

Product Name	Sponsor	Indication	Development Status
Alinia® nitazoxanide	Romark Laboratories <i>Tampa, FL</i>	hepatitis C, influenza virus infections	Phase II (813) 282-8544
AzaSite Plus™ azithromycin/ dexamethasone combination	Insite Vision <i>Alameda, CA</i>	blepharoconjunctivitis	Phase III (510) 865-8800
CZEN-002	Zengen <i>Woodland Hills, CA</i>	vulvovaginal candidiasis	Phase I/II (818) 887-8688
		mycoses	in clinical trials (818) 887-8688
DE-094	Santen Pharmaceutical <i>Napa, CA</i>	infectious keratitis	Phase II (707) 254-1750
FST-201 (povidone iodine/ dexamethasone otic suspension)	Foresight Biotherapeutics <i>New York, NY</i>	otitis externa	Phase III (646) 747-9100
itraconazole topical (Orphan Drug)	Fera Pharmaceuticals <i>New York, NY</i>	otitis externa	Phase II (414) 434-6604
MK-3118	Merck <i>Whitehouse Station, NJ</i>	bacterial infections, viral infections	Phase I (800) 672-6372
MK-6186	Merck <i>Whitehouse Station, NJ</i>	bacterial infections, viral infections	Phase I (800) 672-6372
MK-6406	Merck <i>Whitehouse Station, NJ</i>	bacterial infections, viral infections	Phase I (800) 672-6372

ANTI-INFECTIVES

Product Name	Sponsor	Indication	Development Status
MK-V114	Merck <i>Whitehouse Station, NJ</i>	bacterial infections, viral infections	Phase I (800) 672-6372
moxifloxacin/ dexamethasone	Alcon Laboratories <i>Fort Worth, TX</i>	otitis externa, otitis media	Phase III (800) 862-5266
NOX 100	Medinox <i>Carlsbad, CA</i>	septic shock	Phase I/II (760) 603-8989
NVC-422	NovaBay Pharmaceuticals <i>Emeryville, CA</i>	viral conjunctivitis, catheter-associated urinary tract infections	Phase II (510) 899-8800
rifamycin controlled-release	Cosmo Pharmaceuticals <i>Lainate, Italy</i> Santarus <i>San Diego, CA</i>	traveler's diarrhea	Phase III (858) 314-5700

ANTI-MALARIALS

Product Name	Sponsor	Indication	Development Status
chloroquine/ azithromycin	Pfizer <i>New York, NY</i>	malaria	Phase II/III (860) 732-5156
ferroquine (SSR97193)	sanofi-aventis <i>Bridgewater, NJ</i>	malaria	Phase II (800) 633-1610
GSK932121	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	malaria	Phase I (888) 825-5249
NuarteTM artesunate intravenous (Orphan Drug)	Sigma-Tau Pharmaceuticals <i>Gaithersburg, MD</i>	immediate treatment of severe and complicated <i>P. falciparum</i> malaria	Phase III completed (800) 447-0169
SAR97276	sanofi-aventis <i>Bridgewater, NJ</i>	malaria	Phase II (800) 633-1610
tafenoquine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Walter Reed Army Institute of Research <i>Silver Spring, MD</i>	prevention of <i>Plasmodium vivax</i> malaria	Phase II (888) 825-5249

ANTI-PARASITICS

Product Name	Sponsor	Indication	Development Status
BGC-200582	BTG International <i>West Conshohocken, PA</i>	pediculosis (head lice)	Phase II (610) 278-1660
DeOvoTM	Hatchtech <i>Carlton Vic, Australia</i>	pediculosis (head lice)	Phase II www.hatchtech.com.au
malathion gel	Taro Pharmaceuticals U.S.A. <i>Hawthorne, NY</i>	pediculosis (head lice)	Phase III (800) 544-1449

ANTI-PARASITICS

Product Name	Sponsor	Indication	Development Status
moxidectin	Pfizer <i>New York, NY</i>	onchocerciasis	Phase III (860) 732-5156
NatrOVA™ spinosad	ParaPRO <i>Carmel, IN</i>	pediculosis (head lice)	application submitted (877) 542-3639
Resultz® isopropyl myristate rinse	Piedmont Pharmaceuticals <i>Greensboro, NC</i>	pediculosis (head lice)	Phase III (336) 544-0320
sitamaquine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	visceral leishmaniasis	Phase II (888) 825-5249
VQD-001 (Orphan Drug)	VioQuest Pharmaceuticals <i>Basking Ridge, NJ</i>	cutaneous leishmaniasis	Phase II (908) 766-4400

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
ABT-072	Abbott Laboratories <i>Abbott Park, IL</i>	hepatitis C	Phase II (847) 937-6100
ABT-267	Abbott Laboratories <i>Abbott Park, IL</i>	hepatitis C	Phase I (847) 937-6100
ABT-333	Abbott Laboratories <i>Abbott Park, IL</i>	hepatitis C	Phase II (847) 937-6100
ABT-450	Abbott Laboratories <i>Abbott Park, IL</i> Enanta Pharmaceuticals <i>Watertown, MA</i>	hepatitis C	Phase II (847) 937-6100 (617) 607-0800
ACH-1625	Achillion Pharmaceuticals <i>New Haven, CT</i>	hepatitis C	Phase I (203) 624-7000
aciclovir extended-release (BA021)	BioAlliance Pharma <i>Paris, France</i>	herpes labialis	Phase III www.bioalliance pharma.com
aciclovir topical patch	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	herpes labialis	Phase I (888) 825-5249
ADS-8902	Adamas Pharmaceuticals <i>Emeryville, CA</i>	influenza A virus infections, including pandemic strains	Phase II (510) 450-3500
AIC246	AiCuris <i>Wuppertal, Germany</i>	prevention of cytomegalovirus infections	Phase II www.aicuris.com
AIC316	AiCuris <i>Wuppertal, Germany</i>	herpes simplex virus infections	Phase II www.aicuris.com
Alferon N Injection® interferon-alpha-n3	Hemispherx Biopharma <i>Philadelphia, PA</i>	prevention of coronavirus infections, prevention of West Nile virus infection	Phase II (215) 988-0080
Alferon N LDO® interferon-alpha-n3	Hemispherx Biopharma <i>Philadelphia, PA</i>	influenza virus infections	Phase I (215) 988-0080
alisporivir	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hepatitis C	Phase II (888) 669-6682

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
ALN-RSV01	Alnylam Pharmaceuticals <i>Cambridge, MA</i>	respiratory syncytial virus infections	Phase II (617) 551-8200
ANA598	Anadys Pharmaceuticals <i>San Diego, CA</i>	hepatitis C (Fast Track)	Phase II (858) 530-3600
ARYS-01 (sorivudine topical)	aRigen Pharmaceuticals <i>Tokyo, Japan</i>	herpes zoster (shingles)	Phase II/III www.arigen.jp
BI-207127	Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	hepatitis C	Phase I/II (800) 243-0127
BMS-650032 (NS3 inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hepatitis C	in clinical trials (212) 546-4000
BMS-790052 (NS5A inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hepatitis C	in clinical trials (212) 546-4000
BMS-791325 (NS5B inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hepatitis C	in clinical trials (212) 546-4000
BMS-824393 (NS5A inhibitor)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hepatitis C	in clinical trials (212) 546-4000
BMS-914143 (PEG-interferon lambda)	Bristol-Myers Squibb <i>Princeton, NJ</i>	hepatitis C	in clinical trials (212) 546-4000
BTA-798	Biota <i>Notting Hill, Australia</i>	rhinovirus infections	Phase II www.biota.com.au
CB5300	Canopus BioPharma <i>Century City, CA</i>	hepatitis C	Phase II www.canopus biopharma.com
cell therapy	Cell Medica <i>London, United Kingdom</i> Center for Cell and Gene Therapy <i>Houston, TX</i>	viral infections	Phase I/II (713) 798-1246
clemizole	Eiger Pharmaceuticals <i>Palo Alto, CA</i>	hepatitis C	Phase I (650) 320-9900
CMX-001	Chimerix <i>Madison, WI</i>	cytomegalovirus infections	Phase II (800) 535-9506
		human polyomavirus infections	Phase I/II (800) 535-9506
		smallpox	Phase I completed (800) 535-9506
CTC-96	OPKO Health <i>Miami, FL</i>	infectious keratoconjunctivitis (pink eye)	Phase II (305) 575-4100
		ocular herpes infection	Phase I completed (305) 575-4100

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
Famvir® famciclovir	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	Epstein-Barr virus infections	Phase III (888) 669-6682
Fludase® (DAS-181)	NexBio <i>San Diego, CA</i>	influenza A virus H1N1 subtype, influenza virus infections	Phase II (858) 452-2631
		prevention of influenza virus infections	Phase I (858) 452-2631
FV-100	Inhibitex <i>Alpharetta, GA</i>	herpes zoster (shingles)	Phase II (678) 746-1100
golotimod	SciClone Pharmaceuticals <i>Foster City, CA</i>	hepatitis C	Phase II (650) 358-3456
GS-9190	Gilead Sciences <i>Foster City, CA</i>	hepatitis C	Phase II (800) 445-3235
GS-9191	Graceway Pharmaceuticals <i>Bristol, TN</i>	human papillomavirus infections	Phase I completed (434) 274-2100
GS-9256	Gilead Sciences <i>Foster City, CA</i>	hepatitis C	Phase II (650) 358-3456
HQK-1004	HemaQuest Pharmaceuticals <i>Seattle, WA</i>	Epstein-Barr virus infections	Phase II (206) 682-1233
IDX184	Idenix Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase II (617) 995-9800
IDX320	Idenix Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I/II (617) 995-9800
IDX375	Idenix Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I (617) 995-9800
IMO-2125	Idera Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I (617) 679-5500
interferon-alpha	Nautilus Biotech <i>Paris, France</i>	hepatitis C	Phase I www.nautilusbiotech.com
INX-189	Inhibitex <i>Alpharetta, GA</i>	hepatitis C	Phase I (678) 746-1100
ITCA 638 (interferon omega)	Intarcia Therapeutics <i>Hayward, CA</i>	hepatitis C	Phase II (510) 782-7800
ITX-5061	iTherX <i>San Diego, CA</i>	hepatitis C	Phase I (858) 824-1100
laninamivir	Biota <i>Melbourne, Australia</i> Daiichi Sankyo <i>Parsippany, NJ</i>	influenza virus infections	Phase I (973) 359-2600
MDT-637	MicroDose Therapeutx <i>Monmouth Junction, NJ</i>	respiratory syncytial virus infections	Phase I (732) 355-2100
MEDI-557 (respiratory syncytial virus mAb)	MedImmune <i>Gaithersburg, MD</i>	respiratory syncytial virus infections	Phase I (301) 398-0000

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
MGAWN1	Macrogenics <i>Rockville, MD</i>	West Nile virus infections	Phase II (301) 251-5172
miglustat	United Therapeutics <i>Rsch. Triangle Park, NC</i>	hepatitis C	Phase I (919) 485-8350
MK-5172	Merck <i>Whitehouse Station, NJ</i>	hepatitis C	Phase I (800) 672-6372
MTCH-24	Meditech Pharmaceuticals <i>Scottsdale, AZ</i>	herpes simplex virus infections	Phase I/II (480) 614-2874
NA808	Chugai Pharma USA <i>Berkeley Heights, NJ</i>	hepatitis C	Phase I (908) 516-1350
narlaprevir	Merck <i>Whitehouse Station, NJ</i>	hepatitis C	Phase II (800) 672-6372
NB-001	NanoBio <i>Ann Arbor, MI</i>	herpes labialis (cold sores)	Phase II completed (734) 302-4000
NOV-205	Novelos Therapeutics <i>Newton, MA</i>	hepatitis C	Phase II (617) 244-1616
Numax[®] motavizumab	MedImmune <i>Gaithersburg, MD</i>	prevention of respiratory syncytial virus infections (intramuscular)	application submitted (301) 398-0000
		respiratory syncytial virus infection (intravenous)	Phase II (301) 398-0000
PEG-interleukin-29	ZymoGenetics <i>Seattle, WA</i>	hepatitis C	Phase II (800) 775-6686
peramivir	BioCryst Pharmaceuticals <i>Birmingham, AL</i>	influenza virus infections	Phase III (205) 444-4600
PF-868554 (filibuvir)	Pfizer <i>New York, NY</i>	hepatitis C	Phase II (860) 732-5156
PHX-1766 (NS3 protease inhibitor)	Phenomix <i>San Diego, CA</i>	hepatitis C	Phase I (858) 731-5200
pleconaril	Merck <i>Whitehouse Station, NJ</i>	rhinovirus infections	Phase II (800) 672-6372
PPA-461	Presidio Pharmaceuticals <i>San Francisco, CA</i>	hepatitis C	Phase I (415) 655-7560
PSI-938	Pharmasset <i>Princeton, NJ</i>	hepatitis C	Phase I (609) 613-4100
PSI-7977	Pharmasset <i>Princeton, NJ</i>	hepatitis C (Fast Track)	Phase II (609) 613-4100
PTX-111	Phytrix <i>Denver, CO</i>	hepatitis B	Phase II (303) 415-2034
RG7128	Pharmasset <i>Princeton, NJ</i> Roche <i>Nutley, NJ</i>	hepatitis C (Fast Track)	Phase II (609) 613-4100 (973) 235-5000

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
RG7227/ ITMN-191 (danoprevir)	InterMune <i>Brisbane, CA</i> Roche <i>Nutley, NJ</i>	hepatitis C	Phase II (415) 466-2200 (973) 235-5000
RG7348	Ligand Pharmaceuticals <i>La Jolla, CA</i> Roche <i>Nutley, NJ</i>	hepatitis C	Phase I (858) 550-7500 (973) 235-5000
RI-001	ADMA Biologics <i>Hackensack, NJ</i>	prevention of respiratory tract infections	Phase II completed (201) 478-5552
RSV604	Novartis Pharmaceuticals <i>East Hanover, NJ</i>	respiratory syncytial virus infections	Phase II (888) 669-6682
SCY-635	SCYNEXIS <i>Rsch. Triangle Park, NC</i>	hepatitis C	Phase I (919) 544-8600
SD-101	Dynavax Technologies <i>Berkeley, CA</i>	hepatitis C	Phase I completed (510) 848-5100
SoloVir™ aciclovir transdermal	Transport Pharmaceuticals <i>Framingham, MA</i>	herpes labialis	Phase II (508) 872-0433
SPL-7013	Starpharma <i>Melbourne, Australia</i>	prevention of herpes simplex virus infections	Phase I www.starpharma.com
T-705	Toyama Chemical <i>Tokyo, Japan</i>	influenza virus infections	Phase II www.toyama-chemical.co.jp
TAK-851	Takeda Pharmaceuticals North America <i>Deerfield, IL</i>	human papillomavirus infections	Phase II (877) 582-5332
Tarvacin™ bavituximab	Peregrine Pharmaceuticals <i>Tustin, CA</i>	hepatitis C	Phase I (714) 508-6000
tecovirimat (Orphan Drug)	SIGA Technologies <i>New York, NY</i>	smallpox (Fast Track), orthopoxvirus infections	Phase II (212) 672-9100
telaprevir	Johnson & Johnson Pharmaceutical Research & Development <i>Raritan, NJ</i> Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C (Fast Track)	application submitted (800) 817-5286 (617) 444-6100
TJ 9	Tsumura USA <i>Rockville, MD</i>	hepatitis C	Phase II (301) 468-1030
TMC435	Tibotec <i>Yardley, PA</i>	hepatitis C	Phase II (609) 730-7500
Truvada® emtricitabine/ tenofovir disoproxil fumarate	Gilead Sciences <i>Foster City, CA</i>	hepatitis B ----- prevention of hepatitis B	Phase III (800) 445-3235 Phase II (800) 445-3235

ANTIVIRALS

Product Name	Sponsor	Indication	Development Status
valomaciclovir	Epiphany Biosciences <i>San Francisco, CA</i>	herpes zoster (shingles), infectious mononucleosis	Phase II (415) 765-7193
vaniprevir	Merck <i>Whitehouse Station, NJ</i>	hepatitis C	Phase II (800) 672-6372
VariZIG® varicella zoster immune globulin (Orphan Drug)	Cangene <i>Winnipeg, Canada</i>	varicella zoster virus infections	Phase III (204) 275-4200
VBY-376	ViroBay <i>Menlo Park, CA</i>	hepatitis C	Phase I completed (650) 833-5700
VCH-916	Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I/II (617) 444-6100
Veldona® interferon-alpha (Orphan Drug)	Amarillo Biosciences <i>Amarillo, TX</i>	human papillomavirus infections	Phase II (806) 376-1741
VX-222	Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase II (617) 444-6100
VX-759	Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I/II (617) 444-6100
VX-813	Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I (617) 444-6100
VX-985	Vertex Pharmaceuticals <i>Cambridge, MA</i>	hepatitis C	Phase I (617) 444-6100
West Nile immune globulin (Orphan Drug)	Omrix Biopharmaceuticals <i>Tel Aviv, Israel</i>	West Nile virus infections	Phase II
Zadaxin® thymalfasin (Orphan Drug)	SciClone Pharmaceuticals <i>Foster City, CA</i>	hepatitis B, hepatitis C	Phase III (650) 358-3456
Zalbin™ albinterferon alfa-2b	Human Genome Sciences <i>Rockville, MD</i> Novartis Pharmaceuticals <i>East Hanover, NJ</i>	hepatitis C	application submitted (301) 309-8504 (888) 669-6682
Zyclara™ imiquimod 3.75%	Graceway Pharmaceuticals <i>Bristol, TN</i>	human papillomavirus infections	application submitted (434) 274-2100

VACCINES

Product Name	Sponsor	Indication	Development Status
ACAM-Cdiff	sanofi pasteur <i>Swiftwater, PA</i>	prevention of <i>Clostridium difficile</i> - associated diarrhea	Phase II (570) 839-7187
ACE393	ACE BioSciences <i>Odense, Denmark</i> TD Vaccines <i>Skørping, Denmark</i>	prevention of traveler's diarrhea caused by <i>Campylobacter jejuni</i> infection	Phase II www.acebiosciences.com www.tdvaccines.com

VACCINES

Product Name	Sponsor	Indication	Development Status
ACE527	ACE BioSciences <i>Odense, Denmark</i> TD Vaccines <i>Skørping, Denmark</i>	prevention of traveler's diarrhea caused by <i>Escherichia coli</i> infections	Phase II www.acebiosciences.com www.tdvaccines.com
Adacel [®] DTP vaccine	sanofi pasteur <i>Swiftwater, PA</i>	diphtheria, tetanus, pertussis (ages 4-6 years)	Phase III (570) 839-7187
AERAS-402/ Ad35 Crucell	Aeras Global TB Vaccine Foundation <i>Rockville, MD</i> Crucell <i>Leiden, The Netherlands</i>	tuberculosis	Phase I (301) 547-2900
Aflunov [™] pre-pandemic H5N1 influenza vaccine	Novartis Vaccines <i>Cambridge, MA</i>	prevention of influenza A virus H5N1 subtype infection	Phase II (888) 669-6682
AG-707	Antigenics <i>Lexington, MA</i>	treatment of herpes simplex virus infection	Phase I completed (781) 674-4400
anthrax biodefense vaccine	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	anthrax	Phase I/II (847) 478-0500
anthrax transdermal vaccine	Intercell USA <i>Gaithersburg, MD</i>	anthrax	Phase I (301) 556-4500
antibody fragment vaccine (KB-001)	KaloBios Pharmaceuticals <i>South San Francisco, CA</i> sanofi pasteur <i>Swiftwater, PA</i>	<i>Pseudomonas aeruginosa</i> infections	Phase I (650) 243-3100 (570) 839-7187
ANZ-521	Aduro BioTech <i>Berkeley, CA</i>	treatment of hepatitis C	Phase I (510) 848-4400
AV-7909	Emergent BioSolutions <i>Rockville, MD</i>	anthrax	Phase I (301) 795-1800
AVX-502	AlphaVax <i>Rsch. Triangle Park, NC</i>	prevention of influenza virus infections in elderly patients	Phase I/II (919) 595-0400
botulinum toxin vaccine	DynPort Vaccine <i>Frederick, MD</i>	botulism	Phase I (301) 607-5000
chikungunya virus vaccine	Inviragen <i>Fort Collins, CO</i>	<i>Chikungunya</i> virus infections	Phase II (970) 672-4918
CholeraGarde [®] cholera vaccine live attenuated	Celldex Therapeutics <i>Needham, MA</i> Vaccine Technologies <i>Wellesley, MA</i>	cholera	Phase II (781) 433-0771
ChronVac-C [®] hepatitis C DNA vaccine	ChronTech Pharma <i>Huddinge, Sweden</i> Inovio Pharmaceuticals <i>Blue Bell, PA</i>	hepatitis C	Phase I/II (267) 440-4200
C-Vax hepatitis C vaccine	Virionics <i>Scottsdale, AZ</i>	prevention and treatment of hepatitis C	Phase I (480) 254-5871

VACCINES

Product Name	Sponsor	Indication	Development Status
cytomegalovirus DNA vaccine (Orphan Drug)	Vical <i>San Diego, CA</i>	prevention of cytomegalovirus infections	Phase II (858) 646-1100
cytomegalovirus vaccine	AlphaVax <i>Rsch. Triangle Park, NC</i> Novartis Vaccines <i>Cambridge, MA</i>	prevention of cytomegalovirus infections	Phase I (888) 669-6682
DEN-1-80E	Hawaii Biotech <i>Aiea, HI</i>	prevention of dengue fever	Phase I (808) 486-5333
dengue attenuated tetravalent vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of dengue fever	Phase II completed (888) 825-5249
dengue DNA vaccine	U.S. Naval Medical Research Center <i>Silver Spring, MD</i> Vical <i>San Diego, CA</i>	prevention of dengue fever	Phase I (858) 646-1100
dengue fever vaccine	Acambis <i>Cambridge, MA</i> sanofi pasteur <i>Swiftwater, PA</i>	mild to severe dengue fever	Phase II (617) 761-4200 (570) 839-7187
DTP-HepB-polio-Hib vaccine	sanofi pasteur <i>Swiftwater, PA</i>	diphtheria, tetanus, pertussis, hepatitis B, polio, <i>Haemophilus influenzae</i> type b	Phase II (570) 839-7187
DV-601	Dynavax <i>Berkeley, CA</i>	treatment of hepatitis B	Phase I (510) 848-5100
Ebola vaccine	Crucell <i>Leiden, The Netherlands</i> Vaccine Research Center <i>Bethesda, MD</i>	prevention of Ebola virus infections	Phase I www.crucell.com
Ebola virus DNA vaccine	Vical <i>San Diego, CA</i> Vaccine Research Center <i>Bethesda, MD</i>	prevention of Ebola virus infections	Phase I completed (858) 646-1100
Ebola virus vaccine	GenPhar <i>Mt. Pleasant, SC</i>	Ebola virus infections	in clinical trials (843) 884-0120
Epstein-Barr virus recombinant vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	treatment of Epstein-Barr virus infections, prevention of infectious mononucleosis	Phase II (888) 825-5249
<i>Escherichia coli</i> vaccine	Emergent BioSolutions <i>Rockville, MD</i>	<i>Escherichia coli</i> infections	Phase I (301) 795-1800
ETEC vaccine	Celldex Therapeutics <i>Needham, MA</i> Vaccine Technologies <i>Wellesley, MA</i>	prevention of cholera, <i>Escherichia coli</i> infections	Phase I (781) 433-0771

VACCINES

Product Name	Sponsor	Indication	Development Status
FluBlok® influenza virus vaccine (rHA)	Protein Sciences <i>Meriden, CT</i>	prevention of influenza virus infections in adults and children	application submitted (800) 488-7099
flu cell culture vaccine (new production method)	sanofi pasteur <i>Swiftwater, PA</i>	influenza virus infections	Phase II (570) 839-7187
Flu ID (seasonal influenza vaccine intradermal micro-injection)	sanofi pasteur <i>Swiftwater, PA</i>	prevention of influenza virus infections	Phase III (570) 839-7187
FluNhance™ influenza virus vaccine (rNA)	Protein Sciences <i>Meriden, CT</i>	influenza virus infections	Phase II (800) 488-7099
GSK444563	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	rotavirus infections in infants	Phase I (888) 825-5249
GSK1492903A (cytomegalovirus recombinant vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of cytomegalovirus infection	Phase I completed (888) 825-5249
GSK1557482A (thimerosal-free trivalent influenza vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	influenza virus infections in children ages 3-17	Phase III completed (888) 825-5249
GSK2186877A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza virus infections	Phase III (888) 825-5249
GSK2189242A (<i>S. pneumoniae</i> recombinant-conjugated vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of <i>Streptococcus pneumoniae</i> disease	Phase I/II (888) 825-5249
GSK2202083A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of diphtheria, tetanus, pertussis, <i>Haemophilus</i> infections, hepatitis B, meningococcal group C infections, poliomyelitis (infants)	Phase II (888) 825-5249
GSK2231395A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of <i>Haemophilus</i> and pneumococcal infections	Phase I (888) 825-5249
GSK2254232A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of <i>Haemophilus</i> infections, prevention of pneumococcal infections	Phase I completed (888) 825-5249
GSK2254233A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of <i>Haemophilus</i> infections, prevention of pneumococcal infections	Phase I completed (888) 825-5249
GSK2321138A (influenza virus vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza virus infection in children	Phase II completed (888) 825-5249

VACCINES

Product Name	Sponsor	Indication	Development Status
GSK2340273A (influenza A virus H1N1 vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza A virus H1N1 subtype in children and infants	Phase II (888) 825-5249
GSK2340274A (influenza A virus H1N1 vaccine)	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza A virus H1N1 subtype in children and infants	Phase II (888) 825-5249
GSK2392102A	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	staphylococcal infections	Phase I (888) 825-5249
H5N1 avian influenza intranasal vaccine	MedImmune <i>Gaithersburg, MD</i>	influenza A virus H5N1 subtype	Phase I (301) 398-0000
H5N1 influenza virus vaccine	Novavax <i>Rockville, MD</i>	prevention of influenza A virus H5N1 subtype	Phase II (240) 268-2000
HBV-002	Hawaii Biotech <i>Aiea, HI</i>	prevention of West Nile virus infection	Phase I completed (808) 486-5333
<i>Helicobacter pylori</i> vaccine	Novartis Vaccines <i>Cambridge, MA</i>	helicobacter infections	Phase I (888) 669-6682
hepatitis B DNA vaccine	Pfizer <i>New York, NY</i>	hepatitis B	Phase I (860) 732-5156
hepatitis B vaccine	Emergent BioSolutions <i>Rockville, MD</i>	hepatitis B	Phase II (301) 795-1800
hepatitis B vaccine	GenPhar <i>Mt. Pleasant, SC</i>	hepatitis B	Phase I (843) 884-0120
hepatitis C vaccine (HCV/MF59)	Novartis Vaccines <i>Cambridge, MA</i>	treatment of hepatitis C	Phase I/II (888) 669-6682
hepatitis E recombinant vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Novavax <i>Rockville, MD</i>	hepatitis E	Phase II completed (888) 825-5249 (240) 268-2000
Heplisav™ hepatitis B vaccine	Dynavax <i>Berkeley, CA</i>	prevention of hepatitis B	Phase III (510) 848-5100
herpes simplex DNA vaccine	Pfizer <i>New York, NY</i>	treatment of herpes simplex virus infections	Phase I (860) 732-5156
herpes simplex vaccine	AuRx <i>Elkridge, MD</i>	prevention and treatment of herpes simplex virus infections	Phase I/II (410) 796-7559
Hexaxim™ DTP-HepB-polio-Hib vaccine	sanofi pasteur <i>Swiftwater, NJ</i>	diphtheria, tetanus, pertussis, hepatitis B, polio, <i>Haemophilus influenzae</i> type b	Phase III (570) 839-7187
IC31® seasonal influenza vaccine	Intercell <i>Vienna, Austria</i> Novartis Vaccines <i>Cambridge, MA</i>	prevention of influenza virus infections	Phase II (888) 669-6682
ImmunoVex HSV2	BioVex <i>Woburn, MA</i>	prevention of herpes simplex virus infections	Phase I (781) 376-4900

VACCINES

Product Name	Sponsor	Indication	Development Status
Imojev™ Japanese encephalitis vaccine	Acambis <i>Cambridge, MA</i> sanofi pasteur <i>Swiftwater, PA</i>	prevention of encephalitis virus infections	Phase III (617) 761-4200 (570) 839-7187
Imvamune® smallpox vaccine	Bavarian Nordic <i>Washington, DC</i>	smallpox	Phase II (202) 536-1581
influenza A virus H1N1 vaccine	sanofi pasteur <i>Swiftwater, PA</i>	prevention of influenza A virus H1N1 subtype in adolescents, children and infants	Phase II (570) 839-7187
influenza A virus H1N1 vaccine (CSL-425)	CSL Behring <i>King of Prussia, PA</i>	prevention of influenza A virus H1N1 subtype in the elderly	Phase II (610) 878-4000
influenza A virus H1N1 vaccine	Baxter Healthcare <i>Deerfield, IL</i>	prevention of influenza A virus H1N1 subtype	Phase I/II (800) 422-9837
influenza virus DNA vaccine	Vical <i>San Diego, CA</i>	prevention of influenza A virus H1N1 subtype	Phase I completed (858) 646-1100
influenza A virus H5N1 vaccine	Baxter Healthcare <i>Deerfield, IL</i> DynPort Vaccine <i>Frederick, MD</i>	prevention of influenza A virus H5N1 subtype	Phase I (800) 422-9837 (301) 607-5000
influenza virus H5N1 vaccine	Antigen Express <i>Worcester, MA</i>	influenza virus infections	Phase I (508) 852-8783
influenza virus-like particle vaccine	Novavax <i>Rockville, MD</i>	prevention of influenza virus infections	Phase II (240) 268-2000
influenza virus vaccine	Dynavax <i>Berkeley, CA</i>	prevention of influenza virus infections	Phase I (510) 848-5100
influenza virus vaccine intranasal	Vaxin <i>Birmingham, AL</i>	influenza virus infections	Phase I (205) 413-8238
Influvac® TC cell culture-derived influenza vaccine	Abbott Laboratories <i>Abbott City, IL</i>	prevention of influenza virus infections	Phase I (847) 937-6100
Ixiaro® Japanese encephalitis vaccine	Intercell <i>Vienna, Austria</i> Novartis Vaccines <i>Cambridge, MA</i>	prevention of Japanese encephalitis in children	Phase III (888) 669-6682
malaria DNA vaccine	U.S. Naval Medical Research Center <i>Silver Spring, MD</i> Vical <i>San Diego, CA</i>	malaria	Phase I/II (858) 646-1100
malaria vaccine	BioSante Pharmaceuticals <i>Lincolnshire, IL</i> U.S. Naval Medical Research Center <i>Silver Spring, MD</i>	prevention of malaria	Phase I/II (847) 478-0500

VACCINES

Product Name	Sponsor	Indication	Development Status
malaria vaccine	GenVec Gaithersburg, MD PATH Malaria Vaccine Initiative Bethesda, MD U.S. Naval Medical Research Center Silver Spring, MD	malaria	Phase I/II (877) 943-6832
malaria vaccine	Crucell Leiden, The Netherlands	malaria	Phase I completed www.crucell.com
malaria vaccine	Sanaria Rockville, MD	malaria	Phase I (301) 770-3222
Marburg virus DNA vaccine	GenPhar Mt. Pleasant, SC	Marburg virus disease	in clinical trials (843) 884-0120
MEDI-534 (parainfluenza/respiratory syncytial virus vaccine)	MedImmune Gaithersburg, MD	parainfluenza virus infections in children and infants, respiratory syncytial virus infections in children and infants	Phase I/II (301) 398-0000
MEDI-559 (respiratory syncytial virus vaccine)	MedImmune Gaithersburg, MD	prevention of respiratory syncytial virus infections in infants	Phase I/II (301) 398-0000
MEDI-560 (parainfluenza recombinant vaccine)	MedImmune Gaithersburg, MD	prevention of parainfluenza virus infections in children and infants	Phase I/II (301) 398-0000
MEDI-3250 (quadrivalent seasonal influenza vaccine)	MedImmune Gaithersburg, MD	prevention of influenza virus infections in adolescents and children	Phase III (301) 398-0000
		prevention of influenza virus infections	Phase II/III (301) 398-0000
Menactra® Toddler	sanofi pasteur Swiftwater, PA	<i>Neisseria meningitidis</i> A, C, W-135, and Y in toddlers 9 months-12 months	Phase III (570) 839-7187
MenHibrix® Hib-meningococcal groups C and Y tetanus toxoid conjugate vaccine	GlaxoSmithKline Rsch. Triangle Park, NC	prevention of <i>Neisseria meningitidis</i> groups C and Y infections and <i>Haemophilus influenzae</i> type B	application submitted (888) 825-5249
meninge ACWY 2nd generation conjugate vaccine	sanofi pasteur Swiftwater, PA	meningitis in infants	Phase II (570) 839-7187
meningococcal vaccine group B (MenB)	Novartis Vaccines Cambridge, MA	meningococcal group B infections	Phase II completed (888) 669-6682

VACCINES

Product Name	Sponsor	Indication	Development Status
Menveo® meningococcal vaccine groups ACYW-135 conjugate	Novartis Vaccines <i>Cambridge, MA</i>	meningococcal group A, C, W-135, Y infections in children	application submitted (888) 669-6682
Menveo® Infants meningococcal vaccine groups ACYW-135 conjugate	Novartis Vaccines <i>Cambridge, MA</i>	meningococcal group A,C,W-135, Y infections in infants	application submitted (888) 669-6682
Mosquirix™ malaria recombinant vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of malaria	Phase III (888) 825-5249
NB-1008 (intranasal)	NanoBio <i>Ann Arbor, MI</i>	prevention of influenza virus infections	Phase I completed (734) 302-4000
new generation flu inactivated split-trivalent vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza virus infections	Phase III (888) 825-5249
Nimenrix™ MenACWY-TT conjugated vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of <i>Neisseria meningitidis</i> groups A, C, W-135, Y disease in children	Phase III (888) 825-5249
		prevention of <i>Neisseria meningitidis</i> groups A, C, W-135, Y disease in adolescents and adults	Phase II (888) 825-5249
norovirus vaccine	LigoCyte Pharmaceuticals <i>Bozeman, MT</i>	norovirus infections (intranasal)	Phase I/II (406) 585-2733
		norovirus infections (intramuscular)	Phase I (406) 585-2733
Optafu® influenza virus vaccine	Novartis Vaccines <i>Cambridge, MA</i>	prevention of influenza virus infections	application submitted (888) 669-6682
PanBlok™ pandemic H5N1 influenza vaccine	Protein Sciences <i>Meriden, CT</i>	prevention of influenza A virus H5N1 subtype	Phase I/II (800) 488-7099
parvovirus B19 vaccine	Meridian Biosciences <i>Cincinnati, OH</i>	parvovirus infections	Phase I/II (513) 271-3700
PER-C-flu	Crucell <i>Leiden, The Netherlands</i>	prevention of influenza virus infections	Phase II www.crucell.com
PF-5212366 (meningococcal group B vaccine)	Pfizer <i>New York, NY</i>	meningococcal group B infections	Phase II (860) 732-5156
plague vaccine injectable	DynPort Vaccine <i>Frederick, MD</i>	<i>Yersinia</i> infections	Phase II (301) 607-5000

VACCINES

Product Name	Sponsor	Indication	Development Status
Preflucel™ seasonal influenza virus vaccine	Baxter Healthcare <i>Deerfield, IL</i> DynPort Vaccine <i>Frederick, MD</i>	prevention of influenza virus infections	Phase III (800) 422-9837
Prepandrix™ H5N1 pre-pandemic influenza virus vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of influenza A virus H5N1 subtype	Phase III (888) 825-5249
Prevnar 13 Adult™ pneumococcal vaccine conjugate 13-valent	Pfizer <i>New York, NY</i>	prevention of pneumococcal infection in the elderly	Phase III (860) 732-5156
rabies VRVg vaccine	sanofi pasteur <i>Swiftwater, PA</i>	rabies	Phase II (570) 839-7187
ricin biodefense vaccine	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	ricin poisoning	Phase I/II (847) 478-0500
RiVax™ ricin vaccine	Soligenix <i>Princeton, NJ</i>	ricin poisoning	Phase I (609) 538-8200
rotavirus vaccine (shantha)	sanofi pasteur <i>Swiftwater, PA</i>	prevention of rotavirus infections	Phase I (570) 839-7187
rotavirus vaccine 116E	Bharat Biotech <i>Hyderabad, India</i>	prevention of rotavirus infections	Phase I www.bharatbiotech.com
rPA-102 (recombinant protective antigen anthrax vaccine)	Emergent BioSolutions <i>Rockville, MD</i>	anthrax (Fast Track)	Phase II (301) 795-1800
SA3Ag	Inhibitex <i>Alpharetta, GA</i> Pfizer <i>New York, NY</i>	staphylococcal infections	Phase I (678) 746-1100 (860) 732-5156
SARS DNA vaccine	Vical <i>San Diego, CA</i>	prevention of severe acute respiratory syndrome (SARS) (coronavirus infections)	Phase I completed (858) 646-1100
shigella vaccine	Emergent BioSolutions <i>Rockville, MD</i>	shigella infections	Phase I (301) 795-1800
Simplirix™ herpes simplex glycoprotein vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of herpes simplex virus infections	Phase III (888) 825-5249
SparVax™ recombinant protective antigen (rPA) anthrax vaccine	PharmAthene <i>Annapolis, MD</i>	anthrax	Phase II completed (410) 269-2600

VACCINES

Product Name	Sponsor	Indication	Development Status
staphylococcal biodefense vaccine	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	staphylococcal infections	Phase I/II (847) 478-0500
<i>Staphylococcus aureus</i> type 336 vaccine	Nabi Biopharmaceutical <i>Boca Raton, FL</i>	prevention of staphylococcal infections	Phase I/II (800) 635-1766
<i>Staphylococcus aureus</i> vaccine conjugate	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i> Nabi Biopharmaceutical <i>Boca Raton, FL</i>	prevention of staphylococcal infections	Phase I/II (888) 825-5249 (800) 635-1766
streptococcal B vaccine	Emergent BioSolutions <i>Rockville, MD</i>	streptococcal infections	Phase I (301) 795-1800
streptococcal B vaccine conjugate	Novartis Vaccines <i>Cambridge, MA</i>	prevention of streptococcal infections	Phase I (888) 669-6682
streptococcus pneumonia vaccine	sanofi pasteur <i>Swiftwater, PA</i>	prevention of meningitis and pneumonia	Phase I (570) 839-7187
tetravalent hybrid dengue virus vaccine	Inviragen <i>Fort Collins, CO</i>	treatment of dengue fever	Phase I (970) 672-4918
traveler's diarrhea vaccine patch	Intercell USA <i>Gaithersburg, MD</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	<i>Escherichia coli</i> infection, prevention of traveler's diarrhea	Phase II (301) 556-4500 (888) 825-5249
tuberculosis recombinant vaccine (Mtb72F/AS02A)	Aerus Global TB Vaccine Foundation <i>Rockville, MD</i> GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of tuberculosis in young children, adjunct to treatment in adolescents and adults	Phase II completed (888) 825-5249
tuberculosis vaccine	sanofi pasteur <i>Swiftwater, PA</i>	prevention of tuberculosis	Phase I (570) 839-7187
tularemia vaccine	DynPort Vaccine <i>Frederick, MD</i>	tularemia	Phase I (301) 607-5000
Typhella [™] typhoid vaccine live oral	Emergent BioSolutions <i>Rockville, MD</i>	prevention of typhoid	Phase II completed (301) 795-1800
typhoid vaccine	Novartis Vaccines Institute for Global Health <i>Siena, Italy</i>	prevention of typhoid	Phase I (888) 669-6682
typhoid vaccine (Ty800)	Celldex Therapeutics <i>Needham, MA</i>	typhoid	Phase II (781) 433-0771
V212	Merck <i>Whitehouse Station, NJ</i>	prevention of herpes zoster (shingles)	Phase I completed (800) 672-6372
V419	Merck <i>Whitehouse Station, NJ</i>	hepatitis B in infants	Phase II completed (800) 672-6372

VACCINES

Product Name	Sponsor	Indication	Development Status
V502	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections	Phase II completed (800) 672-6372
V503	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections	Phase III (800) 672-6372
V505	Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections	Phase II (800) 672-6372
V710	Merck <i>Whitehouse Station, NJ</i>	staphylococcal infections	Phase II/III (800) 672-6372
varicella zoster recombinant vaccine	GlaxoSmithKline <i>Rsch. Triangle Park, NC</i>	prevention of varicella zoster virus infections	Phase III (888) 825-5249
VAX-102	VaxInnate <i>Cranbury, NJ</i>	prevention of influenza A virus infections	Phase I/II (609) 860-2260
VAX-125	VaxInnate <i>Cranbury, NJ</i>	influenza A virus infections in elderly patients	Phase II (609) 860-2260
VAX-128	VaxInnate <i>Cranbury, NJ</i>	prevention of influenza A virus H1N1 subtype	Phase I (609) 860-2260
VGX-3100	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	human papillomavirus infections	Phase I (877) 446-6846
VGX-3400	Inovio Pharmaceuticals <i>Blue Bell, PA</i>	prevention of influenza A virus H5N1 subtype	Phase I (877) 446-6846
XRX-001	Xcellerex <i>Marlborough, MA</i>	prevention of yellow fever	Phase I (508) 480-9235

OTHER

Product Name	Sponsor	Indication	Development Status
amustaline	Baxter Healthcare <i>Deerfield, IL</i> Cerus <i>Concord, CA</i>	prevention of infections in red blood cell transfusions	Phase I (800) 422-9837 (925) 288-6000
BI-201335	Boehringer-Ingelheim Pharmaceuticals <i>Ridgefield, CT</i>	hepatitis C	Phase II (800) 243-0127
BLX-883 (interferon alpha-2b controlled release)	Biolex <i>Pittsboro, NC</i>	hepatitis C	Phase II (919) 542-9901
boceprevir	Merck <i>Whitehouse Station, NJ</i>	hepatitis C (Fast Track)	Phase III (800) 672-6372
CL-184 (foravirumab)	Crucell <i>Leiden, The Netherlands</i> sanofi pasteur <i>Swiftwater, PA</i>	post-exposure prevention of rabies (Fast Track)	Phase II (570) 839-7187
CT-1027 (emricasen)	Conatus Pharmaceuticals <i>San Diego, CA</i>	hepatitis C	Phase II www.conatuspharma.com

OTHER

Product Name	Sponsor	Indication	Development Status
CTV-05 (Lactin-V)	Osel <i>Santa Clara, CA</i>	bacterial vaginosis, urinary tract infections	Phase II (408) 986-0012
CytoFab™ anti-TNF alpha polyclonal antibody	AstraZeneca <i>Wilmington, DE</i>	severe sepsis	Phase II completed (800) 236-9933
eritoran (E5564)	Eisai <i>Ridgefield Park, NJ</i>	severe sepsis (Fast Track)	Phase III (888) 274-2378
Ganite® gallium nitrate (intravenous)	Genta <i>Berkeley Heights, NJ</i>	infections in cystic fibrosis patients	Phase I (908) 286-9800
GI-5005	Globelimmune <i>Louisville, CO</i>	hepatitis C	Phase II (303) 625-2700
hepatitis C immune globulin (Orphan Drug)	Biotech Pharmaceuticals <i>Boca Raton, FL</i>	prevention of hepatitis C	Phase II (800) 327-7106
interferon alpha-2b	Helix BioPharma <i>Aurora, Canada</i> Merck <i>Whitehouse Station, NJ</i>	human papillomavirus infections	Phase II (905) 841-2300 (800) 672-6372
interferon alpha-2b infusion	Medtronic <i>Minneapolis, MN</i>	hepatitis C	Phase II (800) 633-8766
interferon alpha-2b inhalation	BioSante Pharmaceuticals <i>Lincolnshire, IL</i>	hepatitis B, hepatitis C	in clinical trials (847) 478-0500
NTCD	ViroPharma <i>Exton, PA</i>	prevention of <i>Clostridium</i> infections	Phase I (888) 651-0201
Remicade® infliximab	Centocor Ortho Biotech <i>Horsham, PA</i>	hepatitis C	Phase III (800) 457-6399
Tc 99m ciprofloxacin	Draxis Specialty Pharmaceuticals <i>Montreal, Canada</i>	diagnosis of infections	Phase II (800) 361-2356

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 August 27, 2010.** 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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acne vulgaris—The common form of acne seen most often in teenagers or young adults, which is the result of overactive oil glands that become plugged, red, and inflamed. Most outbreaks of acne can be treated by keeping the skin clear and avoiding irritating soaps, foods, drinks, and cosmetics. Severe acne and acne in those who are prone to scarring can be treated with topical creams and anti-inflammatory medications.

application submitted—An application for marketing has been submitted to the Food and Drug Administration (FDA). The application can either be an NDA (new drug application) or a BLA (biologic license application).

aspergillosis—Infection caused by *Aspergillus fumigatus*, a fungus found in old buildings or decaying plant matter.

bacteremia—Presence of bacteria in the bloodstream.

blepharoconjunctivitis—Inflammation of the eyelids and conjunctiva.

botulism—A severe, sometimes fatal food poisoning caused by ingestion of food containing botulin and characterized by nausea, vomiting, disturbed vision, muscular weakness, and fatigue.

bronchiectasis—An irreversible widening (dilation) of portions of the bronchi resulting from damage to the bronchial wall.

Campylobacter infections—Infections caused by the *Campylobacter* organism, which is actually a group of spiral-shaped bacteria that can cause disease in humans and animals. *Campylobacter* is one of the most common bacterial causes of diarrheal illness in the United States.

candidiasis—A fungal infection, caused by *Candida albicans*,

usually of the moist cutaneous areas of the body.

cervical dysplasia—The abnormal appearance of cells on the surface of the cervix when they are looked at underneath a microscope. It is considered a precancerous condition.

chikungunya—A disease resembling dengue fever, seen mainly in Africa, the Indian subcontinent, and Southeast Asia, caused by an arbovirus transmitted by *Aedes* mosquitoes. The most prominent frequent feature is severe arthritis. Human infections are acquired by the bite of infected *Aedes aegypti* mosquitoes, and epidemics are sustained by human-mosquito-human transmission. Chikungunya fever is characterized by sudden onset, chills and fever, headache, nausea, vomiting, arthralgia, and rash. In contrast to dengue, chikungunya is characterized by the fortunate absence of fatalities.

chlamydial infections—Chlamydiae are a group of microorganisms that cause various infectious diseases in humans and animals. The most important impact of the strain *Chlamydia trachomatis* is its role as a cause of nonspecific urethritis, or nongonococcal genital infection. This is the most common sexually transmitted disease in the United States, and almost half of all cases are due to a chlamydial infection.

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

coronavirus—A genus of viruses of the family *Coronaviridae* that cause respiratory disease and possibly gastroenteritis in humans and hepatitis, gastroenteritis, encephalitis, and respiratory disease in other animals.

cytomegalovirus (CMV)—An opportunistic infection that afflicts people whose immune systems are

weak, such as AIDS patients, and can be fatal.

diphtheria—A bacterial infection characterized by mucus coating the membranes of the nose and throat, causing breathing problems, a fever, sore throat, vomiting, stomach pains, and chills.

Ebola virus—The cause of Ebola hemorrhagic (bloody) fever, a severe, often fatal disease in humans and nonhuman primates (monkeys, gorillas, and chimpanzees). Researchers believe that the virus is animal-borne (zoonotic) and is normally maintained in an animal host that is native to the African continent.

enterococcal infections—Caused by a *Streptococcus* bacterium normally present in the human intestine. It can cause infections during or after surgery.

Epstein-Barr virus (EBV)—A member of the herpes virus family and one of the most common human viruses. The virus occurs worldwide, and most people become infected with EBV sometime during their lives. In the United States, as many as 95 percent of adults between 35 and 40 years of age have been infected. When infection with EBV occurs during adolescence or young adulthood, it causes infectious mononucleosis up to 50 percent of the time.

Escherichia coli (E. coli)—A common bacteria that is a cause of traveler's diarrhea. Certain strains of *E. coli* infect the large intestine and produce serious complications.

Fast Track—Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The status is assigned by the U.S. Food and Drug Administration. The purpose is to get important new

drugs to the patient earlier. Fast Track addresses a broad range of serious diseases. Generally, determining factors include whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially superior to existing therapy. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

gram-positive/negative bacteria—Gram's stain is a method of staining bacteria in order to identify them. Gram-positive bacteria stain violet; gram-negative bacteria stain red.

Haemophilus influenzae—A type of bacteria found in the respiratory tract that causes acute respiratory infections and meningitis in children but rarely in adults.

helicobacter infections—Caused by *Helicobacter pylori*, a bacterium that is commonly found in the stomach. It is present in approximately one-half of the world's population. The vast majority of people infected with *H. pylori* have no symptoms and will never develop problems; however, *H. pylori* is capable of causing a number of digestive problems, including ulcers, and much less commonly, stomach cancer. It is not clear why some people with *H. pylori* get these conditions and others do not.

hepatic fibrosis—Overly exuberant wound healing in which excessive connective tissue builds up in the

liver. Fibrosis itself causes no symptoms, but scarring can lead to distorted blood flow through the liver or to cirrhosis. Treatment involves correcting the underlying condition when possible.

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

herpes simplex—**Herpes simplex virus 1** causes cold sores or fever blisters on the mouth or around the eyes and can be transmitted to the genital area. **Herpes simplex 2** causes painful sores of the anus or genitals.

herpes varicella zoster virus (HVZ)—Also called **shingles**, consists of very painful blisters on the skin and affects areas innervated by specific nerves. It may appear in adulthood as a result of having had chicken pox (caused by the varicella virus) as a child.

human papillomavirus (HPV)—Viral agent of warts, believed to be contagious and mostly harmless, affecting only the skin's topmost layer.

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.

keratitis—An inflammation of the cornea, the transparent membrane that covers the colored part of the eye (iris) and pupil of the eye.

keratoconjunctivitis—Inflammation of the eye involving both the cornea and the conjunctiva. It can be due to diverse causes, including infection and autoimmunity.

leishmaniasis—Diseases affecting skin (cutaneous), mucous membranes and internal organs (visceral) caused by a parasite called *Leishmania*, which is transmitted from infected animals or people to new hosts by sand flies.

malaria—A serious parasitic disease, spread by the bite of the Anopheles mosquito. Malaria is characterized by severe fever and chills and complications affecting the kidneys, liver, brain and blood.

Marburg virus disease—Also called Marburg hemorrhagic fever, a rare, severe type of hemorrhagic fever that affects both humans and non-human primates. It is caused by a genetically unique animal-borne (zoonotic) RNA virus of the filovirus family. Marburg virus is indigenous to Africa, including parts of Uganda, Western Kenya, and perhaps Zimbabwe.

meningococcal infections—Caused by the bacterium *Neisseria meningitidis* (also termed meningococcus). It carries a high mortality rate if untreated. While it is best known as a cause of meningitis, it also causes widespread blood infection (**sepsis**), which is more damaging and dangerous. Meningitis and meningococcal sepsis are major causes of illness, death, and disability in both developed and underdeveloped countries worldwide.

methicillin-resistant *Staphylococcus aureus* (MRSA)—A type of bacteria that is resistant to certain antibiotics, including methicillin and other more common antibi-

otics such as oxacillin, penicillin and amoxicillin. Staph infections, including MRSA, occur most frequently among patients in hospitals and healthcare settings.

mycoses—Diseases caused by fungi.

Neisseria meningitidis—The gram-negative bacterium that causes meningococcal meningitis in humans, the only natural hosts in which it causes disease. Meningococci enter the nasal passage and may cause no symptoms (up to 30 percent of the population may harbor them between epidemics), or they may enter the bloodstream and produce the symptoms of meningitis.

noroviruses—A group of viruses that cause the “stomach flu,” or gastroenteritis. Symptoms usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people also have a low-grade fever, chills, headache, muscle aches, and tiredness. The illness often begins suddenly and lasts for one or two days.

nosocomial—Refers to infections that have been caught in a hospital.

onchocerciasis—A parasitic disease caused by the filarial worm *Onchocerca volvulus*, which is transmitted from human to human through the bites of infected black-flies of the *Simulium* species.

onychomycosis—Disease, deformity or wasting of the nails caused by fungal infection.

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 status is assigned by the U.S. Food and Drug Administration.

otitis externa—Also called “swimmer’s ear,” which is an infection of the skin covering the outer ear canal that leads in to the ear drum, usually due to bacteria.

otitis media—Inflammation of the middle ear, often caused by a pneumococcal infection.

parainfluenza viruses—Human parainfluenza viruses (HPIVs) rank second only to respiratory syncytial virus (RSV) as a common cause of lower respiratory tract disease in young children. HPIVs can cause repeated infections throughout life, which are usually manifested by an upper respiratory tract illness (such as a cold or sore throat). HPIVs can also cause serious lower respiratory tract disease with repeat infection (including pneumonia, bronchitis, and bronchiolitis), especially among the elderly and patients with compromised immune systems. There are four serotypes of HPIV (1 through 4). Each of the four HPIVs has different clinical and epidemiologic features.

parvovirus infection—Also called “fifth disease,” which is caused by infection with human parvovirus B19. The virus infects only humans, resulting in a mild rash illness that occurs most commonly in children. The ill child typically has a “slapped-cheek” rash on the face and a lacy red rash on the trunk and limbs. Occasionally, the rash may itch, but it usually resolves in 7 to 10 days.

pediculosis—Infestation with lice, which are ectoparasites that live on the body. The three types of lice that infest humans are: *Pediculus humanus capitis* (head louse), *Pediculus humanus corporis* (body louse), and *Phthirus pubis* (pubic louse). The lice are spread from person to person by close physical contact or through objects such as combs and clothes. The body louse is the vector of typhus, trench fever, and relapsing fever.

pertussis—Also called “whooping cough,” a communicable, potentially deadly bacterial illness characterized by fits of coughing followed by a noisy, “whooping” indrawn breath. The illness is most likely to affect young children, but sometimes appears in teenagers and adults, even those who have been previously immunized. Immunization with DPT (diphtheria-pertussis-tetanus) vaccine provides protection, although that immunity may wear off with age. When teenagers and adults get pertussis, it appears first as coughing spasms, and then a stubborn dry cough lasting up to eight weeks.

pharyngitis—Acute inflammation of the pharynx, the part of the throat between the tonsils and the larynx. The chief symptom is a sore throat.

Phase 0—First-in-human trials conducted in accordance with FDA’s 2006 guidance on exploratory Investigational New Drug (IND) studies designed to speed up development of promising drugs by establishing very early on whether the agent behaves in human subjects as was anticipated from pre-clinical studies.

Phase I—Safety testing and pharmacological profiling in humans.

Phase II—Effectiveness testing and identification of side effects in humans.

Phase III—Extensive clinical trials in humans to verify effectiveness and monitor adverse reactions.

pneumococcal infections—Caused by *Streptococcus pneumoniae*, or **pneumococcus**, a gram-positive human pathogenic bacterium. The organism causes many types of pneumococcal infections, including pneumonia, otitis media, meningitis, sepsis, endocarditis, and brain abscess. *S. pneumoniae* is the most common cause of bacterial menin-

gitis in adults and children and one of the top two isolates found in ear infection (otitis media.). Pneumococcal pneumonia is more common in the very young and the very old.

pseudomonal infections—

Infections due to *Pseudomonas aeruginosa*, a Gram-negative bacterium common in soil and water. *Pseudomonas aeruginosa* is an opportunistic pathogen, meaning that it exploits some break in the host's defenses to initiate an infection. It causes urinary tract infections, respiratory system infections, dermatitis, soft tissue infections, bacteremia, bone and joint infections, gastrointestinal infections and a variety of systemic infections, particularly in patients with severe burns and in cancer and AIDS patients who are immunosuppressed.

pyelonephritis—An inflammation of the kidney and upper urinary tract that usually results from non-contagious bacterial infection of the bladder (cystitis).

respiratory syncytial virus (RSV)—One of the most important causes of lower respiratory tract disease in children. In severe cases, cyanosis (bluish discoloration of skin and mucous membranes due to deficient oxygenation of the blood) can result.

rhinitis—Inflammation of the nasal mucous membrane.

rhinovirus—A genus of viruses that infect the upper respiratory tract and cause the common cold.

rotavirus—A group of viruses that are wheel-like in appearance and are a major source of infant diarrhea throughout the world.

sepsis—The presence of bacteria and/or their toxins in the blood or tissues.

septic shock—Blood poisoning in which there is a sudden drop in blood pressure and an increased heart rate and temperature.

Shigella—A family of bacteria that can cause diarrhea in humans. There are several different kinds of *Shigella* bacteria. One type found in the developing world, *Shigella dysenteriae* type 1, causes deadly epidemics there. *Shigella* causes shigellosis, an infectious disease characterized by (often bloody) diarrhea, fever, and stomach cramps.

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

streptococcal infections—There are two types of "strep" infections—group A and group B—both of which are treated by antibiotics. Group A strep causes strep throat, scarlet fever, impetigo, toxic shock syndrome, cellulites, and necrotizing fasciitis (flesh-eating disease). Group B can cause blood infections, pneumonia, and meningitis in newborns. Adults can also get group B strep infections, especially if they are elderly or already have health problems. Strep B can cause urinary tract infections, blood infections, skin infections, and pneumonia in adults.

tetanus—Also known as lockjaw, tetanus is a serious but preventable disease that affects the body's muscles and nerves. It typically arises from a skin wound that becomes contaminated by a bacterium, which is often found in soil. Once the bacteria are in the body, they produce a neurotoxin (a protein that acts as a poison to the body's nervous system) that causes muscle spasms. The toxin can travel through-

out the body via the bloodstream and lymph system. As it circulates more widely, the toxin interferes with the normal activity of nerves throughout the body, leading to generalized muscle spasms. Without treatment, tetanus can be fatal. Tetanus is rare in the United States and other nations with tetanus vaccination programs; however, the disease is much more common in many developing countries.

tinea pedis—Also called "athlete's foot," a skin infection caused by a fungus.

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.

tularemia—Also called "rabbit fever" or "deerfly fever," caused by the bacterium *Francisella tularensis* found in animals (especially rodents, rabbits, and hares). It is a potentially serious illness that can be fatal if not treated with the right antibiotics.

vaginosis, bacterial—An overgrowth of the bacteria *Gardnerella* and others, often associated with increased malodorous discharge without obvious vulvitis or vaginitis (inflammation and infection of the vulva and vagina).

Yersinia—Three Gram-negative bacilli *Yersinia* species cause infection in humans: *Y. enterocolitica* causes gastroenteritis; *Y. pseudotuberculosis* causes mesenteric lymphadenitis; and *Y. pestis* causes plague.

SELECTED FACTS ABOUT INFECTIOUS DISEASES

Overview

- Diseases caused by **bacteria**, **viruses**, **fungi** and other **parasites** are major causes of death, disability, and social and economic disruption for millions of people. More than 9.5 million people die each year due to infectious diseases—nearly all live in developing countries. Children are particularly vulnerable to infectious diseases.

Pneumonia, **diarrhea** and **malaria** are leading causes of death among children under age 5.¹ Three infectious diseases alone—**malaria**, **tuberculosis**, and **AIDS**—account for about 1 out of every 13 deaths, mostly among children and young adults.²

Bacterial Infections

- According to the U.S. Centers for Disease Control and Prevention, the ***Clostridium difficile*** bacterium was responsible for 165,000 hospital-acquired infections in 2007. *C. difficile* hospital-acquired infections cause some 9,000 deaths annually, resulting in \$1.3 billion in excess costs. In nursing home-onset cases, *C. difficile* caused 263,000 infections in 2007. *C. difficile* nursing home-onset cases result in 16,500 deaths annually and \$2.2 billion in excess costs.³
- **Nosocomial** (hospital-acquired) infections are a major challenge to patient safety. In 2002, an estimated 1.7 million hospital-acquired infections occurred (4.5 per 100 admissions). In 2002, almost 99,000 deaths resulted from or were associated with a hospital-acquired infection, making such infections the sixth leading cause of death in the United States. Approximately one-third or more of nosocomial infections are preventable. Their estimated costs to the U.S. health care budget are \$5 billion to \$10 billion annually.⁴
- **Sepsis** is the 10th leading cause of death in the United States and one of only two infectious conditions listed in the leading 15 causes of death. Sepsis incidence and mortality have increased over the course of several decades. From 1999 to 2005, nearly 17 million people died in the United States. Of that number, more than 1 million deaths were associated with sepsis (6 percent of all deaths).⁵ Severe sepsis accounts for an estimated 40 percent of all intensive care unit (ICU) expenditures, totaling \$16.7 billion in the United States. The average length of stay and cost per case is 19.6 days and \$22,100, respectively. The cost of treating an ICU patient with sepsis is six times greater than that of treating a patient without sepsis.⁶
- Hospitalizations caused by the ***Staphylococcus aureus*** bacteria are on the rise in the United States, increasing 62 percent between 1999 and 2005. During the same period, **methicillin-resistant *Staphylococcus aureus***, or **MRSA**, accounted for a 119 percent jump in hospitalizations, growing from 127,036 to 278,203, according to the U.S. Centers for Disease Control. The estimated number of hospitalizations involving *S. aureus*-related infections also increased remarkably from 294,570 to 477,927 during the same period.⁷
- In 2006, the U.S. Centers for Disease Control and Prevention (CDC) reported 13,799 cases of active **tuberculosis (TB)**. While the overall rate of new TB cases continues to decline in the United States (since national reporting began in 1953), the annual decrease in TB cases has slowed from an average of 7.1 percent (1993–2000) to the current average of 3.8 percent (2001–2005). In addition to those with active TB, an estimated 10 million to 15 million people in the United States have latent TB.²
- According to the World Health Organization (WHO), studies show that each **tuberculosis (TB)** patient loses, on average, 3–4 months of work time annually due to the disease. Those lost earnings amount to 20 percent–30 percent of household income. Families of people who die from the disease lose approximately 15 years of income. The global burden of TB in economic terms can therefore be easily calculated: given 8.4 million patients yearly, according to the most recent WHO estimates, the majority of whom are potential wage-earners, and assuming a 30 percent decline in average productivity, the toll amounts to approximately \$1 billion each year. Annual deaths are estimated at 2 million and, with an average loss of 15 years of income per death, there is an additional deficit of \$11 billion.⁸

SELECTED FACTS ABOUT INFECTIOUS DISEASES

Fungal Infections

- In 2003, 10,400 **aspergillosis** cases were discharged from U.S. hospitals, resulting in an incidence rate of 36 per 1 million population annually. The median length of stay for an aspergillosis patient was 10 days, and the median total hospital charge was \$44,845.⁹

Malaria

- In 2008, there were 247 million cases of **malaria** and nearly 1 million deaths—mostly among children living in Africa, where a child dies every 45 seconds of malaria, which accounts for 20 percent of all childhood deaths. Malaria causes significant economic losses and can decrease gross domestic product (GDP) by as much as 1.3 percent in countries with high levels of transmission.¹⁰

Viral Infections

- In 2007, an estimated 43,000 new **acute hepatitis B virus (HBV)** infections occurred in the United States; however, the official number of reported hepatitis B cases is much lower because many people don't know they are infected. The rates of acute hepatitis B have declined by approximately 82 percent since 1990, when the routine vaccination of children for the disease was implemented. An estimated 800,000 to 1.4 million people in the United States have **chronic hepatitis B** virus infection. Worldwide, chronic hepatitis B affects some 350 million people and contributes to an estimated 620,000 deaths each year.³ The lifetime health care costs for a patient with chronic hepatitis B have been estimated at \$65,000 in the absence of a liver transplantation. For the 150,000 HBV carriers with significant liver damage, the lifetime health care costs in the United States have been estimated to be \$9 billion. Assuming an estimated survival of 25 years, the annual health care costs for the affected U.S. population with chronic hepatitis B is \$360 million.¹¹
- In 2007, an estimated 17,000 new **hepatitis C virus (HCV)** infections occurred in the United States; however, the official number of reported HCV cases is much lower because many people who are infected never have symptoms and never come to the attention of medical or public health officials. An estimated 3.2 million people have chronic HCV infection, yet most people do not know they are infected because they do not look or feel sick. Up to 85% of people who become infected with HCV develop chronic infection.³ Worldwide, an estimated 180 million people have chronic hepatitis C.² Hepatitis C is responsible for about one-third of all liver transplants in the United States. Approximately 1,000 patients are transplanted each year due to hepatitis C. With the cost per liver transplantation in the range of \$280,000 for one year, liver transplantation for HCV alone totals nearly \$300 million per year. Without having a liver transplant, the average lifetime cost for chronic HCV has been estimated to be about \$100,000 for individual patients. Assuming an estimated survival of 40 years, the annual health care costs for the affected U.S. population with chronic hepatitis C may be as high as \$9 billion.¹¹
- Approximately 30 million Americans have the herpes virus, and between 500,000 to 1 million new cases of herpes occur each year.¹² An estimated one in five adults have **genital herpes**, and 50 percent to 80 percent have **oral herpes** (cold sores).¹³ The average number of genital herpes outbreaks is four to five a year. Genital herpes is more common in women (approximately 1 out of 4 women) than in men (almost 1 out of 5). Genital herpes is the most prevalent viral sexually transmitted disease. Studies have shown that the vast majority (up to 90 percent) of people who have genital herpes have not been diagnosed with the condition. Every 30 seconds, another person gets genital herpes. The number of cases of genital herpes has gone up by more than 30 percent in the last decade. If the number of people infected with genital herpes continues to grow at the present rate, it is predicted that in time nearly half the U.S. adult population will have genital herpes.¹²
- For all its familiarity, **influenza** is a serious virus. It sickens 5 percent to 15 percent of the U.S. population and hospitalizes up to 250,000 people each year. Some 30,000 to 40,000 people die after becoming infected. Influenza costs the economy more than \$10 billion a year in an average season.² The estimated economic impact of pandemic influenza would cost this country \$71.3 billion to \$166.5 billion, *excluding* disruptions to commerce and society.¹⁴

SELECTED FACTS ABOUT INFECTIOUS DISEASES

Viral Infections (continued)

- **Respiratory syncytial virus (RSV)** is the single most important cause of severe respiratory illness in infants and young children. In the United States alone, between 85,000 to 144,000 infants with RSV infection are hospitalized annually, resulting in 20 percent to 25 percent of pneumonia cases and up to 70 percent of bronchiolitis cases in the hospital. Global RSV disease burden is estimated at 64 million cases and 160,000 deaths every year. RSV is also a significant problem in the elderly, in persons with cardiopulmonary diseases, and in immunocompromised individuals. RSV attack rates in nursing homes in the United States are approximately 5 percent to 10 percent per year with a 2 percent to 8 percent case fatality rate, amounting to some 10,000 deaths per year among people older than age 64.¹⁰ In 2000, nearly 98 percent of RSV infection-related hospitalizations occurred in children younger than age 5. That year, there were approximately 86,000 hospitalizations, 1.7 million office visits, 402,000 emergency room visits, and 236,000 hospital outpatient visits for children under age 5 that were attributable to RSV infection. The total annual direct medical costs for all RSV infection-related hospitalizations (\$394 million) and other medical encounters (\$258 million) for those children were estimated to be \$652 million.⁹
- **Rotavirus**—the most common and lethal form of diarrhea—is one of the most deadly diseases that children in the developing world face. Rotavirus kills more than 500,000 children and hospitalizes millions annually. Nearly every child in the world will have at least one rotavirus infection before age 3. Each year, rotavirus is responsible for 114 million illnesses, 24 million clinic visits, and 2.4 million hospitalizations. Some 70 deaths each year are attributed to rotavirus in industrialized nations, while nearly 1,400 children die from rotavirus each day in the developing world. In the United States, rotavirus vaccination has led to dramatic drops in severe rotavirus-related hospitalizations and has reduced emergency room visits by as much as 80 percent. Rotavirus vaccines stand to make the greatest impact in high-burden regions in Africa and Asia, where more than 85 percent of rotavirus deaths occur. If **rotavirus vaccines** were used in the world's poorest countries, they would have the potential to prevent the deaths of approximately 225,000 children each year and more than 2.5 million children between 2007 and 2025. Historically, it can be as long as 10 to 15 years from the time a vaccine is licensed for use in industrialized nations to the time it reaches developing nations.¹⁰
- The impact of **severe acute respiratory syndrome (SARS)** in 2002 and 2003 was striking. SARS—a novel virus that causes acute respiratory disorder—is believed to have emerged in China where it is assumed to have made a zoonotic leap (moving from an animal to humans). Within months, the disease spread around the world, from Asia to North and South America and Europe. Before it was finally contained, SARS infected 8,098 people, nearly 800 of whom died. But many more people around the world felt the deep financial impact of SARS, which measurably lowered the gross domestic product of Asian countries and Canada. The total worldwide impact of \$50 billion in losses was largely from industries such as tourism, retail, and trade, as people cancelled trips and business deals due to the fear and uncertainty about how the new disease was being spread.¹⁴

Sources:

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

THE DRUG DEVELOPMENT AND APPROVAL PROCESS

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

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

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

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

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

Investigational New Drug Application (IND). After completing preclinical testing, a company files an IND with the U.S. Food and Drug Administration (FDA) to begin to test the drug in people. The IND 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 usually 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 and determine the early side effect profile.

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 25 new therapeutics approved by the FDA in 2009 was 13.3 months.

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

Discovering and developing safe and effective new medicines is a long, difficult, and expensive process. Pharmaceutical companies invested an estimated \$65.3 billion in research and development in 2009.

TRACKING THE PHARMACEUTICAL AND BIOTECHNOLOGY RESEARCH PIPELINES

Today, more than 2,900 new medicines are in development in the United States. Many of these potential new medicines will fail in clinical trials, but some may represent tomorrow's new treatments. Bringing each new medicine to patients will require, on average, 10 to 15 years of testing and review.

PhRMA publishes several reports that track the pharmaceutical and biotechnology research pipelines for many diseases, including the leading causes of death among Americans—heart disease, cancer, and stroke. The reports include medicines currently in clinical trials or at the U.S. Food and Drug Administration (FDA) for review. Below is a summary of our most popular reports.

- **Cancer**—There are few things that cause patients more fear and uncertainty as a cancer diagnosis. Yet today—because of a steady stream of new and improved medicines and treatments—cancer can increasingly be managed and even beaten. *The 2009 report found 861 medicines in the pipeline.*
- **Heart Disease and Stroke**—Keeping up the momentum of drug discovery that has helped cut deaths from heart disease and stroke in half in the past three decades, biopharmaceutical companies are working on new medicines for these diseases. *The 2009 report found 312 medicines in the pipeline.*
- **Diabetes**—Approximately 4,110 people are diagnosed with diabetes every day. To help fight this disease, pharmaceutical and biotechnology researchers are working on new medicines to treat it and related conditions. *The 2010 report found 235 medicines in the pipeline.*
- **Mental Illnesses**—Pharmaceutical and biotechnology researchers are testing many new medicines to help the more than 450 million people worldwide who suffer from some form of mental illness. *The 2010 report found 313 medicines in the pipeline.*
- **Biotechnology**—Millions of people have already benefited from medicines and vaccines developed through biotechnology, and a new report offers hope that many more will benefit in the future. *The 2008 report found 633 medicines in the pipeline.*
- **Children**—Biopharmaceutical researchers are testing medicines to meet the special needs of children. These medicines offer hope that the significant improvements achieved in children's health over the past few decades will continue and even accelerate. *The 2010 report found 234 medicines in clinical trials.*
- **Older Americans**—The population of Americans over 65 is surging, and the pace will only increase over the coming years. As life expectancy continues to expand, older Americans face new and growing challenges to their health, productivity and independence. *The 2008 report found 1,026 medicines in the pipeline.*



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950 F Street, NW
Washington, DC 20004