

Medicines in Development – Infectious Diseases

Bacterial Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
514G3 (True Human™ mAb)	XBiotech Austin, TX	<i>Staphylococcus aureus</i> infections (Fast Track)	Phase II www.xbiotech.com
AB569 (acidified nitrite) ORPHAN DRUG	Arch Biopartners Toronto, Canada	multidrug-resistant bacterial infections	Phase I www.archbiopartners.com
ABV3	Hennepin Life Sciences Plymouth, MN	bacterial vaginosis	Phase II www.hennepinlifesciences.com
AeroVanc inhaled vancomycin ORPHAN DRUG	Savara Pharmaceuticals Austin, TX	methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) infections in cystic fibrosis (Fast Track)	Phase III www.savarapharma.com
afabacin (DEBIO 1450) (FabI inhibitor)	Debiopharm Lausanne, Switzerland	acute bacterial skin and skin structure infections (ABSSSI) (Fast Track), bone and joint infections (Fast Track)	Phase II www.debiopharm.com
AOB101 (topically applied ammonia oxidizing bacteria-based therapeutic)	AOBiome Cambridge, MA	acne vulgaris	Phase II www.aobiome.com

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AR-101 mAb (lipopolysaccharide inhibitor)	Aridis Pharmaceuticals San Jose, CA	nosocomial pneumonia caused by <i>Pseudomonas aeruginosa</i> (Fast Track)	Phase II www.aridispharma.com
AR-301 mAb (bacterial toxin inhibitor) ORPHAN DRUG	Aridis Pharmaceuticals San Jose, CA	hospital-acquired pneumonia and ventilator-associated pneumonia due to <i>Staphylococcus aureus</i> (Fast Track)	Phase III www.aridispharma.com
AR-501 (gallium citrate inhaled) ORPHAN DRUG	Aridis Pharmaceuticals San Jose, CA	cystic fibrosis-associated respiratory tract infections (Fast Track)	Phase I/II www.aridispharma.com
Arikayce [®] amikacin liposome inhalation suspension	Insmed Bridgewater, NJ	nontuberculous mycobacterium infections caused by <i>m. avium</i> (1L, maintenance treatment), nontuberculous mycobacterium infections caused by <i>m. abscessus</i>	Phase II www.insmed.com
ART24 (direct-acting live biotherapeutic)	Artugen Therapeutics Concord, MA	prevention of recurrence of <i>Clostridium difficile</i> infections (Fast Track)	Phase I www.artugentherapeutics.com
ARV-1801 (protein synthesis inhibitor) ORPHAN DRUG	Arrevus Raleigh, NC	cystic fibrosis-associated respiratory tract infections	Phase II www.arrevus.com

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ASP3772 (conjugate pneumococcal vaccine)	Affinivax Cambridge, MA Astellas Pharma US Northbrook, IL	pneumococcal infections	Phase II www.affinivax.com www.astellas.com
AV0328 (PNAG-expressing pathogenic microbes vaccine)	Alopexx Vaccine Concord, MA	bacterial infections (prevention and treatment)	Phase I/II www.alopexx.com
AV7909 (anthrax vaccine)	Emergent BioSolutions Gaithersburg, MD	anthrax (Fast Track)	Phase III www.emergentbiosolutions.com
Avycaz® ceftazidime and avibactam	Allergan Madison, NJ Pfizer New York, NY	gram-negative bacterial infections (neonates and infants)	Phase II www.allergan.com www.pfizer.com
		nosocomial pneumonia (3 months to 17 years)	Phase I www.allergan.com www.pfizer.com
aztreonam-avibactam (PF-06947387) (beta lactam/beta lactamase inhibitor)	Pfizer New York, NY	gram-negative bacterial infections for which there are limited or no treatment options	Phase III www.pfizer.com
Bexsero meningococcal group B vaccine	GlaxoSmithKline Research Triangle Park, NC	meningococcal B disease (prevention) (infants) (+13-valent pneumococcal vaccine)	Phase III www.gsk.com

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BOS-228 (novel monobactam)	Boston Pharmaceuticals Cambridge, MA	bacterial infections (Fast Track)	Phase II www.bostonpharmaceuticals.com
BPX-01 (minocycline topical gel)	Timber Pharmaceuticals Woodcliff Lake, NJ	acne vulgaris	Phase II www.timberpharma.com
BPZE1 (live attenuated pertussis vaccine)	ILiAD Biotechnologies Weston, FL	pertussis (prevention)	Phase II www.iliadbio.com
brilacidin (defensin biomimetic)	Innovation Pharmaceuticals Wakefield, MA	ABSSSI	Phase II www.ipharminc.com
BTX1503 (synthetic cannabidiol)	Botanix Pharmaceuticals King of Prussia, PA	moderate to severe acne	Phase II www.botanixpharma.com
BW-1010 (intranasal nanoemulsion-based mucosal vaccine)	BlueWillow Biologics Ann Arbor, MI	anthrax (prevention)	Phase I www.bluewillow.com
Cayston® aztreonam for inhalation	Gilead Sciences Foster City, CA	<i>Pseudomonas aeruginosa</i> infections in cystic fibrosis patients (3 months and older)	Phase III www.gilead.com
cefepime/enmetazobactam (cell wall inhibitor/beta lactamase inhibitor FDC)	Allegra Therapeutics Saint-Louis, France	urinary tract infections	Phase III www.allegra.com

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cefepime/taniborbactam (cell wall inhibitor/beta lactamase inhibitor FDC)	VenatoRx Pharmaceuticals Malvern, PA	urinary tract infections (Fast Track)	Phase III www.venatorx.com
ceftibuten/VNRX-7145 (beta lactamase inhibitor/cell wall inhibitor FDC)	VenatoRx Pharmaceuticals Malvern, PA	bacterial infections	Phase I www.venatorx.com
ceftobiprole medocaril (intravenous antibiotic)	Basilea Pharmaceutica Basel, Switzerland	ABSSSI, <i>Staphylococcus aureus</i> blood-stream bacterial infections (bacteremia)	Phase III www.basilea.com
		bacterial infections (up to 3 months)	Phase I www.basilea.com
ceftriaxone controlled release	scPharmaceuticals Burlington, MA	bacterial infections	Phase II/III completed www.scpharmaceuticals.com
clofazimine (LAM320) (mycobacterial DNA binder)	Novartis East Hanover, NJ	multidrug-resistant tuberculosis	Phase III www.novartis.com
Contepo™ fosfomicin intravenous	Nabriva Therapeutics King of Prussia, PA	complicated urinary tract infections (Fast Track)	application submitted www.nabriva.com
		complicated urinary tract infections (pediatric)	Phase I www.nabriva.com

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contezolid (MRX-1) (protein synthesis inhibitor)	MicRx Pharmaceuticals Foster City, CA	complicated skin and skin structure infection (cSSSI) bacterial infections, including MRSA and vancomycin-resistant enterococcus (VRE) (Fast Track)	Phase II www.micrxchina.com
contezolid acefosamil (MRX-4) (protein synthesis inhibitor)	MicRx Pharmaceuticals Foster City, CA	gram-positive bacterial infections, including MRSA and VRE (Fast Track)	Phase II www.micrxchina.com
CP101 (gastrointestinal microbiome modulator)	Finch Therapeutics Somerville, MA	recurrent <i>Clostridium difficile</i> infections (Fast Track)	Phase II www.finchtherapeutics.com
Dalvance [®] dalbavancin	Allergan Madison, NJ	ABSSSI (pediatric)	Phase III www.allergan.com
DARE-BV1 (clindamycin gel)	Dare Bioscience San Diego, CA	bacterial vaginosis (Fast Track)	Phase III www.darebioscience.com
Deltayba delamanid	Otsuka America Pharmaceutical Rockville, MD	multidrug-resistant tuberculosis	Phase III www.otsuka.com
DNV3837 (DNA topoisomerase inhibitor)	Deinove Grabels, France	<i>Clostridium difficile</i> infections	Phase II www.deinove.com
D-PLEX ₁₀₀ (doxycycline hyclate CR)	PolyPid Summit, NJ	surgical site infections (prevention) (Fast Track)	Phase III www.polypid.com

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DSTA4637S (RG7861) (anti-S. aureus THIOMAB™ antibiotic conjugate)	Genentech South San Francisco, CA	<i>Staphylococcus aureus</i> infections	Phase I www.gene.com
enmetazobactam (AAI101) (beta lactamase inhibitor)	Allegra Therapeutics Rhein, Germany	gram-negative bacterial infections	Phase I www.allegra.com
ETX0282CPDP (class A/C beta-lactamase broad spectrum inhibitor)	Entasis Therapeutics Waltham, MA	complicated urinary tract infections	Phase I www.entasistx.com
ETX2514SUL (sulbactam durlobactam)	Entasis Therapeutics Waltham, MA	multidrug-resistant Acinetobacter infections (Fast Track)	Phase III www.entasistx.com
EVO100 (L-lactic acid, citric acid, potassium bitartrate)	Evoform Biosciences San Diego, CA	chlamydial infections (Fast Track), gonorrhea	Phase II/III www.evofem.com
exebacase (CF-301) (cell wall inhibitor)	ContraFect Yonkers, NY	bacteremia, including endocarditis (Fast Track)	Phase III www.contrafect.com
		prothetic joint infections	Phase I www.contrafect.com
F598 (surface antigen inhibitor)	Alopexx Pharmaceuticals Concord, MA	bacterial infections	Phase II completed www.alopexx.com

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FCD105 (adapalene/minocycline)	Foamix Pharmaceuticals Bridgewater, NJ	acne vulgaris	Phase II www.foamix.com
Fetroja [®] cefiderocol	Shionogi Florham Park, NJ	hospital-acquired bacterial pneumonia and ventilator pneumonia caused by gram-negative infections	application submitted www.shionogi.com
		complicated urinary tract infections (3 months to 17 years), gram-negative bacterial infections (3 months to 12 years)	Phase II www.shionogi.com
gepotidacin (GSK2140944) (type II DNA topoisomerase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	uncomplicated urinary tract infections, gonorrhea	Phase III www.gsk.com
GSK2904545A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	active immunization to prevent <i>Clostridium difficile</i> infections and recurrences	Phase I www.gsk.com
GSK3036656 (leucyl t-RNA synthetase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	tuberculosis	Phase II www.gsk.com
GSK3536819A (recombinant protein vaccine, conjugated)	GlaxoSmithKline Research Triangle Park, NC	meningococcal A, B, C, W and Y disease (adolescents) (prevention)	Phase II www.gsk.com

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GSK3902986A (conjugated tetravalent vaccine)	GlaxoSmithKline Research Triangle Park, NC	shigella infections (prevention)	Phase II www.gsk.com
ibezapolstat (DNA polymerase III inhibitor)	Acurx Pharmaceuticals White Plains, NY	<i>Clostridium difficile</i> infections (Fast Track)	Phase II www.acurxpharma.com
IDP-120 gel (benzoyl peroxide/tretinoin)	Bausch Health Americas Bridgewater, NJ	acne vulgaris	Phase III www.bauschhealth.com
JNJ-63871860 (ExPEC4V) (multivalent vaccine)	Janssen Raritan, NJ	Escherichia coli infections (prevention)	Phase II www.janssen.com
KB109 (microbiome modulator)	Kaleido Biosciences Lexington, MA	multidrug-resistant bacterial infections	in clinical trials www.kaleido.com
KBP-7072 (protein synthesis inhibitor)	KBP Biosciences Princeton, NJ	bacterial infections (Fast Track)	Phase I www.kbpbio.com
LACTIN-V (vaginal microbiome modulator)	Osel Mountain View, CA	recurrent bacterial vaginosis, recurrent urinary tract infections (prevention)	Phase II/III www.oselinc.com
LBP-EC01 (CRISPR Cas3-enhanced bacteriophage therapy)	Locus Biosciences Morrisville, NC	urinary tract infections caused by <i>Escherichia coli</i>	Phase I www.locus-bio.com

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ME1100 (arbekacin inhalation)	Meiji Seika Pharma Tokyo, Japan	nosocomial pneumonia (Fast Track)	Phase I www.meiji.com
MenQuadri™ menACYW conjugate vaccine	Sanofi Bridgewater, NJ	meningococcal infections (6 weeks and older) (prevention)	Phase III www.sanofi.com
Menveo™ Liquid meningococcal (groups A,C,Y and W-135) oligosaccharide diphtheria CRM-197 conjugate vaccine (conjugated liquid formulation)	GlaxoSmithKline Research Triangle Park, NC	meningococcal A, C, W and Y disease (adolescents) (prevention)	Phase II www.gsk.com
MGB-BP-3 (genetic transcription inhibitor)	MGB Biopharma Bellshill, United Kingdom	<i>Clostridium difficile</i> infections (Fast Track)	Phase II www.mgb-biopharma.com
Mino-Lok® disodium edetate/ethyl alcohol/ minocycline	Citius Pharmaceuticals Cranford, NJ	catheter infections (Fast Track)	Phase III www.citiuspharma.com
molgramostim inhalation (GM-CSF agonist)	Savara Pharmaceuticals Austin, TX	nontuberculous mycobacterium infections	Phase II www.savarapharma.com
NasoShield™ anthrax intranasal vaccine	Altimune Gaithersburg, MD	anthrax (prevention)	Phase I www.altimmune.com

Bacterial Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
NDV-3A (alum-adjuvanted recombinant protein vaccine)	NovaDigm Therapeutics Grand Forks, ND	staphylococcal infections (prevention)	Phase II completed www.novadigm.net
nemonoxacin (DNA topoisomerase inhibitor)	Taigen Biotechnology Taipei City, Taiwan	diabetic foot infections	Phase II completed www.taigenbiotech.com
Neutrolin® citrate/heparin/taurolidine	CorMedix Berkeley Heights, NJ	catheter infections (Fast Track)	application submitted www.cormedix.com
Next Gen PCV (pneumococcal conjugate vaccine)	Sanofi Bridgewater, NJ	pneumococcal infections	Phase I www.sanofi.com
NM001 (oral) (glutathione synthase stimulant) ORPHAN DRUG	NovaBiotics Aberdeen, United Kingdom	cystic fibrosis-associated respiratory tract infections (Fast Track)	Phase II completed www.novabiotics.co.uk
Nuzyra® omadacycline	Paratek Pharmaceuticals Boston, MA	pulmonary anthrax	application submitted www.paratekpharma.com
		community-acquired bacterial pneumonia (oral-only dosing regimen)	Phase I www.paratekpharma.com
OMNivance™ beta-lactamase inhibitor IV	Qpex Biopharma San Diego, CA	drug-resistant gram-negative bacterial infections	Phase I www.qpxbio.com

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OP0201 (drug-device combination)	Novus Therapeutics Irvine, CA	acute otitis media	Phase II www.novustherapeutics.com
		chronic otitis media with effusion	Phase I www.novustherapeutics.com
OPC-167832 (DPrE1 inhibitor)	Otsuka America Pharmaceutical Rockville, MD	tuberculosis	Phase I/II www.otsuka.com
ORAvance™ beta lactamase inhibitor oral	Qpex Biopharma San Diego, CA	drug-resistant gram-negative bacterial infections	Phase I www.qpexbio.com
Orbactiv® oritavancin	Melinta Therapeutics New York, NY	ABSSSI (new formulation-reduced infusion time)	Phase II www.melinta.com
		gram-positive bacterial infections (up to 18 years)	Phase I www.melinta.com
PF-06425090 (prophylactic vaccine)	Pfizer New York, NY	<i>Clostridium difficile</i> infections (prevention) (Fast Track)	Phase III www.pfizer.com
PF-06482077 (20-valent pneumococcal conjugate vaccine)	Pfizer New York, NY	invasive and non-invasive pneumococcal infections (adults) (prevention) (Fast Track) (Breakthrough Therapy), pneumococcal infections (infants)	Phase III www.pfizer.com

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<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
PF-06760805 (multivalent vaccine)	Pfizer New York, NY	invasive group B streptococcus infections (prevention of maternal transmission)	Phase II www.pfizer.com
PF-06842433 (prophylactic vaccine)	Pfizer New York, NY	invasive and non-invasive pneumococcal infections (pediatric) (prevention)	Phase II www.pfizer.com
PF-06886992 (pentavalent prophylactic vaccine)	Pfizer New York, NY	serogroups ABCWY meningococcal infections (prevention)	Phase III www.pfizer.com
plasma gelsolin (protein replacement)	BioAegis Therapeutics Morristown, NJ	community-acquired pneumonia	Phase I/II www.bioaegistherapeutics.com
PLG-0206 (cationic antibiotic peptide)	Peptilogics Pittsburgh, PA	bacterial infections	Phase I www.peptilogics.com
polyvalent pneumococcal conjugate vaccine (pPCV)	Merck Kenilworth, NJ	pneumococcal infections (adults) (prevention)	Phase I/II www.merck.com
pravibismane (MBN-101) (microbial bioenergetic inhibitor)	Microbion Bozeman, MT	bacterial infections in diabetic foot ulcers (Fast Track), bacterial infections at fracture site following osteosynthesis procedures (Fast Track)	Phase II www.microbiocorp.com

Bacterial Infections

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RBX2660 (gastrointestinal microbiome modulator) ORPHAN DRUG	Rebiotix Roseville, MN	recurrent <i>Clostridium difficile</i> infections (prevention) (Fast Track)	Phase III www.rebiotix.com
		multidrug-resistant urinary tract infections, vancomycin-resistant enterococcus elimination	Phase I www.rebiotix.com
RBX7455 (gastrointestinal microbiome modulator)	Rebiotix Roseville, MN	recurrent <i>Clostridium difficile</i> infections (prevention)	Phase I www.rebiotix.com
RC-01 (novel LpxC inhibitor)	Recida Therapeutics Menlo Park, CA	gram-negative bacterial infections	Phase I
Recarbrio™ cilastatin/imipenem/relebactam	Merck Kenilworth, NJ	gram-negative bacterial infections (up to 17 years)	Phase II/III www.merck.com
reltecimod (CD28 antigen modulator) ORPHAN DRUG	Atox Bio Durham, NC	necrotizing soft tissue infections (Fast Track)	Phase III www.atoxbio.com
RHB-204 (clarithromycin/clofazimine/rifabutin)	RedHill Biopharma Raleigh, NC	nontuberculous mycobacterial infections	Phase II www.redhillbio.com

Bacterial Infections

Drug Name

Organization

Indication

Development Phase

ridinilazole (SMT-1969)
(cell division inhibitor)

Summit Therapeutics
Cambridge, MA

Clostridium difficile infections
(Fast Track)

Phase III
www.summitplc.com

S6G5T
(microencapsulated benzoyl peroxide
and microencapsulated tretinoin)

Sol-Gel Technologies
Ness Ziona, Israel

acne vulgaris

Phase III
www.sol-gel.com

SER-109
(microbiome therapeutic)
ORPHAN DRUG

Seres Therapeutics
Cambridge, MA

recurrent *Clostridium difficile*
infections

Phase III
www.serestherapeutics.com

Sivextro[®]
tedizolid

Merck
Kenilworth, NJ

ABSSSI (birth to 12 years)

Phase III
www.merck.com

gram-positive infections
(neonates and infants)

Phase I
www.merck.com

SP0173
(Tdap booster vaccine)

Sanofi
Bridgewater, NJ

pertussis, tetanus, diphtheria
(prevention)

Phase II
www.sanofi.com

SPR206
(cell wall inhibitor)

Spero Therapeutics
Cambridge, MA

multidrug-resistant gram-negative
bacterial infections

Phase I
www.sperotherapeutics.com

SPR720
(DNA gyrase inhibitor)
ORPHAN DRUG

Spero Therapeutics
Cambridge, MA

nontuberculous mycobacterial
infections

Phase I
www.sperotherapeutics.com

Bacterial Infections

Drug Name

Organization

Indication

Development Phase

sulopenem (intravenous)
(cell wall inhibitor)

Iterum Therapeutics
Chicago, IL

complicated urinary tract infections
(Fast Track), complicated intra-
abdominal infections (Fast Track)

Phase III
www.iterumtx.com

sulopenem etzadroxil (oral)
(cell wall inhibitor)

Iterum Therapeutics
Chicago, IL

complicated urinary tract infections
(Fast Track), uncomplicated urinary
tract infections (Fast Track),
complicated intra-abdominal infections
(Fast Track)

Phase III
www.iterumtx.com

sutezolid
(30S ribosomal subunit inhibitor)

Sequella
Rockville, MD

tuberculosis

Phase I completed
www.sequella.com

suvratoxumab
(bacterial toxin modulator)

AstraZeneca
Bridgewater, NJ

nosocomial pneumonia (prevention)
(Fast Track)

Phase II
www.astrazeneca.com

SYN-004 (ribaxamase)
(gastrointestinal microbiome
modulator)

Synthetic Biologics
Rockville, MD

Clostridium difficile infections,
pathogenic overgrowth, antimicrobial
resistance (+intravenous antibiotics)

Phase II
www.syntheticbiologics.com

tebipenem HBr
(oral beta-lactam)

Spero Therapeutics
Cambridge, MA

complicated urinary tract infections

Phase III
www.sperotherapeutics.com

Bacterial Infections

Drug Name

Organization

Indication

Development Phase

TNP-2092
(dual-acting antibacterial)
ORPHAN DRUG

TenNor Therapeutics
Suzhou, China

ABSSSI

Phase II
www.tennorrx.com

prosthetic joint infections (Fast Track)

Phase I
www.tennorrx.com

Tobrate™
tobramycin oral

Enteris BioPharma
Boonton, NJ

urinary tract infections

Phase I
www.enterisbiopharma.com

TOL-463
(bacterial growth inhibitor)

Toltec Pharmaceuticals
Chicago, IL
National Institutes of Allergy and
Infectious Diseases
Bethesda, MD

recurrent bacterial vaginosis

Phase II completed

TP-271
(fully synthetic tetracycline antibiotic)

Tetraphase Pharmaceuticals
Watertown, MA

bacterial respiratory infections
(Fast Track)

Phase I
www.tphase.com

TP-6076
(fully synthetic tetracycline antibiotic)

Tetraphase Pharmaceuticals
Watertown, MA

gram-negative bacterial infections

Phase I
www.tphase.com

TXA709
(bacterial FtsZ protein inhibitor)

TAXIS Pharmaceuticals
Monmouth Junction, NJ

MRSA infections

Phase I
www.taxispharma.com

Typhvax
typhoid fever vaccine

Matrivax
Boston, MA

typhoid (prevention)

Phase I
www.mativax.com

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UTI vaccine	Sequoia Sciences St. Louis, MO	recurrent urinary tract infections (Fast Track)	Phase I www.sequoiasciences.com
V114 (pneumoconjugate vaccine)	Merck Kenilworth, NJ	pneumococcal infections (prevention)	Phase III www.merck.com
V180 (tetravalent subunit vaccine)	Merck Kenilworth, NJ	dengue (prevention)	Phase I completed www.merck.com
Vabomere™ meropenem and vaborbactam	Melinta Therapeutics New York, NY	bacterial infections (up to 17 years)	Phase I www.melinta.com
VAC52416 (ExPEC10V) (10 valent bioconjugate vaccine)	Janssen Raritan, NJ	Escherichia coli infections (60 years to 85 years) (prevention)	Phase I/II www.janssen.com
Vaxchora cholera vaccine, live, oral	Emergent BioSolutions Gaithersburg, MD	cholera (pediatric) (prevention)	Phase III www.emergentbiosolutions.com
VB 1953 (dual inhibitor of DNA gyrase/ topoisomerase IV and MD2-TLR inhibitor)	Vyome Therapeutics Princeton, NJ	antibiotic-resistant inflammatory acne	Phase II www.vyometx.com
VE303 (gastrointestinal microbiome modulator) ORPHAN DRUG	Vedanta Biosciences Cambridge, MA	<i>Clostridium difficile</i> infections	Phase II www.vedantabio.com

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VivoGel® BV astodimer sodium	Starpharma Victoria, Australia	bacterial vaginosis (prevention) (Fast Track)	application submitted www.starpharma.com
VLA15 (multivalent vaccine)	Pfizer New York, NY Valneva Saint-Herblain, France	Lyme disease (prevention) (Fast Track)	Phase II www.valneva.com
VLA84 (anti-bacterial vaccine)	Valneva Saint-Herblain, France	<i>Clostridium difficile</i> infections (prevention)	Phase II www.valneva.com
vonoprazan (potassium-competitive acid blocker)	Phathom Pharmaceuticals Florham Park, NJ	helicobacter infections (Fast Track)	Phase III www.phathompharma.com
WCK-4282 (cefepime/tazobactam)	Wockhardt Mumbai, India	gram-negative infections	Phase I completed www.wockhardt.com
WCK-4873 (nafithromycin)	Wockhardt Mumbai, India	multidrug-resistant pneumococcal infections	Phase II completed www.wockhardt.com
WCK-5222 (cefepime/zidebactam)	Wockhardt Mumbai, India	gram-negative infections	Phase I completed www.wockhardt.com
Xenleta™ lefamulin	Nabriva Therapeutics King of Prussia, PA	ABSSSI (Fast Track)	Phase II www.nabriva.com

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Xerava™ eravacycline	Tetraphase Pharmaceuticals Watertown, MA	bacterial infections (8 years to 17 years)	Phase I www.tphase.com
XF-73 (cell membrane modulator)	Destiny Pharma Brighton, United Kingdom	staphylococcal infections (Fast Track)	Phase II www.destinypharma.com
Zempia® myeloperoxidase	Exoxemis Little Rock, AR	serious and resistant bacterial infections	Phase III www.exoxemis.com
Zerbaxa® ceftolozane/tazobactam	Merck Kenilworth, NJ	complicated urinary tract infections, complicated intra-abdominal infections (up to 17 years)	Phase II www.merck.com
		nosocomial pneumonia (up to 17 years)	Phase I www.merck.com
Zinplava® bezlotoxumab	Merck Kenilworth, NJ	<i>Clostridium difficile</i> infections (1 year to 17 years)	Phase III www.merck.com
zolidnadacin (DNA gyrase inhibitor)	Entasis Therapeutics Waltham, MA	uncomplicated gonorrhea (Fast Track)	Phase III www.entasistx.com

Fungal Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
ABV3	Hennepin Life Sciences Plymouth, MN	candidiasis	Phase II www.hennepinlifesciences.com
BB2603 (terbinafine nanoformulation)	Blueberry Therapeutics Cheshire, United Kingdom	onychomycosis of the toenail	Phase II www.blueberrytherapeutics.com
Cresemba® isavuconazonium	Astellas Pharma US Rockville, MD	invasive aspergillosis, invasive mucormycosis (1 year to 17 years)	Phase II www.astellas.com
DBI-001 (microbiome-based therapeutic)	DermBiont Boston, MA	tinea pedis	Phase II www.dermbiont.com
Eraxis® anidulafungin	Pfizer New York, NY	invasive candidiasis (1 month to 17 years)	Phase III completed www.pfizer.com
F901318 (olorofim) (dihydroorotate dehydrogenase inhibitor) ORPHAN DRUG	F2G Manchester, England	invasive fungal infections	Phase II www.f2g.com
fosmanogepix (GWT1 protein inhibitor) ORPHAN DRUG	Amplix Pharmaceuticals San Diego, CA	invasive candidiasis/candidemia (Fast Track), invasive aspergillosis	Phase II www.amplix.com
HTS-519 (terbinafine subungual)	Hallux Laguna Hills, CA	onychomycosis	Phase II completed www.halluxinc.com

Fungal Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
ibrexafungerp (glucan synthetase inhibitor) ORPHAN DRUG	Scynexis Jersey City, NJ	vulvovaginal candidiasis (Fast Track)	Phase III www.scynexis.com
		invasive aspergillosis (Fast Track)	Phase II www.scynexis.com
MAT2203 (oral enochleated amphotericin B) ORPHAN DRUG	Matinas BioPharma Bedminster, NJ	candidiasis (Fast Track)	Phase II www.matinasbiopharma.com
		cryptococcosis (Fast Track)	Phase I/II www.matinasbiopharma.com
miconazole (14-alpha demethylase inhibitor)	Hill Dermaceuticals Sanford, FL	otomycosis	Phase II www.hillderm.com
MOB-015 (terbinafine topical)	Moberg Pharma Bromma, Sweden	onychomycosis (otitis externa)	Phase III completed www.mobergpharma.com
NDV-3A (alum-adjuvanted recombinant protein vaccine)	NovaDigm Therapeutics Grand Forks, ND	candidiasis (prevention)	Phase II www.novadigm.net
Noxafil [®] posaconazole	Merck Kenilworth, NJ	invasive aspergillosis (2 years to 18 years)	Phase II www.merck.com

Fungal Infections

Drug Name

Organization

Indication

Development Phase

Pulmazole
itraconazole inhaled
ORPHAN DRUG

Pulmatrix
Lexington, MA

aspergillosis (Fast Track)

Phase II
www.pulmatrix.com

rezafungin
(glucan synthase inhibitor)
ORPHAN DRUG

Cidara Therapeutics
San Diego, CA

candidemia, invasive candidiasis
(treatment) (Fast Track)

Phase III
www.cidara.com

invasive fungal infections in blood and
bone marrow transplant patients
(prevention)

Phase II
www.cidara.com

SB208
(nitric oxide gel)

Novan
Morrisville, NC

tinea pedis

Phase II
www.novan.com

SVT-15652
(single dose vials, preservative-free
antifungal)

Salvat
Barcelona, Spain

otomycosis (fungal otitis externa)

Phase III
www.svt.om

TFF VORI
(voriconazole dry-powder inhalation)

TFF Pharmaceuticals
Austin, TX

invasive aspergillosis

Phase I
www.tffpharma.com

VT-1161
(14-alpha demethylase inhibitor)

Mycovia Pharmaceuticals
Durham, NC

recurrent vulvovaginal candidiasis
(Fast Track)

Phase III
www.mycovia.com

onychomycosis

Phase II
www.mycovia.com

Parasitic Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
ABBV-4083 (anti-wolbachia therapy)	AbbVie North Chicago, IL	filarial disease (onchocerciasis)	Phase I www.abbvie.com
emodepside (G protein-coupled receptor modulator)	Bayer Pharmaceuticals Whippany, NJ Drugs for Neglected Diseases Initiative Geneva, Switzerland	filariasis	Phase I www.pharma.bayer.com
GSK3186899 (CRK-12 inhibitor)	GlaxoSmithKline Research Triangle Park, NC	visceral leishmaniasis	Phase I www.gsk.com
KAE609 (cipargamin) (PfATP4 protein inhibitor)	Novartis East Hanover, NJ	malaria	Phase II www.novartis.com
KAF156 (ganaplacide) (imidazolopiperazines derivative)	Novartis East Hanover, NJ	malaria (+lumefantrine)	Phase II www.novartis.com
Lampit [®] nifurtimox	Bayer Pharmaceuticals Whippany, NJ	Chagas disease (pediatric)	application submitted www.pharma.bayer.com
LJPC-0118 (artesunate intravenous) ORPHAN DRUG	La Jolla Pharmaceutical San Diego, CA	malaria (Breakthrough Therapy)	application submitted www.lajollapharmaceutical.com
LXE408 (kinetoplastid proteasome inhibitor)	Novartis East Hanover, NJ	visceral leishmaniasis	Phase II www.novartis.com

Parasitic Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Natroba™ spinosad	ParaPRO Carmel, IN	scabies	Phase III www.parapro.com
PfSPZ-Cvac (infectious PfSPZ vaccine administered with malaria chemoprophylaxis)	Sanaria Rockville, MD	malaria (prevention)	Phase II www.sanaria.com
PfSPZ-GA1 (genetically attenuated PfSPZ vaccine)	Sanaria Rockville, MD	malaria (prevention) (Fast Track)	Phase I www.sanaria.com
PfSPZ vaccine (radiation attenuated PfSPZ vaccine)	Sanaria Rockville, MD	malaria (prevention)	Phase II www.sanaria.com
Solosec® secnidazole	Lupin Pharmaceuticals Baltimore, MD	trichomoniasis	Phase III www.lupin.com/us
VLPM01 (VLP vaccine)	VLP Therapeutics Gaithersburg, MD	malaria (prevention)	Phase I www.vlptherapeutics.com
VYR 006 (DHFR inhibitor)	Vyera Pharmaceuticals New York, NY	toxoplasmosis	Phase I www.vyera.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
60P002 (platelet-activating factor receptor antagonist)	60 Degrees Pharmaceuticals Washington, DC	dengue	Phase I completed www.60degreespharma.com
ABBV-181 (anti-PD1 mAb)	AbbVie North Chicago, IL	HIV infections (treatment-experienced)	Phase I www.abbvie.com
ABI-H0731 (core protein inhibitor)	Assembly Biosciences South San Francisco, CA	hepatitis B (Fast Track)	Phase II www.assemblybio.com
ABI-H2158 (viral core protein inhibitor)	Assembly Biosciences South San Francisco, CA	hepatitis B	Phase II www.assemblybio.com
ABI-H3733 (core protein allosteric modulator)	Assembly Biosciences South San Francisco, CA	hepatitis B	Phase I www.assemblybio.com
Actemra [®] tocilizumab	Roche Basel, Switzerland	COVID-19 infections with severe pneumonia	Phase III www.roche.com
ADX-1612 (chaperone protein HSP90 inhibitor)	Aldeyra Therapeutics Lexington, MA	COVID-19 infections	Phase I www.aldeyra.com
AGS-v Plus vaccine	Imutex London, United Kingdom	mosquito-borne infectious diseases	Phase I www.imutex.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
albuvirtide (maleimide modified peptide)	Frontier Biotechnologies Nanjing, China	HIV infections (+ 3BNC117)	Phase II www.frontierbiotech.com
Alinia [®] nitazoxanide	Romark Laboratories Tampa, FL	enterovirus infections, rhinovirus infections, uncomplicated influenza (pediatric)	Phase III www.romark.com
ALN-HBV02 (VIR-2218) (RNA interference)	Alnylam Pharmaceuticals Cambridge, MA Vir Biotechnology San Francisco, CA	hepatitis B	Phase I/II www.alnylam.com www.vir.bio
Alvesco ciclesonide	Covis Pharma Luxembourg	COVID-19 infections	Phase III www.covispharma.com
APH-0812 (combination therapy consisting of PKC modulators with or without HDAC inhibitors)	Aphios Woburn, MA	HIV infections (latency)	Phase I www.aphios.com
Asceniv [™] immune globulin	ADMA Biologics Ramsey, NJ	respiratory syncytial virus (RSV) infections	in clinical trials www.admabiologics.com
AT-527 (NS5B protein inhibitor)	Atea Pharmaceuticals Boston, MA	COVID-19 infections, hepatitis C	Phase II www.ateapharma.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
AT-752 (novel purine nucleotide prodrug)	Atea Pharmaceuticals Boston, MA	dengue	Phase I www.ateapharma.com
AT-777 (NS5A protein inhibitor)	Atea Pharmaceuticals Boston, MA	hepatitis C	Phase I/II www.ateapharma.com
AT-787 (NS5B/NS5A protein inhibitor)	Atea Pharmaceuticals Boston, MA	hepatitis C	Phase I www.ateapharma.com
ATI-2173 (DNA-directed RNA polymerase inhibitor)	Antios Therapeutics Atlanta, GA	hepatitis B	Phase I www.antiotherapeutics.com
AV-1 mAb (immunostimulant)	AbViro Bethesda, MD	dengue	Phase I
AZD-1222 (synthetic viral vaccine)	AstraZeneca Wilmington, DE	COVID-19 infections (prevention)	Phase II/III www.astrazeneca.com
azithromycin	Pfizer New York, NY University of Oxford Oxford, United Kingdom	COVID-19 infections	Phase III www.pfizer.com
baricitinib (JAK1/JAK2 inhibitor)	Lilly Indianapolis, IN	COVID-19 infections (hospitalized patients)	Phase III www.lilly.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Biktarvy™ bictegravir/emtricitabine/tenofovir alafenamide	Gilead Sciences Foster City, CA	HIV-1 infections (pediatric)	Phase III www.gilead.com
BLD-2660 (virus replication inhibitor)	Blade Therapeutics South San Francisco, CA	COVID-19 infections	Phase II www.blademed.com
BMS-986253 (anti-IL8 mAb)	Bristol-Myers Squibb Princeton, NJ	COVID-19 infections	Phase II www.bms.com
BPL-HRIG (human rabies immunoglobulin vaccine)	Bio Products Laboratory Durham, NC	rabies (prevention)	Phase II/III completed www.bplgroup.com
brequinar (dihydroorotate dehydrogenase inhibitor)	Clear Creek Bio Cambridge, MA	COVID-19 infections	Phase I/II www.clearcreekbio.com
brincidofovir (DNA-directed DNA polymerase inhibitor) ORPHAN DRUG	Chimerix Durham, NC	smallpox (Fast Track)	Phase III www.chimerix.com
BTL-TML (virus replication inhibitor)	Beech Tree Labs Delanson, NY	herpes labialis, herpes simplex virus (HSV) infections	Phase II www.beechtreelabs.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
bulevirtide (lipopeptide) ORPHAN DRUG	MYR Pharma Burgwedel, Germany	hepatitis D	Phase III www.myr-pharma.com
BW-1008 (intranasal vaccine)	BlueWillow Biologics Ann Arbor, MI	influenza virus infections (prevention)	Phase I www.bluewillow.com
cabotegravir LA injection (integrase strand transfer inhibitor)	ViiV Healthcare Research Triangle Park, NC	HIV infections	Phase III www.viivhealthcare.com
cabotegravir LA + rilpivirine LA (integrase strand transfer inhibitor/ non-nucleoside reverse transcriptase inhibitor)	Janssen Raritan, NJ ViiV Healthcare Research Triangle Park, NC	HIV infections	application submitted www.viivhealthcare.com
Candin® candida antigen	Nielsen BioSciences San Diego, CA	common warts (verruca vulgaris)	Phase II completed www.nielsonbio.com
CAP-1002 (allogeneic cardiosphere-derived stem cell therapy)	Capricor Therapeutics Beverly Hills, CA	severe COVID-19 infections	Phase I www.capricor.com
CC-31244 (non-nucleoside NS5B polymerase inhibitor)	Cocrystal Pharma Bothell, WA	hepatitis C infections	Phase II www.cocrystalpharma.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
CD24Fc (non-viral immunomodulator)	Oncolmune Rockville, MD	COVID-19 infections	Phase III www.oncoimmune.com
censavudine (nucleoside reverse transcriptase inhibitor)	Oncolys BioPharma Edison, NJ	HIV-1 infections	Phase II www.oncolys.com
CHIKV VLP (Chikungunya virus VLP vaccine)	Emergent BioSolutions Gaithersburg, MD	Chikungunya virus infections (prevention) (Fast Track)	Phase II www.emergentbiosolutions.com
CodaVax-H1N1 (universal intranasal influenza vaccine)	Codagenix Farmingdale, NY	influenza infections (prevention)	Phase I www.codagenix.com
combinectin (GSK3732394) (HIV entry inhibitor)	ViiV Healthcare Research Triangle Park, NC	HIV infections	Phase I www.viivhealthcare.com
COVID-EIG (Equine-derived polyclonal hyperimmune with antibodies to SARS-CoV-2)	Emergent BioSolutions Gaithersburg, MD	COVID-19 infections	Phase I www.emergentbiosolutions.com
COVID-HIG (human polyclonal hyperimmune with antibodies to SARS-CoV-2)	Emergent BioSolutions Gaithersburg, MD	COVID-19 infections	Phase I www.emergentbiosolutions.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
CRV-101 (varicella vaccine)	Curevo Vaccine Seattle, WA	shingles (herpes zoster) (prevention)	Phase I www.curevovaccine.com
CRV431 (cyclophilin inhibitor)	Hepion Pharmaceuticals Edison, NJ	hepatitis B	Phase I/II www.hepionpharma.com
CYNK-001 (allogeneic natural killer cell therapy)	Celularity Warren, NJ	COVID-19 infections	Phase I/II www.celularity.com
DAS181 (virus internalization inhibitor) ORPHAN DRUG	Ansun Biopharma San Diego, CA	parainfluenza virus infections (Fast Track) (Breakthrough Therapy), COVID-19 infections	Phase III www.ansunbiopharma.com
		influenza	Phase II www.ansunbiopharma.com
		metapneumovirus infections, enterovirus68 infections	Phase I www.ansunbiopharma.com
deltaFLU (universal intranasal influenza vaccine)	Vivaldi Biosciences Fort Collins, CO	seasonal influenza infections (prevention)	Phase II www.vivaldibiosciences.com
DermaVir HIV DNA topical vaccine	Genetic Immunity Baltimore, MD	HIV-1 infections (treatment)	Phase II www.geneticimmunity.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Descovy® emtricitabine/tenofovir alafenamide	Gilead Sciences Foster City, CA	HIV-1 infections (14kg to 25kg)	Phase II/III www.gilead.com
dolutegravir dispersible tablet	ViiV Healthcare Research Triangle Park, NC	HIV-1 infections (pediatric)	application submitted www.viivhealthcare.com
Dovato® dolutegravir and lamivudine	ViiV Healthcare Research Triangle Park, NC	HIV-1 infections in virologically suppressed adults	application submitted www.viivhealthcare.com
		HIV-1 infections (12 years to 17 years), HIV-1 infections (newly diagnosed)	Phase III www.viivhealthcare.com
DST-9256	DisperSol Technologies Georgetown, TX	viral infections	Phase I www.dispersoltech.com
Ebola GP vaccine (recombinant glycoprotein nanoparticle vaccine)	Novavax Gaithersburg, MD	Ebola virus infections (prevention)	Phase I www.novavax.com
EDP-514 (viral core protein inhibitor)	Enanta Pharmaceuticals Watertown, MA	hepatitis B (Fast Track)	Phase I www.enanta.com
EDP-938 (N-protein Inhibitor)	Enanta Pharmaceuticals Watertown, MA	RSV infections (Fast Track)	Phase II www.enanta.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
EIDD-2801 (virus replication inhibitor)	Merck Kenilworth, NJ Ridgeback Biotherapeutics Miami, FL	COVID-19 infections	Phase II www.ridgebackbio.com
elipovimab (GS-9722) (broadly neutralizing HIV-1 antibody)	Gilead Sciences Foster City, CA	HIV infections (functional cure)	Phase I www.gilead.com
favipiravir (RNA replicase inhibitor)	FujiFilm Pharmaceuticals U.S.A. Cambridge, MA	COVID-19 infections	Phase II www.fujifilmusa.com
Flucelvax Quadrivalent [®] influenza vaccine	Seqirus Holly Springs, NC	influenza virus infections (6 months to 47 months) (prevention)	Phase III www.seqirus.com
FLU-IGIV (seasonal influenza A therapeutic) vaccine)	Emergent BioSolutions Gaithersburg, MD	influenza A virus	Phase II www.emergentbiosolutions.com
FT516 (natural killer cell therapy)	Fate Therapeutics San Diego, CA University of Minnesota Minneapolis, MN	COVID-19 infections	Phase I www.fatetherapeutics.com
furaprevir (HCV NS3/NS4 protein inhibitor)	TaiGen Biotechnology Taipei City, Taiwan	hepatitis B	Phase II www.taigenbiotech.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
galidesivir (BCX-4430) (nucleoside RNA polymerase inhibitor)	BioCryst Pharmaceuticals Durham, NC	yellow fever	Phase II www.biocryst.com
		COVID-19 infections, Marburg virus disease	Phase I www.biocryst.com
GBV-006 (virus internalization/replication inhibitor)	Globavir Biosciences Los Altos, CA	COVID-19 infections	Phase II www.globavir.com
		dengue	Phase I www.globavir.com
GLS-1200 topical nasal spray	GeneOne Life Science Seoul, South Korea	COVID-19 infections (prevention)	Phase II www.inovio.com
GOVX-B01 (DNA vaccine)	GeoVax Labs Smyrna, GA	HIV infections (therapeutic)	Phase I www.geovax.com
GOVX-B11 (DNA vaccine)	GeoVax Labs Smyrna, GA	HIV infections (prevention)	Phase II www.geovax.com
GS-1156 (unboosted protease inhibitor)	Gilead Sciences Foster City, CA	HIV infections	Phase I www.gilead.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
GS-2872 (neutralizing antibody [bNAbs])	Gilead Sciences Foster City, CA	HIV infections (functional cure)	Phase II www.gilead.com
GS-4224 (PD-L1 inhibitor)	Gilead Sciences Foster City, CA	hepatitis B	Phase I www.gilead.com
GS-5423 (neutralizing antibody [bNAbs])	Gilead Sciences Foster City, CA	HIV infections (functional cure)	Phase II www.gilead.com
GS-6207 (lenacapavir) (capsid inhibitor)	Gilead Sciences Foster City, CA	HIV infections in heavily treatment- experienced patients Breakthrough Therapy	Phase II/III www.gilead.com
		HIV infections in treatment naïve patients	Phase II www.gilead.com
GSK3228836 (IONIS-HBV _{RX}) (antisense medicine)	GlaxoSmithKline Research Triangle Park, NC Ionis Pharmaceuticals Carlsbad, CA	hepatitis B	Phase II www.gsk.com www.ionispharma.com
GSK3277511A (recombinant protein vaccine)	GlaxoSmithKline Research Triangle Park, NC	reduction of exacerbations in COPD patients by targeting non-typeable Haemophilus influenzae and Moraxella catarrhalis	Phase II www.gsk.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
GSK3389245A (replication-defective recombinant viral vector vaccine)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (pediatric) (prevention)	Phase II www.gsk.com
GSK3389404 (IONIS-HBV-L _{RX}) (antisense medicine)	GlaxoSmithKline Research Triangle Park, NC Ionis Pharmaceuticals Carlsbad, CA	hepatitis B	Phase II completed www.gsk.com www.ionispharma.com
GSK3437949A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	malaria (prevention)	Phase II www.gsk.com
GSK3528869A (prime-boost vaccine)	GlaxoSmithKline Research Triangle Park, NC	hepatitis B (treatment)	Phase I/II www.gsk.com
GSK3640254 (HIV maturation inhibitor)	ViiV Healthcare Research Triangle Park, NC	HIV infections	Phase II www.viivhealthcare.com
GSK3810109 (broadly neutralizing antibody [bNab])	ViiV Healthcare Research Triangle Park, NC	HIV-1 infections	Phase I www.viivhealthcare.com
GSK3844766A (recombinant protein vaccine, adjuvanted)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (prevention) (older adults)	Phase I/II www.gsk.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
GSK3888550A (recombinant protein vaccine)	GlaxoSmithKline Research Triangle Park, NC	RSV infections (prevention)	Phase II www.gsk.com
GSK3903133A (self-amplifying mRNA vaccine)	GlaxoSmithKline Research Triangle Park, NC	rabies (prevention)	Phase I www.gsk.com
H1N1 seasonal influenza virus vaccine (monovalent)	Vaxart South San Francisco, CA	influenza A virus H1N1 infections (prevention)	Phase II www.vaxart.com
H7N9 influenza vaccine	EpiVax Providence, RI	H7N9 influenza infections (prevention)	Phase I www.epivax.com
HB-101 (bivalent vaccine)	Hookipa Biotech New York, NY	cytomegalovirus (CMV) infections (prevention)	Phase II www.hookipapharma.com
HB-AdMSC autologous (autologous adipose-derived mesenchymal stem cell therapy)	Hope Biosciences Sugar Land, TX	COVID-19 infections (prevention)	Phase II www.hope.bio
HB-AdMSC allogeneic (allogeneic adipose-derived mesenchymal stem cell therapy)	Hope Biosciences Sugar Land, TX	COVID-19 infections (prevention), COVID-19 infections (treatment)	Phase II www.hope.bio
HCVax (SIV-based HCV vaccine)	GeneCure Biotechnologies Norcross, GA	hepatitis C (treatment)	Phase I www.genecure.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Heplisav-B® adjuvanted hepatitis B vaccine (recombinant)	Dynavax Technologies Emeryville, CA	hepatitis B (prevention) in patients with end-stage renal disease under- going hemodialysis (4-dose regimen)	Phase I www.dynavax.com
HepTcell™ peptide therapeutic vaccine	Altimmune Gaithersburg, MD	hepatitis B (treatment)	Phase I www.altimmune.com
herpes simplex virus type 2 therapeutic vaccine	Immune Design (Merck) Seattle, WA Sanofi Bridgewater, NJ	HSV-2 infections (treatment)	Phase I/II www.sanofi.com
HeV-sG-V (hendra virus vaccine)	Auro Vaccines Pearl River, NY	nipah virus infections (prevention)	Phase I www.aurobindousa.com
HIVAX (HIV-1 therapeutic vaccine)	GeneCure Biotechnologies Norcross, GA	HIV-1 infections (treatment)	Phase I www.genecure.com
HTNV/PUUV DNA vaccine	Ichor Medical Systems San Diego, CA U.S. Army Medical Research and Materiel Command Frederick, MD	viral hemorrhagic fevers (Hantaan & Pumala) (prevention)	Phase II www.ichorms.com
IMU-838 (selective immune modulator)	Immunic New York, NY	COVID-19 infections	Phase II/III www.immunic-therapeutics.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
INO-4201 (DNA-based vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	Ebola virus infections (prevention)	Phase I www.inovio.com
INO-4500 (Lassa fever vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA Coalition for Epidemic Preparedness Innovations Washington, DC	Lassa fever (prevention)	Phase I www.inovio.com
INO-4600 (GLS-5700) (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA GeneOne Life Science Seoul, South Korea	Zika virus infections (prevention)	Phase I www.inovio.com
INO-4700 (GLS-5300) (MERS DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA GeneOne Life Science Seoul, South Korea	MERS coronavirus infections (prevention)	Phase II www.inovio.com
INO-4800 (DNA vaccine)	Inovio Pharmaceuticals Plymouth Meeting, PA	COVID-19 infections (prevention)	Phase I www.inovio.com
INO-A002 (DNA-encoded mAb)	Inovio Pharmaceuticals Plymouth Meeting, PA	Zika virus infection	Phase I www.inovio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
islatravir (nucleoside reverse transcriptase inhibitor)	Merck Kenilworth, NJ	HIV infections	Phase III www.merck.com
JNJ-53718678 (viral fusion protein inhibitor)	Janssen Raritan, NJ	RSV infections	Phase II www.janssen.com
JNJ-56136379 (capsid protein inhibitor)	Janssen Raritan, NJ	hepatitis B	Phase II www.janssen.com
JNJ-63682918 (Ad26.HPV16 vector vaccine)	Janssen Raritan, NJ	HPV infections (prime-boost regimen) (prevention)	Phase I/II www.janssen.com
JNJ-63682931 (Ad26.HPV18 vector vaccine)	Janssen Raritan, NJ	HPV infections (prime-boost regimen) (prevention)	Phase I/II www.janssen.com
JNJ-64152348 (Sabin inactivated polio vaccine)	Janssen Raritan, NJ	poliomyelitis (prevention)	Phase II completed www.janssen.com
JNJ-64213175 (RSV preF protein vaccine)	Janssen Raritan, NJ	RSV infections (60 years and older) (prevention)	Phase I/II www.janssen.com
JNJ-64300535 (DNA vaccine)	Janssen Raritan, NJ	hepatitis B (treatment)	Phase I www.janssen.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
JNJ-64400141 (VAC18193/VAC18194) (Ad26.RSV.preF vaccine)	Janssen Raritan, NJ	RSV infections (60 years and older) (prevention) (Breakthrough Therapy)	Phase II www.janssen.com
		RSV infections (prevention) (12 months to 24 months) (18 years to 50 years)	Phase I/II www.janssen.com
JNJ-64417184 (polymerase inhibitor)	Janssen Raritan, NJ	RSV infections	Phase I www.janssen.com
JNJ-65195208 (MVA-HPV16/18)	Bavarian Nordic Morrisville, NC Janssen Raritan, NJ	HPV infections (prime-boost regimen) (prevention)	Phase I/II www.janssen.com
JNJ-66684657 (Ad26.ZIKV.001 Zika virus vaccine)	Janssen Raritan, NJ	Zika virus infections (prevention)	Phase I completed www.janssen.com
JNJ-73763989 (RNA interference)	Janssen Raritan, NJ	hepatitis B	Phase I www.janssen.com
JS016 (coronavirus spike glycoprotein inhibitor)	Lilly Indianapolis, IN Junshi Biosciences Shanghai, China	COVID-19 infections	Phase I www.lilly.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Jynneos® smallpox and monkeypox vaccine, live, non-replicating (freeze-dried formulation)	Bavarian Nordic Morrisville, NC	smallpox, monkeypox (prevention)	Phase III www.bavarian-nordic.com
KBP-V001 (quadrivalent influenza vaccine)	Kentucky BioProcessing Owensboro, KY	influenza (prevention)	Phase I www.kentuckybioprocessing.com
Ieronlimab (CCR5 antagonist)	CytoDyn Vancouver, WA	HIV infections (combination therapy) (Fast Track)	application submitted www.cytodyn.com
		HIV infections (monotherapy)	Phase III www.cytodyn.com
		COVID-19 infections	Phase II/III www.cytodyn.com
LHF-535 (viral fusion inhibitor)	Kineta Seattle, WA	Lassa fever	Phase I www.kinetabio.com
Ionafarnib (farnesyltransferase inhibitor) ORPHAN DRUG	Eiger BioPharmaceuticals Palo Alto, CA	hepatitis D infections (+ritonavir) (Fast Track) (Breakthrough Therapy)	Phase III www.eigerbio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
LY-CoV555 (LY3819253) (IgG1 mAb vs spike protein)	Lilly Indianapolis, IN AbCellera Vancouver, Canada	COVID-19 infections (early mild to moderate illness)	Phase II www.lilly.com
		COVID-19 infections (hospitalized patients)	Phase I www.lilly.com
M-001 (universal influenza vaccine)	BiondVax Pharmaceuticals Jerusalem, Israel National Institutes of Health Bethesda, MD	influenza virus infections (prevention)	Phase II completed www.biondvax.com
M2SR (H3N2 influenza vaccine)	FluGen Madison, WI	influenza A virus H3N2 subtype (prevention)	Phase II www.flugen.com
mAb 114 (virus attachment inhibitor) ORPHAN DRUG	Ridgeback Biotherapeutics Miami, FL	Ebola virus infections	Phase II/III www.ridgebackbio.com
MAU868 (BK virus-specific mAb)	Amplify Pharmaceuticals San Diego, CA	BK virus infections (prevention and treatment)	Phase I www.amplyx.com
MB-66 (viral fusion inhibitor)	Mapp Biopharmaceutical San Diego, CA	HIV infections, HSV infections	Phase I www.mappbio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
MB-110 (NS5 protein inhibitor)	Microbio Taipei, Taiwan	hepatitis C	Phase I www.microbio.com/tw
MBL-HCV1 (virus envelope protein inhibitor) ORPHAN DRUG	MassBiologics Boston, MA	hepatitis C	Phase I completed www.umassmed.edu/massbiologics
MBX-400 (filociclovir) (potent/novel nucleoside analog dual DNA polymerase/kinase inhibitor)	Microbiotix Worcester, MA	CMV-related infections in transplant recipients	Phase I completed www.microbiotix.com
MGD014 (viral RNA inhibitor)	MacroGenics Rockville, MD	HIV infections	Phase I www.macrogenics.com
MK-1654 (viral fusion protein inhibitor)	Merck Kenilworth, NJ	RSV infections (prevention) (adults)	Phase II www.merck.com
		RSV infections (prevention) (infants)	Phase I/II www.merck.com
MK-8504 (nucleotide reverse transcriptase inhibitor)	Merck Kenilworth, NJ	HIV-1 infections	Phase I completed www.merck.com
MK-8527 (antiretroviral)	Merck Kenilworth, NJ	HIV-1 infections	Phase I completed www.merck.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
MK-8558 (antiretroviral)	Merck Kenilworth, NJ	HIV-1 infections	Phase I completed www.merck.com
MK-8583 (nucleotide reverse transcriptase inhibitor)	Merck Kenilworth, NJ	HIV-1 infections	Phase I completed www.merck.com
MK-8591A (doravirine/islatravir) (NNRTI/NRTI fixed-dose combination)	Merck Kenilworth, NJ	HIV-1 infections	Phase III www.merck.com
mRNA-1172 (V172) (mRNA prophylactic vaccine)	Merck Kenilworth, NJ Moderna Therapeutics Cambridge, MA	RSV infections (prevention)	Phase I www.modernatx.com
mRNA-1273 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	COVID-19 virus infections (prevention) (Fast Track)	Phase II www.modernatx.com
mRNA-1647 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	CMV infections (prevention)	Phase II www.modernatx.com
mRNA-1653 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	metapneumovirus infections, parainfluenza virus infections (prevention)	Phase I www.modernatx.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
mRNA-1777 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	RSV infections	Phase I www.modernatx.com
mRNA-1851 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	influenza H7N9 virus infections (prevention)	Phase I www.modernatx.com
mRNA-1893 (mRNA prophylactic vaccine)	Moderna Therapeutics Cambridge, MA	Zika virus infections (Fast Track) (prevention)	Phase I www.modernatx.com
mRNA-1944 (mRNA IgG antibody)	Moderna Therapeutics Cambridge, MA	chikungunya virus infections (prevention)	Phase I www.modernatx.com
MV-012-968 (recoded RSV vaccine)	Meissa Vaccines South San Francisco, CA	RSV infections (prevention) (Fast Track)	Phase I www.meissavaccines.com
MVA-BN RSV vaccine (multivalent vaccine)	Bavarian Nordic Morrisville, NC	RSV infections (prevention)	Phase II www.bavarian-nordic.com
MVA-BN WEV vaccine (multivalent vaccine)	Bavarian Nordic Morrisville, NC	equine encephalomyelitis	Phase I www.bavarian-nordic.com
MV-CHIK (chikungunya virus vaccine)	Themis Bioscience Vienna, Austria	chikungunya virus infections (prevention) (Fast Track)	Phase II www.themisbio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
N-803 (IL-15 superagonist)	ImmunityBio Culver City, CA	HIV infections	Phase I www.immunitybio.com
NA-831	NeuroActiva San Jose, CA	COVID-19 infections (monotherapy and combination therapy)	Phase II/III www.neuroactiva.com
NanoFlu™ nanoparticle influenza vaccine	Novavax Gaithersburg, MD	seasonal influenza infections (65 and older) (Fast Track)	Phase III www.novavax.com
NasoVAX™ influenza A vaccine intranasal	Altimune Gaithersburg, MD	influenza A virus H5N1 infections (prevention)	Phase II www.altimmune.com
NCO-48 fumarate (nucleotide reverse transcriptase Inhibitor)	Nucorion Pharmaceuticals San Diego, CA	hepatitis B	Phase I www.nucorionpharma.com
nirsevimab (RSV mAb-YTE)	AstraZeneca Wilmington, DE Sanofi Bridgewater, NJ	RSV infections (passive immunization) (Fast Track) (Breakthrough Therapy)	Phase III www.astrazeneca.com www.sanofi.com
norketotifen (histamine H1 receptor antagonist)	Emergo Therapeutics Durham, NC	influenza virus infections	Phase II www.emergotherapeutics.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Nowarta-110	Nowarta Biopharma Huntington Beach, CA	plantar warts caused by HPV	Phase I/II completed www.nowarta.com
NT-300 (nitazoxanide extended release)	Romark Laboratories Tampa, FL	post-exposure prevention of COVID-19 infections and other viral respiratory illnesses in populations at high risk of infection	Phase III www.romark.com
NVX-CoV2373 (recombinant nanoparticle vaccine)	Novavax Gaithersburg, MD	COVID-19 infections (prevention)	Phase I www.novavax.com
OKG-0301 (protein synthesis inhibitor)	Okogen San Diego, CA	acute adenoviral conjunctivitis	Phase II www.okogen.com
PBSVax™ HIV-MAG DNA vaccine	Profectus Biosciences Baltimore, MD	HIV infections (treatment and prevention)	Phase I completed www.profectusbiosciences.com
peginterferon lambda ORPHAN DRUG	Eiger BioPharmaceuticals Palo Alto, CA	COVID-19 infections (prevention and treatment), hepatitis D (Fast Track) (Breakthrough Therapy)	Phase II www.eigerbio.com
PENNVAX®-GP HIV DNA vaccine	Inovio Pharmaceuticals Plymouth Meeting, PA National Institutes of Health Bethesda, MD	HIV infections (prevention and treatment)	Phase II www.inovio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
PF-06928316 (RSVpreF) (prophylactic vaccine)	Pfizer New York, NY	RSV infections (prevention of maternal transmission)	Phase II www.pfizer.com
PF-07302048 (BNT162) (mRNA vaccine)	BioNTech Mainz, Germany Pfizer New York, NY	COVID-19 infections (prevention)	Phase I www.pfizer.com
pimodivir (JNJ-3872) (viral protein inhibitor)	Janssen Raritan, NJ	influenza A virus infections (Fast Track)	Phase III www.janssen.com
Prevymis™ letermovir	Merck Kenilworth, NJ	CMV infections (up to 17 years)	Phase II www.merck.com
pritelivir (DNA helicase-primase inhibitor)	AiCuris Wuppertal, Germany	acyclovir-resistant HSV infections in immunocompromised patients (Fast Track)	Phase II www.aicuris.com
PUL-042 (innate immune stimulating therapy)	Pulmotect Houston, TX	COVID-19 infections (prevention of infection and disease progression)	Phase II www.pulmotect.com
PVX-2 (prime-boost therapeutic vaccine)	PapiVax Biotech New Taipei City, Taiwan	HPV infections (treatment)	Phase II www.papivaxbiotech.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
ranpirnase (ribonuclease [Rnase])	Orgenesis Germantown, MD	HPV-related genital warts	Phase I/II www.orgenesis.com
ravidasvir (NS5A protein inhibitor)	Presidio Pharmaceuticals San Francisco, CA	hepatitis C	Phase I completed www.presidiopharma.com
REGN-COV2 (two mAb cocktail)	Regeneron Pharmaceuticals Tarrytown, NY	COVID-19 infections (ambulatory and hospitalized patients)	Phase I/II www.regeneron.com
REGN-EB3 (triple antibody therapy) ORPHAN DRUG	Regeneron Pharmaceuticals Tarrytown, NY	Ebola virus infections	application submitted www.regeneron.com
remdesivir (GS-5734) (Nuc inhibitor)	Gilead Sciences Foster City, CA	COVID-19 infections	Phase III www.gilead.com
Remune [®] GP120-depleted HIV-1 vaccine ORPHAN DRUG	Immune Response BioPharma Atlantic City, NJ	HIV-1 infections	application submitted www.immuneresponsebio.com
		HIV-1 infections (pediatric)	Phase I/II www.immuneresponsebio.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
ResVax RSV F protein vaccine	Novavax Gaithersburg, MD	RSV infections (infants via maternal immunization) (Fast Track)	Phase III www.novavax.com
		RSV infections (60 years and older) (Fast Track)	Phase II www.novavax.com
		RSV infections (6 months to 5 years)	Phase I www.novavax.com
RG6084 (RNA interference)	Roche Basel, Switzerland	hepatitis B	Phase I www.roche.com
RG6217	Roche Basel, Switzerland	hepatitis B	Phase I www.gene.com
RG6346 (RNA interference)	Dicerna Pharmaceuticals Lexington, MA Roche Basel, Switzerland	hepatitis B	Phase I www.dicerna.com www.roche.com
RG7854 (toll-like receptor 7 agonist)	Roche Basel, Switzerland	hepatitis B	Phase II www.roche.com
RG7907 (capsid protein inhibitor)	Roche Basel, Switzerland	hepatitis B	Phase II www.roche.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
rilpivirine long acting nanosuspension for injection	Janssen Raritan, NJ	HIV-1 infections	application submitted www.janssen.com
Rotarix [®] rotavirus vaccine, live, oral (procine circovirus free)	GlaxoSmithKline Research Triangle Park, NC	rotavirus infections (prevention)	Phase III www.gsk.com
RSV vaccine	Sanofi Bridgewater, NJ	RSV infections (infants 4 months and older)	Phase I www.sanofi.com
RTB101 (TORC1 inhibitor)	Restorbio Boston, MA	COVID-19 infections (prevention in nursing home residents)	Phase III www.restorbio.com
RV521 (viral fusion protein inhibitor)	ReViral Durham, NC	RSV infections	Phase II www.reviral.co.uk
S-648414 (antiretroviral)	Shionogi Florham Park, NJ	HIV infections	Phase II www.shionogi.com
SAB-176 (immunotherapy)	SAb Biotherapeutics Sioux Falls, SD	seasonal influenza in hospitalized patients	Phase I www.sabtherapeutics.com
SAB-301 (immunotherapy)	SAb Biotherapeutics Sioux Falls, SD	Middle East respiratory syndrome (MERS) coronavirus	Phase I www.sabtherapeutics.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
SAR441236 (tri-specific neutralizing mAb)	Sanofi Bridgewater, NJ	HIV infections	Phase I www.sanofi.com
SB206 (nitric oxide gel)	Novan Morrisville, NC	molluscum contagiosum	Phase III www.novan.com
		genital warts	Phase II www.novan.com
SB209762 (live attenuated vaccine)	GlaxoSmithKline Research Triangle Park, NC	measles, mumps, rubella (prevention)	Phase III www.gsk.com
SB-728mR-HSPC (zinc finger DNA binding protein)	Sangamo BioSciences Brisbane, CA City of Hope Medical Center Duarte, CA	HIV infections	Phase I www.sangamo.com
SB-728-mR-T (zinc finger DNA binding protein)	Sangamo BioSciences Brisbane, CA Case Western Reserve University Cleveland, OH	HIV infections	Phase I www.sangamo.com
SB-728-T (zinc finger DNA binding protein)	Sangamo BioSciences Brisbane, CA Case Western Reserve University Cleveland, OH	HIV infections	Phase I www.sangamo.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Sci-B-Vac® hepatitis B recombinant vaccine	VBI Vaccines Cambridge, MA	hepatitis B infections (prevention)	Phase III www.vbivaccines.com
selgantolimod (GS-9688) (TLR-8 agonist)	Gilead Sciences Foster City, CA	hepatitis B	Phase II www.gilead.com
Shan 6 (pediatric hexavalent vaccine)	Sanofi Bridgewater, NJ	haemophilus infections, tetanus, pertussis, poliomyelitis, hepatitis B, diphtheria	Phase III www.sanofi.com
Shingrix® zoster vaccine, recombinant, adjuvanted	GlaxoSmithKline Research Triangle Park, NC	prevention of shingles in children with kidney transplant (1 year to 17 years)	Phase II www.gsk.com
sirukumab (IL-1 inhibitor mAb)	Janssen Raritan, NJ	COVID-19 infections (adjuvant therapy)	Phase II www.janssen.com
SQX770 (topical Immunomodulator)	Squarex St. Paul, MN	herpes simplex virus (HSV) infections (herpes labialis)	Phase II www.squarex-pharma.com
StealthVector®HGTV43™ antisense HIV-1 therapy	Enzo Biochem New York, NY	HIV-1 infections	Phase II www.enzo.com
Symtuza® cobicistat/darunavir/emtricitabine/ tenofovir alafenamide	Janssen Raritan, NJ	HIV-1 infections (6 years to 11 years)	Phase I www.janssen.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
SYN023 (anti-rabies mAb)	Synermore Biologics Taipei City, Taiwan	rabies (post-exposure prevention)	Phase I/II completed www.synermore.com
TAK-003 (tetraivalent hybrid virus vaccine)	Takeda Deerfield, IL	dengue (prevention) (Fast Track)	Phase III www.takeda.com
TAK-021 (EV71 vaccine)	Takeda Deerfield, IL	enterovirus A infections	Phase I www.takeda.com
TAK-214 (VLP bivalent vaccine)	Takeda Deerfield, IL	norovirus infections (prevention)	Phase II www.takeda.com
TAK-426 (whole virus vaccine)	Takeda Deerfield, IL	Zika virus infections (prevention) (Fast Track)	Phase I www.takeda.com
TAK-620 (ganciclovir kinase inhibitor) ORPHAN DRUG	Takeda Deerfield, IL	CMV infections in transplantation (Fast Track)	Phase III www.takeda.com
TMB-365 (anti-CD4 recombinant mAb)	TaiMed Biologics Irvine, CA	HIV-1 infections	Phase I www.taimedbiologics.com
TPOXX® IV tecovirimat intravenous	SIGA technologies New York, NY	smallpox	Phase I www.siga.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Triplex cytomegalovirus gene MVA virus vaccine	HeloCyte New York, NY	CMV infections in patients undergoing hematopoietic stem cell transplantation and solid organ transplantation (prevention)	Phase II www.helocyte.com
Trogarzo® ibalizumab via undiluted "IV Push	TaiMed Biologics Irvine, CA	HIV-1 infections	Phase III www.taimedbiologics.com
V160 (CMV vaccine)	Merck Kenilworth, NJ	CMV infections (prevention)	Phase II www.merck.com
V180 (tetraivalent subunit vaccine)	Merck Kenilworth, NJ	dengue (prevention)	Phase I completed www.merck.com
VAC52150 (monovalent Ebola virus vaccine)	Janssen Raritan, NJ	Ebola virus infections (prevention)	Phase III www.janssen.com
VAC52150/MVA-BN-Filo (multivalent Ebola virus vaccine)	Janssen Raritan, NJ	Ebola virus infections (prevention)	Phase III www.janssen.com
VAC89220 (Ad26.MOS4.HIV vaccine)	Janssen Raritan, NJ	HIV infections (prevention) (prime-boost regimen)	Phase III www.janssen.com
VBI-1501 (eVLP-based vaccine)	VBI Vaccines Cambridge, MA	CMV infections (prevention)	Phase I completed www.vbivaccines.com

Viral Infections

Drug Name

Organization

Indication

Development Phase

VBI-2601
(VLP-based vaccine)

VBI Vaccines
Cambridge, MA

hepatitis B (treatment)

Phase I/II
www.vbivaccines.com

VBP-245 gel
(HN protein inhibitor)

Veloce BioPharma
Fort Lauderdale, FL

molluscum contagiosum,
common warts (verruca vulgaris)

Phase II
www.velocebiopharma.com

Vemlidy[®]
tenofovir alafenamide

Gilead Sciences
Foster City, CA

hepatitis B (pediatric)

Phase II
www.gilead.com

VerorabVax[®]
purified vero rabies vaccine

Sanofi
Bridgewater, NJ

rabies (prevention)

Phase III
www.sanofi.com

vesatolimod (GS-9620)
(TLR-7 agonist)

Gilead Sciences
Foster City, CA

HIV-1 infections (functional cure)

Phase I
www.gilead.com

VGX-3100
(DNA vaccine)

Inovio Pharmaceuticals
Plymouth Meeting, PA

HPV-related cervical HSIL

Phase III
www.inovio.com

HPV-related vulvar HSIL,
HPV-related anal HSIL

Phase II
www.inovio.com

Vicromax[™]
merimepodib

ViralClear Pharmaceuticals
Westport, CT

COVID-19 infections (+remdesivir)

Phase II
www.biosig.com/viralclear

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Viekira Pak® ombitasvir, paritaprevir and ritonavir, dasabuvir	AbbVie North Chicago, IL	hepatitis C (3 years to 17 years)	Phase II www.abbvie.com
Viekira XR® dasabuvir, ombitasvir, paritaprevir and ritonavir	AbbVie North Chicago, IL	hepatitis C (3 years to 17 years)	Phase II www.abbvie.com
VIR-2482 (mAb)	Vir Biotechnology San Francisco, CA	influenza A virus infections	Phase I www.vir.bio
Viralymp-M (ALVR105) multivirus-specific T cell therapy	AlloVir Houston, TX	adenovirus infections, CMV infections, virus-associated hemorrhagic cystitis in hematopoietic stem cell transplantation	Phase II www.allovir.com
VIS410 (influenza virus fusion inhibitor)	Visterra Waltham, MA	influenza A virus infections (Fast Track)	Phase II www.visterrainc.com
VIS513 (envelope protein)	Visterra Waltham, MA	dengue	Phase I www.visterrainc.com
VLA1553 (monovalent, single dose, live-attenuated vaccine)	Valneva Saint-Herblain, France	Chikungunya virus infections (prevention) (Fast Track)	Phase II www.valneva.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
VLA1601 (inactivated whole virus vaccine)	Valneva Saint-Herblain, France	Zika virus infections (prevention)	Phase I www.valneva.com
VM1500A long-acting injectable	Viriom San Diego, CA	HIV infections (prevention and treatment)	Phase II www.viriom.com
VP-102 (cantharidin-based therapy)	Verrica Pharmaceuticals West Chester, PA	common warts, genital warts	Phase II www.verrica.com
VP-103 (cantharidin-based therapy)	Verrica Pharmaceuticals West Chester, PA	plantar warts	Phase II www.verrica.com
VRC07-523LS (neutralizing HIV-1 antibody)	TaiMed Biologics Irvine, CA	HIV-1 infections	Phase I www.taimedbiologics.com
VXA-G2.4-NS/VAX-G1.1-NN (bivalent Ad5-based norovirus vaccine)	Vaxart South San Francisco, CA	norovirus infections (prevention)	Phase I www.vaxart.com
Xofluza® baloxavir marboxil	Genentech South San Francisco, CA	seasonal influenza A and B (0 to 1 year, 1 year to 12 years, direct transmission, hospitalized patients, post-exposure prevention, high-risk patients, otherwise healthy patients with influenza)	Phase III www.gene.com

Viral Infections

<u>Drug Name</u>	<u>Organization</u>	<u>Indication</u>	<u>Development Phase</u>
Xpovio [®] selinexor	Karyopharm Therapeutics Newtown, MA Precision in Medicine Budapest, Hungary	COVID-19 infections	Phase II www.karyopharm.com
Ycanth [™] cantharidin topical solution	Verrica Pharmaceuticals West Chester, PA	molluscum contagiosum	application submitted www.verrica.com
yellow fever vaccine (vero cell vaccine)	Sanofi Bridgewater, NJ	yellow fever (prevention)	Phase I/II www.sanofi.com
Zepatier [®] elbasvir and grazoprevir	Merck Kenilworth, NJ	hepatitis C (3 years to 17 years)	Phase II www.merck.com
ZIKV-IG (immunoglobulin therapeutic vaccine)	Emergent BioSolutions Gaithersburg, MD	Zika virus infection (treatment) (Fast Track)	Phase I www.emergentbiosolutions.com
ZM-H1505R (capsid protein inhibitor)	Shanghai Zhimeng Biopharma Shanghai, China	hepatitis B	Phase I www.core-biopharma.com
Zmapp porgaviximab	Mapp Biopharmaceutical San Diego, CA NIAID Bethesda, MD	Ebola virus infections	Phase II www.mappbio.com

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. Report current as of **July 7, 2020**. The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States and abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. Some products may not be in active clinical trials. 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 website: www.phrma.org.

Definitions

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

Breakthrough Therapy—Upon request by a sponsor, the FDA can grant this designation to expedite the development and review of a drug or biologic intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as a Breakthrough Therapy, the FDA will expedite the development and review. With this designation, all Fast Track features convey to the medicine.

Fast Track—Upon request by a sponsor, the FDA can grant this designation to facilitate the development and expedite the review of a drug or biologic to treat a serious condition and fill an unmet medical need. When considering a biopharmaceutical company's request for Fast Track designation for an investigational drug or biologic, the FDA evaluates whether it will affect factors such 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, and whether a condition can be adequately addressed by available therapy. With Fast Track designation, early and frequent communication between the FDA and the biopharmaceutical company is encouraged throughout the entire drug development and review process to help to quickly resolve any questions or issues that arise, potentially leading to an earlier approval and access by patients.

Orphan Designation—Upon request by a sponsor, the FDA can grant special status ("orphan status") to a drug or biologic to treat a rare disease or condition. In order to receive an orphan designation, a qualifying drug or biologic must be intended for the treatment, diagnosis, or prevention of a rare disease or condition that affects usually fewer than 200,000 people in the United States.

Phase I—Researchers test the investigational drug or biologic in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Phase II—The investigational drug or biologic is given to volunteer patients, usually between 100 and 500, to determine whether it is effective, identify an optimal dose, and to further evaluate its short-term safety.

Phase III—The investigational drug or biologic is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.