

## Medicines in Development – Antimicrobial Resistance (AMR)

<u>Product Name</u>	<u>Sponsor</u>	<u>Indication</u>	<u>Development Phase</u>
514G3 (omodembamab)	Xbiotech USA Austin, TX	<i>Staphylococcus aureus</i> infections, including methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) (Fast Track)	Phase I/II completed <a href="http://www.xbiotech.com">www.xbiotech.com</a>
AB103 (reltecimod) (synthetic peptide) ORPHAN DRUG	Atox Bio Durham, NC	necrotizing soft tissue infections (adjuvant) (Fast Track)	application submitted <a href="http://www.atoxbio.com">www.atoxbio.com</a>
afabycin (Debio 1450) (FabI inhibitor)	Debiopharm Lausanne, Switzerland	bone and joint infections due to <i>Staphylococcus aureus</i> , including MRSA and methicillin-susceptible <i>Staphylococcus aureus</i> (MSSA) (Fast Track)	Phase II <a href="http://www.debiopharm.com">www.debiopharm.com</a>
ALS-4 (bacterial virulence inhibitor)	Aptorum New York, NY	<i>Staphylococcus aureus</i> infections, including MRSA	Phase I <a href="http://www.aptorumgroup.com">www.aptorumgroup.com</a>
AP-PA02 (bacteriophage cocktail)	Armata Pharmaceuticals Marina del Rey, CA	multi-drug resistant <i>Pseudomonas aeruginosa</i> lung infections in cystic fibrosis	Phase I/II <a href="http://www.armatapharma.com">www.armatapharma.com</a>
AR-101 IgM mAb (lipopolysaccharide inhibitor) ORPHAN DRUG	Aridis Pharmaceuticals Los Gatos, CA	hospital-acquired bacterial pneumonia (HABP)/ventilator-acquired bacterial pneumonia (VABP) caused by multi-drug resistant <i>Pseudomonas aeruginosa</i> LPS serotype 011	Phase II <a href="http://www.aridispharma.com">www.aridispharma.com</a>

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AR-301 IgG1 mAb (bacterial toxin inhibitor)	Aridis Pharmaceuticals Los Gatos, CA	HABP/VABP caused by <i>Staphylococcus aureus</i> , including MRSA and MSSA (Fast Track)	Phase III <a href="http://www.aridispharma.com">www.aridispharma.com</a>
AR-501 (bacterial growth inhibitor) ORPHAN DRUG	Aridis Pharmaceuticals Los Gatos, CA	antibiotic-resistant gram-negative and gram-positive infections in cystic fibrosis, including <i>Pseudomonas aeruginosa</i> (Fast Track)	Phase I/II <a href="http://www.aridispharma.com">www.aridispharma.com</a>
ART24 (direct-acting live biotherapeutic)	Artugen Therapeutics Concord, MA	prevention of recurrent <i>Clostridioides difficile</i> infections (Fast Track)	Phase I <a href="http://www.artugentherapeutics.com">www.artugentherapeutics.com</a>
ARV-1801 (fusidic acid) (sodium fusidate-protein synthesis inhibitor) ORPHAN DRUG	Arrebus Raleigh, NC	<i>Staphylococcus aureus</i> respiratory tract infections in cystic fibrosis	Phase II <a href="http://www.arrebus.com">www.arrebus.com</a>
aztreonam-avibactam (PF-06947387) (beta lactam/beta lactamase inhibitor)	Pfizer New York, NY	gram-negative bacterial infections with limited or no treatment options	Phase III <a href="http://www.pfizer.com">www.pfizer.com</a>
BOS-228 (monobactam)	Boston Pharmaceuticals Cambridge, MA	multi-drug resistant bacterial infections (Fast Track)	Phase II <a href="http://www.bostonpharmaceuticals.com">www.bostonpharmaceuticals.com</a>
brilacidin (defensin biomimetic)	Innovation Pharmaceuticals Wakefield, MA	acute bacterial skin and skin structure infections (ABSSSI)	Phase II <a href="http://www.ipharminc.com">www.ipharminc.com</a>

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cefepime/enmetazobactam (beta lactam/beta lactamase inhibitor)	Allegra Therapeutics Lörrach, Germany	complicated urinary tract infections (cUTI), including pyelonephritis (Fast Track)	Phase III <a href="http://www.allegra.com">www.allegra.com</a>
cefepime/taniborbactam (IV) (beta lactam/beta lactamase inhibitor)	VenatoRx Pharmaceuticals Malvern, PA	cUTI, including pyelonephritis (Fast Track)	Phase III <a href="http://www.venatorx.com">www.venatorx.com</a>
ceftibuten/VNRX-7145 (oral) (cell wall inhibitor/beta lactamase inhibitor)	VenatoRx Pharmaceuticals Malvern, PA	multi-drug resistant bacterial infections (Fast Track)	Phase I <a href="http://www.venatorx.com">www.venatorx.com</a>
CG400549 (enoyl-ACP reductase inhibitor)	CrystalGenomics Seongnam-si, South Korea	ABSSSI	Phase II completed <a href="http://www.crystalgenomics.com">www.crystalgenomics.com</a>
colistimethate sodium inhaled (cell membrane modulator)	Zambon Bresso, Italy	non-cystic fibrosis bronchiectasis caused by <i>Pseudomonas aeruginosa</i>	Phase III <a href="http://www.zambon.com">www.zambon.com</a>
<b>Contepo™</b> (ZTI-01) fosfomicin (intravenous epoxide antibiotic)	Nabriva Therapeutics King of Prussia, PA	cUTI (Fast Track)	application submitted <a href="http://www.nabriva.com">www.nabriva.com</a>
		cUTI (pediatric)	Phase I <a href="http://www.nabriva.com">www.nabriva.com</a>
contezolid (MRX-1) (protein synthesis inhibitor)	Micurx Pharmaceuticals Foster City, CA	ABSSSI (Fast Track)	Phase II <a href="http://www.micurx.com">www.micurx.com</a>

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contezolid acefosamil (MRX-4) (protein synthesis inhibitor)	MicuRx Pharmaceuticals Foster City, CA	ABSSSI (Fast Track)	Phase II <a href="http://www.micurx.com">www.micurx.com</a>
CP101 (microbiome therapeutic)	Finch Therapeutics Somerville, MA	prevention of recurrent <i>Clostridioides difficile</i> infections (Breakthrough Therapy) (Fast Track)	Phase II <a href="http://www.finchtherapeutics.com">www.finchtherapeutics.com</a>
CRS3123 (MetRS inhibitor)	Crestone Boulder, CO	<i>Clostridioides difficile</i> infections	Phase II <a href="http://www.crestonepharma.com">www.crestonepharma.com</a>
CYT107 (recombinant interleukin-7)	RevImmune Bethesda, MD	NTM infections	Phase II <a href="http://www.revimmune.com">www.revimmune.com</a>
<b>Defencath</b> <sup>®</sup> taurolidine, citrate, heparin (antibacterial/antifungal solution)	CorMedix Berkeley Heights, NJ	prevention of catheter-related bloodstream infections caused by gram-negative and gram-positive bacteria in patients on dialysis (Fast Track)	application submitted <a href="http://www.cormedix.com">www.cormedix.com</a>
<b>Deltyba</b> <sup>®</sup> delamanid	Otsuka Pharmaceutical Princeton, NJ	multi-drug resistant <i>Mycobacterium tuberculosis</i>	Phase III <a href="http://www.otsuka.com">www.otsuka.com</a>
DNV3837 (hybrid oxazolidanone-quinolone)	Deinove Grabels, France	<i>Clostridioides difficile</i> infections (Fast Track)	Phase II <a href="http://www.deinove.com">www.deinove.com</a>
D-PLEX-100 (doxycycline polymer-lipid encapsulated matrix)	PolyPid Summit, NJ	prevention of surgical site infections (Breakthrough Therapy) (Fast Track)	Phase III <a href="http://www.polypid.com">www.polypid.com</a>

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ETX0282CPDP (cefepodoxime/ETX 0282)	Entasis Therapeutics Waltham, MA	cUTI	Phase I <a href="http://www.entasistx.com">www.entasistx.com</a>
exebacase (CF-301) (recombinant bacteriophage- derived lysin)	ContraFect Yonkers, NY	bacteremia, including endocarditis caused by <i>Staphylococcus aureus</i> (Breakthrough Therapy) (Fast Track)	Phase III <a href="http://www.contrafect.com">www.contrafect.com</a>
F901318 (olorofim) (antifungal) <b>ORPHAN DRUG</b>	F2G Biotech Manchester, United Kingdom	invasive fungal infections refractory or intolerant to current treatments (Breakthrough Therapy)	Phase II <a href="http://www.f2g.com">www.f2g.com</a>
fosmanogepix (Gwt1 fungal enzyme inhibitor) <b>ORPHAN DRUG</b>	Amplyx Pharmaceuticals San Diego, CA	invasive candidiasis/candidemia (Fast Track), invasive aspergillosis, drug-resistant <i>Candida auris</i>	Phase II <a href="http://www.amplyx.com">www.amplyx.com</a>
gepotidacin (GSK2140944) (triazacacenaphthylene bacterial type II topoisomerase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	gonorrhea, uncomplicated urinary tract infections (uUTI)	Phase III <a href="http://www.gsk.com">www.gsk.com</a>
GSK2556286 ( <i>Mycobacterium tuberculosis</i> cholesterol dependent inhibitor)	GlaxoSmithKline Research Triangle Park, NC	<i>Mycobacterium tuberculosis</i>	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3036656 (Leucyl t-RNA synthetase inhibitor)	GlaxoSmithKline Research Triangle Park, NC	<i>Mycobacterium tuberculosis</i>	Phase II <a href="http://www.gsk.com">www.gsk.com</a>

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GSK3729098 (BVL-GSK098) (ethionamide booster)	BioVersys Basel, Switzerland GlaxoSmithKline Research Triangle Park, NC	<i>Mycobacterium tuberculosis</i>	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
GSK3882347 (FimH antagonist)	GlaxoSmithKline Research Triangle Park, NC	uUTI	Phase I <a href="http://www.gsk.com">www.gsk.com</a>
ibezapolstat (ACX-362E) (Pol IIIC inhibitor)	Acurx Pharmaceuticals White Plains, NY	<i>Clostridioides difficile</i> infections (Fast Track)	Phase II <a href="http://www.acurxpharma.com">www.acurxpharma.com</a>
ibrexafungerp (glucan synthase inhibitor) <b>ORPHAN DRUG</b>	SCYNEXIS Jersey City, NJ	acute vulvovaginal candidiasis (Fast Track)	application submitted <a href="http://www.scynexis.com">www.scynexis.com</a>
		recurrent vulvovaginal candidiasis, refractory or intolerant invasive fungal infections	Phase III <a href="http://www.scynexis.com">www.scynexis.com</a>
		invasive aspergillosis (Fast Track)	Phase II <a href="http://www.scynexis.com">www.scynexis.com</a>
KBP-7072 (third generation tetracycline)	KBP Biosciences Princeton, NJ	multi-drug resistant bacterial infections (Fast Track)	Phase I <a href="http://www.kbpbio.com">www.kbpbio.com</a>
LBP-EC01 (CRISPR-Cas3 bacteriophage)	Locus Biosciences Research Triangle Park, NC	UTI	Phase I <a href="http://www.locus-bio.com">www.locus-bio.com</a>

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LMN-101 (neutralizing antibody cocktail)	Lumen Bioscience Seattle, WA	Traveler's diarrhea caused by <i>Campylobacter jejuni</i> and <i>Escherichia coli</i>	Phase II <a href="http://www.lumen.bio">www.lumen.bio</a>
MAT2203 (enochleated amphotericin B)	Matinas BioPharma Nanotechnologies Bridgewater, NJ	invasive fungal infections (mucocutaneous candidiasis) (Fast Track)	Phase II <a href="http://www.matinasbiopharma.com">www.matinasbiopharma.com</a>
MAT2501 (oral enochleated amikacin) <b>ORPHAN DRUG</b>	Matinas BioPharma Nanotechnologies Bridgewater, NJ	NTM infections	Phase I <a href="http://www.matinasbiopharma.com">www.matinasbiopharma.com</a>
ME1100 (arbecacin inhalation)	Meiji Seika Pharma Tokyo, Japan	HABP/VABP (Fast Track)	Phase I completed <a href="http://www.meiji.com">www.meiji.com</a>
MGB-BP-3 (oral) (genetic transcription inhibitor)	MGB Biopharma Bellshill, United Kingdom	<i>Clostridioides difficile</i> infections (Fast Track)	Phase II <a href="http://www.mgb-biopharma.com">www.mgb-biopharma.com</a>
MRX-8 (polymyxin derivative)	MicuRx Pharmaceuticals Foster City, CA	multi-drug resistant gram-negative infections	Phase I <a href="http://www.micurx.com">www.micurx.com</a>
nemonoxcin (bacterial DNA topoisomerase inhibitor)	TaiGen Biotechnology Taipei City, Taiwan	community-acquired bacterial pneumonia (CABP) (Fast Track), diabetic foot infections	Phase II completed <a href="http://www.taigenbiotech.com">www.taigenbiotech.com</a>
NTCD-M3 (non-toxicogenic strain of <i>C. difficile</i> , bacteria replacement)	Destiny Pharma Brighton, United Kingdom	<i>Clostridioides difficile</i> infections (Fast Track)	Phase II completed <a href="http://www.destinypharma.com">www.destinypharma.com</a>

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Nu-3 (bisphosphocin synthetic antibiotic)	Lakewood-Amedex Sarasota, FL	complicated diabetic foot infections	Phase I/II completed <a href="http://www.lakewoodamedex.com">www.lakewoodamedex.com</a>
OPC-167832 (DPrE1 inhibitor)	Otsuka Pharmaceutical Princeton, NJ	<i>Mycobacterium tuberculosis</i>	Phase I/II <a href="http://www.otsuka.com">www.otsuka.com</a>
<b>PhageBank™</b> bacteriophage therapeutic	Adaptive Phage Therapeutics Gaithersburg, MD	multi-drug resistant prosthetic joint infections, recurrent UTI	Phase I/II <a href="http://www.aphage.com">www.aphage.com</a>
plasma gelsolin (pGSN) (protein replacement)	BioAegis Therapeutics North Brunswick, NJ	severe CABP	Phase I/II <a href="http://www.bioaegistherapeutics.com">www.bioaegistherapeutics.com</a>
PLG0206 (engineered cationic antibiotic peptide) <b>ORPHAN DRUG</b>	Peptilogics Pittsburgh, PA	prosthetic joint infections	Phase II <a href="http://www.peptilogics.com">www.peptilogics.com</a>
pravibismane (MBN-101) (microbial bioenergetic inhibitor)	Microbion Bozeman, MT	diabetic foot infections (Fast Track), orthopedic implant infections (Fast Track)	Phase II <a href="http://www.microbioncorp.com">www.microbioncorp.com</a>
QPX7728 (OMNivance™) (beta-lactamase inhibitor)	Qpex Biopharma San Diego, CA	drug-resistant bacterial infections (monotherapy & w/QPX2014)	Phase I <a href="http://www.qpexbio.com">www.qpexbio.com</a>
QPX7831 (ORAvance™) (beta-lactamase inhibitor)	Qpex Biopharma San Diego, CA	gram-negative bacterial infections	Phase I <a href="http://www.qpexbio.com">www.qpexbio.com</a>



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RBX2660 (enema formulation) (microbiota restoration therapy) <b>ORPHAN DRUG</b>	Rebiotix Roseville, MN	prevention of recurrent <i>Clostridioides difficile</i> infections (Breakthrough Therapy) (Fast Track)	Phase III <a href="http://www.rebiotix.com">www.rebiotix.com</a>
RBX7455 (oral) (microbiota restoration therapy)	Rebiotix Roseville, MN	prevention of recurrent <i>Clostridioides difficile</i> infections	Phase I <a href="http://www.rebiotix.com">www.rebiotix.com</a>
rezafungin (long-acting echinocandin and glucan synthase inhibitor) <b>ORPHAN DRUG</b>	Cidara Therapeutics San Diego, CA	fungal infections caused by <i>Candida spp.</i> , including, candidemia and invasive candidiasis (Fast Track), prevention of fungal infections caused by <i>Aspergillosis</i> and <i>Pneumocystis</i> in patients undergoing allogeneic blood and bone marrow transplantation	Phase III <a href="http://www.cidara.com">www.cidara.com</a>
RG6006 (antibiotic macrocyclic peptide)	Roche/Genentech South San Francisco, CA	<i>Acinetobacter baumannii</i> infections	Phase I <a href="http://www.roche.com">www.roche.com</a>
RHB-204 (clarithromycin/clofazimine/rifabutin) <b>ORPHAN DRUG</b>	RedHill BioPharma Raleigh, NC	NTM infections (Fast Track)	Phase III <a href="http://www.redhillbio.com">www.redhillbio.com</a>
ribaxamase (SYN-004) (beta-lactamase enzyme)	Synthetic Biologics Rockville, MD	prevention of <i>Clostridioides difficile</i> infections co-administered with beta-lactam antibacterials	Phase II <a href="http://www.syntheticbiologics.com">www.syntheticbiologics.com</a>
ridinilazole (cell division inhibitor)	Summit Therapeutics Cambridge, MA	<i>Clostridioides difficile</i> infections (Breakthrough Therapy) (Fast Track)	Phase III <a href="http://www.summittxinc.com">www.summittxinc.com</a>

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SER-109 (microbiome therapeutic) <b>ORPHAN DRUG</b>	Seres Therapeutics Cambridge, MA	prevention of recurrent <i>Clostridioides difficile</i> infections (Breakthrough Therapy)	Phase III <a href="http://www.serestherapeutics.com">www.serestherapeutics.com</a>
SPR206 (direct-acting antibiotic polymyxin)	Spero Therapeutics Cambridge, MA	multi-drug resistant gram-negative infections in the hospital	Phase I <a href="http://www.sperotherapeutics.com">www.sperotherapeutics.com</a>
SPR720 (DNA replication inhibitor) <b>ORPHAN DRUG</b>	Spero Therapeutics Cambridge, MA	NTM infections	Phase I completed <a href="http://www.sperotherapeutics.com">www.sperotherapeutics.com</a>
sulbactam-durlobactam (IV) (beta lactam-beta lactamase inhibitor)	Entasis Therapeutics Waltham, MA	multi-drug resistant <i>Acinetobacter baumannii</i> infections (Fast Track)	Phase III <a href="http://www.entasistx.com">www.entasistx.com</a>
sulopenem (IV) (synthetic penem)	Iterum Therapeutics Chicago, IL	cUTI (Fast Track), complicated intra-abdominal infections (cIAI) (Fast Track)	Phase III <a href="http://www.iterumtx.com">www.iterumtx.com</a>
sulopenem etzadroxil-probenecid (oral prodrug of sulopenem)	Iterum Therapeutics Chicago, IL	uUTI (Fast Track)	application submitted <a href="http://www.iterumtx.com">www.iterumtx.com</a>
		cUTI (Fast Track), cIAI (Fast Track)	Phase III <a href="http://www.iterumtx.com">www.iterumtx.com</a>
suvratoxumab (MEDI-4893) (mAb binding to <i>S. aureus</i> toxin)	AstraZeneca Wilmington, DE	prevention of nosocomial <i>Staphylococcus aureus</i> pneumonia (Fast Track)	Phase II <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>

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tebipenem (SPR859) (oral carbapenem prodrug)	Spero Therapeutics Cambridge, MA	gram-negative infections	Phase I <a href="http://www.sperotherapeutics.com">www.sperotherapeutics.com</a>
tebipenem HBr (SPR994) (oral carbapenem prodrug)	Spero Therapeutics Cambridge, MA	cUTI, including pyelonephritis (Fast Track)	Phase III <a href="http://www.sperotherapeutics.com">www.sperotherapeutics.com</a>
telacebec (Q203) (bacterial growth inhibitor) <b>ORPHAN DRUG</b>	Qurient Therapeutics Seongnam-si, South Korea	<i>Mycobacterium tuberculosis</i> (Fast Track)	Phase II completed <a href="http://www.qurient.com">www.qurient.com</a>
TNP-2092 (dual-acting antibacterial) <b>ORPHAN DRUG</b>	TenNor Therapeutics Suzhou, China	ABSSSI infections (Fast Track)	Phase II <a href="http://www.tennorx.com">www.tennorx.com</a>
		prosthetic joint infections	Phase I <a href="http://www.tennorx.com">www.tennorx.com</a>
TP-271 (synthetic tetracycline antibiotic)	Tetraphase Pharmaceuticals Watertown, MA	respiratory bacterial infections (Fast Track)	Phase I completed <a href="http://www.tphase.com">www.tphase.com</a>
TP-6076 (synthetic tetracycline antibiotic)	Tetraphase Pharmaceuticals Watertown, MA	gram-negative bacterial infections	Phase I completed <a href="http://www.tphase.com">www.tphase.com</a>
TRL1068 (broad-spectrum biofilm disruptor human mAb)	Trellis Bioscience Redwood City, CA	prosthetic joint infections	Phase I <a href="http://www.trellisbio.com">www.trellisbio.com</a>
TXA709 (FtsZ inhibitor)	TAXIS Pharmaceuticals Monmouth Junction, NJ	methicillin-resistant <i>Staphylococcus aureus</i> infections	Phase I <a href="http://www.taxispharma.com">www.taxispharma.com</a>

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VE303 (microbiome therapeutic) <b>ORPHAN DRUG</b>	Vedanta Biosciences Cambridge, MA	high-risk recurrent <i>Clostridioides difficile</i> infections (high-risk)	Phase II <a href="http://www.vedantabio.com">www.vedantabio.com</a>
VT-1161 (oteseconazole)	Mycovia Pharmaceuticals Durham, NC	recurrent vulvovaginal candidiasis (Fast Track)	Phase III <a href="http://www.mycovia.com">www.mycovia.com</a>
VT-1598 (tetrazole antifungal) <b>ORPHAN DRUG</b>	Mycovia Pharmaceuticals Durham, NC NQP 1598 Grand Cayman	coccidioidomycosis (Fast Track)	Phase I <a href="http://www.mycovia.com">www.mycovia.com</a>
WCK 4873 (nafithromycin) (protein synthesis inhibitor)	Wockhardt Maharashtra, India	CABP	Phase II completed <a href="http://www.wockhardt.com">www.wockhardt.com</a>
XF-73 (exeporfinium chloride) (nasal cell membrane modulator)	Destiny Pharma Brighton, United Kingdom	prevention of post-surgical <i>Staphylococcus aureus</i> infections (Fast Track)	Phase II <a href="http://www.destinypharma.com">www.destinypharma.com</a>
XNW4107 (beta lactamase inhibitor)	Sinovent Suzhou, China	bacterial infections (alone or with imipenem/cilastatin)	Phase I <a href="http://www.sinovent.com.cn">www.sinovent.com.cn</a>
YPT 01 (inhaled bacteriophage therapy)	Felix Biotechnology San Francisco, CA	<i>Pseudomonas aeruginosa</i> infections in cystic fibrosis	Phase I/II <a href="http://www.felixbt.com">www.felixbt.com</a>
<b>Zempia</b> <sup>®</sup> myeloperoxidase-based microbicide (E-101)	Exoxemis Little Rock, AR	prevention of surgical site infections	Phase III completed <a href="http://www.exoxemis.com">www.exoxemis.com</a>

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<b>Zevtera®</b> ceftobiprole	Basilea Pharmaceutica Basel, Switzerland	ABSSSI and bloodstream infections caused by <i>Staphylococcus aureus</i>	Phase III <a href="http://www.basilea.com">www.basilea.com</a>
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zoliflodacin (ETX0914) (DNA gyrase inhibitor)	Entasis Therapeutics Waltham, MA Global Antibiotic Research and Development Partnership Geneva, Switzerland	uncomplicated gonorrhea due to <i>N. gonorrhoeae</i> (Fast Track)	Phase III <a href="http://www.extasistx.com">www.extasistx.com</a>
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### Approved Medicines in Testing for Additional Indications or Pediatric Population

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<b>AriKayce®</b> amikacin liposome inhalation	Insmed Bridgewater, NJ	1L nontuberculous mycobacteria (NTM) infections	Phase III <a href="http://www.insmed.com">www.insmed.com</a>
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<b>Cayston®</b> aztreonam for inhalation solution	Gilead Sciences Foster City, CA	<i>Pseudomonas aeruginosa</i> respiratory tract infections in cystic fibrosis (3 months to 18 years)	Phase III <a href="http://www.gilead.com">www.gilead.com</a>
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<b>Cresemba®</b> isavuconazonium (azole prodrug)	Astellas Pharma US Northbrook, IL	invasive aspergillosis, invasive mucormycosis (1 year to 17 years)	Phase II <a href="http://www.astellas.com">www.astellas.com</a>
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<b>Fetroja®</b> cefiderocol	Shionogi Florham Park, NJ	cUTI, HABP, VABP gram-negative bacterial infections (3 months to 17 years )	Phase II <a href="http://www.shionogi.com">www.shionogi.com</a>
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<b>Noxafil®</b> posaconazole	Merck Whitehouse Station, NJ	invasive aspergillosis (2 years to 18 years), invasive fungal infections (up to 2 years)	Phase II <a href="http://www.merck.com">www.merck.com</a>
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<b>Nuzyra</b> <sup>®</sup> omadacycline	Paratek Pharmaceuticals King of Prussia, PA	NTM infections	Phase II <a href="http://www.paratekpharma.com">www.paratekpharma.com</a>
<b>Recarbrio</b> <sup>™</sup> imipenem, cilastatin, relebactam	Merck Whitehouse Station, NJ	gram-negative bacterial infections (birth to 18 years)	Phase II/III <a href="http://www.merck.com">www.merck.com</a>
<b>Sivextro</b> <sup>®</sup> tedizolid (IV and Oral)	Merck Whitehouse Station, NJ	gram-positive bacterial infections (up to 24 months)	Phase I <a href="http://www.merck.com">www.merck.com</a>
<b>Xenleta</b> <sup>®</sup> lefamulin (IV/oral)	Nabriva Therapeutics King of Prussia, PA	ABSSSI (Fast Track)	Phase II completed <a href="http://www.nabriva.com">www.nabriva.com</a>
		CABP (pediatric)	Phase I <a href="http://www.nabriva.com">www.nabriva.com</a>
<b>Xerava</b> <sup>®</sup> eravacycline	Tetraphase Pharmaceuticals Watertown, MA	bacterial infections (8 years to 17 years)	Phase I <a href="http://www.tphase.com">www.tphase.com</a>
<b>Zerbaxa</b> <sup>®</sup> ceftolozane and tazobactam	Merck Whitehouse Station, NJ	cUTI, including pyelonephritis (up to 17 years)	Phase II <a href="http://www.merck.com">www.merck.com</a>

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 **April 19, 2021**. 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](http://www.clinicaltrials.gov). The entire series of *Medicines in Development* is available on PhRMA's website: [www.phrma.org](http://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.