Antibiotics Currently in Global Clinical Development

Note: This data visualization was originally published in February 2014.

As of June 2019, approximately 42 new antibiotics with the potential to treat serious bacterial infections are in clinical development. The success rate for clinical drug development is low; historical data show that, generally, only 1 in 5 infectious disease products that enter human testing (phase 1 clinical trials) will be approved for patients.* Below is a snapshot of the current antibiotic pipeline, based on publicly available information and informed by external experts.

Please note that this resource focuses exclusively on small molecule products that act systemically (drugs that work throughout the body), contain at least one component not previously approved, and have the potential to treat serious or life-threatening infections.[1] In September 2017, Pew's assessment of the antibiotic pipeline was expanded to include products in development globally.

Because this resource is updated periodically, endnote numbers may not be sequential. Please contact abxpipeline@pewtrusts.org with additions or updates.

Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Nuzyra (omadacycline)	Approved Oct. 2, 2018 (U.S. FDA)	Paratek Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes: *E. faecium, S. aureus, K. pneumoniae, Enterobacter spp.*	No	*Approved for:* **Community-acquired bacterial pneumonia, acute bacterial skin and skin structure infections**; *other potential indications*: **complicated urinary tract infections** and **uncomplicated urinary tract infections**
Xerava (eravacycline)	Approved Aug. 27, 2018 (U.S. FDA)	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes: *E. faecium, S. aureus, K. pneumoniae, Enterobacter spp.;* Possibly: *A. baumannii*	Yes (ESBL); possibly (CRE, CRAB)	**Complicated intra-abdominal infections**
Iclaprim	Complete response letter to new drug application (U.S. FDA)	Motif Bio PLC	2,4-diaminopyrimidine	Dihydrofolate reductase	Yes: *S. aureus*	No	**Acute bacterial skin and skin structure infections** and **hospital-acquired bacterial pneumonia**[6]

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Cefiderocol (S-649266)	New drug application (U.S. FDA) and marketing authorization application (EMA) submitted	Shionogi & Co. Ltd.	Siderophore-β-lactam (cephalosporin)	PBP	Yes: *K. pneumoniae, A. baumannii, P. aeruginosa, Enterobacter spp.*	Yes (CRE, CRAB, and CRPA)	**Complicated urinary tract infections**, hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia, bloodstream infections, and sepsis
Imipenem/ cilastatin + relebactam (MK-7655A)	New drug application (U.S. FDA) and marketing authorization application (EMA) submitted	Merck & Co. Inc.	β-lactam (carbapenem)/ dehydropeptidase inhibitor + β-lactamase inhibitor (diazabicyclooctane)	PBP + β-lactamase	Yes: *K. pneumoniae, P. aeruginosa, Enterobacter spp.*	Yes (CRE), possibly (CRPA)	**Complicated urinary tract infections** including pyelonephritis, **complicated intra-abdominal infections**, and **hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**
Lascufloxacin (KRP-AM1977)[8]	New drug application submitted for community-acquired bacterial pneumonia (Japan PMDA)	Kyorin Pharmaceutical Co. Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	Yes: *S. aureus;* Possibly: *K. pneumoniae, A. baumannii*	No	Community-acquired bacterial pneumonia
Lefamulin (BC-3781)	New drug application (U.S. FDA) and marketing authorization application (EMA) submitted	Nabriva Therapeutics PLC	Pleuromutilin[10]	50S ribosomal subunit at the peptidyl transferase center	Yes: *S. aureus*	Possibly (*N. gonorrhoeae*)	**Acute bacterial skin and skin structure infections,**[6] **community-acquired bacterial pneumonia**, hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia,[6] cervicitis,[6] and urethritis[6]
ACX-362E	Phase 1[6]	Acurx Pharmaceuticals LLC	DCBG {(dichlorobenzyl) guanine}[10]	*C. difficile* DNA polymerase IIIC	No	Yes (*C. difficile*)	***C. difficile* infections**[6]
CRS3123	Phase 1	Crestone Inc.	Diaryldiamine[10]	Methionyl-tRNA synthetase[11]	Yes: *E. faecium, S. aureus*	Yes (*C. difficile*)	*C. difficile* infections

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Delpazolid[13] (LCB01-0371)	Phase 1	LegoChem Biosciences Inc. (Shanghai Haihe Pharmaceutical Co., Ltd./CSPC Pharmaceutical Group Ltd. licensees)	Oxazolidinone	50S subunit of bacterial ribosome	Yes: *E. faecium, S. aureus*	No	Gram-positive bacterial infections
ETX0282CPDP[14]/ ETX1317	Phase 1	Entasis Therapeutics Inc.	β-lactam (cephalosporin) + β-lactamase inhibitor (diazabicyclooctane)	PBP + β-lactamase	Yes: *K. pneumoniae, Enterobacter spp.*	Yes (CRE)	Urinary tract infections[6]
KBP-7072	Phase 1	KBP BioSciences Pharmaceutical Technical Co. Ltd.	Tetracycline	30S subunit of bacterial ribosome	Possibly: *E. faecium, S. aureus, A. baumannii*	Possibly (CRAB)	**Community-acquired bacterial pneumonia**[6] and hospital-acquired bacterial pneumonia[6]/ ventilator-associated bacterial pneumonia[6]
Meropenem + nacubactam (OP0595/ RG6080)	Phase 1	NacuGen Therapeutics Inc. (joint venture of Meiji Seika Pharma Co. Ltd./Fedora Pharmaceuticals Inc.)	β-lactam (carbapenem) + β-lactamase inhibitor (diazabicyclooctane)	PBP + β-lactamase/ PBP2	Yes: *K. pneumoniae, Enterobacter spp.*	Yes (CRE)	Complicated urinary tract infections,[6] complicated intra-abdominal infections,[6] and hospital-acquired bacterial pneumonia[6]/ ventilator-associated bacterial pneumonia[6]
SPR206	Phase 1	Spero Therapeutics Inc.	Polymyxin	Cell membrane	Yes: *K. pneumoniae, A. baumannii, P. aeruginosa, Enterobacter spp.*	Yes (CRE, CRPA, CRAB)	**Complicated urinary tract infections** and **hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**
SPR741[12]	Phase 1	Spero Therapeutics Inc.	Polymyxin	Cell membrane	Possibly: *K. pneumoniae, A. baumannii*	Possibly (CRE, CRPA, CRAB)	Gram-negative bacterial infections
TP-271	Phase 1	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes: *S. aureus, A baumannii*	Possibly (CRAB)	**Community-acquired bacterial pneumonia**[6]
TP-6076	Phase 1	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes: *K. pneumoniae, A. baumannii, Enterobacter spp.*	Yes (CRE and CRAB)	Gram-negative bacterial infections

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
WCK 5222 (cefepime + zidebactam)	Phase 1	Wockhardt Ltd.	β-lactam (cephalosporin) + β-lactamase inhibitor (diazabicyclooctane)	PBP + β-lactamase	Yes: *K. pneumoniae, A. baumannii, P. aeruginosa, Enterobacter spp.;* Possibly: *S. aureus*	Yes (CRE), possibly (CRAB, CRPA)	**Complicated urinary tract infections**[6] and **hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**[6]
Afabicin (Debio 1450)	Phase 2	Debiopharm International SA	Benzofuran naphthyridine[10]	FabI[11]	Yes: *S. aureus*	No	**Acute bacterial skin and skin structure infections** and **bone and joint infections** (Staphylococcus-specific)
ARV-1801 (Taksta, fusidic acid)[7]	Phase 2	Arrevus Inc. (acquired from Melinta Therapeutics Inc.)	Fusidane	Elongation factor G	Yes: *S. aureus*	No	**Acute bacterial skin and skin structure infections** and prosthetic joint infections
BOS-228 (LYS228)	Phase 2[6]	Boston Pharmaceuticals Inc. (In-licensed from Novartis AG)	β-lactam (monobactam)	PBP	Yes: *K. pneumoniae, Enterobacter spp.*	Yes (CRE)	Complicated urinary tract infections[6] and complicated intra-abdominal infections[6]
Brilacidin	Phase 2	Innovation Pharmaceuticals Inc.	Defensin mimetic[10]	Cell membrane	Yes: *S. aureus*	No	**Acute bacterial skin and skin structure infections**
CG-549	Phase 2	CrystalGenomics Inc.	Benzyl pyridinone[10]	FabI[11]	Yes: *S. aureus*	No	Acute bacterial skin and skin structure infections
DNV3837[14]/ DNV3681 (MCB3837[14]/ MCB3681)	Phase 2	Deinove SA	Oxazolidinone-quinolone hybrid	50S subunit of bacterial ribosome, bacterial type II topoisomerase	No	Yes (*C. difficile*)	***C. difficile* infections**
Finafloxacin[9]	Phase 2	MerLion Pharmaceuticals Pte Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	Yes: *S. aureus, K. pneumoniae, A. baumannii;* Possibly: *Enterobacter spp.*	Possibly (ESBL)	**Acute bacterial skin and skin structure infections,**[6] **complicated intra-abdominal infections,**[6] **complicated urinary tract infections** including pyelonephritis, and uncomplicated urinary tract infections

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Gepotidacin (GSK2140944)	Phase 2	GlaxoSmithKline PLC	Triazaacenaphthylene[10]	Bacterial type II topoisomerase (novel A subunit site)[11]	Yes: *S. aureus*	Yes (*N. gonorrhoeae*), possibly (ESBL)	Complicated urinary tract infections,[6] **uncomplicated urinary tract infections,** acute bacterial skin and skin structure infections, **uncomplicated urogenital gonorrhea**, and community-acquired bacterial pneumonia[6]
MGB-BP-3	Phase 2	MGB Biopharma Ltd.	Distamycin[10]	DNA minor groove binder[11]	Possibly: *E. faecium, S. aureus*	Yes (*C. difficile*)	***C. difficile* infections**
Nafithromycin (WCK 4873)	Phase 2	Wockhardt Ltd.	Macrolide	50S subunit of bacterial ribosome	Yes: *S. aureus*	No	**Community-acquired bacterial pneumonia**
OPS-2071	Phase 2	Otsuka Pharmaceutical Co. Ltd.	Quinolone	Bacterial type II topoisomerase	No	Yes (*C. difficile*)	*C. difficile* infections
Taigexyn (Nemonoxacin)[7]	Phase 2	TaiGen Biotechnology Co. Ltd.	Quinolone	Bacterial type II topoisomerase	Yes: *S. aureus*	No	**Community-acquired bacterial pneumonia, diabetic foot infection,** and **acute bacterial skin and skin structure infections**[6]
TNP-2092	Phase 2	TenNor Therapeutics Ltd.	Rifamycin-quinolone hybrid	RNA polymerase, DNA gyrase, DNA topoisomerase IV	Yes: *S. aureus*	No	**Acute bacterial skin and skin structure infections**
Cefepime + AAI101	Phase 3	Allecra Therapeutics GmbH	β-lactam (cephalosporin) + β-lactamase inhibitor (β-lactam)	PBP + β-lactamase	Yes: *K. pneumoniae, Enterobacter spp.*	Yes (ESBL), possibly (CRE)	**Complicated urinary tract infections** including pyelonephritis, **complicated intra-abdominal infections,**[6] and **hospital-acquired bacterial pneumonia[6]/ ventilator-associated bacterial pneumonia**[6]

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Cefepime + taniborbactam (VNRX-5133)	Phase 3	VenatoRx Pharmaceuticals Inc.	β-lactam (cephalosporin) + β-lactamase inhibitor (cyclic boronate)	PBP + β-lactamase	Yes: *K. pneumoniae, P. aeruginosa, Enterobacter spp.*	Yes (CRE), possibly (CRPA)	**Complicated urinary tract infections**[6]
Cefilavancin (TD-1792)	Phase 3[6]	R-Pharm/ Theravance Biopharma Inc.	Glycopeptide-β-lactam (cephalosporin) hybrid	PG chain elongation + PBP	Yes: *S. aureus*	No	Acute bacterial skin and skin structure infections
Ceftobiprole[7]	Phase 3	Basilea Pharmaceutica International Ltd.	β-lactam (cephalosporin)	PBP	Yes: *S. aureus, K. pneumoniae, Enterobacter spp.*	No	**Acute bacterial skin and skin structure infections, *S. aureus* bacteremia, community-acquired bacterial pneumonia**, and hospital-acquired bacterial pneumonia
Contezolid (MRX-I) & contezolid acefosamil (MRX-4)[14]	Phase 3[6]	MicuRx Pharmaceuticals Inc.	Oxazolidinone	50S subunit of bacterial ribosome	Yes: *E. faecium, S. aureus*	No	**Acute bacterial skin and skin structure infections**
Murepavadin (POL7080)	Phase 3	Polyphor AG	Antimicrobial peptide mimetic[10]	LptD[11]	Yes: *P. aeruginosa*	Yes (CRPA)	**Hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia, acute bacterial skin and skin structure infection,**[6] **bloodstream infection,**[6] and **complicated intra-abdominal infection**[6]
Ridinilazole (SMT 19969)	Phase 3	Summit Therapeutics PLC	Bis-benzimidazole[10]	Inhibition of cell division and reduction of toxin production[15]	No	Yes (*C. difficile*)	***C. difficile* infections**
Sulbactam-durlobactam (SUL- DUR) (ETX2514SUL)	Phase 3	Entasis Therapeutics Inc.	β-lactam (sulbactam) + β-lactamase inhibitor (diazabicyclooctane)	PBP + β-lactamase	Yes: *A. baumannii*	Yes (CRAB)	Complicated urinary tract infection including acute pyelonephritis, and **hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Sulopenem/ sulopenem-etzadroxil[14]	Phase 3	Iterum Therapeutics PLC	β-lactam (carbapenem)	PBP	Yes: *K. pneumoniae, Enterobacter spp.*	Yes (*N. gonorrhoeae*, ESBL)	**Complicated urinary tract infections, uncomplicated urinary tract infections, complicated intra-abdominal infections, community-acquired pneumonia,[6] acute bacterial prostatitis,[6] gonococcal urethritis,[6] and pelvic inflammatory disease[6]**
T-4288 (solithromycin)[8]	Phase 3[6]	Toyama Chemical Co. Ltd.	Macrolide	50S subunit of bacterial ribosome	No	Yes (*N. gonorrhoeae*)	**Community-acquired bacterial pneumonia** and **uncomplicated urogenital gonorrhea**
Tebipenem-Pivoxil (SPR994[14]/ SPR859)[7]	Phase 3	Spero Therapeutics Inc.	β-lactam (carbapenem)	PBP	Yes: *K pneumoniae, P. aeruginosa*	Yes (ESBL)	**Community-acquired bacterial pneumonia,[6] complicated urinary tract infections, diabetic foot infection**,[6] and acute pyelonephritis
WCK 771/ WCK 2349[14] (levonadifloxacin, alalevonadifloxacin)	Phase 3[6]	Wockhardt Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	Yes: *S. aureus*	No	**Hospital-acquired bacterial pneumonia**,[6] acute bacterial skin and skin structure infections, diabetic foot infection,[6] and community-acquired bacterial pneumonia[6]
Zoliflodacin (ETX0914)	Phase 3	Entasis Therapeutics Inc.	Spiropyrimidinetrione[10]	Bacterial type II topoisomerase (GyrB)[11]	Yes: *S. aureus*	Yes (*N. gonorrhoeae*)	**Uncomplicated gonorrhea**

For definitions of drug development terms, visit:

https://www.pewtrusts.org/en/research-and-analysis/articles/2014/03/12/glossary-for-the-antibiotic-pipeline

Note: The following drugs have been removed from the pipeline. Removed candidates will be included in future updates if development resumes. In the case of the September 2017 update, candidates were added to reflect the expanded global scope of the pipeline.

June 2019 review: AIC499 was removed during the June 2019 review because there was direct communication from the company regarding the termination of development.

December 2018 review: No changes.

June 2018 review: Cadazolid, DS-2969, GSK3342830, and Zabofloxacin were removed during the June 2018 review. These drugs were either no longer included in the research and development pipelines on the company website, or there was direct communication from the company regarding the status of the drugs.

September 2017 review: The antibiotics pipeline was expanded to include global development. With the expanded global methodology, the following antibiotics were added: lascufloxacin, AIC499, and AAI-101. Ramoplanin and TD-1607 were removed during the September 2017 review because they were no longer included in the research and development pipelines on the company's website. Aztreonam + Avibactam was removed from the pipeline because avibactam is an approved beta-lactamase inhibitor.

March 2017 review: Ceftaroline + Avibactam was removed during the March 2017 review because it was no longer included in the research and development pipelines on the company's website.

September 2016 review: BAL30072 was removed during the September 2016 review because it was no longer included in the research and development pipelines on the company website.

March 2016 review: Radezolid, Debio 1452, avarofloxacin, and surotomycin were removed during the March 2016 review. Radezolid was removed because systemic indications for this product were no longer included in the development plans listed on the sponsor website. Debio 1452, avarofloxacin, and surotomycin were no longer included in the research and development pipelines on the company website.

September 2015 review: No changes.

March 2015 review: No changes.

December 2014 review: EDP-788 (Enanta Pharmaceuticals) and TD-1792 (Theravance Biopharma) were removed during the December 2014 review. These drugs were either no longer included in the research and development pipelines on the company website, or there was direct communication from the company regarding the status of the drugs. Additionally, GSK-2696266, which had been removed during the September 2014 review, is included in this pipeline again as S-649266, which is being developed by Shionogi.

September 2014 review: GSK-2696266 and GSK-1322322 (GlaxoSmithKline), ACHN-975 (Achaogen), and LFF571 (Novartis) were removed during the September 2014 review. These drugs were either no longer included in the research and development pipelines on the company website, or there was direct communication from the company regarding the status of the drugs.

June 2014 review: Ceftobiprole, an antibiotic developed by Basilea Pharmaceutica, had been included in our analysis; however, the company announced in June 2014 that it is not pursuing further development in the United States until a partner has been acquired. As of April 2016, Basilea announced a partnership with BARDA for Phase 3 development of ceftobiprole in the United States.

* Michael Hay et al., "Clinical Development Success Rates for Investigational Drugs," *Nature Biotechnology* 32, no. 1 (2014): 40–51, https://www.ncbi.nlm.nih.gov/pubmed/24406927.

See more at http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinicaldevelopment.

Endnotes

1 Drugs with the potential to treat *Clostridioides difficile*-associated disease are also included in this resource, even though they do not necessarily work systemically, as the Centers for Disease Control and Prevention (CDC) cited *C. difficile* as an urgent public health threat in a 2013 report ("Antibiotic Resistance Threats in the United States, 2013": http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf). Specifically excluded are drugs to treat mycobacterial infections, such as tuberculosis and *Mycobacterium avium complex*, *Helicobacter pylori*, and biothreat pathogens. Locally acting drugs such as topical, ophthalmic, and inhaled products are also excluded. Biological products, including vaccines and antibodies, are tracked separately in Pew's nontraditional pipeline ("Nontraditional Products for Bacterial Infections in Clinical Development," http://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development).

2 Based on the most advanced development phase for any indication according to trials registered in a government clinical trial registry (United States, http://www.clinicaltrials.gov; Australian New Zealand Clinical Trials Registry, http://www.anzctr.org.au; European Union Clinical Trials Register, https://www.clinicaltrialsregister.eu; Japan Pharmaceutical Information Center, http://www.clinicaltrials.jp), unless direct communication from the company indicated differently. If no trials were included in a clinical trial registry, then the phase listed on the company website or provided directly by the company is noted by endnote 6. Antibiotics that have been approved will remain listed for one year following approval of the initial indication. The country and regulatory agency that approved the drug will be indicated in parentheses. Antibiotics that are approved in a country outside of the U.S., but are still in clinical development for the U.S. market, will remain in the pipeline and noted.

3 A "yes" in this column indicates that a drug has *in vitro* and/or *in vivo* data showing activity against bacteria that are considered ESKAPE pathogens (Gram-positive: *Enterococcus faecium, Staphylococcus aureus*; Gram-negative: *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, or *Enterobacter species*). An ESKAPE pathogen indicated as "yes" requires activity against at least one bacterial species. A "possibly" in this column indicates a candidate with activity information reported by the company via a corporate website, news release, or direct communication, and/or with inconclusive *in vitro/in vivo* data. Drugs noted with an endnote 12 may be listed as "possibly" because activity is uncertain until the paired antibiotic is confirmed. The column definition was revised in September 2019. In previous versions of this chart, the column included all drugs with Gram-negative activity (including drugs active against *Neisseria gonorrhoeae* or *Haemophilus influenzae*), and drugs with activity against resistant Gram-negative ESKAPE pathogens.

4 A "yes" in this column indicates a drug with the potential to address at least one of the pathogens identified by CDC as an urgent threat or World Health Organization (WHO) critical threat. The target pathogen is listed in parentheses. CDC urgent threats include *C. difficile*, carbapenem-resistant Enterobacteriaceae (CRE), and drug-resistant *N. gonorrhoeae*. WHO critical priority pathogens include carbapenem-resistant *Acinetobacter baumannii* (CRAB), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant Enterobacteriaceae (CRE)/extended spectrum β-lactamase (ESBL) producing Enterobacteriaceae (WHO, "Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics" (2017), https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed). Because a drug with activity against CRE is also generally active against ESBL-producing Enterobacteriaceae, ESBL activity is not noted unless the drug is not active against CRE, but is against ESBL-producing Enterobacteriaceae. A "possibly" in this column indicates a drug with activity information reported by the company via a corporate website, news release, or direct communication, and/or with inconclusive *in vitro/in vivo* data. Drugs noted with an endnote 12 may be listed as "possibly" because activity is uncertain until the paired antibiotic is confirmed. This column was revised in September 2017 to include WHO's critical threat pathogens.

5 Based on clinical trials currently registered on a government clinical trial registry, and/or reported qualified infectious disease product (QIDP) designations, unless otherwise noted. Bolded indications are reported QIDP designations. QIDP designations are given by the FDA to antibiotics intended to treat serious or life-threatening infections. QIDPs are eligible to receive benefits under the Generating Antibiotic Incentives Now Act (signed into law as part of the Food and Drug Administration Safety and Innovation Act), including expedited FDA review and extended exclusivity for approved products.

6 Information not currently registered on a clinical trial registry. Information obtained from the company via a corporate website, news release, and/or direct communication.

7 This antibiotic has been approved in a country outside the U.S., but remains in the pipeline because it is currently in development for the U.S. market. Taigexyn (Nemonoxacin) has been approved for community-acquired bacterial pneumonia in Taiwan, Province of China and China. ARV-1801 (Taksta, fusidic acid) has been approved for acute bacterial skin and soft tissue infections in outside markets. Ceftobiprole has been approved for community-acquired pneumonia and hospital-acquired bacterial pneumonia in outside markets. SPR994 has been approved for pneumonia, otitis media, and sinusitis in Japan.

8 Products added after expanded methodology in September 2017 pipeline update to include global antibiotic development (see **methodology section** for further details on determining product inclusion). Currently, there is no public information available indicating that these antibiotics are in development for the U.S. market.

9 In February 2015, FDA approved an otic suspension formulation of finafloxacin to treat acute otitis externa. Because a systemic formulation of finafloxacin has not received approval in any country, this drug remains listed in our pipeline. Finafloxacin has shown the potential for improved activity under certain conditions, namely acidic environments. Additionally, a company press release noted that Phase 2 complicated urinary tract infection study results have shown improved clinical outcomes in patients treated with finafloxacin compared with patients treated with the current standard of care.

10 A novel drug class is defined as a core chemical structure (scaffold) that has not previously been used systemically as an antibacterial in humans.

11 A target is defined as novel if the drug acts on a bacterial structure that has not previously been targeted by a systemic antibacterial in humans.

12 This drug is an antibiotic potentiator, which increases the entry and, therefore, the efficacy of antibiotics. The antibiotic this drug will be paired with has not yet been announced.

13 Delpazolid (LCB01-0371) is also in development for tuberculosis, but remains in the pipeline because it is also being developed for bacterial infections.

14 This is the prodrug form of the antibiotic, which has the same mechanism of action and core chemical structure, and is being developed for the distinct benefit of being able to be administered in other ways, e.g., oral or intravenously.

15 The drug target has not yet been fully elucidated.

Sources

i Citeline, "Pharmaprojects," (2012), http://www.citeline.com/products/pharmaprojects.

ii U.S. National Institutes of Health, "Search for Studies," http://www.clinicaltrials.gov.

iii Helen W. Boucher et al., "10 x '20 Progress—Development of New Drugs Active Against Gram-Negative Bacilli: An Update From the Infectious Diseases Society of America," *Clinical Infectious Diseases* 56 (2013): 1685-94, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3707426.

iv Michael J. Pucci and Karen Bush, "Investigational Antimicrobial Agents of 2013," *Clinical Microbiology Reviews* 26, no. 4 (2013): 792-821, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3811234.

v Centers for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States, 2013" (2013), http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf.

vi World Health Organization, "Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics" (2017), http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en.

vii World Health Organization, "Antibacterial Agents in Clinical Development: An Analysis of the Antibacterial Clinical Development Pipeline, Including Tuberculosis," (2017), http://www.who.int/medicines/areas/rational_use/antibacterial_agents_clinical_development/en/.

For further information, please visit:

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