Antibiotics Currently in Global Clinical Development

Note: This data visualization was updated in December 2017 with new data.

As of September 2017, approximately 48 new antibiotics[1] 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. It will be updated periodically, as products advance or are known to drop out of development. Because this list is updated periodically, endnote numbers may not be sequential. In September 2017, the antibiotics pipeline was expanded to include products in development globally. Please contact **abxpipeline@pewtrusts.org** with additions or updates.

Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Baxdela (delafloxacin)	Approved June 19, 2017 (U.S. FDA)	Melinta Therapeutics Inc.	Fluoroquinolone	Bacterial type II topoisomerase	Possibly	No	*Approved for:* **Acute bacterial skin and skin structure infections;** *other potential indications:* **community-acquired bacterial pneumonia** and complicated urinary tract infections[6]
Vabomere (Meropenem + Vaborbactam)	Approved Aug. 30, 2017 (U.S. FDA)	Rempex Pharmaceuticals Inc. (wholly owned subsidiary of The Medicines Co.)	β-lactam (carbapenem) + β-lactamase inhibitor (cyclic boronate)[11,13]	PBP; β-lactamase	Yes	Yes (CRE)	*Approved for:* **Complicated urinary tract infections** including pyelonephritis; *other potential indications*: **complicated intra-abdominal infections, hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**
Plazomicin	New drug application submitted for complicated urinary tract infections (U.S. FDA)	Achaogen Inc.	Aminoglycoside	30S subunit of bacterial ribosome	Yes	Yes (CRE)	**Complicated urinary tract infections** including acute pyelonephritis**, hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia, complicated intra-abdominal infections**
AIC499[9]	Phase 1[6]	AiCuris	β-lactam	PBP	Possibly	Possibly (CRE, CRPA, CRAB)	Bacterial infections

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Cefepime + Zidebactam (WCK 5222)	Phase 1	Wockhardt Ltd.	β-lactam (cephalosporin) + β-lactamase inhibitor (diazabicyclooctane)	PBP; β-lactamase	Yes	Yes (CRE); possibly (CRPA)	**Complicated urinary tract infections,[6]** and **hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia[6]**
CRS3123	Phase 1	Crestone Inc.	Diaryldiamine[11]	Methionyl-tRNA synthetase[12]	No	Yes (*C. difficile*)	*C. difficile* infections
Delpazolid[15] (LCB01-0371)	Phase 1	LegoChem Biosciences Inc.	Oxazolidinone	50S subunit of bacterial ribosome	No	No	Bacterial infections
DS-2969	Phase 1[6]	Daiichi Sankyo	Unknown	Bacterial type II topoisomerase (GyrB)	No	Yes (*C. difficile*)	Bacterial enteritis
ETX2514SUL	Phase 1	Entasis Therapeutics Inc.	β-lactam (sulbactam) + β-lactamase inhibitor (diazabicyclooctane)	PBP; β-lactamase	Yes	Yes (CRAB)	Bacterial infections (caused by *A. baumannii*)[6]
GSK3342830	Phase 1	GlaxoSmithKline PLC (Shionogi licensee)	Siderophore-β-lactam (cephalosporin)	PBP	Yes	Yes (CRE, CRAB, CRPA)	Bacterial infections
KBP-7072	Phase 1	KBP BioSciences Pharmaceutical Technical Co. Ltd.	Tetracycline	30S subunit of bacterial ribosome	Possibly	No	**Community-acquired bacterial pneumonia[6]**
MCB3837	Phase 1[6]	Morphochem Ag.	Oxazolidinone-quinolone hybrid	50S subunit of bacterial ribosome; bacterial type II topoisomerase	No	Yes (*C. difficile*)	***C. difficile* infections[6]**
MGB-BP-3	Phase 1	MGB Biopharma Ltd.	Distamycin[11]	DNA minor groove binder[12]	No	Yes (*C. difficile*)	***C. difficile*-associated diarrhea**
Nacubactam (OP0595/ RG6080)	Phase 1	Meiji Seika Pharma Co. Ltd./Fedora Pharmaceuticals Inc. (Roche licensee)	β-lactamase inhibitor (diazabicyclooctane)	β-lactamase, PBP2	Yes	Yes (CRE); possibly (CRPA)	**Bacterial infections**
SPR741[14]	Phase 1	Spero Therapeutics Inc.	Polymyxin	Cell membrane[12]	Possibly	Possibly (CRE, CRPA, CRAB)	**Bacterial infections**

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
SPR994[7]	Phase 1[6]	Spero Therapeutics Inc.	β-lactam (carbapenem)	PBP	Yes	No	**Community-acquired bacterial pneumonia**[6] and **complicated urinary tract infections**[6]
TP-271	Phase 1	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	No	No	**Community-acquired bacterial pneumonia**
TP-6076	Phase 1[6]	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes	Yes (CRE and CRAB)	Bacterial infections
VNRX-5133	Phase 1	VenatoRx Pharmaceuticals	β-lactamase inhibitor	β-lactamase	Possibly	Possibly (CRE, CRPA, CRAB)	Bacterial infections
Afabicin (Debio 1450)/ Debio 1452[16]	Phase 2	Debiopharm International SA	Benzofuran naphthyridine[11]	FabI[12]	No	No	**Acute bacterial skin and skin structure infections** (*Staphylococcus*-specific)
Brilacidin	Phase 2	Innovation Pharmaceuticals Inc. (formerly Cellceutix Corp.)	Defensin mimetic[11]	Cell membrane	No	No	**Acute bacterial skin and skin structure infections**
Cefepime + AAI101[9]	Phase 2	Allecra	β-lactam (cephalosporin) + β-lactamase inhibitor (β-lactam)	PBP; β-lactamase	Yes	Possibly (CRE)	**Complicated urinary tract infections** including pyelonephritis, **complicated intra-abdominal infections, and hospital-acquired bacterial pneumonia/ ventilator-associated bacterial pneumonia**
CG400549	Phase 2	CrystalGenomics Inc.	Benzyl pyridinone[11]	FabI[12]	No	No	Acute bacterial skin and skin structure infections
Finafloxacin[10]	Phase 2	MerLion Pharmaceuticals Pte Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	Yes	No	**Acute bacterial skin and skin structure infections, complicated intra-abdominal infections,** and **complicated urinary tract infections,** including pyelonephritis
Gepotidacin (GSK2140944)	Phase 2	GlaxoSmithKline PLC	Triazaacenaphthylene[11]	Bacterial type II topoisomerase (novel A subunit site)[12]	No	Yes (*N. gonorrhoeae*)	Complicated urinary tract infections,[6] **uncomplicated urinary tract infections,**[6] acute bacterial skin and skin structure infections, **uncomplicated urogenital gonorrhea,**[6] and community-acquired bacterial pneumonia[6]

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
LYS228	Phase 2	Novartis Ag.	β-lactam (monobactam)	PBP	Yes	Yes (CRE)	**Bacterial infections**
Murepavadin (POL7080)	Phase 2	Polyphor Ltd.	Antimicrobial peptide mimetic[11]	LptD[12]	Yes	Yes (CRPA)	**Ventilator-associated bacterial pneumonia** (caused by *P. aeruginosa*)
Nafithromycin (WCK 4873)	Phase 2	Wockhardt Ltd.	Macrolide	50S subunit of bacterial ribosome	No	No	**Community-acquired bacterial pneumonia**
Nemonoxacin[7]	Phase 2	TaiGen Biotechnology Co. Ltd.	Quinolone	Bacterial type II topoisomerase	No	No	**Community-acquired bacterial pneumonia,** diabetic foot infection, and **acute bacterial skin and skin structure infections**
OPS-2071	Phase 2	Otsuka Pharmaceutical Co. Ltd.	Quinolone	Bacterial type II topoisomerase	No	Yes (*C. difficile*)	*C. difficile* infection
Ridinilazole (SMT 19969)	Phase 2	Summit Therapeutics PLC	Bis-benzimidazole[11]	Unknown	No	Yes (*C. difficile*)	***C. difficile* infection**
WCK 771/ WCK 2349[16]	Phase 2[6]	Wockhardt Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	No	No	**Hospital-acquired bacterial pneumonia[6]**
Zoliflodacin (ETX0914)	Phase 2	Entasis Therapeutics Inc.	Spiropyrimidinetrione[11]	Bacterial type II topoisomerase (GyrB)[12]	No	Yes (*N. gonorrhoeae*)	**Uncomplicated gonorrhea**
Cadazolid	Phase 3	Actelion Pharmaceuticals Ltd. (wholly owned subsidiary of Johnson & Johnson Services Inc.)	Oxazolidinone-quinolone hybrid	50S subunit of bacterial ribosome; bacterial type II topoisomerase	No	Yes (*C. difficile*)	***C. difficile* infection**
Cefiderocol (S-649266)	Phase 3	Shionogi & Co. Ltd.	Siderophore-β-lactam (cephalosporin)	PBP	Yes	Yes (CRE, CRAB, and CRPA)	**Complicated urinary tract infections**
Cefilavacin (TD-1792)	Phase 3[6]	R-Pharm/ Theravance Biopharma Inc.	Glycopeptide-β-lactam (cephalosporin) hybrid	PG chain elongation; PBP	No	No	Acute bacterial skin and skin structure infections

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Ceftobiprole[7]	Phase 3	Basilea Pharmaceutica	β-lactam (cephalosporin)	PBP	Yes	No	**Acute bacterial skin and skin structure infections, community-acquired bacterial pneumonia** and hospital-acquired bacteria pneumonia
Eravacycline	Phase 3	Tetraphase Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes	Yes (CRE); possibly (CRAB)	**Complicated intra-abdominal infections** and **complicated urinary tract infections**
Iclaprim	Phase 3	Motif Bio PLC	2,4-diaminopyrimidine	Dihydrofolate reductase	No	No	**Acute bacterial skin** and **skin structure infections** and **hospital-acquired bacterial pneumonia**
Imipenem/ cilastatin + relebactam (MK-7655)	Phase 3	Merck & Co. Inc.	β-lactam (carbapenem) + β-lactamase inhibitor (diazabicyclooctane)	PBP; β-lactamase	Yes	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)[9]	Phase 3	Kyorin Pharmaceutical Co. Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	No	No	Community-acquired bacterial pneumonia
Lefamulin (BC-3781)	Phase 3	Nabriva Therapeutics Ag.	Pleuromutilin[11]	50S subunit of bacterial ribosome	No	No	**Acute bacterial skin and skin structure infections,**[6] **community-acquired bacterial pneumonia,** and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia[6]
MRX-I/MRX-4[16]	Phase 3[6]	MicuRx Pharmaceuticals Inc.	Oxazolidinone	50S subunit of bacterial ribosome	No	No	Acute bacterial skin and skin structure infections
Omadacycline	Phase 3	Paratek Pharmaceuticals Inc.	Tetracycline	30S subunit of bacterial ribosome	Yes	Possibly (CRAB)	**Community-acquired bacterial pneumonia, acute bacterial skin and skin structure infections, complicated urinary tract infections,** and **uncomplicated urinary tract infections**
Solithera (solithromycin)	Phase 3	Cempra Inc.	Macrolide	50S subunit of bacterial ribosome	No	Yes (*N. gonorrhoeae*)	**Community-acquired bacterial pneumonia** and **uncomplicated urogenital gonorrhea**
Sulopenem	Phase 3[6]	Iterum Therapeutics Ltd.	β-lactam (carbapenem)	PBP	Yes	No	**Complicated urinary tract infections,**[6] **uncomplicated urinary tract infections,**[6] and **complicated intra-abdominal infections**[6]

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Drug name	Development phase[2]	Company	Drug class	Target	Expected activity against resistant Gram-negative ESKAPE pathogens?[3]	Expected activity against CDC urgent or WHO critical threat pathogen?[4]	Potential indication(s)?[5]
Taksta (fusidic acid)[7,8]	Phase 3	Cempra Inc.	Fusidane	Elongation factor G	No	No	**Acute bacterial skin and skin structure infections** and prosthetic joint infections
Zabofloxacin[7]	Phase 3[6]	Dong Wha Pharmaceutical Co. Ltd.	Fluoroquinolone	Bacterial type II topoisomerase	No	No	Community-acquired bacterial pneumonia

For definitions of drug development terms, visit:

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

Note: The following changes were made to the pipeline. Drugs that have been removed from the list will be included in future updates if development resumes:

February 2018: This data visualization was updated to correct the drug classification of Cefepime + AAI101.

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 β-lactamase inhibitor.

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

September 2016 review: BAL30072 was removed 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. 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. 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. In April 2016, Basilea announced a partnership with BARDA for phase 3 development of ceftobiprole in the United States. This product will be included in our pipeline once development commences.

* Michael Hay et al., "Clinical Development Success Rates for Investigational Drugs," *Nature Biotechnology* 32, no. 1 (2014): 40–51, doi:10.1038/nbt.2786. See more at http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinical-development.

Endnotes

1 Antibiotics listed here include products containing at least one component not previously approved in the United States or in another country. All analyses were strictly limited to systemic antibiotics (drugs that work throughout the body) and drugs to treat *Clostridium difficile*-associated disease. The Centers for Disease Control and Prevention cited *C. difficile* as an urgent public health threat in a 2013 report ("Antibiotic Resistance Threats in the United States, 2013" (2013), http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf). This pipeline is also limited to drugs with the potential to treat serious or life-threatening infections. Specifically excluded were drugs to treat mycobacterial infections, such as tuberculosis and *Mycobacterium avium* complex, *Helicobacter pylori,* and biothreat pathogens. Additionally, biological products, vaccines, and locally acting drugs such as topical, ophthalmic, and inhaled products were excluded.

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 the U.S. but are still in clinical development for the U.S. market will remain on the pipeline and noted.

3 A "yes" in this column indicates that a drug has in vitro data showing both activity against one or more Gram-negative bacteria that are considered ESKAPE pathogens (*Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, or Enterobacter* species) and the potential for clinically significant improved coverage of resistant isolates of these species relative to currently available antibiotics. Excluded are drugs that may have shown in vitro activity but currently have no relevant indications listed in this pipeline. This generally does not apply to phase 1 drugs whose indications are often unknown. Five drugs are listed as "possibly" according to these criteria. It is suspected that KBP-7072, VNRX-5133, and SPR741 will meet the criteria for this column, but each is listed as "possibly" pending identification of the β-lactam antibiotic with which it will be combined. Similarly, there are currently no publicly available in vitro data for AIC499; however, information found in company press releases suggests that this product will meet the criteria for this column. Baxdela (delafloxacin) is also listed as "possibly." Although current data show the potential for improved coverage compared with currently available fluoroquinolones in acidic environments, it is not clear how this in vitro benefit will translate into clinical efficacy. This column focuses on only one area of unmet medical need. However, stakeholders often highlight resistant Gram-negative ESKAPE pathogens as an area in which innovation is urgently needed and drug discovery and development are particularly challenging. This column is based on information available in the literature, but we welcome any additional information a company may be able to provide. The column definition was revised in March 2015. In previous versions of this chart, the column included all drugs with Gram-negative activity (including drugs active against *Neisseria gonorrhoeae* or *Haemophilus influenzae*).

4 A "yes" in this column indicates a drug with the potential to address one of the pathogens identified by the CDC as an urgent threat or World Health Organization (WHO) critical threat. The pathogen targeted is listed in parentheses. CDC urgent threats include *C. difficile*, carbapenem-resistant Enterobacteriaceae (CRE), and drug-resistant *N. gonorrhoeae*. WHO antibiotic-resistant critical priority pathogens include carbapenem-resistant *A. baumannii* (CRAB), carbapenem-resistant *P. aeruginosa* (CRPA), and carbapenem-resistant/extended spectrum β-lactamase producing Enterobacteriaceae ("Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics, 2017" [Aug. 28, 2017], http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/). Excluded are drugs that may have shown in vitro activity but currently have no relevant indications listed in this pipeline. This generally does not apply to phase 1 drugs whose indications are often unknown. AIC499, SPR741, and VNRX-5133 are listed as "possibly" in this column, for the same reasons as explicated in endnote 3. 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 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 government 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 on the pipeline since it is currently in development for the U.S. market. Nemonoxacin has been approved for community-acquired bacterial pneumonia in Taiwan, Province of China and China. Taksta (fusidic acid) has been approved for acute bacterial skin and soft tissue infections in outside markets. Zabofloxacin has been approved for acute exacerbations of chronic obstructive pulmonary disease in South Korea. 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 This drug has been granted an orphan designation from FDA. Taksta received designation for the indication of prosthetic joint infections and iclaprim for cystic fibrosis lung infections.

9 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.

10 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.

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

12 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.

13 Vaborbactam is a cyclic boronate β-lactamase inhibitor and is combined with a previously approved carbapenem. β-lactamase inhibitors have been paired with β-lactams in the past, but this β-lactamase inhibitor has a novel chemical structure.

14 SPR741 is an antibiotic potentiator that makes the outer membrane of Gram-negative bacteria more permeable, increasing the entry and, therefore, the efficacy of antibiotics. The antibiotic that SPR741 will be paired with has not yet been announced.

15 Delpazolid (LCB01-0371) is also in development for tuberculosis but remains on the pipeline since it is also being developed for bacterial infections.

16 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.

Sources

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For further information, please visit:

pewtrusts.org/antibiotic-pipeline

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