Nontraditional Products for Bacterial Infections in Clinical Development

As of June 2018, an estimated 30 new nontraditional products[1] with the potential to treat or prevent serious bacterial infections are in clinical development. Below is a snapshot of the current nontraditional products pipeline, based on publicly available information and informed by external experts. It is 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. Please contact **abxpipeline@pewtrusts.org** with additions or updates.

Drug name	Development phase[2]	Company	Type of product	Potential indication(s)[3]
DSTA4637S	Phase 1	Genentech (member of the Roche Group)	Antibody	Bacterial infections (caused by *S. aureus*)
PolyCAb	Phase 1[6]	MicroPharm Ltd.	Antibody	Recurrent *C. difficile* infections
RBX7455	Phase 1	Rebiotix Inc. (wholly owned subsidiary of Ferring Pharmaceuticals Inc.)	Probiotic	Recurrent *C. difficile* infections
SER-262	Phase 1	Seres Therapeutics Inc.	Probiotic	Recurrent *C. difficile* infections
StebVax	Phase 1	Integrated BioTherapeutics Inc.	Vaccine	Prevention of toxic shock syndrome from staphylococcal enterotoxin B
VE303	Phase 1	Vedanta Biosciences Inc.	Probiotic	Recurrent *C. difficile* infections
514G3	Phase 2	XBiotech Inc.	Antibody	Bacteremia (caused by *S. aureus*)
Aerucin (AR-105)	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (caused by *P. aeruginosa*)

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Drug name	Development phase[2]	Company	Type of product	Potential indication(s)[3]
Aerumab (AR-101)	Phase 2[4]	Aridis Pharmaceuticals Inc.	Antibody	Hospital-acquired/ventilator-associated pneumonia (caused by *P. aeruginosa* serotype 011)
CAL02	Phase 2[6]	Combioxin SA	Virulence inhibitor (liposome)	Severe bacterial pneumonia
CF-301	Phase 2	ContraFect Corp.	Lysin	Bacteremia and endocarditis (caused by *S. aureus*)
CP101	Phase 2	Finch Therapeutics	Probiotic	Recurrent *C. difficile* infections
DAV132	Phase 2[6]	Da Volterra	Antibiotic inactivator[5]	Prevention of *C. difficile* infections
ExPEC4V (JNJ-63871860)	Phase 2	Janssen Research & Development LLC	Vaccine	Prevention of extraintestinal pathogenic *E. coli* serotypes O1, O2, O6, and O25
IMM-529	Phase 2	Immuron Ltd.	Antibody	Recurrent *C. difficile* infections
MEDI3902	Phase 2[4]	MedImmune Inc. (wholly owned subsidiary of AstraZeneca PLC)	Antibody	Prevention of nosocomial bacterial pneumonia (*P. aeruginosa*)
Suvratoxumab (MEDI4893)	Phase 2[4]	MedImmune Inc. (wholly owned subsidiary of AstraZeneca PLC)	Antibody	Prevention of nosocomial bacterial pneumonia (*S. aureus*)
NDV-3A	Phase 2	NovaDigm Therapeutics Inc.	Vaccine	Prevention of bacterial infections (*S. aureus*)
N-Rephasin (SAL200)	Phase 2[4]	iNtRON Biotechnology Inc.	Lysin	Bacterial infections (caused by *Staphylococcus* spp.)
PF-06482077	Phase 2	Pfizer Inc.	Vaccine	Prevention of pneumococcal disease
Ribaxamase (SYN-004)	Phase 2	Synthetic Biologics Inc.	Antibiotic inactivator[5]	Prevention of *C. difficile* infections
***S. pneumoniae* next-generation vaccine (GSK-2189241A)[7]**	Phase 2[6]	GlaxoSmithKline	Vaccine	Prevention of *S. pneumoniae* disease
SA4Ag	Phase 2	Pfizer Inc.	Vaccine	Prevention of *S. aureus* infection

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Drug name	Development phase[2]	Company	Type of product	Potential indication(s)[3]
Salvecin (AR-301)	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (*S. aureus*)
Shigella	Phase 2[6]	GlaxoSmithKline	Vaccine	Prevention of *Shigella* infections
V114[7]	Phase 3	Merck & Co. Inc.	Vaccine	Prevention of pneumococcal disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F
PF-06425090	Phase 3	Pfizer Inc.	Vaccine	Prevention of *C. difficile* infections
RBX2660	Phase 3	Rebiotix Inc. (wholly owned subsidiary of Ferring Pharmaceuticals Inc.)	Probiotic	Recurrent *C. difficile* infections and urinary tract infections
Reltecimod (AB103)	Phase 3	Atox Bio	Peptide immunomodulator	Necrotizing soft tissue infections and sepsis-associated acute kidney injury
SER-109	Phase 3	Seres Therapeutics Inc.	Probiotic	Recurrent *C. difficile* infections

Note: The following drugs have been removed from the pipeline. They will be included in future updates if development resumes:

June 2018: ASN100, GEN 004, Group B *Streptococcus* vaccine, and VLA84 (IC84) were removed because they were no longer included in the research and development pipeline on the company's website.

September 2017: Shigamab and Cdiffense were removed because they were no longer included in the research and development pipeline on the company's website.

Endnotes

1 Products listed here contain at least one component not previously approved in the United States. This pipeline is limited to products with the potential to treat or prevent infections caused by bacterial pathogens considered by the Centers for Disease Control and Prevention to be urgent, serious, or concerning threats (CDC, "Antibiotic Resistance Threats in the United States, 2013," Sept. 16, 2013, https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf). All analyses were limited to systemic products (drugs that work throughout the body) and therapies to treat *Clostridium difficile*-associated disease. Additionally, we excluded drugs to treat mycobacterial infections, such as tuberculosis and *Mycobacterium avium* complex, *Helicobacter pylori*, and biothreat pathogens. Lastly, excluded were locally acting therapies such as topical, ophthalmic, and inhaled products. Additionally, many of these products are not likely to be used as a stand-alone treatment, but as an adjunct to standard-of-care antibiotics.

2 Based on the most advanced development phase for any indication according to trials registered at clinicaltrials.gov, unless direct communication from the company indicated differently. If no trials were included at clinicaltrials.gov, the phase listed on the company website or provided directly by the company is noted.

3 Based on clinical trials currently registered at clinicaltrials.gov unless otherwise noted.

4 Registered at clinicaltrials.gov but with no current study sites within the United States.

5 Ribaxamase is a β-lactamase, which is given orally and prophylactically with an IV antibiotic. Ribaxamase degrades antibiotics in the gastrointestinal tract to minimize collateral damage to the gut microbiome and prevent occurrence of *C. difficile*. DAV132 is an activated charcoal approach, which is given prophylactically and acts to absorb antibiotics in the GI tract to minimize damage to the gut microbiome and prevent the occurrence of *C. difficile*.

6 Information obtained from the company via a corporate website, news release, and/or direct company communication.

7 Vaccines for *S. pneumoniae* have been approved and widely used. The products in development listed in this table have the potential for expanded serotype coverage.

For further information, please visit:

pewtrusts.org/antibiotic-pipeline

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