Nontraditional Products for Bacterial Infections in Clinical Development

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

As of September 2017, an estimated 32 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 (*S. aureus*)
NDV-3A	Phase 1	NovaDigm Therapeutics Inc.	Vaccine	Prevention of bacterial infections (*S. aureus*)
PolyCAb	Phase 1	MicroPharm Ltd.	Antibody	Recurrent *C. difficile* infection
RBX7455	Phase 1	Rebiotix Inc.	Probiotic	Recurrent *C. difficile* infection
SER-262	Phase 1	Seres Therapeutics Inc.	Probiotic	Recurrent *C. difficile* infection
StebVax	Phase 1	Integrated BioTherapeutics	Vaccine	Prevention of toxic shock syndrome from staphylococcal enterotoxin B (SEB)
514G3	Phase 2	Xbiotech Inc.	Antibody	Bacteremia (*S. aureus*)
Aerucin (AR-105)	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (*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 (*P. aeruginosa* serotype 011)
ASN100	Phase 2	Arsanis Inc.	Antibody	Prevention of ventilator-associated pneumonia (*S. aureus*)
CAL02	Phase 2[7]	Combioxin SA	Virulence inhibitor (liposome)	Severe pneumonia (*S. pneumoniae*)
CF-301	Phase 2	ContraFect Corp.	Lysin	Bacteremia (*S. aureus*)
CP101	Phase 2	Finch Therapeutics	Probiotic	Recurrent *C. difficile* infection
ExPEC4V (JNJ-63871860)	Phase 2	Janssen Research & Development LLC	Vaccine	Prevention of extraintestinal pathogenic *E. coli* serotypes O1, O2, O6, and O25 infection
GEN-004	Phase 2[4]	Genocea Biosciences Inc.	Vaccine	Prevention of pneumococcal infections (*S. pneumoniae*)
Group B *Streptococcus* vaccine	Phase 2	GlaxoSmithKline	Vaccine	Prevention of Group B streptococcal infection[6]
IMM-529	Phase 2	Immuron Ltd.	Antibody	Recurrent *C. difficile* infection
MEDI3902	Phase 2[4]	MedImmune Inc.	Antibody	Prevention of ventilator-associated bacterial pneumonia (*P. aeruginosa*)
MEDI4893	Phase 2[4]	MedImmune Inc.	Antibody	Hospital-acquired pneumonia (*S. aureus*)
N-Rephasin (SAL200)	Phase 2[4]	iNtRON Biotechnology Inc.	Lysin	Bacterial infections (*S. aureus*)
PF-06482077	Phase 2	Pfizer Inc.	Vaccine	Prevention of Group B streptococcal infection
Ribaxamase (SYN-004)	Phase 2	Synthetic Biologics Inc.	Antibiotic inactivator[5]	Prevention of *C. difficile* infection
***S. pneumoniae* next generation + vaccine (GSK-2189241A)[8]**	Phase 2[7]	GlaxoSmithKline	Vaccine	Prevention of *S. pneumoniae* disease

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Drug name	Development phase[2]	Company	Type of product	Potential indication(s)[3]
SA4Ag	Phase 2	Pfizer Inc.	Vaccine	Prevention of *S. aureus* infection
Salvecin (AR-301)	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (*S. aureus*)
Shigella+	Phase 2[7]	GlaxoSmithKline	Vaccine	Prevention of *Shigella* infection
V114[8]	Phase 2	Merck & Co. Inc.	Vaccine	Prevention of pneumococcal disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F
VLA84 (IC84)	Phase 2	Valneva SE	Vaccine	Prevention of *C. difficile* infection
PF-06425090	Phase 3	Pfizer Inc.	Vaccine	Prevention of *C. difficile* infection
RBX2660	Phase 3	Rebiotix Inc.	Probiotic	Recurrent *C. difficile* infection
Reltecimod (AB103)	Phase 3	Atox Bio	Peptide immunomodulator	Necrotizing soft tissue infections
SER-109	Phase 3	Seres Therapeutics Inc.	Probiotic	Recurrent *C. difficile* infection

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

September 2017: Cdiffense and Shigamab were removed during the September 2017 review because they were no longer included in the research and development pipeline on the company's website or discontinuation of development was announced through a company press release.

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. We excluded drugs to treat mycobacterial infections, such as tuberculosis and *Mycobacterium avium complex, Helicobacter pylori,* and biothreat pathogens. Also excluded were locally acting therapies such as topical, ophthalmic, and inhaled products. Many of these products probably will not be used as a stand-alone treatment, but as an adjunctive to standard-of-care antibiotics.

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

3 Based on clinical trials currently registered in http://www.clinicaltrials.gov unless otherwise noted.

4 Registered in http://www.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 GI tract to minimize collateral damage to the gut microbiome and prevent occurrence of *C. difficile*.

6 In these clinical trials, the Group B *Streptococcus* vaccine is administered to pregnant women with the goal of preventing streptococcal infections in newborns.

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

8 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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