



Nontraditional Products for Bacterial Infections in Clinical Development

As of March 2017, an estimated 32 new products¹ 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
Zinplava (bezlotoxumab)	Approved Oct. 21, 2016	Merck & Co. Inc.	Antibody	Recurrent <i>C. difficile</i> infection
DSTA4637S	Phase 1	Genentech (member of the Roche Group)	Antibody	Bacterial infections (<i>S. aureus</i>)
CF-301	Phase 1	ContraFect Corp.	Lysin	Bacteremia (<i>S. aureus</i>)
FIN-403	Phase 1 ⁷	Finch Therapeutics	Probiotic	Recurrent <i>C. difficile</i> infection
NDV-3A	Phase 1	NovaDigm Therapeutics Inc.	Vaccine	Prevention of bacterial infections (<i>S. aureus</i>)
RBX7455	Phase 1	Rebiotix Inc.	Probiotic	Recurrent <i>C. difficile</i> infection
SER-262	Phase 1	Seres Therapeutics Inc.	Probiotic	Recurrent <i>C. difficile</i> infection
StebVax	Phase 1	Integrated BioTherapeutics	Vaccine	Prevention of toxic shock syndrome from staphylococcal enterotoxin B (SEB)

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514G3	Phase 2	Xbiotech Inc.	Antibody	Bacteremia (<i>S. aureus</i>)
Aerucin	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (<i>P. aeruginosa</i>)
Aerumab (AR-101)	Phase 2 ⁴	Aridis Pharmaceuticals Inc.	Antibody	Hospital-acquired/ventilator-associated bacterial pneumonia (<i>P. aeruginosa</i> serotype O11)
ASN100	Phase 2	Arsanis Inc.	Antibody	Prevention of ventilator-associated bacterial pneumonia (<i>S. aureus</i>)
CAL02	Phase 2 ^{4,7}	Combioxin SA	Virulence inhibitors (liposome)	Severe pneumonia (<i>S. pneumoniae</i>)
ExPEC4V (JNJ-63871860)	Phase 2	Janssen Research & Development LLC	Vaccine	Prevention of extraintestinal pathogenic <i>E. coli</i> serotypes O1, O2, O6, and O25 infection
GEN-004	Phase 2 ⁴	Genocea Biosciences Inc.	Vaccine	Prevention of pneumococcal infections (<i>S. pneumoniae</i>)
Group B <i>Streptococcus</i> vaccine	Phase 2	GlaxoSmithKline	Vaccine	Prevention of Group B streptococcal infection ⁶
MEDI3902	Phase 2 ⁴	MedImmune Inc.	Antibody	Prevention of ventilator-associated bacterial pneumonia (<i>P. aeruginosa</i>)
MEDI4893	Phase 2 ⁴	MedImmune Inc.	Antibody	Hospital-acquired pneumonia (<i>S. aureus</i>)
N-Rephasin (SAL200)	Phase 2 ⁴	iNtRON Biotechnology Inc.	Lysin	Bacterial infections (<i>S. aureus</i>)
RBX2660	Phase 2	Rebiotix Inc.	Probiotic	Recurrent <i>C. difficile</i> infection
Ribaxamase (SYN-004)	Phase 2	Synthetic Biologics Inc.	Antibiotic inactivator ⁵	Prevention of <i>C. difficile</i> infection
<i>S. pneumoniae</i> next generation + vaccine (GSK-2189241A)⁸	Phase 2	GlaxoSmithKline	Vaccine	Prevention of <i>S. pneumoniae</i> disease
SA4Ag	Phase 2	Pfizer Inc.	Vaccine	Prevention of <i>S. aureus</i> infection

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Salvecin (AR-301)	Phase 2	Aridis Pharmaceuticals Inc.	Antibody	Pneumonia (<i>S. aureus</i>)
SER-109	Phase 2	Seres Therapeutics Inc.	Probiotic	Recurrent <i>C. difficile</i> infection
Shigamab	Phase 2	Taro Pharmaceuticals Industries Ltd.	Antibody	Treatment of hemolytic uremic syndrome caused by Shiga toxin-producing <i>E. coli</i>
Shigella+	Phase 2 ⁴	GlaxoSmithKline	Vaccine	Prevention of <i>Shigella</i> infection
V114 ⁸	Phase 2	Merck & Co. Inc.	Vaccine	Prevention of pneumococcal disease caused by <i>S. pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F
VLA84 (IC84)	Phase 2	Valneva SE	Vaccine	Prevention of <i>C. difficile</i> infection ⁷
AB103	Phase 3	Atox Bio	Peptide immunomodulator	Necrotizing soft tissue infections
Cdiffense (<i>C. difficile</i> toxoid vaccine)	Phase 3	Sanofi Pasteur SA	Vaccine	Prevention of <i>C. difficile</i> infection
PF-06425090	Phase 3 ⁷	Pfizer Inc.	Vaccine	<i>C. difficile</i> infection

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 products 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.
- 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](http://www.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 Not currently registered on <http://www.clinicaltrials.gov>. 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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