**Nontraditional Products for Bacterial Infections in Clinical Development**

As of June 2018, an estimated 30 new nontraditional products 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.

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Development phase</th>
<th>Company</th>
<th>Type of product</th>
<th>Potential indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSTA4637S</td>
<td>Phase 1</td>
<td>Genentech (member of the Roche Group)</td>
<td>Antibody</td>
<td>Bacterial infections (caused by S. aureus)</td>
</tr>
<tr>
<td>PolyCAb</td>
<td>Phase 1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>MicroPharm Ltd.</td>
<td>Antibody</td>
<td>Recurrent C. difficile infections</td>
</tr>
<tr>
<td>RBX7455</td>
<td>Phase 1</td>
<td>Rebiotix Inc. (wholly owned subsidiary of Ferring Pharmaceuticals Inc.)</td>
<td>Probiotic</td>
<td>Recurrent C. difficile infections</td>
</tr>
<tr>
<td>SER-262</td>
<td>Phase 1</td>
<td>Seres Therapeutics Inc.</td>
<td>Probiotic</td>
<td>Recurrent C. difficile infections</td>
</tr>
<tr>
<td>StebVax</td>
<td>Phase 1</td>
<td>Integrated BioTherapeutics Inc.</td>
<td>Vaccine</td>
<td>Prevention of toxic shock syndrome from staphylococcal enterotoxin B</td>
</tr>
<tr>
<td>VE303</td>
<td>Phase 1</td>
<td>Vedanta Biosciences Inc.</td>
<td>Probiotic</td>
<td>Recurrent C. difficile infections</td>
</tr>
<tr>
<td>514G3</td>
<td>Phase 2</td>
<td>XBiotech Inc.</td>
<td>Antibody</td>
<td>Bacteremia (caused by S. aureus)</td>
</tr>
<tr>
<td>Aerucin (AR-105)</td>
<td>Phase 2</td>
<td>Aridis Pharmaceuticals Inc.</td>
<td>Antibody</td>
<td>Pneumonia (caused by P. aeruginosa)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Data table from Sept 2018. Continued on the next page
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<thead>
<tr>
<th>Drug name</th>
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<th>Company</th>
<th>Type of product</th>
<th>Potential indication(s)³</th>
</tr>
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<tbody>
<tr>
<td>Aerumab (AR-101)</td>
<td>Phase 2</td>
<td>Aridis Pharmaceuticals Inc.</td>
<td>Antibody</td>
<td>Hospital-acquired/ventilator-associated pneumonia (caused by <em>P. aeruginosa</em> serotype 011)</td>
</tr>
<tr>
<td>CAL02</td>
<td>Phase 2</td>
<td>Combioxin SA</td>
<td>Virulence inhibitor (liposome)</td>
<td>Severe bacterial pneumonia</td>
</tr>
<tr>
<td>CF-301</td>
<td>Phase 2</td>
<td>ContraFect Corp.</td>
<td>Lysin</td>
<td>Bacteremia and endocarditis (caused by <em>S. aureus</em>)</td>
</tr>
<tr>
<td>CP101</td>
<td>Phase 2</td>
<td>Finch Therapeutics</td>
<td>Probiotic</td>
<td>Recurrent <em>C. difficile</em> infections</td>
</tr>
<tr>
<td>DAV132</td>
<td>Phase 2</td>
<td>Da Volterra</td>
<td>Antibiotic inactivator⁴</td>
<td>Prevention of <em>C. difficile</em> infections</td>
</tr>
<tr>
<td>ExPEC4V (JNJ-63871860)</td>
<td>Phase 2</td>
<td>Janssen Research &amp; Development LLC</td>
<td>Vaccine</td>
<td>Prevention of extraintestinal pathogenic <em>E. coli</em> serotypes O1, O2, O6, and O25</td>
</tr>
<tr>
<td>IMM-529</td>
<td>Phase 2</td>
<td>Immuron Ltd.</td>
<td>Antibody</td>
<td>Recurrent <em>C. difficile</em> infections</td>
</tr>
<tr>
<td>MEDI3902</td>
<td>Phase 2</td>
<td>MedImmune Inc. (wholly owned subsidiary of AstraZeneca PLC)</td>
<td>Antibody</td>
<td>Prevention of nosocomial bacterial pneumonia (<em>P. aeruginosa</em>)</td>
</tr>
<tr>
<td>Suvratoxumab (MEDI4893)</td>
<td>Phase 2</td>
<td>MedImmune Inc. (wholly owned subsidiary of AstraZeneca PLC)</td>
<td>Antibody</td>
<td>Prevention of nosocomial bacterial pneumonia (<em>S. aureus</em>)</td>
</tr>
<tr>
<td>NDV-3A</td>
<td>Phase 2</td>
<td>NovaDigm Therapeutics Inc.</td>
<td>Vaccine</td>
<td>Prevention of bacterial infections (<em>S. aureus</em>)</td>
</tr>
<tr>
<td>N-Rephasin (SAL200)</td>
<td>Phase 2</td>
<td>iNTRON Biotechnology Inc.</td>
<td>Lysin</td>
<td>Bacterial infections (caused by <em>Staphylococcus</em> spp.)</td>
</tr>
<tr>
<td>PF-06482077</td>
<td>Phase 2</td>
<td>Pfizer Inc.</td>
<td>Vaccine</td>
<td>Prevention of pneumococcal disease</td>
</tr>
<tr>
<td>Ribaxamase (SYN-004)</td>
<td>Phase 2</td>
<td>Synthetic Biologics Inc.</td>
<td>Antibiotic inactivator⁵</td>
<td>Prevention of <em>C. difficile</em> infections</td>
</tr>
<tr>
<td><em>S. pneumoniae</em> next-generation vaccine (GSK-2189241A)⁷</td>
<td>Phase 2</td>
<td>GlaxoSmithKline</td>
<td>Vaccine</td>
<td>Prevention of <em>S. pneumoniae</em> disease</td>
</tr>
<tr>
<td>SA4Ag</td>
<td>Phase 2</td>
<td>Pfizer Inc.</td>
<td>Vaccine</td>
<td>Prevention of <em>S. aureus</em> infection</td>
</tr>
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<td>Salvecin (AR-301)</td>
<td>Phase 2</td>
<td>Aridis Pharmaceuticals Inc.</td>
<td>Antibody</td>
<td>Pneumonia (S. aureus)</td>
</tr>
<tr>
<td>Shigella</td>
<td>Phase 2</td>
<td>GlaxoSmithKline</td>
<td>Vaccine</td>
<td>Prevention of Shigella infections</td>
</tr>
<tr>
<td>V114(^7)</td>
<td>Phase 3</td>
<td>Merck &amp; Co. Inc.</td>
<td>Vaccine</td>
<td>Prevention of pneumococcal disease caused by S. pneumonia serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F</td>
</tr>
<tr>
<td>PF-06425090</td>
<td>Phase 3</td>
<td>Pfizer Inc.</td>
<td>Vaccine</td>
<td>Prevention of C. difficile infections</td>
</tr>
<tr>
<td>RBX2660</td>
<td>Phase 3</td>
<td>Rebiotix Inc. (wholly owned subsidiary of Ferring Pharmaceuticals Inc.)</td>
<td>Probiotic</td>
<td>Recurrent C. difficile infections and urinary tract infections</td>
</tr>
<tr>
<td>Reltecimod (AB103)</td>
<td>Phase 3</td>
<td>Atox Bio</td>
<td>Peptide immunomodulator</td>
<td>Necrotizing soft tissue infections and sepsis-associated acute kidney injury</td>
</tr>
<tr>
<td>SER-109</td>
<td>Phase 3</td>
<td>Seres Therapeutics Inc.</td>
<td>Probiotic</td>
<td>Recurrent C. difficile infections</td>
</tr>
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</table>

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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