SYN-004 (Ribaxamase), an Orally Administered β-Lactamase, Prevents Clostridium difficile Infection, Reduces New Colonization by Opportunistic Pathogens and Reduces Changes in the Gut Resistome

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SYN-004 (Ribaxamase) is a novel recombinant β-lactamase (an enzyme of ~29kDa) which is delivered orally to inactivate β-lactam antibiotics (including most penicillins and cephalosporins) by cleaving the β-lactam ring.

The use of intravenous β-lactam antibiotics, including cephalosporins, are an important risk factor for the development of gastrointestinal infections like Clostridium difficile. These antibiotics can be excrated, via the bile, into the intestine where they disrupt the balance of the gut microbiome and potentially lead to the growth of opportunistic pathogens like C. difficile and the emergence of antimicrobial resistant organisms.

SYN-004 (ribaxamase) is a novel recombinant β-lactamase which is orally administered to inactivate β-lactam antibiotics excreted into the intestine thus protecting the gut microbiome from disruption. The primary indication being pursued is prevention of C. difficile infection (CDI). The use of SYN-004 may also have potential benefits of reducing development of antibiotic resistance in the gut microbiome. Adding SYN-004 to any treatment with IV β-lactam antibiotics (including most penicillins and cephalosporins) by cleaving the β-lactam ring of the antibiotics would represent a paradigm shift from the current management of CDI.

Phase 1 studies demonstrated that SYN-004 was well tolerated in dogs up to 57 mg/kg/day for 28 days.

SYN-004 is also well tolerated in normal healthy volunteers.

SYN-004 was granted Breakthrough Therapy Designation by the FDA for the prevention of CDI with additional endpoints of diarrhea caused by C. difficile infection and the emergence of antimicrobial resistance in the gut microbiome.