

Venatorx Pharmaceuticals' Novel Antibiotic Pipeline Addresses the Next Pandemic: Superbugs

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Company to Watch – Venatorx Pharmaceuticals

For more than ten years, Venatorx Pharmaceuticals has used its medicinal chemistry chops to develop a robust pipeline of novel anti-infectives that address multi-drug resistant bacterial infections — superbugs that could become the next pandemic — and hard-to-treat viral infections. We will explore the company's pipeline over the next few days.

by Marie Daghlian



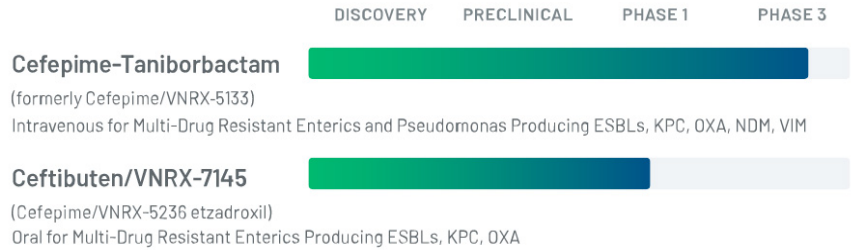
Tony Meehan, Ph.D., Chief Business Officer at Venatorx Pharmaceuticals

Venatorx's lead clinical-stage antibiotics address the growing problem of antibiotic resistance. The antibiotic market is dominated by a class of compounds known as beta-lactams, which include many commonly used antibiotics (penicillins, cephalosporins, and carbapenems), and make up about 78 percent of the \$35 billion global market.

“This beta-lactam standard of care exists because they work, are broad spectrum, and, for the most part, are safe, with the exception of penicillin allergies,” says Tony Meehan, Ph.D., chief business officer at Venatorx. “Physicians often don't know what specific bacteria are causing a patient's infection when they need to make the first prescription decision. They know that the patient has all the characteristics of a bacterial infection, and if there is a beta-lactam that has not shown concerning levels of bacterial resistance at that hospital, they will prefer to use it.”

Because of the long history of beta-lactam preference and use, bacteria have slowly but steadily developed multiple types of “resistance enzymes” called beta-lactamases, which allow the bacteria to shut down the action of the beta-lactam antibiotics. These enzymes “chew up” the beta-lactams before they can destroy the bacteria and thus the bacteria are able to continue their infection.

Pipeline of Venatorx's lead clinical-stage compounds, cefepime-taniborbactam and ceftibuten/VNRX-7145



To counter these resistance enzymes, Venatorx has invented and entered two different beta-lactamase enzyme inhibitors into clinical development: (i) taniborbactam (formerly VNRX-5133), a novel intravenous drug to be administered in the hospital setting; and (ii) VNRX-7145, a novel oral drug for community and outpatient use. Each of these bacterial enzyme inhibitors is paired with a different, appropriate beta-lactam antibiotic. Venatorx's drugs knock out the bacterial resistance enzymes and this allows the beta-lactam partner to do its work: killing bacteria.

Venatorx's most clinically advanced experimental combination, cefepime-taniborbactam, combines cefepime, a generic cephalosporin—and the second most prescribed intravenous beta-lactam antibiotic in the United States—and taniborbactam. "We quite consciously selected cefepime as the combination partner," said Meehan. It is a very powerful beta-lactam antibiotic, and the first and only 4th generation cephalosporin approved in the United States. By combining it with taniborbactam, cefepime is no longer prone to inactivation by many types of beta-lactamases and it works as if it were brand new."

While cefepime-taniborbactam will compete against other new drugs, launched since 2015, to combat bacterial resistance, its coverage against different types of bacteria with *in vitro* studies has consistently been demonstrated as superior. One of the unique features of cefepime-taniborbactam is that it remains active against bacteria producing a new class of resistance enzymes called metallo-beta-lactamases, which currently used intravenous drugs do not cover. Resistance driven by metallo-beta lactamases is already significantly higher in China, India, Russia, Eastern and Southern Europe. However, just like viral infections, bacterial resistance tends to spread geographically over time, and the metallo-beta-lactamase-producing bacteria have slowly moved into Western Europe and the Americas, with expected growth rates concerning to infectious disease physicians.

Cefepime-taniborbactam is currently in a Phase 3 study in 16 countries, with the trial expected to complete before the end of 2021, after which the company expects to file a



New Drug Application in 2022 with the U.S. Food and Drug Administration for a potential approval in 2023.

Venatorx's oral program follows the same combination recipe. In this case, the Company combines an oral beta-lactam, ceftibuten, and its proprietary oral beta-lactamase enzyme inhibitor, VNRX-7145. The oral dosing regimen could allow an infected patient to be treated at home, without requiring

admittance to emergency department or the hospital. Ceftibuten/VNRX-7145 is currently in the latter stages of Phase 1 clinical studies in healthy volunteers and is expected to progress to later-stage clinical studies in 2022.

This is part of the Big4Bio Company to Watch program for May 2021: Venatorx Pharmaceuticals.

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