BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

FDA approves new antibiotic to treat community-acquired bacterial pneumonia

20 August 2019 | News

The FDA granted the approval of Xenleta to Nabriva Therapeutics.

The U.S. Food and Drug Administration, on 19 August 2019, approved Xenleta (lefamulin) to treat adults with community-acquired bacterial pneumonia.

“This new drug provides another option for the treatment of patients with community-acquired bacterial pneumonia, a serious disease,” said Ed Cox, M.D., M.P.H., director of FDA’s Office of Antimicrobial Products. “For managing this serious disease, it is important for physicians and patients to have treatment options. This approval reinforces our ongoing commitment to address the treatment of infectious diseases by facilitating the development of new antibiotics.”

Community-acquired pneumonia occurs when someone develops pneumonia in the community (not in a hospital). Pneumonia is a type of lung infection that can range in severity from mild to severe illness and can affect people of all ages. According to data from the Centers from Disease Control and Prevention, each year in the United States, about one million people are hospitalized with community-acquired pneumonia and 50,000 people die from the disease.

The safety and efficacy of Xenleta, taken either orally or intravenously, was evaluated in two clinical trials with a total of 1,289 patients with CABP. In these trials, treatment with Xenleta was compared to another antibiotic, moxifloxacin with or without linezolid. The trials showed that patients treated with Xenleta had similar rates of clinical success as those treated with moxifloxacin with or without linezolid.

The most common adverse reactions reported in patients taking Xenleta included diarrhea, nausea, reactions at the injection site, elevated liver enzymes and vomiting. Xenleta has the potential to cause a change in an ECG reading (prolonged QT interval). Patients with prolonged QT interval, patients with certain irregular heart rhythms (arrhythmias), patients receiving treatment for certain irregular heart rhythms (antiarrhythmic agents), and patients receiving other drugs that prolong the QT interval should avoid Xenleta. In addition, Xenleta should not be used in patients with known hypersensitivity to lefamulin or any other members of the pleuromutilin antibiotic class, or any of the components of Xenleta. Based on findings of fetal harm in animal studies, pregnant women and women who could become pregnant should be advised of the potential risks of Xenleta to a fetus. Women who could become pregnant should be advised to use effective contraception during treatment with Xenleta and for two days after the final dose.

Xenleta received FDA's Qualified Infectious Disease Product (QIDP) designation. The QIDP designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act. As part of QIDP designation, Xenleta was granted Priority Review under which the FDA's goal is to take action on an application within an expedited time frame.

The FDA granted the approval of Xenleta to Nabriva Therapeutics.

A key global challenge the FDA faces as a public health agency is addressing the threat of antimicrobial-resistant infections. Among the FDA's other efforts to address antimicrobial resistance, is the focus on facilitating the development of safe and effective new treatments to give patients more options to fight serious infections.