FDA approves new antibiotic for three indications

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The U.S. Food and Drug Administration has approved the antibiotic Zevtera (ceftobiprole medocaril sodium for injection) for three different indications, including treatment of adults with Staphylococcus aureus bloodstream infections, adults with acute bacterial skin and skin structure infections, and adult and pediatric patients (age 3 months and

older) with community-acquired bacterial pneumonia.

The priority review approval was based on four randomized controlled trials.

For S. aureus bloodstream infections, a trial with 390 participants showed 69.8% of those receiving Zevtera achieved overall success (survival, symptom improvement, S. aureus bacteremia bloodstream clearance, no new S. aureus bacteremia complications, and no use of other potentially effective antibiotics) versus 68.7% of those receiving the comparator.

For acute bacterial skin and skin structure infections, among 679 participants, 91.3% of those receiving Zevtera achieved an early clinical response (48 to 72 hours after start of treatment) versus 88.1% of those receiving the comparator.

For community-acquired bacterial pneumonia, efficacy (clinical cure rates at test-of-cure visit at seven to 14 days after end of treatment) occurred in 76.4% with Zevtera versus 79.3% of those receiving the comparator.

Patients should not use Zevtera if they have a history of severe hypersensitivity to ceftobiprole or other members of the cephalosporin antibacterial class. Additionally, Zevtera comes with warnings and precautions regarding increased mortality in ventilator-associated bacterial pneumonia patients (an unapproved use), hypersensitivity reactions, seizures and other central nervous system reactions, and Clostridioides difficile-associated diarrhea.

"The FDA is committed to fostering new antibiotic availability when they prove to be safe and effective, and Zevtera will provide an additional treatment option for a number of serious bacterial infections,"

Peter Kim, M.D., from the FDA Center for Drug Evaluation and Research, said in a statement.

Approval of Zevtera was granted to Basilea Pharmaceutica International.