

New Drug Approvals

Generic Name (Trade Name) Company

October 4, 2018

Omadacycline

Uses/Notes

[Paratek announced](#) FDA approval of omadacycline 100 mg for injection/150 mg tablets for treatment of community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI) in adults.

Omadacycline, a modernized tetracycline, is a once-daily I.V. and oral antibiotic that targets a spectrum of bacteria, including Gram-positive, Gram-negative, atypicals, and drug-resistant strains.

Approval was supported by multiple clinical trials involving nearly 2,000 adult patients.

Warnings and precautions include the following:

Use during tooth development (last half of pregnancy, infancy, and childhood to age 8) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

Use during the second and third trimester of pregnancy, infancy and childhood up to age 8 years may cause reversible inhibition of bone growth.

Omadacycline is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

The most common adverse reactions (incidence ≥2%) in clinical trials were nausea, vomiting, infusion-site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

The drug is expected to become available in the first

(Nuzyra—Paratek)

quarter of 2019.

FDA approves once-daily I.V. and oral antibiotic for treatment of CABP and ABSSSI

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