Generic Name:
Omadacycline
Trade Name:
Nuzyra
Company:
Paratek
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 quarter of 2019.

Medication Monitor Categories:
New Drug Approvals