RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	Xerava™
Generic Name	eravacycline
Drug Manufacturer	Tetraphase Pharmaceuticals, Inc.

Clinical Update

TYPE OF CLINICAL UPDATE

New Strength of Xerava™ for injection containing 100 mg of eravacycline per vial

FDA APPROVAL DATE

June 3, 2020

LAUNCH DATE

September 25, 2020 (FDB addition date)

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Supplemental New Drug Application (sNDA)

DISPENSING RESTRICTIONS

None

Overview

INDICATION(S) FOR USE

Xerava™ is indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older.

MECHANISMS OF ACTION

Eravacycline is a fluorocycline antibacterial within the tetracycline class of antibacterial drugs. Eravacycline disrupts bacterial protein synthesis by binding to the 30S ribosomal subunit thus preventing the incorporation of amino acid residues into elongating peptide chains.

In general, eravacycline is bacteriostatic against gram-positive bacteria (e.g., *Staphylococcus aureus* and *Enterococcus faecalis*); however, in vitro bactericidal activity has been demonstrated against certain strains of *Escherichia coli* and *Klebsiella pneumoniae*.

DOSAGE FORM(S) AND STRENGTH(S)

For injection: 50 mg and 100 mg of eravacycline (equivalent to 63.5 mg and 127 mg eravacycline dihydrochloride, respectively) as a lyophilized powder in a single-dose vial.

DOSE & ADMINISTRATION

1 mg/kg IV every 12 hours for 4 to 14 days.

CLINICAL UPDATE

EFFICACY

Xerava™ was investigated for the treatment of cIAI as part of the Company's IGNITE (Investigating Gram-Negative Infections Treated with Eravacycline) phase 3 programs. In the first pivotal phase 3 trial in patients with cIAI, twice-daily intravenous (IV) eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem and was well-tolerated. In the second phase 3 clinical trial in patients with cIAI, twice daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to meropenem and was well-tolerated. In both trials, Xerava™ achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates.