Baxdela™ (delafloxacin) – New drug approval

- On June 19, 2017 Melinta Therapeutics announced the FDA approval of Baxdela (delafloxacin) tablets and injection for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by certain susceptible bacteria in adults.
    - Refer to the drug label for a specific list of susceptible bacteria.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela and other antibacterial drugs, Baxdela should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.
    - When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
- Baxdela is a fluoroquinolone that exhibits activity against both gram-positive and gram-negative pathogens.
- The safety and efficacy of Baxdela were based on two phase 3, non-inferiority trials in 1,510 patients with ABSSSI. In both studies, the comparator was the intravenous (IV) combination of vancomycin and aztreonam. The primary endpoint was the objective clinical response at 48 to 72 hours post initiation of treatment, defined as ≥ 20% decrease in lesion size.
    - In both studies, Baxdela IV and oral monotherapy was statistically non-inferior to the combination of vancomycin plus aztreonam for the primary endpoint.
- Similar to other fluoroquinolones, Baxdela carries a boxed warning for serious adverse reactions, including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis.
- Baxdela is contraindicated in patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs, or any of the components of Baxdela.
- Warnings and precautions of Baxdela include hypersensitivity reactions, *Clostridium difficile*-associated diarrhea, and development of drug-resistant bacteria.
- The most common adverse reactions (incidence ≥ 2%) with Baxdela use were nausea, diarrhea, headache, transaminase elevations, and vomiting.
- The recommended dosage of Baxdela is 300 mg by IV infusion over 60 minutes, every 12 hours or the 450 mg tablet administered orally every 12 hours for 5 to 14 days total duration.
    - Baxdela may be initiated as an IV infusion and then switched to the tablet formulation at the discretion of the physician.
    - Dose adjustments may be necessary for patients with renal impairment.

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- Melinta's launch plans for Baxdela are pending. Baxdela will be available as a 300 mg single dose vial for injection and 450 mg tablets.