Baxdela® (delafloxacin) – New indication

- On October 24, 2019, Melinta Therapeutics announced the FDA approval of Baxdela (delafloxacin) tablets and injection, for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms:

    — *Streptococcus pneumoniae, Staphylococcus aureus (methicillin- susceptible isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila,* and *Mycoplasma pneumoniae.*

- Baxdela is also approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults.

- The FDA approval of Baxdela's new indication was based on a non-inferiority study of 859 patients with CABP. Patients received Baxdela or moxifloxacin for 5 to 10 days. Early clinical response (ECR) at 72-120 hours after the first dose was defined as survival with improvement in at least two of four symptoms (cough, sputum production, chest pain, dyspnea) from baseline without deterioration in any of these symptoms, and without use of additional antimicrobial therapy for treatment of the current CABP infection due to lack of efficacy. Clinical success was also assessed at the test of cure (TOC) visit and defined as survival with resolution or near resolution of the symptoms of CABP present at study entry, and no use of additional antimicrobial therapy for the current CABP infection, and no new symptoms associated with the current CABP infection.

    — ECR was achieved in 88.9% of Baxdela patients vs. 89.0% of moxifloxacin patients (treatment difference: -0.2; 95% CI: -4.4, 4.1).
    — At the TOC visit, success was seen in 90.5% of Baxdela patients vs. 89.7% of moxifloxacin patients (treatment difference: 0.8; 95% CI: -3.3, 4.8).

- Baxdela carries a boxed warning for serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis.

- The recommended dose of Baxdela for the treatment of CABP is given for 5 to 10 days in one of the following treatment regimens:

    — 300 mg of Baxdela every 12 hours over 60 minutes by intravenous (IV) infusion, or
    — 300 mg of Baxdela every 12 hours over 60 minutes by IV infusion, then switch to 450 mg of Baxdela orally every 12 hours at the discretion of the physician, or
    — 450 mg of Baxdela orally every 12 hours.

- Consult the Baxdela drug label for dosing recommendations for ABSSSI infections.

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