



Melinta Therapeutics Provides Baxdela NDA Update

NEW HAVEN, Conn, Feb. 27, 2017 -- Melinta Therapeutics, a privately held company focused on developing novel antibiotics to treat serious bacterial infections, today announced that the U.S. Food and Drug Administration (FDA) has informed the Company, as part of its mid-cycle review process, that it does not currently plan to hold an Advisory Committee meeting for Melinta's New Drug Applications (NDAs) for Baxdela™ (delafloxacin). Baxdela™ is an investigational fluoroquinolone with first-in-class activity against MRSA (methicillin-resistant *Staphylococcus aureus*). The NDAs for Baxdela™, which has been granted QIDP (Qualified Infectious Disease Product) status, are under priority review by the FDA for serious skin infections, following successful completion of two Phase 3 studies comparing Baxdela™ monotherapy with the combination of vancomycin plus aztreonam.

“We look forward to progressing our ongoing discussions with the FDA as part of the priority review process for Baxdela™, as well as continuing our work to bring much-needed new antibiotics to patients and physicians,” said Eugene Sun, M.D., CEO of Melinta. The FDA PDUFA date for the Baxdela™ NDAs is June 19, 2017.

About Baxdela

Baxdela (delafloxacin) is an investigational anionic fluoroquinolone antibiotic for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI). Baxdela has robust in-vitro antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA), a major cause of hospital-treated skin infections, a favorable tolerability profile, and both intravenous and oral dosage forms, which may facilitate hospital discharge. The studies (studies 302 and 303) were Phase 3, multicenter, randomized, double-blind, active-controlled trials to evaluate IV and oral Baxdela monotherapy compared with vancomycin plus aztreonam combination therapy for the treatment of patients with ABSSSI. Both studies met the primary endpoints for efficacy.

Overall adverse event rates were similar between treatment arms in the Phase 3 studies which enrolled over 1,500 individuals. The most common treatment-emergent adverse events in the Phase 3 studies on Baxdela were diarrhea and nausea, which were generally mild and did not lead to treatment discontinuation. The treatment discontinuation rate due to treatment-related adverse events for patients treated with Baxdela in the Phase 3 trials was 0.8%. Unlike some other quinolones, Baxdela has not shown any potential for QT prolongation or phototoxicity in definitive clinical studies. In addition, there were no elevated rates of liver or glucose abnormalities compared to vancomycin plus aztreonam in the clinical studies conducted to date.



The 450 mg tablet has been shown to have bioequivalent exposure (area under the curve) to the 300 mg IV dose, and can be dosed without regard to food. There are no anticipated drug-drug interactions with delafloxacin other than co-administration with chelating agents.

Melinta submitted NDAs (New Drug Applications) to the US FDA for the ABSSSI indication in October 2016 which are currently undergoing regulatory review. A PDUFA date of June 19, 2017 has been set by the FDA.

Melinta is also assessing Baxdela in a clinical trial in patients with hospital-treated community-acquired bacterial pneumonia (CABP) and planning to initiate a clinical trial in complicated urinary tract infections (cUTI) in the near future. Baxdela has been designated a Qualified Infectious Disease Product (QIDP) and has been granted fast track designation for community-acquired bacterial pneumonia by the U.S. Food and Drug Administration.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is dedicated to saving lives threatened by the global public health crisis of bacterial infections, through the development of novel antibiotics that provide new and better therapeutic solutions. Melinta has submitted an NDA to the FDA for its late-stage investigational antibiotic, Baxdela, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Baxdela is also being studied in Phase 3 clinical development for the treatment of community-acquired bacterial pneumonia (CABP). Melinta is committed to developing, through the application of Nobel Prize-winning science, a new class of antibiotics designed to overcome the multi- and extremely-drug-resistant pathogens for which there are few to no options, known collectively as ESKAPE pathogens (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter species and Escherichia coli), which cause the majority of life-threatening hospital infections.

Melinta Therapeutics is privately held and backed by Vatera Healthcare Partners (www.vaterahealthcare.com) and Malin Corporation plc (www.malinplc.com) among other private investors. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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