Melinta Therapeutics' New Drug Application for Baxdela Accepted for Filing by US FDA

Melinta Invited to Present at Annual JP Morgan Healthcare Conference

NEW HAVEN, Conn., Jan. 05, 2017 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced today the U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Applications (NDAs) for IV and oral Baxdela™ (delafloxacin) for filing and granted Priority Review status to both NDAs. The acceptance of the NDAs indicates that the FDA has deemed the applications sufficiently complete to allow a substantive review.

Baxdela is an investigational anionic fluoroquinolone with a broad spectrum of antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA). Melinta submitted NDAs for Baxdela in October for the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). Baxdela has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. FDA, which provides for Priority Review. Consistent with the priority review timelines, Melinta has been informed that the FDA has set a Prescription Drug User Fee Act (PDUFA) target date of June 19, 2017, by which time it expects to provide the company with a regulatory decision.

"Baxdela, if approved, represents a potentially attractive monotherapy treatment option for the nearly 3 million patients hospitalized annually in the U.S. with serious skin infections," stated Eugene Sun, M.D., Melinta's Chief Executive Officer. "These patients are often challenging to treat, with a high rate of treatment failure, and underlying medical conditions that pose challenges to the choice of antibiotic. Baxdela may represent a new option for these patients, with activity against gram positive (including MRSA) and gram negative pathogens, a favorable observed safety profile, and the convenience of both IV and oral formulations."

John Temperato, Melinta's President and Chief Operating Officer stated, "If approved, we look forward to launching Baxdela for the treatment of ABSSSI with a focused commercial infrastructure, including an acute-care hospital sales force."

Melinta has also been invited to present at the 35th annual JP Morgan Healthcare Conference taking place in San Francisco next week. Melinta will provide a company update and review the clinical results supporting the NDAs as well as commercialization plans during the company's presentation at 3:00pm PT on January 11, 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 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.

Lyn Baranowski
(312) 724-9400
news@melinta.com

Aline Sherwood
(312) 238-8957
asherwood@scientapr.com