Melinta Therapeutics Submits Baxdela New Drug Application for Hospital-Treated Skin Infections

NEW HAVEN, Conn., October 24, 2016 – Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced today that it has submitted New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) for approval of IV and oral Baxdela™ (delafloxacin) for the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). Baxdela is an investigational anionic fluoroquinolone with a broad spectrum of antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA). Melinta's NDAs are based on the results of two Phase 3 studies (NCT01811732 and NCT01984684), in both of which Baxdela met the primary endpoint of non-inferiority to a combination regimen of vancomycin plus aztreonam in reducing lesion size at the primary infection site at 48-to-72 hours. In addition, Baxdela met the primary endpoint, the investigator assessment of clinical cure, for the European Medicines Agency (EMA) in both studies. Baxdela was shown to be well tolerated among Phase 3 study participants, with less than 1% of patients discontinuing for treatment-related adverse events.

"Baxdela, if approved, represents a potentially attractive 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 have a high rate of treatment failure, and frequently have underlying medical conditions that pose challenges to the choice of antibiotic. Baxdela has been tested in over 2,600 patients to date, and was well-tolerated with fewer than 1% of Baxdela-treated patients discontinuing due to treatment-related adverse events."

Baxdela has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. FDA, which provides for priority review. Melinta therefore could receive a regulatory decision by mid-year 2017 consistent with Prescription Drug User Fee Act (PDUFA) priority review timelines.

"Baxdela has demonstrated in clinical trials a broad spectrum of activity and the ability to treat patients with serious co-morbidities, both of which are compelling characteristics sought by physicians according to our market research. We believe that Baxdela's ability to treat challenging patients in hospitals will be a major driver of adoption," concluded John Temperato, Melinta's President and Chief Operating Officer. "If approved, we plan to support the introduction of Baxdela for the treatment of ABSSSI with a focused acute-care hospital sales force. We believe we can further leverage the resources of such a sales team in the future as we seek to complete clinical studies and file applications to market Baxdela in additional indications such as community-acquired bacterial pneumonia and complicated urinary tract infections."

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 compared with vancomycin plus aztreonam 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.

For More Information:

MSLGROUP
Michelle Thaler/Jayme Maniatis
781-684-0770
Melinta@MSLGROUP.com