

Melinta Therapeutics' Phase 3 trials of Baxdela Document Challenges in Antibiotic Selection in Patients Treated for ABSSSI

Phase 3 Subgroup Analysis Presented at Society of Hospital Medicine Meeting

New Haven, Conn, May 02, 2017 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced an upcoming presentation of findings from the Baxdela™ (delafloxacin) Phase 3 clinical program. These findings suggest Baxdela may represent an important treatment option for patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI), particularly obese patients, diabetics, and the elderly, who typically provide challenges in antibiotic selection and dosing. In particular, obese patients, representing 42% of the Baxdela Phase 3 clinical program, were demonstrated to be aggregators of co-morbidities, with twice the rate of important co-morbidities when compared to non-obese patients. These factors are important considerations for physicians when choosing an antibiotic.

The Phase 3 patient population was diverse, enrolling individuals with diabetes (11%), renal impairment (16.2%) and obesity (42%). In addition, 13% of trial participants were over 65 years of age. Treatment with IV/oral Baxdela monotherapy yielded clinical outcomes that were comparable to the control combination of vancomycin/aztreonam in these patient subgroups. No increases in glucose or liver function test were observed in the Baxdela treatment arm compared to the vancomycin/aztreonam group. The most common adverse events were mild-to-moderate gastrointestinal complaints, which did not routinely lead to discontinuation.

“The obese population shows twice the rate of comorbidities, such as vascular disease, metabolism and nutrition disorders, and cardiac disease, compared to the non-obese population, making this patient group especially challenging to treat. Obesity, diabetes and age also increase a person’s general risk of infection, making these patients as prevalent as they are challenging,” added Sue Cammarata, MD, Melinta Therapeutics’ chief medical officer. “When choosing an antibiotic, the physician has to consider what potential bacteria might be present as well as potential contraindications to a particular antibiotic due to the patient’s underlying diseases or medications or lack of IV access. We believe that the ability to administer IV/oral Baxdela without burdensome monitoring or the need to dose-adjust by weight will be appealing to many doctors.”

Melinta submitted New Drug Applications to the FDA for the intravenous and oral formulations of Baxdela for the treatment of patients with serious hospital-treated skin infections (ABSSSI) in October 2016, and a PDUFA date of June 19, 2017 has been set.

Details of the Society of Hospital Medicine poster:

Title: *Obese Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Have Double the Rate of Key Comorbidities Compared to Non-Obese Patients, which Impacts Antibiotic Selection.*

Poster Session: Research and Innovations. 5:30-7:30 pm local time on Tuesday, May 2, 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 of 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 U.S. FDA for the intravenous and oral formulations of Baxdela 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 NDAs to the FDA for the intravenous and oral formulations of 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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