Melinta Therapeutics' Baxdela™ to be Featured in Six Poster Presentations at IDWeek 2016™

Data presented highlight efficacy of broad-spectrum antibiotic for the treatment of serious skin infections including MRSA

NEW ORLEANS, Oct. 26, 2016 (GLOBE NEWSWIRE) -- Melinta Therapeutics, a privately held company exclusively focused on developing novel antibiotics to treat serious bacterial infections, announced today that Baxdela™ (delafloxacin), an investigational, registration-phase anionic fluoroquinolone, will be the subject of six poster presentations at IDWeek 2016, held October 26-30 at the New Orleans Ernest N. Morial Convention Center. Baxdela is a unique fluoroquinolone with activity against a broad array of pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA).

On October 20, 2016, Melinta submitted two new drug applications (NDAs) to the U.S. Food and Drug Administration (FDA) for oral and IV formulations of Baxdela for the treatment of acute bacterial skin and skin structure infections (ABSSSI). This submission includes two Phase 3 studies in which Baxdela successfully met its primary endpoint of non-inferiority to the combination of vancomycin plus aztreonam in the primary endpoint, requiring at least 20% reduction in lesion size at 48-to-72 hours. In addition, Baxdela met the key 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. The most common adverse events were mild to moderate gastrointestinal events which did not lead to treatment discontinuation. Designated as a Qualified Infectious Disease Product (QIDP) by the FDA, Baxdela is a candidate for priority review. Melinta anticipates a regulatory decision by mid-year 2017 consistent with PDUFA priority review timelines.

Baxdela is also being assessed for the treatment of community-acquired bacterial pneumonia (CABP) and complicated urinary tract infections (cUTI).

"Development of new antibiotics has slowed over the past three decades, yet is now more vital than ever as bacteria evolve and, increasingly, become resistant to existing treatments," said Dr. Donald P. Levine, Professor Emeritus of Medicine, Division of Infectious Disease at Wayne State University. "The presentation of data on a new antibiotic nearing market entry represents important progress in the fight against infectious disease and antibiotic resistance."

During IDWeek, infectious disease leaders who have studied Baxdela will share clinical results in the following poster presentations:

- Thursday, October 27: Characteristics of Patients Hospitalized for Acute Bacterial Skin and Skin Structure Infections from 2009-2013 (#279)
- Friday, October 28: Comparison of Delafloxacin (DLX) and Vancomycin (VAN) by Age and Gender in Two Phase 3 Trials in the Treatment of Acute Bacterial Skin and Skin Structure Infections (#1153)
- Friday, October 28: Evaluation of Digital vs. Manual Measures of Lesion Size in a Phase 3 Trial of Delafloxacin (DLX) in Patients with Acute Bacterial Skin and Skin Structure Infections (#1154)
- Friday, October 28: A Global Phase 3 Study of Delafloxacin (DLX) Compared to Vancomycin/Aztreonam (VAN/AZ) in Patients with Acute Bacterial Skin and Skin Structure Infections (#1347)
- Saturday, October 29: Pharmacokinetic-Pharmacodynamic (PK-PD) Target Attainment Analyses for Delafloxacin to Provide Dose Selection Support for the Treatment of Patients with Community-Acquired Bacterial Pneumonia (#1972)
- Saturday, October 29: Population Pharmacokinetic (PPK) Analysis for Intravenous (IV) and Oral (PO) Delafloxacin Using Data from Phase 1 Studies (#1975)
- Saturday, October 29: *In Vitro* Activity of Delafloxacin and Microbiological Response Against Fluoroquinolone Susceptible and Non-Susceptible *S. aureus* Isolates from two Phase 3 Studies of Acute Bacterial Skin and Skin Structure Infections (#2039)

Melinta Therapeutics will additionally host a satellite symposium on Friday, October 28 at 8:00 p.m. entitled, "The Bug-Drug-Host Triad in the Era of Antibiotic Resistance: Focus on the Spectrum of ABSSSI."

"Each year, nearly 3 million patients are hospitalized for serious skin infections. Many of these patients are inadequately treated with therapies that do not provide sufficient pathogen coverage or are not well tolerated," said Eugene Sun, M.D., Melinta's Chief Executive Officer. "If approved, we believe Baxdela will provide another option for patients with difficult-to-treat skin infections. We look forward to working with FDA to bring this important new treatment to patients."

For more information about Baxdela, please visit Melinta Therapeutics at IDWeek 2016 in booth in #1228.

About IDWeek

IDWeek 2016™ is the annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA) and the Pediatric Infectious Diseases Society (PIDS). With the theme "Advancing Science, Improving Care," IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan. IDWeek 2016 takes place October 26-30 at the New Orleans Ernest N. Morial Convention Center in New Orleans. For more information, visit www.idweek.org.

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.

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