Melinta Therapeutics Presents Complete Delafloxacin Results from Phase 3 Study in Patients with Acute Bacterial Skin and Skin Structure Infections at ID Week

NEW HAVEN, CT and SAN DIEGO, Oct. 9, 2015 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, today announced complete results from the first of two Phase 3 studies (RX-3341-302, NCT01811732) of delafloxacin, an investigational fluoroquinolone in late-stage development for the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). Delafloxacin met the study's primary endpoint, reduction in lesion size by at least 20% at 48-72 hours in the intent-to-treat (ITT) population without nonstudy antibiotics or major procedures, which was comparable to the response in the control arm receiving vancomycin plus aztreonam. Delafloxacin also was comparable to vancomycin+aztreonam in the study's secondary endpoint of cure, defined as the complete resolution of signs and symptoms at the follow-up visit (Day 14). Delafloxacin-treated patients experienced fewer treatment-emergent adverse events (AEs), and fewer discontinuations due to AEs than patients in the vancomycin+aztreonam arm. The most frequent AEs in the delafloxacin arm were infection, infusion site extravasation, diarrhea, and nausea. Melinta also provided an analysis of obese patients in this study. Among study participants, 214 patients had body mass index (BMI) of at least 30 kg/m^2. More obese patients in the delafloxacin arm achieved cure than in the vancomycin+aztreonam arm.

"These results are very encouraging, and demonstrate a potential role for delafloxacin in serious skin infections," commented Dr. Eugene Sun, interim Chief Executive Officer and EVP of R&D at Melinta Therapeutics. "We are expecting results from our second Phase 3 study (RX-3341-303) of IV and oral delafloxacin in patients with ABSSSI in the first half of 2016. Together, these two studies will form the basis of a new drug application that we anticipate filing with the U.S. Food and Drug Administration in 2016."

In this double-blind, Phase 3, multicenter study, 660 patients with ABSSSIs were randomized to receive either intravenous (IV) delafloxacin or vancomycin plus aztreonam for 5-14 days. Patients had wounds, burns, major abscesses, or cellulitis with lesions of at least 75 cm^2 in size (average lesion size was 307 cm^2) and at least 2 systemic signs of infection. *Staphylococcus aureus* was the most frequently identified pathogen, with 52% being methicillin-resistant (MRSA). Patients were evaluated for efficacy through assessments of signs and symptoms of infection; measurement of lesion size; and culture and susceptibility testing of bacterial isolates.

Complete results from this study and other studies on delafloxacin are being presented at ID Week, the annual meeting of both the Infectious Disease Society of America and the Society for Healthcare Epidemiology of America, which is being held October 7-11 in San Diego, CA. Details of these presentations are as follows:

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- Outcomes in Obese Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in a Trial Comparing Delafloxacin to Vancomycin/Aztreonam. Session Time: 12:30 PM - 2:00 PM. Poster #783. Session: 130 (Antimicrobial Agents: Novel Agents).

- Results of a Global Phase 3 Study of Delafloxacin (DLX) Compared to Vancomycin With Aztreonam (VAN) in Acute Bacterial Skin and Skin Structure Infections (ABSSSI). Session Time: 12:30 PM - 2:00 PM. Poster #776. Session: 130 (Antimicrobial Agents: Novel Agents).

- A Phase 1, Open-Label, Evaluation of the Single-Dose Pharmacokinetics of Delafloxacin (DLX) in Subjects With and Without Hepatic Impairment. Session Time: 12:30 PM - 2:00 PM. Poster #911. Session: 135 (Clinical Trials).

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- Evaluation of Health-Related Quality of Life (HRQL) in ABSSSI Patients after Antibiotic Discontinuation in a Phase 3 Trial. Session Time: 12:30 PM - 2:00 PM. Poster #1538. Session: 220 (Clinical Infectious Diseases: Soft Tissue Infections (ABSSSSIs)).

About Delafloxacin

Delafloxacin is an investigational anionic fluoroquinolone antibiotic currently in Phase 3 clinical development for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI). The PROCEED studies (studies 302 and 303) are Phase 3, multicenter, randomized, double-blind, active-controlled trials to evaluate delafloxacin compared with vancomycin + aztreonam for the treatment of patients with ABSSSI. The PROCEED studies are evaluating delafloxacin in both IV and oral formulations. Delafloxacin has been designated a Qualified Infectious Disease Product (QIDP) for both ABSSSI and 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 is rapidly progressing its late-stage investigational antibiotic, delafloxacin, which is currently in Phase 3 development for acute bacterial skin and skin structure infections (ABSSSI). 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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