Melinta Therapeutics Presenting In Vivo and In Vitro Results from Baxdela Studies at ASM Microbe

Bactericidal Data on a Novel Pyrrolocytosine for Gonorrhea also presented

New Haven, Conn, June 01, 2017 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced today that five presentations of clinical, in vitro and pharmacokinetic results from studies of Baxdela™ (delafloxacin), an investigational anionic fluoroquinolone, will be presented at the ASM Microbe 2017 meeting. In addition there will be an oral presentation on the potential of RX-P2177, a novel pyrrolocytosine antibiotic developed internally as part of our ESKAPE pathogen program that uses our proprietary ribosome-targeting platform. RX-P2177 shows promising activity for the treatment of gonorrhea; details will be shared during a symposium on antimicrobial pharmacokinetics and pharmacodynamics. ASM Microbe 2017 will take place June 1–5, 2017 in New Orleans, LA. Details of these presentations are as follows:

- Poster 235 - Delafloxacin (DLX) is Effective and Well-Tolerated Compared to Vancomycin/Aztreonam (VAN/AZ) in Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) and History of Infectious Hepatitis. Friday, June 2, 2017 from 12:45 - 2:45pm
- Poster 423 - Comparison of Delafloxacin MIC Test Strip and Broth Microdilution MIC Results for Staphylococcus spp., E. faecalis, Enterobacteriaceae and P. aeruginosa. Saturday, June 3, 2017 from 12:15 - 2:15pm
- Poster 275 - A Multi-Site Study Comparing a Commercially Prepared Dried MIC Susceptibility System to the CLSI Broth Microdilution Method for Delafloxacin Using Non-Fastidious Gram-Positive Organisms. Saturday, June 3, 2017 from 12:15 - 2:15pm
- Poster 349 - In Vivo PK/PD of Delafloxacin against Escherichia coli and Pseudomonas aeruginosa in the Mouse Thigh Infection Model. Sunday, June 4, 2017 from 12:15 - 2:15pm
- Poster 1929 - In Vitro Evaluation of Delafloxacin Activity When Tested against Contemporary ABSSSI Isolates from the United States (2014-2016): Results from the SENTRY Antimicrobial Surveillance Program. Sunday, June 4, 2017 from 12:15 - 2:15pm
- Oral Presentation - RX-P2177: A Pyrrolocytosine for Gonorrhea. Session 480: Pharmacodynamics in the Intracelluar Space. Monday, June 5, 2017 from 11:30 - 11:45am in Room 225

About ASM Microbe

ASM Microbe is an integrated meeting of the American Society of Microbiology's General Meeting and the Interscience Conference on Antimicrobial agents and Chemotherapy. The meeting is the largest gathering of microbiologists in the world and is designed to provide a one-of-a-kind forum to explore the complete spectrum of microbiology from basic science to translation and application. For more information on the ASM Microbe meeting, please refer to the conference website.

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 nausea, diarrhea, vomiting, headache, and transaminase elevations, which were generally mild. The treatment discontinuation rate due to treatment-related adverse events for patients treated with Baxdela in the Phase 3 trials was 0.9%. 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. Food and Drug Administration ("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 FDA.

About the ESKAPE Pathogen Program

Melinta's ESKAPE pathogen program is built on the Company's technology platform based on Nobel laureate science developed at Yale University. Melinta owns the exclusive licenses to the three-dimensional structure of the ribosome and has created the drug-design tools and associated discovery process to exploit the ribosome structure. With these, the Company is able both to improve on existing classes and to design and optimize completely new classes of antibiotics. In the ESKAPE pathogen program, Melinta has created three new classes of antibiotics that inhibit the bacterial ribosome, binding in a validated site that is not the home to commercially available antibiotics. In addition to utilizing this novel binding site, these new classes are also chemically novel; these two features offer a potential advantage vis-à-vis resistance development. Our studies demonstrate that these optimized compounds do not share cross-resistance to currently marketed therapies, including extended-beta-lactamases, carbapenemases and colistin resistance. Compounds in the lead class, known as the pyrrolocytosines, have been optimized to enhance bacterial influx and to minimize bacterial efflux. Further, they are active in many preclinical models of efficacy. Compounds in the class represent many potential target product profiles, including for infections caused by drug-resistant Neisseria gonorrhoeae, carbapenem-resistant Enterobacteriaceae (CRE) and the full complement of ESKAPE pathogens, which are multidrug- and extremely-drug-resistant Enterococcus faecium, Staphylococcus aureus (MRSA), Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter sp. and Escherichia coli. The program is in late lead optimization, focused on selecting at least one development candidate for IND-enabling studies.

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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