



# Melinta Therapeutics Presenting Results from Baxdela and ESKAPE Programs at ASM Microbe 2016 Meeting

## Chief Scientific Officer Erin Duffy to Present in Meet-the-Experts Session: Antimicrobial Discovery Approaches

NEW HAVEN, Conn, June 14, 2016 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced that the company and investigators will be making five presentations at [ASM Microbe 2016](#), which takes place in Boston, MA on June 16-20. Specifically, Melinta will present four posters on [Baxdela™](#) (delafloxacin), an investigational anionic quinolone being assessed for the treatment of patients with serious bacterial infections including acute bacterial skin and skin structure infections (ABSSSI), community-acquired bacterial pneumonia (CABP) and complicated urinary tract infections (cUTI).

Melinta will also present results from preclinical studies from its innovative [ESKAPE Pathogen Program](#). The ESKAPE Pathogen Program aims to introduce completely novel classes of antibiotics to meet the challenge posed by the emergence of multi-drug-resistant (MDR) and extensively drug-resistant (XDR) bacteria. Such “superbug” pathogens include *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacter* species and *Escherichia coli*.

In addition, Chief Scientific Officer [Erin Duffy, Ph.D.](#) will present “*U.S. Experiences in Antibiotic Development*” during a Meet-the-Experts session. Dr. Duffy was invited to participate based on her considerable experience in the discovery and development of novel antibiotics. As the sole U.S. participant, Dr. Duffy will also provide insight into the development and regulation of antimicrobial agents in the U.S. This Meet-the-Expert session is titled Antimicrobial Discovery Approaches and will be held on Saturday, June 18, 2016 from 7:00 - 8:00 AM.

Dr. Duffy added, “I hope to illustrate how the discovery, development, and regulatory landscape have shifted in recent years in the antibiotics space by describing our own experience at Melinta. We have adapted our drug discovery programs to the changing environment -- from modifying plans for novel entrants in existing classes, to *de novo* design of new classes in our ESKAPE program, which is designed to treat the modern superbugs. This work is especially critical, considering the CDC’s recent identification of a strain of *E. coli* harboring the *mcr-1* gene, conferring resistance to colistin, a last-resort antibiotic.”

### Poster Details:

Friday, June 17, 2016, 12:30 - 2:30 PM

Session 060 - Assessment of Novel Antibacterial Strategies



- Poster 420 - *Evaluation of the Development of Resistance in a Novel Class of Antimicrobial Agents*

Sunday, June 19, 2016, 12:30 - 2:30 PM

#### Session 306 - Fluoroquinolones and Other Topoisomerase Inhibitors

- Poster 457 - *In Vitro Activity of Delafloxacin (DLX) When Tested against Contemporary Bacterial Pathogens from the USA (2014)*
- Poster 472 - *Bactericidal Activity of Delafloxacin Against Recent Isolates of Staphylococcus aureus*
- Poster 473 - *In Vivo Pk/Pd of a Delafloxacin Against Staphylococcus aureus (Sa), Streptococcus pneumoniae (Spn), and Klebsiella pneumoniae (Kpn) in the Murine Lung Infection Model*

Monday, June 20, 2016, 12:30 - 2:30 PM

#### Session 421 - Pharmacokinetic/Pharmacodynamic (PK/PD) of New Drugs

- Poster 521 - *A Phase I, Open-label Study of the Effect of Delafloxacin (Dlx) on the Pharmacokinetics (Pk) of a Single Oral Dose of Midazolam (Mid)*

#### **About Baxdela**

Baxdela (delafloxacin) is an investigational anionic fluoroquinolone antibiotic currently completing development for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI). Baxdela has robust antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA), a major cause of serious 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 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.

Melinta is also assessing Baxdela in clinical trials in patients with hospital-treated community-acquired bacterial pneumonia (CABP) and hospital-treated complicated urinary



tract infections (cUTI). Baxdela has been designated a Qualified Infectious Disease Product (QIDP) and has been granted fast track designation 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, Baxdela, which is completing development for acute bacterial skin and skin structure infections (ABSSSI) and 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](http://www.vaterahealthcare.com)) and Malin Corporation plc ([www.malinplc.com](http://www.malinplc.com)) among other private investors. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit [www.melinta.com](http://www.melinta.com) for more information.

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