



## **Melinta Therapeutics Highlighting Activity of Baxdela as well as Progress on Macrolide and Pyrrolocytosine Candidates at ECCMID 2017**

Presentations includes Baxdela activity in obese and other challenging patient types, as well as a presentation on activity of pyrrolocytosine family against MCR-1 MDR bacteria

**New Haven, Conn, April 19, 2017** -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced today that there will be nine presentations on Melinta programs at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), which is being held April 22-25, 2017 in Vienna, Austria. These presentations include six posters and e-posters describing the clinical experience with Baxdela<sup>TM</sup> (delafloxacin), an investigational anionic fluoroquinolone, including important insights into the treatment of challenging patient types such as those who have diabetes, renal impairment or obesity. Details of these presentations are as follows:

- E-poster EV0435 (abstract A1467): Patients tolerate switch from IV to oral antibiotics in acute bacterial skin and skin structure Infections (ABSSSI) earlier than European physicians may predict. Session: Pharmacoepidemiology, improved prescribing and antibiotic stewardship. Saturday, April 22, 2017 at 8:45 - 3:30.
  
- Poster P1351 (abstract A1567): In vitro evaluation of delafloxacin activity when tested against contemporary ABSSSI isolates from Europe and surrounding areas (2014-2016): results from the SENTRY antimicrobial surveillance programme. Session: New antibiotics – new approaches. Sunday April 23, 2017 at 12:30 - 1:30
  
- Poster P1352 (abstract A1210): Delafloxacin (DLX) is effective and well-tolerated in treatment of European patients with acute bacterial skin and skin structure infections (ABSSSI) versus vancomycin/aztreonam (VAN/AZ). Session: New antibiotics – new approaches. Sunday April 23, 2017 at 12:30 - 1:30

- Poster P1353 (abstract A1261): Delafloxacin (DLX) is effective and well-tolerated in treatment of diabetic (DM) patients with acute bacterial skin and skin structure infections (ABSSSI) versus vancomycin/aztreonam (VAN/AZ). Session: New antibiotics – new approaches. Sunday April 23, 2017 at 12:30 - 1:30

- Poster P1354 (abstract A1465): Delafloxacin (DLX) is effective and well-tolerated in treatment of obese patients with acute bacterial skin and skin structure infections (ABSSSI) versus vancomycin/aztreonam (VAN/AZ). Session: New antibiotics – new approaches. Sunday April 23, 2017 at 12:30 - 1:30

- Poster P1355 (abstract A1466): Delafloxacin (DLX) is effective and well-tolerated in treatment of patients with renal impairment and acute bacterial skin and skin structure infections (ABSSSI) versus vancomycin/aztreonam (VAN/AZ). Session: New antibiotics – new approaches. Sunday April 23, 2017 at 12:30 - 1:30

Three presentations will also be made on Melinta's preclinical development programs. Collaborators of the company have been invited to make a moderated e-poster presentation on the development of a novel class of pyrrolocytosines and its activity against multi-drug resistant (MDR) Gram-negative bacteria, including those producing carbapenemases or other beta-lactam resistance mechanisms, those expressing the colistin resistance gene *mcr-1*, and those armed with antibiotic efflux pumps. In addition, two posters will be presented describing Melinta's development of enhanced macrolides, the activity of these candidates against Gram-positive bacteria and their unique robustness to macrolide resistance mechanisms. Details of these preclinical presentations are as follows:

- E-poster EP0399 (abstract A5925): Activity of novel pyrrolocytosine protein synthesis inhibitors against multi-resistant Gram-negative bacteria, including carbapenemase producers and those with MCR-1. Session: New antibiotics – new approaches. Sunday April 23, 2017 at 1:30 - 2:30



- Poster P1317 (abstract A7033): Unique mode of action and non-induction of resistance by novel 14- and 15-membered macrolides. Session: New drugs against Gram-positives. Monday April 24, 2017 at 12:30 - 1:30
- Poster P1328 (abstract A7078): Atomic eyesight is key to design of enhanced macrolides with true robustness to target-based resistance. Session: New drugs against Gram-positives. Monday April 24, 2017 at 12:30 - 1:30

For more information about Melinta Therapeutics' clinical or preclinical programs, please visit the company's booth #95.

### **About ECCMID**

ECCMID is the annual meeting of the European Society of Clinical Microbiology and Infectious Diseases and is being held April 22-25, 2017 in Vienna, Austria. It attracts approximately 10,000 participants, making it the largest European congress for the presentation and discussion of research in the fields of clinical microbiology and infection. The scientific program is a synthesis of current priorities in the fields of clinical microbiology and infection. The diagnosis, treatment, epidemiology and prevention of infectious diseases, as well as related basic microbiology, are addressed by leading scientists during keynote lectures, symposia, meet-the-expert sessions, educational workshops, as well as poster and oral sessions. For more information, visit [www.eccmid.org](http://www.eccmid.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 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 US 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](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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