

Melinta Therapeutics Presentations at ECCMID Show Potential of Baxdela in Obese and other Challenging Patient Types

New Haven, Conn, April 21, 2017 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, announced today that the company and investigators will be presenting clinical evidence from the Baxdela™ (delafloxacin) clinical program at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). Baxdela, an investigational fluoroquinolone, has completed Phase 3 testing and is the subject of a New Drug Application (NDA) currently under review at the U.S. Food and Drug Administration for the treatment of patients with serious hospital-treated skin infections (ABSSSI). The presentations at ECCMID include data from the complete Baxdela Phase 3 program, and demonstrate that Baxdela is comparable to vancomycin/aztreonam combination therapy in the treatment of patients with ABSSSI. Importantly, this comparability was demonstrated not only in the global study population, but in three key subgroups: patients with diabetes, renal impairment and obesity.

“It has long been understood that renal insufficiency, diabetes and obesity put patients at risk for infection and impair a patient's ability to heal from bacterial skin infections,” explained Dr. Sue Cammarata, Melinta's chief medical officer. “Further, comorbidities like obesity and renal impairment pose dosing challenges for many current antibiotics. That Baxdela (IV and oral formulations) was comparable to a two-drug regimen that included the gold-standard treatment vancomycin in these difficult-to-treat patients, including patients with MRSA as well as Gram-negative infections, was an important finding. We believe that hospital formularies and physicians will view these characteristics favorably when evaluating antibiotics for use in their most challenging ABSSSI patients.”

The two Phase 3 clinical trials that comprise the Baxdela Phase 3 program enrolled a total of 1,510 patients with ABSSSI. Within this patient population, 164 patients were diabetic, 244 had renal impairment, and 639 were obese. Baxdela met both studies' primary and secondary endpoints, including both the FDA and EU primary endpoints, and was shown to be well tolerated among study participants. Diarrhea and nausea were the most frequent treatment-related adverse events reported for Baxdela, and did not lead to study discontinuation. Success rates at follow up in the Intent-to-Treat population among diabetic patients were 85.5% for patients receiving Baxdela and 84% for those receiving vancomycin/aztreonam. Patients with renal impairment experienced success rates of 87.7% and 88.5%, respectively; and obese patients 86.1% and 85.1%, respectively.

In each subgroup, *Staphylococcus aureus* was the most common source of infection. The microbiologic response rates were 87% vs 88%, respectively among diabetic patients, 94.9% and 94.1%, respectively among those with renal impairment and 98.0% vs 92.8%, respectively among obese patients with this type of infection.

Details of the Baxdela 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

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.

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 U.S. 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) 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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