Melinta Therapeutics Presenting Detailed Analyses from Baxdela Phase 3 ABSSSI Trials and In Vitro Performance against Isolates of Resistant CABP and other Infections

NEW HAVEN, Conn., Sept. 25, 2017 -- Melinta Therapeutics, a privately held company developing and commercializing novel antibiotics to treat serious bacterial infections, announced that it will be making nine poster presentations and participating in an oral session at the upcoming IDWeek 2017 annual scientific meeting. These presentations will provide detailed analyses of the safety and efficacy results from the two Phase 3 studies of Baxdela™ (delafloxacin) in the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). In addition, *in vitro* findings characterizing Baxdela's activity against pathogens associated with community-acquired respiratory tract infections will be presented.

Melinta is also sponsoring several educational events for IDWeek attendees. An open educational gallery is being held on October 3 from 7:00 - 9:00 pm in the Coronado Room at the Marriott Marquis San Diego Marina. This is followed by an educational reception on October 4 from 6:00 – 8:00 pm at Eddie V's Prime Seafood Restaurant. More information for this event may be found at www.regonline.com/meetmelinta. Lastly, an educational product theater presentation, "A New Development in Antibiotics for the treatment of Acute Bacterial Skin and Skin Structure Infections," is being hosted on October 6 from 1:15 - 2:00 pm in Learning Lounge 2, Booth 1035.

Sue Cammarata, MD, Melinta's chief medical officer, commented, "As a whole, these presentations will provide a significant dataset highlighting the compelling outcomes and safety profiles we have observed with Baxdela against a number of important pathogens in the treatment of ABSSSI."

Baxdela is indicated in adults for the treatment of ABSSSI caused by susceptible organisms. It is currently being assessed in a Phase 3 clinical trial for community-acquired bacterial pneumonia (CABP), an indication for which it has received a Qualified Infectious Disease Product (QIDP) designation from the U.S. FDA. Baxdela is not approved for use in CABP.

"An estimated 50,000 people die every year from community-acquired pneumonia. It is particularly dangerous in patients with weakened immune responses, such as the elderly and those whose immune systems are compromised," continued Dr. Cammarata. "We look forward to concluding the ongoing Phase 3 CABP study in 2018."

Poster and presentation details are as follows:

Thursday, October 5, 2017

- Symposium 088: New Antibiotics: What's in the Pipeline. Room: 20ABCD from 2:00-3:30 PM.
- Poster 331: Molecular Characterization of Fluoroquinolone Resistance Mechanisms in Isolates from the Delafloxacin Acute Bacterial Skin and Skin Structure Infections Clinical Trials.

Friday, October 6, 2017

- Session 107: Pipeline 2.0.(Q&A session for Symposium 088), Room: 06DE from 7:00-8:15 AM.

- Poster 1208: *In vitro* Evaluation of Delafloxacin Activity When Tested against Contemporary Community-Acquired Bacterial Respiratory Tract Infection Isolates (2014-2016): Results from the SENTRY Antimicrobial Surveillance Program.
- Poster 1222: Activity of delafloxacin when tested against bacterial surveillance isolates collected in the USA and Europe during 2014-2016 as part of a global surveillance program.
- Poster 1532: Human Target Attainment Probabilities for Delafloxacin against *Escherichia coli* and *Pseudomonas aeruginosa*.

Saturday, October 7, 2017

- Poster 1851: Population Pharmacokinetic and Pharmacokinetic-Pharmacodynamic Target Attainment Analyses for Delafloxacin to Support Dose Selection for the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections.
- Poster 1854: Impact of Delafloxacin and Vancomycin/Aztreonam on Resolution of Signs and Symptoms of Acute Bacterial Skin and Skin Structure Infections.
- Poster 1856: Outcomes with IV/oral Delafloxacin Compared to Vancomycin/Aztreonam in Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections and Gram-negative Pathogens.
- Poster 1857: Outcomes with IV/oral Delafloxacin Compared to Vancomycin/Aztreonam in Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections and Gram-positive Pathogens.
- Poster 1858: Comparison of Safety Profile of Delafloxacin versus Vancomycin/Aztreonam in the Treatment of Patients with Acute Bacterial Skin and Skin Structure Infections: Integrated Safety Findings from Two Phase III Studies.

About IDWeek
IDWeek is the combined annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS). With this year's theme - Advancing Science, Improving Care - IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan. The meeting is being held October 5-8 in San Diego, CA. For more information, please visit: www.idweek.org.

About Baxdela

Baxdela (delafloxacin) tablets and intravenous injection are approved for the treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections). Baxdela was given priority review by the FDA due to its designation as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act of 2012. The QIDP designation qualifies Baxdela for certain incentives related to the development of new antibiotics, including a five-year extension of any non-patent exclusivity period awarded to the drug.

INDICATION & USAGE

Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

Gram-positive organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus* group (including *Streptococcus anginosus*,

Streptococcus intermedius, and *Streptococcus constellatus*), *Streptococcus pyogenes*, and *Enterococcus faecalis*;

Gram-negative organisms: *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*

IMPORTANT SAFETY INFORMATION:
WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, AND EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- **Tendinitis and tendon rupture**
- **Peripheral neuropathy**
- **Central nervous system effects**

Discontinue Baxdela immediately and avoid the use of fluoroquinolones, including Baxdela, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Baxdela in patients with known history of myasthenia gravis.

Contraindications
Baxdela is contraindicated in patients with known hypersensitivity to Baxdela or other fluoroquinolones.

Warnings and Precautions
Risk of tendinitis, tendon rupture, peripheral neuropathy and central nervous system effects is increased with use of fluoroquinolones. Discontinue Baxdela immediately at the first signs or symptoms of any of these serious adverse reactions.

Avoid Baxdela in patients with known history of myasthenia gravis.

Hypersensitivity Reactions may occur after first or subsequent doses of Baxdela. Discontinue Baxdela at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported in users of nearly all systemic antibacterial drugs, including Baxdela. Evaluate if diarrhea occurs.

Prescribing Baxdela in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions
The most common adverse reactions in patients treated with Baxdela were nausea (8%), diarrhea (8%), headache (3%), transaminase elevations (3%), and vomiting (2%).

Use in Specific Populations
In patients with severe renal impairment (eGFR of 15-29 mL/min/1.73 m^2) dosing of Baxdela should be dosed at 200 mg IV every 12 hours or 450 mg orally every 12 hours. Baxdela is not

recommended in patients with End Stage Renal Disease [ESRD] (eGFR of <15 mL/min/1.73 m^2) due to insufficient information to provide dosing recommendations.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is dedicated to saving lives threatened by the global public health crisis of bacterial infections, through the development and commercialization of novel antibiotics that provide new and better therapeutic solutions. Melinta's lead product is Baxdela, an antibiotic approved for use in the treatment of acute bacterial skin and skin structure infections (ABSSSI). Melinta is also 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. In August, Melinta announced its entry into a merger agreement with Cempra, Inc. (Nasdaq:CEMP). The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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