Melinta Therapeutics Presents Outcomes of Baxdela Treatment of Gram-Positive and Gram-Negative Pathogens at IDWeek

NEW HAVEN, Conn., Oct. 04, 2017 -- Melinta Therapeutics, a privately held commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, announced nine poster presentations and an oral presentation at the IDWeek 2017 annual scientific meeting.

Among these posters are three (poster numbers 1856-8) that detail the microbiologic outcomes and safety results from the two Phase 3 PROCEED studies of Baxdela™ (delafloxacin) in the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). Baxdela demonstrated strong activity against both gram-negative and gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA). Importantly, its activity was consistent in difficult-to-treat patients, such as those with obesity (42% of the study population) or diabetes (11% of the study population).

Baxdela demonstrated potency against gram-positive pathogens, including susceptible and resistant *Staphylococcus aureus* and *Streptococcus pyogenes*, in the PROCEED studies. The microbiologic eradication (documented or presumed) seen with Baxdela was 98.4% against *Staphylococcus aureus* strains and 94.7% against *Streptococcus pyogenes* in the evaluable group, which were comparable outcomes to vancomycin/aztreonam combination. Gram-negative pathogens, including *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Escherichia coli* and *Pseudomonas aeruginosa* were observed in the same studies. Treatment with Baxdela generated microbiologic eradication (documented or presumed) of 100% for *Klebsiella pneumoniae*, *Escherichia coli* and *Pseudomonas aeruginosa*, and 91.7% for *Enterobacter cloacae*, in evaluable patients.

Overall, Baxdela was well tolerated in the 741 ABSSSI patients who received Baxdela in the PROCEED studies. The most frequent treatment-related adverse events were gastrointestinal in nature including nausea (in 6.1% of Baxdela-treated patients and 4.3% of vancomycin/aztreonam - treated patients) and diarrhea (6.1% and 2%, respectively). Less than 1% of Baxdela-treated patients discontinued treatment due to adverse events. Notably, there were no cases of tendon rupture or reports of patients with symptoms consistent with fluoroquinolone-associated disability (FQAD), a constellation of symptoms associated with peripheral nerve damage as qualified by the Food and Drug Administration (FDA) in 2015.

Details of the Baxdela presentations are as follows:

Thursday, October 5, 2017

- Symposium 088: New Antibiotics: What's in the Pipeline. Room: 20ABCD from 2:00-3:30 PM PT.
- 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. Room: 06DE from 7:00-8:15 AM PT
- 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 (ABSSSI)
- 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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