MELINTA THERAPEUTICS ANNOUNCES U.S. FDA APPROVAL OF BAXDELA™ (DELAFLOXACIN) FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)

- Baxdela offers a new option for treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) including hospital-treated skin infections in oral and IV formulations as monotherapy -

NEW HAVEN, Conn. – June 19, 2017 – Melinta Therapeutics, a privately held company focused on discovering, developing, and commercializing novel antibiotics to treat serious bacterial infections, announced today that the U.S. Food and Drug Administration (FDA) has approved Baxdela™ (delafloxacin), indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria. Baxdela is a fluoroquinolone that exhibits activity against both gram-positive and gram-negative pathogens, including MRSA (methicillin-resistant *Staphylococcus aureus*), and is available in both intravenous (IV) and oral formulations.

“The approximately 3 million patients hospitalized each year in the U.S. with ABSSSI often present treatment challenges owing to their underlying medical conditions, making optimal antibiotic selection difficult. Baxdela provides a treatment option for adult patients with ABSSSI based on its coverage spectrum, IV and oral dosing flexibility, efficacy and safety profile,” said Eugene Sun, M.D., CEO of Melinta. “The approval of Baxdela demonstrates FDA’s commitment to making new and effective antibiotics available to address unmet needs for hospitalized ABSSSI patients.”

“Antibiotic resistance is a growing concern, and physicians need more tools in the fight against this threat to modern medicine. Approval of new therapies like Baxdela, which is effective against MRSA and other serious pathogens, provides physicians another option in addressing the challenges of ABSSSI patients,” said Dr. David Hooper, professor of medicine, Harvard University, and chief of Infection Control, associate chief, Division of Infectious Diseases, Massachusetts General Hospital.

“The FDA approval of Baxdela is a major milestone for Melinta. We are grateful to the patients, families, investigators and their staffs for their support in developing an important new therapy. We want to thank the Melinta team for its leadership in bringing the first of what we believe will be many innovative antibiotics to patients,” said Kevin Ferro, CEO of Vatera Healthcare Partners, Melinta’s largest investor.

The Baxdela New Drug Application (NDA) approvals were supported by two Phase 3 studies in patients with ABSSSI, demonstrating that IV and oral Baxdela monotherapy was statistically non-inferior to the combination of vancomycin plus aztreonam at the FDA primary endpoint of early clinical response at 48-72 hours. Baxdela was well tolerated with a 0.9% discontinuation rate in the Phase 3 studies due to adverse events. In addition, Baxdela has not shown any potential for QT prolongation or phototoxicity in definitive clinical studies. There have been no signals of adverse effects on liver function, kidney function, or glucose regulation in controlled clinical studies. The 450 mg tablet is bioequivalent (area under the curve) to, and interchangeable with 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, such as antacids.

Full prescribing information and medication guide for Baxdela will be made available at www.baxdelarx.com. For questions or comments, call 1-844-MELINTA (1-844-635-4682).

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. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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