Melinta Therapeutics Announces FDA Clearance of Antimicrobial Susceptibility Tests Concurrent with Baxdela Launch in the United States

NEW HAVEN, Conn., Oct. 30, 2017 (GLOBE NEWSWIRE) -- Melinta Therapeutics, a privately held company developing and commercializing novel antibiotics to treat serious bacterial infections, announced today the U.S. Food and Drug Administration (FDA) has cleared three antimicrobial susceptibility tests (ASTs) that will be available to guide physicians towards the appropriate usage of Baxdela™ (delafloxacin). Baxdela, available in both intravenous and oral forms, is an FDA-approved fluoroquinolone indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria, with demonstrated *in-vitro* and clinical activity against Gram-positive and Gram-negative pathogens, including activity against MRSA (methicillin-resistant *Staphylococcus aureus*). The three ASTs that have been cleared are: Hardy Diagnostics' Delafloxacin Antimicrobial Susceptibility Disk (HardyDisk™), Liofilchem® Delafloxacin MIC Test Strip (MTS), and Thermo Scientific™ Sensititre™ MIC System.

"Antimicrobial susceptibility tests are used to determine how well specific antibiotics work against bacterial pathogens and they are vital for physicians to understand the appropriate use of an antibiotic. However, a significant delay of months to years often follows the approval of a new antimicrobial before its associated ASTs are released," stated Sue Cammarata, M.D., Melinta's chief medical officer. "Melinta's team has been working with manufacturers for the last few years to develop these antimicrobial susceptibility tests in parallel with our Phase 3 PROCEED studies. Owing to the manufacturers' resolve to bring these tests to the FDA without delay, these three cleared testing products were approved in record time."

"The FDA was supportive of our plans to coordinate our New Drug Application approval with AST clearance. It was clear to us that they understood the importance of these tests," added John Temperato, Melinta's president and chief operating officer. "It is unusual for an antibiotic to launch at the same time with approved diagnostic tools. Because these tools will be available with Baxdela at launch, doctors will have the full set of clinical tools they need in order to make a clinical decision on how to treat patients appropriately."

About the ASTs
Hardy Diagnostics' Delafloxacin Antimicrobial Susceptibility Disks, product number Z9301 (single pack) and Z9305 (pack with 5 cartridges) are available along with a large selection of susceptibility disks, which also include the most recent approved antibiotics.

Liofilchem Delafloxacin MIC Test Strip 0.002-32 µg/mL is a quantitative assay for determining the Minimum Inhibitory Concentration of delafloxacin against *Staphylococcus aureus* (including methicillin-resistant and methicillin susceptible isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis*, and *Enterococcus facecalis*.

Delafloxacin MIC Test Strip 0.002-32 µg/mL are available in packs of 10 (ref. 920801), 30 (ref. 92080) and 100 strips (ref. 920800).

The Thermo Scientific™ Sensititre™ System provides minimum inhibitory concentration (MIC) results and a large, up-to-date selection of antimicrobials, including a complete range of standard MIC plates, the ability to create custom plates tailored to a laboratory's formulary, dilution ranges and patient population. FDA approval has been received for all Baxdela indicated organisms. Sensititre can be used to perform delafloxacin susceptibility testing manually, or using the Sensititre™ Vizion™ Digital MIC Viewing System, Sensititre™ OptiRead™ Automated Fluorometric Plate Reading System, or the fully automated Sensititre™ ARIS™ 2X System.

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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