

Melinta Therapeutics Publication Highlights Baxdela Activity Against Fluoroquinolone-Non-Susceptible MRSA Pathogens

NEW HAVEN, Conn., Sept. 18, 2017 -- [Melinta Therapeutics](#), a privately held commercial-stage company developing novel antibiotics to treat serious bacterial infections, announced that an analysis of Baxdela™ (delafloxacin) activity against fluoroquinolone-susceptible and fluoroquinolone-resistant *Staphylococcus aureus* isolates from individuals who had participated in PROCEED, the company's Phase 3 clinical trials, was published in the journal *Antimicrobial Agents and Chemotherapy*. This analysis showed that treatment with [Baxdela](#) yielded high response rates against fluoroquinolone-resistant isolates, eradicating levofloxacin-non-susceptible *S. aureus* infections in 98.8 percent (80/81) of evaluable cases and levofloxacin-non-susceptible methicillin-resistant *S. aureus* infections in 98.6 percent (70/71) of evaluable cases. Baxdela was recently approved by the FDA for treatment of ABSSSI (acute bacterial skin & skin structure infections) and is currently undergoing Phase 3 testing in patients with CABP (community-acquired bacterial pneumonia).

Notably, Baxdela's high response rates were also observed against *S. aureus* isolates with mutations in the Quinolone Resistance Determining Region (QRDR). QRDR mutations alter the structure of the bacteria's gyrase and topoisomerase enzymes, thereby reducing fluoroquinolone binding and increasing resistance. Baxdela's microbiological response rates against *S. aureus* isolates with documented QRDR mutations was 98.8 percent (81/82).

[Sue Cammarata, M.D.](#), Melinta's chief medical officer, commented, "Methicillin-resistant *S. aureus* (MRSA) continues to be a public health threat and it is listed as a high priority on the World Health Organization list of priority pathogens. We believe that Baxdela's activity against MRSA will be an important tool for physicians in combatting these challenging infections."

More details of Melinta's analysis may be found in the open-access article: McCurdy S. et al. [In Vitro Activity of Delafloxacin and Microbiological Response Against Fluoroquinolone Susceptible and Non-Susceptible *S. aureus* Isolates from two Phase 3 Studies of Acute Bacterial Skin and Skin Structure Infections \(ABSSSI\)](#). *Antimicrob. Agents Chemother.* 2017 Aug 24;61(9).

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 m²) 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 m²) 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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