



# Melinta Therapeutics Publication Reinforces Baxdela Tolerability and Activity in Patients with MRSA Infections and Challenging Comorbidities

NEW HAVEN, Conn., Oct. 24, 2017 (GLOBE NEWSWIRE) -- [Melinta Therapeutics](#), a privately held commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, announced that results from the company's first Phase 3 PROCEED study (Study 302; NCT01811732) were published in the *Journal of Antimicrobial Chemotherapy*. Study 302 was a multicenter, randomized, double-blind, active-controlled study that evaluated [Baxdela](#)<sup>™</sup> (delafloxacin) compared with the combination regimen of vancomycin and aztreonam in 660 patients with ABSSSI (acute bacterial skin & skin structure infections). In assessment of the key endpoint, Baxdela was noninferior to vancomycin / aztreonam combination therapy in the Objective Response, showing reduction of at least 20% in lesion size at 48-to-72 hours, thereby meeting the primary endpoint.

Importantly, Baxdela displayed robust activity in two challenging patient populations in this study: patients with confirmed MRSA infections as well as obese patients (those with body mass indices [BMI] greater than 30 kg/m<sup>2</sup>). Baxdela monotherapy was comparable to vancomycin / aztreonam combination therapy in treating MRSA patients, as well as patients with obesity. Approximately 24% of patients in Study 302 had a confirmed MRSA infection and 32% of patients were obese.

Baxdela was well tolerated. The most common adverse events in Baxdela treated patients were gastrointestinal in nature with mild to moderate diarrhea reported in 8.3% of patients. Only three patients (0.9%) discontinued Baxdela therapy due to adverse events, compared to 14 patients (4.3%) who discontinued vancomycin / aztreonam combination therapy. There were no cases of *C. difficile* diarrhea nor were there any Baxdela-related cases of tendinitis or tendon rupture, peripheral neuropathy or myopathy.

[Sue Cammarata, M.D.](#), Melinta's chief medical officer, explained, "Unlike vancomycin, Baxdela does not require weight-based dosing or therapeutic drug monitoring, which is more convenient when treating obese patients. Baxdela also has an oral formulation which allows for transition to treatment outside of the hospital setting, including patients with ABSSSI due to MRSA."

For more information, please refer to the [article](#) published as part of the overall Baxdela publication plan: Pullman J. et al. Efficacy and safety of delafloxacin compared with vancomycin plus aztreonam for acute bacterial skin and skin structure infections: a Phase 3, double-blind, randomized study. *J Antimicrob Chemother.* 2017 [ePub ahead of print]

Baxdela was approved in June 2017 by the FDA for treatment of ABSSSI and is currently undergoing Phase 3 testing in patients with CABP (community-acquired bacterial pneumonia).

## 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<sup>2</sup>) 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<sup>2</sup>) 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](http://www.vaterahealthcare.com)) and Malin Corporation plc ([www.malinplc.com](http://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](http://www.melinta.com) for more information.

### **For More Information:**

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