

Melinta Therapeutics Provides for Distribution of Delafloxacin to 19 Countries via Extended Agreement with Eurofarma Laboratórios

NEW HAVEN, Conn., Sept. 26, 2017 -- [Melinta Therapeutics](#), a privately held commercial-stage company developing novel antibiotics to treat serious bacterial infections, announced that the commercialization and distribution agreement with Eurofarma Laboratórios for delafloxacin (marketed as Baxdela™ in the U.S.) has been expanded to include 19 countries in South and Central America and the Caribbean. Eurofarma Laboratórios previously had the right to market, sell and distribute delafloxacin in Brazil per a 2015 agreement with Melinta. There is a strong need for novel acute bacterial skin & skin structure infection (ABSSSI) agents in Latin America. In Brazil alone, over 265,000 patients are hospitalized with an ABSSSI each year.

[Lyn Baranowski](#), Melinta's senior vice president, corporate development and strategy, commented, "Eurofarma has been an exemplary partner to date, and has made significant progress in their effort to attain regulatory approval in Brazil. We expect that they will put equal effort towards our shared goal of regulatory approval in these additional territories."

"We are very pleased to have expanded our existing partnership with Melinta to cover the rest of Latin America. The need for novel agents to treat serious infections is high in Brazil and Latin America, and Baxdela will provide doctors with an important treatment option for many patients. We feel strongly that through our excellent partnership with Melinta, we can succeed in bringing Baxdela to the many doctors and patients that are looking for additional options for serious infections," said Martha Penna, Eurofarma's innovation vice president.

With this expansion of the 2015 agreement, Melinta will receive an undisclosed upfront payment as well as milestones and royalties on future sales. Eurofarma will be responsible for obtaining regulatory approval in Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela.

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 the Eurofarma Group

As the first 100% Brazilian-owned multinational pharmaceutical company, Eurofarma has been in existence for 45 years, has 6,500 employees, and has operations in 20 Latin American countries.

With 12 manufacturing plants in the region, the company has more than 280 products in its portfolio. In 2016, it produced more than 290 million units and reached revenues of R\$3.3 billion, 15.7% higher than the previous year. The Group invests approximately 5.5% of its net sales in Research & Development and maintains a pipeline of more than 175 projects.

About Eurofarma Brazil

Considered one of the best companies to work for, Eurofarma Brazil is also considered the most sustainable pharmaceutical company in the country based on an analysis by the Exame Sustainability Guide. With operations in all main pharmaceutical segments including Medical Prescriptions, Generics, Hospital, Oncology, Veterinary, and Bids and Services to Third Parties, Eurofarma has the largest medical advertising salesforce in Brazil with more than 2,000 representatives that together perform 450,000 medical contacts per month. The company has the 4th largest pharmacy system in the country and has a portfolio of medicines that is the 2nd largest by prescription volume.

For more information, visit www.eurofarma.com.br

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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