



Melinta Therapeutics' Commercial Partner Eurofarma Laboratórios Submits Marketing Authorization Application for Delafloxacin in Argentina

Represents First Regulatory Submission Outside of the United States

NEW HAVEN, Conn., Feb. 20, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ:MLNT), a commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, today announced that Eurofarma Laboratórios has submitted a marketing authorization application for delafloxacin (marketed under the trade name Baxdela™ in the U.S.) in Argentina with the Ministry of Health's National Administration of Drugs, Foods and Medical Technology (ANMAT). Eurofarma Laboratórios is Melinta's commercialization and distribution partner for all countries in South and Central America and the Caribbean, including Argentina. The proposed indication for delafloxacin in Argentina is for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI).

"In Latin America, as in much of the world, the rising rates of resistance in pathogens responsible for serious skin infections is a growing health concern," stated [Dan Wechsler](#), Melinta's president and chief executive officer. "Delafloxacin offers physicians the flexibility of intravenous and/or oral dosage formulations, does not require therapeutic drug monitoring, can be taken with food, and has a minimal potential for drug interactions, making it a potentially important treatment option for serious skin infections, especially in regions where healthcare services may be difficult to access."

[Lyn Baranowski](#), Melinta's SVP of corporate development and strategy, added, "Eurofarma has been a strong and motivated partner to date, and we are excited to report on their regulatory submission in Argentina, the first for delafloxacin outside of the United States. Eurofarma plans to complete additional submissions within their Latin American territories in the coming months, with expectations to launch in a selection of countries in late 2018."

"The regulatory submission of delafloxacin in Argentina represents an important strategic milestone for Eurofarma," says Martha Penna, VP of Innovation of Eurofarma. "We are a company that is committed to providing new and innovative options for the providers and the patients they serve, and we think upon approval, delafloxacin will be an important option for treating serious skin infections throughout Latin America," added Martha.

Under an agreement initiated in 2015 and expanded in 2017, Eurofarma Laboratórios is responsible for obtaining regulatory approval for delafloxacin in 19 countries: Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay and Venezuela. Melinta received an undisclosed upfront payment upon signing of the agreement and will receive milestones and royalties on future sales.



About Delafloxacin

Delafloxacin tablets and intravenous injection are approved by the U.S. Food and Drug Administration (FDA) for the treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections) and are marketed in the U.S. under the trade name Baxdela™. Baxdela was approved by the FDA in 2017 based on its efficacy against both gram-positive and gram-negative pathogens, including MRSA. It 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. For more information, please visit <http://www.baxdela.com/> or call 1-844-Melinta.

INDICATION & USAGE

In the U.S., 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.

A FDA-approved patient labeling guide (Medication Guide) is available for patients taking Baxdela.

Please also see full Prescribing Information, including Boxed Warning, available at www.baxdela.com.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is the largest pure-play antibiotics company, 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. Its four marketed products include Baxdela™ (delafloxacin); Vabomere™ (meropenem and vaborbactam), Orbactiv® (oritavancin), and Minocin® (minocycline) for Injection. It also has an extensive pipeline of preclinical and clinical-stage products representing many important classes of antibiotics, each targeted at a different segment of the anti-infective market. Together, this portfolio provides Melinta with the unique ability to provide providers and patients with a range of solutions that can meet the tremendous need for novel antibiotics treating serious infections. Visit www.melinta.com for more information.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this communication constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that



the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control.

Risks and uncertainties for Melinta include, but are not limited to: inability to achieve the expected benefits of the acquisition of The Medicines Company's infectious disease business unit; liquidity and trading market for Melinta's shares following the consummation of the acquisition; costs and potential litigation associated with the acquisition; risks related to the costs, timing and regulatory review of the Company's studies and clinical trials; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; inability or the delay in obtaining required regulatory approvals for product candidates, which may result in unexpected cost expenditures; failure to realize any value of certain product candidates developed and being developed, in light of inherent risks and difficulties involved in successfully bringing product candidates to market; inability to develop new product candidates and support existing products; inability to commercialize and launch any product candidate that receives regulatory approval, including Baxdela; risks relating to the Company's substantial indebtedness following the consummation of the acquisition and the Company's anticipated capital expenditures, its estimates regarding its capital requirements and its need for future capital; uncertainties of cash flows and inability to meet working capital needs; cost reductions that may not result in anticipated level of cost savings or cost reductions after the consummation of the acquisition; the approval by the FDA and EMA and any other similar foreign regulatory authorities of other competing or superior products brought to market; risks resulting from unforeseen side effects; risk that the market for the Company's products may not be as large as expected; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; inability to obtain and maintain commercial manufacturing arrangements with third party manufacturers or establish commercial scale manufacturing capabilities; loss of or diminished demand from one or more key customers or distributors; unexpected cost increases and pricing pressures; the possibility of economic recession and its negative impact on customers, vendors or suppliers; and risks associated with the possible failure to realize certain benefits of the proposed transactions, including future financial, tax, accounting treatment, and operating results. Many of these factors that will determine actual results are beyond Melinta's ability to control or predict.

Other risks and uncertainties are more fully described in our Annual Report on Form 10-K for the year ended December 31, 2016, as amended by Form 10-K/A, filed with the SEC on April 13, 2017, and in other filings that Melinta makes and will make with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made in this press release speak only as of the date stated herein, and subsequent events and developments may cause our expectations and beliefs to change. While we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date after the date stated herein.

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