



Melinta Therapeutics Granted European Commission Marketing Authorization for Vabomere® (meropenem and vaborbactam)

NEW HAVEN, Conn., Nov. 27, 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 the European Commission (EC) has approved Vabomere® (meropenem and vaborbactam) for use in adult patients with complicated intra-abdominal (cIAI) and urinary tract infections (cUTI), hospital-acquired pneumonia including ventilator associated pneumonia (HAP/VAP), bacteraemia that occurs in association with any of these infections, and infections due to aerobic gram-negative organisms where treatment options are limited. Marketing authorization was granted in all 28 European Union (EU) member states, as well as Norway, Iceland and Liechtenstein.

"Few effective treatment options and increasing resistance have made KPC-producing Enterobacteriaceae a significant challenge to patients worldwide," said John H. Johnson, Interim CEO and Director of Melinta. "With the EC authorization of Vabomere, we believe Melinta, through its strong partnership with Menarini Group, will be able to make a significant impact on the European effort to address this life-threatening pathogen."

The EC approval follows a positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in September 2018, that was based in part on data from the TANGO clinical program.

TANGO-1, a Phase III, multi-center, randomized, double-blind, double-dummy study, evaluated the efficacy, safety and tolerability of Vabomere compared to piperacillin-tazobactam in the treatment of adults with cUTI, including acute pyelonephritis. TANGO-2, a multi-center, randomized, open-label clinical trial, assessed VABOMERE versus "best available therapy" in adults with known or suspected carbapenem-resistant Enterobacteriaceae (CRE).

About VABOMERE® (meropenem and vaborbactam) for Injection

In the United States, VABOMERE (meropenem and vaborbactam) is indicated for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* species complex.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of VABOMERE and other antibacterial drugs, VABOMERE should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications

VABOMERE is contraindicated in patients with known hypersensitivity to any components of VABOMERE (meropenem and vaborbactam), or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactam antibacterial drugs.



Warnings and Precautions

Hypersensitivity reactions were reported in patients treated with VABOMERE in the clinical trials. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving therapy with beta-lactam antibacterial drugs. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe hypersensitivity reactions when treated with another beta-lactam antibacterial drug. If an allergic reaction to VABOMERE occurs, discontinue the drug immediately.

Seizures and other adverse Central Nervous System (CNS) experiences have been reported during treatment with meropenem, which is a component of VABOMERE. Close adherence to the recommended dosage regimens is urged, especially in patients with known factors that predispose to convulsive activity.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including VABOMERE, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued.

The concomitant use of VABOMERE and valproic acid or divalproex sodium is generally not recommended. Case reports in the literature have shown that co-administration of carbapenems, including meropenem, to patients receiving valproic acid or divalproex sodium results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. If administration of VABOMERE is necessary, consider supplemental anticonvulsant therapy.

In patients with renal impairment, thrombocytopenia has been observed in patients treated with meropenem, but no clinical bleeding has been reported.

Alert patients receiving VABOMERE on an outpatient basis regarding adverse reactions such as seizures, delirium, headaches and/or paresthesias that could interfere with mental alertness and/or cause motor impairment.

Prescribing VABOMERE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of drug-resistant bacteria.

As with other antibacterial drugs, prolonged use of VABOMERE may result in overgrowth of non-susceptible organisms.

Adverse Reactions

The most frequently reported adverse reactions occurring in $\geq 3\%$ of patients treated with VABOMERE were headache, phlebitis/infusion site reactions, and diarrhea.

Please see www.VABOMERE.com for the full US FDA-approved prescribing information.



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 therapeutic solutions. Its four marketed products include Baxdela® (delafloxacin), Vabomere® (meropenem and vaborbactam), Orbactiv® (oritavancin), and Minocin® (minocycline) for Injection. 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, strategies or prospects 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, the fact that we have incurred significant operating losses since inception and will incur continued losses for the foreseeable future; our limited operating history; our need for future capital and risks related to our ability to obtain additional capital to fund future operations; risks related to the satisfaction of the closing conditions under the Vatera equity commitment letter, to the extent drawn by the Company, including receipt of stockholder approval; uncertainties of cash flows and inability to meet working capital needs as well as other milestone, royalty and payment obligations; the fact that our independent registered public accounting firm's report on the Company's 2016 and 2017 financial statements contains an explanatory paragraph that states that our recurring losses from operations and our need to obtain additional capital raises substantial doubt about our ability to continue as a going concern; our substantial indebtedness; risks related to our commercial launches of our products and our inexperience as a company in marketing drug products; the degree of market acceptance of our products among physicians, patients, health care payors and the medical community; the pricing we are able to achieve for our products; and the other risks referenced in the paragraph below. 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, 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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