



Melinta Therapeutics Receives Positive CHMP Opinion for Vabomere™ (meropenem and vaborbactam)

- *Recommended to be approved for treatment of:*
 - *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 -*
- *Infections due to aerobic Gram-negative organisms where treatment options are limited-*

NEW HAVEN, Conn., Sept. 21, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ: MLNT), a commercial-stage company discovering, developing and commercializing novel antibiotics to treat serious bacterial infections, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending Vabomere™ (meropenem and vaborbactam) for approval as a treatment for 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.

The CHMP's opinion will be reviewed by the European Commission (EC), which is expected to make a final decision regarding marketing authorization within 67 days of receiving the CHMP opinion. If approved by the EC, marketing authorization for Vabomere will be granted in all 28 countries of the European Union, Norway, Iceland and Liechtenstein. Milestone payment obligations related to Vabomere's European approval would not take effect until marketing authorization is granted by the EC.

"We are encouraged by the CHMP's positive recommendation for Vabomere, which brings us one step closer to providing access to this important treatment option for patients in Europe," said Dan Wechsler, President and CEO of Melinta. "Additionally, we were pleased to see the range of indications recommended for approval, underscoring our belief that Vabomere represents a significant new advancement in addressing the increasing incidence of KPC-producing Enterobacteriaceae, for which there are currently limited treatment options."

The CHMP opinion was supported by data from the TANGO clinical program, including data from TANGO-1, a Phase III, multi-center, randomized, double-blind, double-dummy study to evaluate the efficacy, safety and tolerability of Vabomere compared to piperacillin-tazobactam in the treatment of cUTI, including acute pyelonephritis, in adults, as well as TANGO-2, a multi-center, randomized, open-label clinical trial of Vabomere versus "best available therapy" in subjects with known or suspected carbapenem-resistant Enterobacteriaceae (CRE).

Vabomere was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis, caused by treatment of adult patients caused by designated

susceptible Enterobacteriaceae – *Escherichia coli*, *Klebsiella pneumoniae* and *Enterobacter cloacae* species complex. Vabomere is a drug containing meropenem, an antibacterial, and vaborbactam, which is a new class of beta-lactamase inhibitor that inhibits certain types of resistance mechanisms used by bacteria.

About VABOMERE™ (meropenem and vaborbactam) for Injection

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 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. 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: 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; 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 the 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; failure to obtain and sustain an adequate level of reimbursement for our products by third-party payors; inaccuracies in our estimates of the market for and commercialization potential of our products; failure to maintain optimal inventory levels to meet commercial demand for any of our products; risks that our competitors are able to develop and market products that are preferred over our products; our dependence upon third parties for the manufacture and supply of our marketed products; failure to achieve the benefits of our recently completed transactions with Cempra and The Medicines Company; failure to establish and maintain development and commercialization collaborations; uncertainty in the outcome or timing of clinical trials and/or receipt of regulatory approvals for our product candidates; undesirable side effects of our products; failure of third parties to conduct clinical trials in accordance with their contractual obligations; our ability to identify, develop, acquire or in-license products; difficulties in managing the growth of our company; the effects of recent comprehensive tax reform; risks related to failure to comply with extensive laws and regulations; product liability risks related to our products; failure to retain key personnel; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; risks relating to third party infringement of intellectual property rights; our ability to maintain effective internal control over financial reporting; unfavorable outcomes in any of the class action and shareholder derivative lawsuits currently pending against the Company; and the fact that a substantial amount of shares of common stock may be sold into the public markets by one or more of our large shareholders in the near future. 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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