

Melinta Therapeutics Publishes Complete Results from Phase 3 TANGO I Study of VABOMERE™ (meropenem and vaborbactam) in Patients with cUTI

- VABOMERE demonstrated a greater numerical overall success rate vs piperacillin-tazobactam

- VABOMERE safety profile comparable to piperacillin-tazobactam

NEW HAVEN, Conn., Feb. 27, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ:MLNT), a commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, announced today that results from the Phase 3 TANGO I study of VABOMERE™ (meropenem and vaborbactam) for injection were published in the [Journal of the American Medical Association](#) (JAMA). VABOMERE was approved by the U.S. Food and Drug Administration (FDA) in August 2017 for the treatment of adult patients with complicated urinary tract infections (cUTI), including pyelonephritis, caused by designated susceptible *Enterobacteriaceae*: *Escherichia coli*, *Klebsiella pneumoniae* and *Enterobacter cloacae* species complex. The Targeting Antibiotic Non-susceptible Gram-negative Organisms (TANGO I) trial was the pivotal Phase 3 study that compared the efficacy and safety of VABOMERE to piperacillin-tazobactam in the treatment of patients with cUTI and acute pyelonephritis (AP).

Complicated UTIs, including AP, are a major cause of hospital admissions and are associated with significant morbidity and mortality. While the most common pathogen in cUTI is *Escherichia coli*, the more problematic pathogens are multidrug-resistant (MDR) gram-negative organisms including other *Enterobacteriaceae* species (i.e., *Klebsiella pneumoniae*). The prevalence of cUTI due to MDR gram-negative bacteria has risen. If left untreated, MDR gram-negative bacteria isolated from the urinary tract can cause bacteremia.

As initially reported in a June 2016 top-line analysis, the results of TANGO I demonstrated that [VABOMERE](#) was non-inferior to piperacillin-tazobactam with overall success in 98.4% of treated patients compared with 94.0% following treatment with piperacillin-tazobactam ($p < 0.001$ for noninferiority) using the FDA primary endpoint of clinical cure plus microbiological eradication at the end of IV treatment. The study also met the European Medicines Association endpoint by demonstrating 66.7% microbial eradication at the test of cure visit following VABOMERE treatment compared with 57.7% following piperacillin-tazobactam treatment ($p < 0.001$ for noninferiority).



In TANGO I, the incidence of adverse events (AEs) and severe AEs was similar in the VABOMERE and piperacillin-tazobactam groups. The most frequent AEs (greater than 2%) reported in this study included headache (8.8% VABOMERE vs 4.4% piperacillin-tazobactam), diarrhea (3.3% vs 4.4%), vaginal infection (0.4% vs 2.2%), and infusion site phlebitis (2.2% vs 0.7%).

Keith S. Kaye, MD, MPH, professor of internal medicine at the University of Michigan Medical School at Ann Arbor and director of research for the Infectious Diseases division at the University of Michigan, commented, "Complicated UTIs, especially those caused by CRE, can be extremely difficult to treat due to a lack of effective therapeutic options. It is therefore essential that products such as VABOMERE, continue to be developed and brought to market where they can play an important role in treating these infections." Dr. Kaye was the primary investigator of TANGO-I. In addition to his role at the University of Michigan, he is president of the Society for Healthcare Epidemiology of America (SHEA).

"Complicated UTIs can be life threatening, with mortality rates of 20-40% among critically ill patients," added [Dan Wechsler](#), Melinta's president and chief executive officer. "Since our inception, Melinta has been dedicated to addressing the serious global health threat of antibiotic resistance. We believe VABOMERE will play an important role in the treatment of cUTIs, particularly those caused by KPC-mediated carbapenem resistant *Enterobacteriaceae* and is a critical product in our commercial portfolio."

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 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 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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