Melinta Therapeutics Enters Into Agreement to Acquire Infectious Disease Business from The Medicines Company

- Acquisition positions Melinta as durable and focused pure-play antibiotics company with four marketed products: Baxdela®, Vabomere®, Orbactiv®, and Minocin IV® -

- Peak sales potential of the portfolio post-closure exceeds $1 billion -

NEW HAVEN, Conn., Nov. 29, 2017 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ:MLNT), a commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, today announced that Melinta and The Medicines Company (NASDAQ:MDCO) have entered into an agreement pursuant to which Melinta will acquire the infectious disease business from The Medicines Company. This includes three marketed products: recently approved and launched Vabomere (vaborbactam/meropenem), and established commercial products Orbactiv (oritavancin) and Minocin IV (minocycline).

The acquisition was unanimously approved by Melinta’s board of directors and is expected to close in the first quarter of 2018, subject to satisfaction of customary closing conditions, including Melinta stockholder approval. Melinta believes that the acquisition will result in a focused portfolio of high-value marketed assets with significant commercial synergies, allowing Melinta to maximize the value associated with the marketed products and drive the company to profitability. It also bolsters Melinta’s commercial team, which has been built out in preparation for the launch of Baxdela (delafloxacin), with experienced anti-infective professionals from The Medicines Company who can drive value across the combined portfolio.

“The assets we are purchasing are an ideal complement to our existing business, allowing us to focus on multiple valuable segments of the anti-infectives market simultaneously,” stated Dan Wechsler, Melinta’s president and chief executive officer. “We will be able to better serve the providers and the patients they serve who need medicines for serious infections by delivering a robust portfolio of treatment options.”

“We believe the transaction announced today places our novel antibiotic products and many of our outstanding employees, into the Melinta organization, a highly-capable, pure-play, emerging leader in the antibiotics space. We believe Melinta will grow these products strongly and – as both partner and shareholder – we look forward to their success as we focus our efforts and resources on inclisiran, which we believe has the potential to be a competitively-dominant, blockbuster product for the millions of at-risk, often non-adherent, patients worldwide who continue to struggle with high cholesterol given the limitations of available therapies,” said Clive Meanwell, M.D., Ph.D., chief executive officer of The Medicines Company.
The acquisition includes the purchase of global rights for three marketed products and the business supporting those products. Recently launched Vabomere is a novel fixed-dose combination agent comprising vaborbactam, a beta-lactamase inhibitor, and meropenem, the leading carbapenem. Vabomere was approved by the U.S. Food & Drug Administration (FDA) after priority review in August 2017 and is indicated for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible Enterobacteriaceae. Vabomere’s Phase 3 TANGO II trial, a randomized trial comparing Vabomere to the best available therapy for the treatment of serious carbapenem-resistant Enterobacteriaceae (CRE) infections, was stopped early by an Independent Data and Safety Monitoring Board following a risk-benefit analysis of available data which was in favor of Vabomere. Vabomere’s Marketing Authorization Application is currently under regulatory review by the European Medicines Agency (EMA) for cUTI.

Orbactiv is an injectable product approved by the FDA and EMA for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible designated gram-positive bacteria including methicillin-resistant Staphylococcus aureus (MRSA). Minocin IV, an injectable product, is a tetracycline derivative approved in the U.S. for the treatment of infections due to susceptible strains of several important designated gram-positive and gram-negative pathogens, including infections due to Acinetobacter species, which typically occur in hospitalized patients.

Vabomere and Orbactiv were granted priority review and approval as Qualified Infectious Disease Products (QIDP) by the FDA in accordance with the Generating Antibiotics Incentives Now (GAIN) Act, which secured five-year regulatory extensions of exclusivity for each product.

Through this acquisition, Melinta will enhance its commercial portfolio, led by Baxdela, a novel fluoroquinolone antibiotic recently approved by the FDA for the treatment of patients with ABSSSI and launching in Q1 2018. Baxdela is differentiated from other therapies currently available, since therapy can be initiated on either IV or oral formulations, has full coverage of gram positive pathogens, including MRSA, and gram negative pathogens, has tolerability and fixed dose simplicity, and has limited drug and disease interactions. Once the acquisition closes, Melinta will have a portfolio of four complementary marketed antibiotic assets: Baxdela, recently launched Vabomere, and established commercial products, Orbactiv and Minocin IV.

More than 14 million patients in the U.S. are treated for ABSSSI on an annual basis. While the majority of these patients are treated successfully in the community, many patients will require treatment in emergency departments and urgent care centers on an outpatient basis (estimated by Melinta to be 1.6 million), and a significant portion will receive treatment as hospital inpatients (2.9 million).

The rise in CRE was formally recognized as an urgent threat by the Centers for Disease Control and Prevention in 2013. Melinta estimates that ~138,000 patients are candidates for antibiotic therapy that targets carbapenem resistance. Patients with CRE infections are at increased risk of poor outcomes, including extended hospital stays, higher rates of mechanical ventilation, higher treatment cost, and death.

Acinetobacter is a genus of gram-negative bacteria belonging to the Moraxellaceae family. According to the CDC, 63 percent of Acinetobacter infections are multi-drug resistant, meaning that they are resistant to three or more classes of antibiotics. Melinta estimates that there are approximately 50,000 cases of multi-drug resistant Acinetobacter infections per year.

The combined Melinta and The Medicines Company infectious disease product portfolio significantly enhances Melinta’s multi-channel strategy of delivering antibiotic solutions for ABSSSI and gram-
negative infections within the hospital, emergency department, and community settings. Each product in the portfolio has distinct value in the marketplace. With Melinta’s commercial team now built out and preparing for Baxdela’s launch, coupled with the professionals that will join from The Medicines Company, Melinta will have an experienced team of focused antibiotic experts as well as the therapeutic scale necessary to maximize the value of the portfolio.

Melinta will continue to progress the additional clinical studies designed to enhance and expand the potential for the four marketed products, and fund the discovery and development of its novel class of antibiotics via the ESKAPE (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter species and Escherichia coli) pathogen program. Outside the U.S., Melinta retains global rights to the acquired products. Melinta will continue ongoing regulatory discussions with the European Medicines Agency for the approval of Vabomere, and pursue ex-U.S. partnering opportunities with the now even more compelling suite of treatment options.

Deal Structure and Financing

Under the terms of the acquisition agreement, the purchase price consists of (i) a payment by Melinta to The Medicines Company of $165 million in cash and the issuance to The Medicines Company of a number of shares of Melinta common stock equal to $50 million, divided by 90% of the volume weighted average price for the trailing 10 trading day period ending 3 trading days prior to closing; (ii) a payment by Melinta to The Medicines Company of $25 million following each of the twelve and eighteen month anniversaries of the closing date, and (iii) payment by Melinta to The Medicines Company of certain royalty payments, based on tiered net sales of the acquired products in certain jurisdictions. Funding for this acquisition will be provided through both debt and equity. In conjunction with the closing of the acquisition, Melinta will enter into a Loan and Security Agreement with Deerfield Management Company, L.P. (“Deerfield”). Deerfield and certain funds managed by Deerfield will initially provide a total of $190 million in debt and equity financing. An additional $50 million of debt is available to Melinta within 24 months of the acquisition close upon the achievement of certain sales thresholds. In addition to the funding from Deerfield, certain investors are committed to make a $30 million equity investment at closing. These funds will be used to fund the initial cash acquisition price of $165 million and to retire existing company debt of $40 million. Additional information on the acquisition and related financing will be contained in the proxy statement related to the proposed transactions. Melinta stockholders holding approximately 52% of the outstanding common stock have executed voting agreements agreeing to vote their shares in favor of the transaction.

Willkie Farr & Gallagher LLP served as legal counsel to Melinta with respect to the transaction.

Conference Call and Webcast

Melinta management will host a webcast and conference call regarding this announcement at 7:45 a.m. ET today. The live call may be accessed by dialing 877-377-7553 for domestic callers and 253-237-1151 for international callers and using conference ID # 8898769. A live webcast of the call will be available online from the investor relations section of the company website at www.melinta.com and will be archived there for 30 days. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference ID # 8898769.

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 by the U.S. FDA for use in the treatment of acute bacterial skin and skin structure infections (ABSSSI). Melinta 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 pipeline 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 complete the proposed transactions; liquidity and trading market for shares prior to and following the consummation of the proposed transactions; costs and potential litigation associated with the proposed transactions; failure or delay in obtaining required approvals by governmental or quasi-governmental entity necessary to consummate the proposed transactions; failure to satisfy other conditions to the closing of the proposed transactions; risks related to the costs, timing and regulatory review of the Company’s studies and clinical trials, including its ability to address the issues identified by the FDA in the complete response letter relating to Melinta’s new drug applications for solithromycin for community acquired bacterial pneumonia; 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; 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 prior to or after the consummation of the proposed transactions; 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 in connection with the proposed transactions, including the proxy statement described below under “Important Information and Where to Find It.” 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 or presentation 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.

No Offer or Solicitation:

This press release is being provided for informational purposes only and does not constitute (i) an offer to purchase, nor a solicitation of an offer to sell, subscribe for or buy any securities, (ii) an offer to exchange any securities or (iii) the solicitation of any vote for approval of any transaction. There shall not be any offer, solicitation, sale or exchange of any securities in any state or other jurisdiction in which such offer, solicitation, sale, or exchange is not permitted.

Participants in this Transaction:

Melinta and certain of its directors and executive officers may be deemed to be participants in the solicitation of proxies from Melinta’s stockholders in connection with the proposed transactions. Additional information regarding persons who may, under the rules of the SEC, be deemed to be participants in the solicitation of Melinta stockholders in connection with the proposed transactions, and a description of their direct and indirect interest, whether as security holders, directors or employees of Melinta or otherwise, which may be different from those of Melinta’s stockholders generally, will be set forth in the definitive proxy statement filed with the SEC in connection with the proposed transactions. You can find information about Melinta’s directors and executive officers in Melinta’s Schedule 14F-1 filed with the SEC on October 24, 2017, as supplemented on November 16, 2017.

Important Information and Where to Find It

Melinta will file a proxy statement with the SEC in connection with the proposed transactions. The proxy statement will be sent to the stockholders of Melinta. Melinta stockholders are advised to read the proxy statement when it becomes available, because it will contain important information about Melinta, and the proposed transactions. When filed, this document and other documents relating to the proposed transactions filed by Melinta can be obtained, free of charge, at the SEC’s website (http://www.sec.gov), at the company’s website (http://ir.melinta.com/), or by writing to the Secretary, Melinta Therapeutics, Inc., at ir@melinta.com.

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