Melinta Therapeutics Announces Initiation of Program for Radezolid in Patients with Bacterial Vaginosis

- FDA Grants Radezolid QIDP for BV Indication -

NEW HAVEN, Conn., Jan. 18, 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 its partner has commenced a new program for a topical formulation of radezolid, a second-generation oxazolidinone antibiotic discovered by Melinta scientists, in preparation for submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the treatment of patients with bacterial vaginosis. Radezolid is also being studied by Melinta's partner in a Phase 2 clinical study for the treatment of mild-to-moderate acne vulgaris.

"Bacterial vaginosis (BV) represents a complex change in vaginal flora, with overgrowth of certain vaginal bacterial species such as *Gardnerella vaginalis*. If left untreated, BV can increase a person's risk of contracting a sexually transmitted disease (STD) or HIV, and may increase the risk of premature delivery and low birth weight in children born from women with BV," explained Sue Cammarata, M.D., Melinta's chief medical officer. "Radezolid has demonstrated in-vitro activity against the species of bacteria often associated with bacterial vaginosis, which suggests it may be effective in this indication."

The United States Food and Drug Administration has also recently designated radezolid a Qualified Infectious Disease Product (QIDP) for the indication of bacterial vaginosis. QIDP designation provides certain incentives for companies developing new antibiotics, including an additional five years of market exclusivity, priority NDA review and eligibility for fast-track development status.

In January 2015, Melinta out-licensed radezolid to an undisclosed partner for topical indications while retaining the option to co-develop or fully regain rights to radezolid upon completion of specific development milestones. The deal structure provides Melinta with a long-term financial return and affords Melinta the opportunity to participate in radezolid's future development and commercialization.

About Radezolid
Radezolid is a second-generation oxazolidinone antibiotic discovered by Melinta scientists using proprietary, structure-based design, to achieve higher ribosomal binding affinity, minimal off-target activity, and a broader spectrum of antimicrobial activity than is currently available in the class. For more information, please visit the company website.

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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