

# Melinta Therapeutics Receives Up to \$6.2 Million from CARB-X to Advance Clinical Development of a Novel Antimicrobial to Combat Antibiotic-Resistant Bacteria

NEW HAVEN, Conn., May 07, 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 it has entered into a partnership with CARB-X, under which Melinta will be awarded up to \$6.2 million to support the development of the company's investigational pyrrolocytosine compounds.

Under the terms of the partnership, Melinta will receive an initial award of up to \$2.3 million from CARB-X, with the possibility of \$3.9 million in additional awards based on the achievement of certain project milestones.

Melinta's novel pyrrolocytosine compounds are a novel class of antibiotics from the company's ESKAPE Pathogen Program, a program based on Melinta's proprietary drug discovery platform focused on developing breakthrough antibiotics for bacterial "superbugs" by targeting the bacterial ribosome.

The pyrrolocytosines have been designed de novo, from the ground up, in a site not previously exploited by the many successful classes of antibiotics that target the ribosome. They are being developed to optimize properties that allow them to get in and stay in bacterial cells. The novelty in chemistry and binding, combined with the optimized properties, have translated to date into an in vitro activity profile that is not affected by current resistance mechanisms of concern. The pyrrolocytosines have also been shown in preclinical studies to be active against multidrug-resistant pathogens on the *Antibiotic Resistant Threats in the United States* report published by the <u>Centers for Disease Control and Prevention (CDC) in 2013</u>, including all of the ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa* and *Enterobacter* species).

"Our structure-based design efforts to create and optimize the pyrrolocytosine class of antibiotics have shown exciting promise, with several compounds demonstrating comprehensive activity and preclinical effect across the full set of bacterial 'superbugs,'" said Erin Duffy, Ph.D., Chief Scientific Officer at Melinta. "We believe this new class of antibiotics could be transformational in the fight against these urgent threats. The support and resources available through CARB-X will provide important assistance as we move to advance one or more pyrrolocytosines into clinical development."

"This funding aims to speed the development of an exciting new class of antibiotics to treat patients with life-threatening Gram-negative infections and to enhance global health security. It's vital we accelerate the discovery of new and innovative approaches to addressing the rising

threat of drug resistance; it has been more than half a century since the last new class was approved," said Kevin Outterson, Executive Director of CARB-X.

CARB-X was launched in August 2016 to accelerate pre-clinical product development in the area of antibiotic-resistant infections, one of the world's greatest health threats. CARB-X was established by the Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. Department of Health and Human Services and the Wellcome Trust, a global charitable foundation dedicated to improving health.

## **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<sup>™</sup> (delafloxacin), Vabomere<sup>™</sup> (meropenem and vaborbactam), Orbactiv<sup>®</sup> (oritavancin), and Minocin<sup>®</sup> (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 <u>www.melinta.com</u> for more information.

### **About CARB-X**

CARB-X is one of the world's largest public-private partnerships devoted to early development antibacterial R&D. Funded by ASPR/BARDA and Wellcome Trust, with in-kind support from NIAID, CARB-X is investing up to \$455 million from 2016-2021 to support innovative antibiotics and other therapeutics, vaccines, rapid diagnostics and devices to treat drug-resistant bacterial infections. CARB-X focuses on high priority drug-resistant bacteria, especially Gram-negatives. CARB-X operates through Boston University. Other partners include RTI International, the Broad Institute of Harvard and MIT, MassBio, and the California Life Sciences Institute (CLSI). http://www.carb-x.org/.

#### 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; 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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