



## Melinta Therapeutics Publishes Findings from Orbactiv® (oritavancin) Real-World Registry Demonstrating Efficacy and Safety Consistent with Phase 3 SOLO Program

NEW HAVEN, Conn., Oct. 05, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ:MLNT), a commercial-stage company discovering, developing and commercializing novel antibiotics to treat serious bacterial infections, announced today that findings from the first phase of the ongoing Clinical and Historic Registry and Orbactiv Medical Evaluation (CHROME) registry, a retrospective observational registry that seeks to characterize the use of Orbactiv® (oritavancin) for injection in real-world settings, have been published in the journal, [Open Forum Infectious Diseases](#)<sup>1</sup>. The findings showed safety and efficacy outcomes for Orbactiv in the real-world setting that were consistent with those seen in the previously published Orbactiv Phase 3 SOLO program.

Orbactiv is approved in the United States and European Union for the treatment of adult patients with acute bacterial skin and skin structure infection (ABSSSI) caused by designated, susceptible gram-positive pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA).

In the retrospective, observational registry, data was recorded from 112 patients who received a single dose of Orbactiv at eight healthcare sites for presumed skin and soft tissue infections are summarized in the publication. Clinical success was observed in 103 of 111 evaluable patients (92.8%). This clinical success rate is nearly identical to the 92.6% observed in the pooled Phase 3 SOLO studies that formed the basis of the Orbactiv marketing approval.

More individuals in the real-world registry than in SOLO presented with comorbidities such as obesity and diabetes that are typically associated with poor treatment outcome. In addition, 71% of patients in CHROME received prior antibiotic therapy for their infections, compared to only 20% in the SOLO studies. Four patients (3.6%) were hospitalized when their primary infection failed to improve or recurred within 28 days following Orbactiv administration.

Safety was evaluable in all 112 patients. Five (4.5%) patients experienced at least one adverse event probably or likely related to Orbactiv; no drug-related serious adverse events (SAEs) were reported. Of the 48 confirmed gram-positive pathogens recovered, 77.1% were caused by *Staphylococcus aureus*, the majority of which were multi-drug resistant (78.4%).

“These real-world results provide valuable insight into the real-world clinical use of Orbactiv,” said Sue Cammarata, MD, Chief Medical Officer of Melinta Therapeutics. “With most patients in CHROME receiving Orbactiv in an outpatient setting, the registry results highlight the important therapeutic option Orbactiv can provide for many patient populations. Furthermore, the prevalence of MRSA in the CHROME registry, as well as the high rate of prior antibiotic failures, underscore Orbactiv’s role as an important treatment option for patients from these challenging populations.”

### About CHROME

CHROME is a multicenter, multiyear, retrospective observational study to characterize the demographics and outcomes of adult patients who have received Orbactiv for the treatment of infections due to presumed or confirmed gram-positive bacteria and to describe the associated clinical and microbiologic outcomes and safety.



Some of the limitations of a registry such as CHROME include the retrospective, noncomparative, unblinded, and nonrandomized nature of the data from a limited number of sites. Assessment of efficacy was based on a subjective assessment extracted from the medical record by the investigators. The rates of treatment emergent adverse events in this study was much lower than those seen in the SOLO trials, and in some cases the severity of the treatment emergent adverse events (TEAEs) experienced was different. Although there was a difference in the incidence of adverse events (AEs) in CHROME vs. SOLO, the types of AEs seen were consistent with those seen in SOLO. The AEs observed in this smaller patient population are not necessarily representative of what may be seen with treatment with oritavancin.

### **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](http://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; 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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<sup>1</sup> Redell M et, al; A Real-world Patient Registry for Oritavancin Demonstrates Efficacy and Safety Consistent with the Phase 3 SOLO Program, 2018 *Open Forum Infectious Diseases*, June; 5(6)