Melinta Therapeutics and Menarini Group Enter Commercial Agreement for Vabomere™ (meropenem and vaborbactam), Orbactiv® (oritavancin) and Minocin® (minocycline) for Injection in 68 Countries

- Total consideration of up to $265 million (including potential royalties)
- Expands on existing commercial and co-development agreement for Baxdela® (delafloxacin)

NEW HAVEN, Conn. and FLORENCE, Italy, Oct. 01, 2018 (GLOBE NEWSWIRE) -- Melinta Therapeutics, Inc. (NASDAQ: MLNT), a commercial-stage company discovering, developing and commercializing novel antibiotics to treat serious bacterial infections, and Menarini Group, an Italian biopharmaceutical group, today announced that they have entered into an agreement under which Menarini will acquire the exclusive rights to co-develop and commercialize Vabomere™ (meropenem and vaborbactam), Orbactiv® (oritavancin) and Minocin® (minocycline) for Injection in 68 countries in Europe, Asia-Pacific including China, South Korea, and Australia (Japan excluded), and the Commonwealth of Independent States (CIS) including Russia for a total consideration of up to $265 million.

Under the terms of the agreement, Melinta will receive an upfront licensing fee, additional approval and sales-based milestone payments, and potential royalty payments based on a percentage of net sales of the three products. Proceeds from the agreement will more than satisfy Melinta’s milestone payment obligation related to Vabomere’s European marketing approval.

The agreement builds on Melinta and Menarini’s existing commercial and co-development agreement for Baxdela® (delafloxacin) – announced in 2017 – in the same 68 markets.

“We are excited to expand our partnership with the Menarini Group and significantly increase global access to our dynamic antibiotic portfolio,” said Dan Wechsler, President and CEO of Melinta. “Menarini has been an excellent partner with us on Baxdela, and with this agreement, we will unite all of our products under a single partner in these key global markets, allowing for significant commercial synergies. Menarini’s strong presence, reputation, and breadth of experience will continue to be integral as we work to drive the global success of our products and bring these important treatment options to patients around the world.”

“As Menarini, after our recent collaboration on delafloxacin, we feel very proud to keep working with Melinta to strengthen our value proposition in infectious disease. The addition of meropenem/vaborbactam, oritavancin and minocycline IV to our current portfolio, gives us the opportunity to build a high-value antibiotics platform supporting our ‘infection in focus’ mission to fight life-threatening bacterial infections,” says Pio Mei General Manager of the Menarini Group.

Melinta will maintain its rights for Vabomere, Orbactiv and Minocin for Injection in the U.S., where all three products are currently marketed.
A marketing authorization application for Vabomere is currently under review by the EMA. On September 20, 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorization for the medicinal product Vabomere, intended for the treatment of complicated intra-abdominal and urinary tract infections, hospital-acquired pneumonia, bacteraemia that occurs in association with any of these infections and infections due to aerobic Gram-negative organisms where treatment options are limited. Orbactiv is approved by the 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).

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 for more information, including product information and related labeling.

About Menarini Group
The Menarini Group is an Italian pharmaceutical company, 13th in Europe out of 5,345 companies, and 35th in the world out of 21,587 companies, with a turnover of more than 3,7 billion Euro and more than 17,000 employees. The Menarini Group has always pursued two strategic objectives: Research and Internationalisation offering high quality solutions in many of the most important therapeutic areas such as Cardiology, Respiratory, Infectious Disease, Gastroenterology, Diabetology and Inflammation/Reumathology. With 16 Manufacturing Sites and 7 Research and Development centers, the Menarini Group has a strong presence throughout Europe, Asia, Africa, Central and South America. Menarini’s products are available in 136 countries worldwide. For further information please visit www.menarini.com

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 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 maintain 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.

For More Information:
Melinta:
Media Inquiries:
David Belian
(203) 848-6276

Investor Inquiries:
Lisa DeFrancesco
(908) 617-1358

Menarini:
Press Office
Valeria Speroni Cardi
pressoffice@menarini.it