Melinta Therapeutics Announces Positive Top-Line Results in Phase III Trial of Baxdela® (delafloxacin) for Treatment of CABP

– Met primary endpoint of Early Clinical Response at 96 hours after the first dose –

– Supplemental NDA expected to be filed with FDA in 1H 2019 –

– Baxdela currently FDA approved for treatment of adult patients with ABSSSI –

NEW HAVEN, Conn., Oct. 29, 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 positive top-line results from its Phase III trial of Baxdela® (delafloxacin) for the treatment of adult patients with community-acquired bacterial pneumonia (CABP).

Baxdela was compared to moxifloxacin in this randomized global trial. Baxdela met all key primary and secondary endpoints in the trial, including the study's primary U.S. Food and Drug Administration (FDA) endpoint showing Early Clinical Response (ECR) with improvement at 96 hours (± 24 hours) after the first dose in at least two of the following symptoms: chest pain, frequency or severity of cough, amount of productive sputum, and difficulty breathing.

In the intent-to-treat population (ITT), IV-to-oral Baxdela met the FDA primary endpoint of statistical non-inferiority (12.5% non-inferiority margin) for the Early Clinical Response at 96 hours (± 24 hours) after initiation of therapy (88.9% ECR in Baxdela patients) compared to IV/oral moxifloxacin (89.0%). The 95% confidence interval for the treatment difference had lower and upper bounds of -4.4% and 4.1%, respectively.

Baxdela also met the FDA secondary endpoint of statistical non-inferiority (90.5%) compared to moxifloxacin (89.7%) based on the investigator's assessment of Success at the Test of Cure visit (5-10 days after last dose) in the ITT population. Lower and upper bounds of the 95% confidence interval for the treatment difference were -3.3% and 4.8%, respectively.

Data also showed that IV/oral Baxdela successfully eradicated key respiratory pathogens at rates comparable to moxifloxacin. Both intravenous (IV) and oral Baxdela were well tolerated in the study participants. Overall adverse event rates were similar between treatment arms. The most common treatment-emergent adverse events on Baxdela (≥ 2%) were diarrhea and transaminase increases, which were generally mild and did not lead routinely to treatment discontinuation.

"These are highly encouraging results that demonstrate the important role we believe Baxdela can play in treating adult patients with CABP," said John Johnson, Interim CEO and Director of Melinta. "We anticipate filing a supplemental new drug application for Baxdela for the treatment of CABP with the FDA in the first half of next year. If approved, it would represent an important addition to Baxdela's label and expand upon its position as a safe and effective treatment option for patients with ABSSSI in both the hospital and community settings."

"The Phase III results showed compelling outcomes and safety profiles for Baxdela in comparison to moxifloxacin for the treatment of adult patients with CABP," said Sue Cammarata, MD, Chief Medical Officer of Melinta. "We look forward to moving ahead with its development

and potential regulatory approval, with the goal of providing physicians with an important new option in the treatment of these serious, often life-threatening infections."

"Community-acquired bacterial pneumonia is a common and potentially life-threatening illness, particularly among the elderly and immunocompromised patients," said G. Ralph Corey, MD, Divisions of Infectious Diseases and Global Health, Duke University Medical Center. "The promising results shown in this study indicate Baxdela has a potential role in treating this serious disease. "

Baxdela was approved by the FDA in 2017 for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. The Menarini Group, Melinta's commercial and co-development partner, submitted a Marketing Authorization Application (MAA) to the EMA in March 2018 for delafloxacin (to be marketed under the trade name Quofenix in Europe) for the treatment of adult patients with ABSSSI.

Melinta anticipates filing a sNDA with the FDA for Baxdela for the treatment of adult patients with CABP in the first half of 2019. The FDA has designated Baxdela as a Qualified Infectious Disease Product (QIDP) for CABP, and therefore the sNDA for CABP is eligible for FDA priority review.

About Baxdela
Baxdela (delafloxacin) tablets and intravenous injection are approved by the U.S. Food and Drug Administration (FDA) for the treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections). Baxdela was approved by the FDA in 2017 based on its efficacy against both gram-positive and gram-negative pathogens, including MRSA. It was given priority review by the FDA due to its designation as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act of 2012. The QIDP designation qualifies Baxdela for certain incentives related to the development of new antibiotics, including a five-year extension of any non-patent exclusivity period awarded to the drug.

INDICATION & USAGE
Baxdela is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

Gram-positive organisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis;

Gram-negative organisms: Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

IMPORTANT SAFETY INFORMATION:
WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, AND EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue Baxdela immediately and avoid the use of fluoroquinolones, including Baxdela, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Baxdela in patients with known history of myasthenia gravis.

Contraindications
Baxdela is contraindicated in patients with known hypersensitivity to Baxdela or other fluoroquinolones.

Warnings and Precautions
Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions. Avoid use in patients who have experienced any of the following serious adverse reactions. If these reactions occur in patients receiving Baxdela, discontinue Baxdela immediately and institute appropriate treatment:

- Tendinitis, tendon rupture, with increased risk in elderly, patients taking corticosteroids and in patients with organ transplants
- Peripheral neuropathy, such as pain, burning, tingling, numbness, and/or weakness or other alterations of sensation in touch and/or motor strength
- Psychiatric adverse reactions, such as toxic psychosis; hallucinations, or paranoia; depression, or suicidal thoughts or acts; delirium, disorientation, confusion, or disturbances in attention; anxiety, agitation, or nervousness; insomnia or nightmares; memory impairment
- Central nervous system adverse reactions such as seizures, increased intracranial pressure, dizziness, and tremors
- Exacerbation of myasthenia gravis, including death and requirement for ventilator

Hypersensitivity reactions have been reported in patients receiving fluoroquinolones, including Baxdela. Reactions can be serious and occasionally fatal (anaphylactic). Discontinue Baxdela at the first sign of hypersensitivity.

Clostridium difficile-associated diarrhea has been reported with nearly all systemic antibacterial agents, including Baxdela, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Prescribing Baxdela in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Fluoroquinolones have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia. Severe cases of hypoglycemia resulting in coma or death have been reported with other fluoroquinolones. Monitor blood glucose carefully in diabetic patients receiving oral hypoglycemic agents or insulin. Discontinue Baxdela and initiate appropriate therapy immediately if a hypoglycemic reaction occurs.

Adverse Reactions
The most common adverse reactions in patients treated with Baxdela were nausea (8%), diarrhea (8%), headache (3%), transaminase elevations (3%), and vomiting (2%).

Use in Specific Populations
In patients with severe renal impairment (eGFR of 15-29 mL/min/1.73 m2) dosing of Baxdela should be dosed at 200 mg IV every 12 hours or 450 mg orally every 12 hours. Baxdela is not

recommended in patients with End Stage Renal Disease [ESRD] (eGFR of <15 mL/min/1.73 m2) due to insufficient information to provide dosing recommendations.

Please see full Prescribing Information, including Boxed Warning and Patient Medication Guide, available at www.baxdela.com.

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.

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 and risks related to our ability to obtain additional capital to fund future operations; 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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