Melinta Therapeutics' Baxdela™ Successfully Achieves Endpoints in Confirmatory Phase 3 Study in Patients with Hospital-Treated Skin Infections

- Study first to prospectively evaluate novel IV-to-oral antibiotic vs. vancomycin standard of care in population enriched for obesity and associated co-morbidities

New Haven, CT, May 12, 2016 -- Melinta Therapeutics, a privately held company developing novel antibiotics to treat serious bacterial infections, today announced top-line results from the second Phase 3 study (RX-3341-303 NCT01984684) of Baxdela (delafloxacin), an investigational anionic quinolone in development for the treatment of patients with acute bacterial skin and skin structure infections (ABSSSI). Baxdela met the primary endpoints required by the U.S. Food and Drug Administration (FDA) as well as the European Medicines Agency (EMA) in this confirmatory pivotal study. Baxdela, with its broad spectrum activity against Gram-positive and Gram-negative bacteria, including MRSA, was tested as an intravenous (IV)-to-oral monotherapy against standard of care, IV-only combination of vancomycin plus aztreonam.

In the intent-to-treat population (ITT), IV-to-oral Baxdela met the FDA's primary endpoint of statistical non-inferiority (10% non-inferiority margin) at the early clinical response at 48-72 hours after initiation of therapy (83.7%) compared to IV vancomycin combination therapy with aztreonam (80.6%). The 95% confidence interval for the treatment difference had lower and upper bounds of -2.0% and 8.3%, respectively. Baxdela also met the EMA's required endpoint of statistical non-inferiority (57.7%) compared to vancomycin plus aztreonam (59.7%) based on the investigator's assessment of complete cure (resolution of all baseline signs and symptoms) at the follow-up visit in the ITT population. Lower and upper bounds of the 95% confidence interval for the treatment difference were -8.6% and 4.6%, respectively. In addition, Baxdela was comparable to vancomycin plus aztreonam in achieving treatment success at Follow-Up (cure or improved, with no further antibiotics needed) with success rate of 87.2% vs 84.8%, respectively. IV/oral Baxdela monotherapy successfully eradicated Gram-positive pathogens, including MRSA, and Gram-negative pathogens at rates comparable to IV vancomycin/aztreonam combination treatment.

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 were diarrhea and nausea, which were generally mild and did not lead to treatment discontinuation. The oral formulation of Baxdela was well tolerated with no increase in GI events compared to the IV formulation. Only 1.2% of Baxdela-treated patients discontinued due to treatment-related adverse events.

In this study, obese patients (BMI≥ 30kg/m^2) constituted 50% of the enrolled population and had a higher prevalence of co-morbidities such as diabetes and cardiovascular disease than non-obese patients. Co-morbidities present challenges to appropriate antibiotic selection due to factors such as pathogen coverage, underlying disease, concomitant medications, drug metabolism and other issues.

Dr. William O'Riordan, Chief Medical Officer of eStudySite stated, "These are encouraging results, especially given Baxdela's full spectrum of coverage of Gram-positive and Gram-negative bacteria including MRSA, which is unique among quinolones. In addition, it performed well in this study against infections in difficult-to-treat patients, such as obese and diabetic patients, an important achievement."

"Baxdela's breadth of activity against difficult pathogens and in difficult patients, together with the favorable safety profile observed to date, and IV-to-oral dosing flexibility, should prove to be a valuable addition to the dwindling arsenal of antibiotics for serious infections," commented Chief Executive Officer Eugene Sun, MD. "We are grateful to our investigators, patients, and Melinta team for successfully completing our Phase 3 program. We anticipate submitting a New Drug Application to the FDA in the second half of this year for the treatment of serious hospital-treated skin infections."

John Temperato, President & COO, stated that: "We look forward to to building a focused commercial organization offering a new treatment option for the nearly 3 million patients per year who are largely treated with therapies that do not meet key needs of pathogen coverage and tolerability. Having IV and oral dosage forms provides the potential for seamless and earlier hospital discharge, an important clinical and economic benefit. We are also eager to continue the ongoing clinical programs in hospital-treated community-acquired bacterial pneumonia (CABP) and complicated urinary tract infections (cUTI) as well. We expect that this will be the first of several follow-on indications we will seek for Baxdela."

About RX-3341-303

This pivotal Phase 3 study, the second of a Phase 3 program, was a randomized, double-blind study of patients with ABSSSI conducted under FDA

Special Protocol Assessment. Patients in the Baxdela arm received 300 mg of IV Baxdela every 12 hours for 6 doses followed by 450 mg oral Baxdela every 12 hours. The recommended vancomycin dose was 15 mg/kg of IV vancomycin every 12 hours based on actual body weight plus 1-2 g of IV aztreonam every 12 hours. Duration of treatment in either the Baxdela or active control arms was 5-14 days based on the physician's judgment. All patients were asked to return for a follow-up visit on day 14 ± 1 and a Late Follow-Up visit on days 21 to 28.

Melinta expects to present complete results from this Phase 3 study at upcoming medical meetings later this year.

About Baxdela

Baxdela (delafloxacin) is an investigational anionic fluoroquinolone antibiotic currently completing development for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI). Baxdela has robust antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA), a major cause of serious skin infections, a favorable tolerability profile, and both intravenous and oral dosage forms, which may facilitate hospital discharge. The studies (studies 302 and 303) were Phase 3, multicenter, randomized, double-blind, active-controlled trials to evaluate Baxdela compared with vancomycin plus aztreonam for the treatment of patients with ABSSSI. Both studies met the primary endpoints for efficacy.

Overall adverse event rates were similar between treatment arms in the Phase 3 studies which enrolled over 1,500 individuals. The most common treatment-emergent adverse events in the Phase 3 studies on Baxdela were diarrhea and nausea, which were generally mild and did not lead to treatment discontinuation. The treatment discontinuation rate due to treatment-related adverse events for patients treated with Baxdela in the Phase 3 trials was 0.8%. Unlike some other quinolones, Baxdela has not shown any potential for QT prolongation or phototoxicity in definitive clinical studies. In addition, there were no elevated rates of liver or glucose abnormalities compared to vancomycin in the clinical studies conducted to date.

The 450 mg tablet has been shown to have bioequivalent exposure (area under the curve) to the 300 mg IV dose, and can be dosed without regard to food. There are no anticipated drug-drug interactions with delafloxacin.

Melinta is also assessing Baxdela in clinical trials in patients with hospital-treated community-acquired bacterial pneumonia (CABP) and hospital-treated complicated urinary tract infections (cUTI). Baxdela has been designated a Qualified Infectious Disease Product (QIDP) and has been granted fast track

designation for both ABSSSI and community-acquired bacterial pneumonia by the U.S. Food and Drug Administration.

About Serious Skin Infections

Serious skin infections are common, and disproportionately affect patients with underlying diseases such as obesity, diabetes, and cardiovascular conditions. These conditions complicate treatment choices, prolong hospitalization, and can result in readmission. Serious skin infections include wounds, abscesses and cellulitis. While many of these infections are caused by Gram-positive pathogens, including MRSA, a significant percentage are Gram-negative or mixed. Importantly, in most cases a pathogen is not identified, requiring empiric therapy.

About Melinta Therapeutics

Melinta Therapeutics, Inc. is dedicated to saving lives threatened by the global public health crisis of bacterial infections, through the development of novel antibiotics that provide new and better therapeutic solutions. Melinta is rapidly progressing its late-stage investigational antibiotic, Baxdela, which is completing development for acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). Melinta is committed to developing, through the application of Nobel Prize-winning science, a new class of antibiotics designed to overcome the multi- and extremely-drug-resistant pathogens for which there are few to no options, known collectively as ESKAPE pathogens (*Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter* species and *Escherichia coli*), which cause the majority of life-threatening hospital infections.

Melinta Therapeutics is privately held and backed by Vatera Healthcare Partners (www.vaterahealthcare.com) and Malin Corporation plc (www.malinplc.com) among other private investors. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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