



# Melinta Therapeutics Initiates Phase 3 Study of Baxdela in Hospital-Treated Community-Acquired Bacterial Pneumonia

New Haven, CT, Jan. 06, 2016 -- [Melinta Therapeutics](#), a privately held company developing novel antibiotics to treat bacterial infections, announced the initiation of an international Phase 3 trial (study ML-3341-306) comparing [Baxdela](#) (delafloxacin), an investigational fluoroquinolone, to moxifloxacin for the treatment of hospitalized patients with radiographic evidence of community-acquired bacterial pneumonia (CABP). The primary efficacy endpoint is improvement at 96 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. Additional efficacy and safety measures will also be captured. The U.S. FDA has designated Baxdela as a Qualified Infectious Disease Product (QIDP) for community-acquired bacterial pneumonia.

“Hospital-treated community-acquired bacterial pneumonia is a common and potentially life-threatening illness, particularly among the elderly and immunocompromised patients,” commented [Dr. Eugene Sun](#), Melinta’s interim Chief Executive Officer and Executive Vice President, Research and Development. “Based on the safety profile we have observed to date in clinical studies of intravenous and oral formulations of Baxdela and the activity we have seen against pathogens associated with CABP, we believe Baxdela has a potential role in treating this serious disease.”

At the 2015 annual Interscience Conference of Antimicrobial Agents and Chemotherapy, *in vitro* studies were presented highlighting delafloxacin’s potency against susceptible and resistant isolates of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*, common pathogens causing CABP. In a Phase 2 study in community-acquired pneumonia, Baxdela demonstrated a robust efficacy and safety profile. In addition, in the recently completed Phase 3 PROCEED study 302, Baxdela demonstrated activity against several species of streptococci and staphylococci, including MRSA, in patients with acute bacterial skin and skin structure infections, further documenting Baxdela’s activity in serious infections. Detailed results from these studies may be found in Melinta’s library of [publications](#), available on their website.

## Study 306 Details

Melinta anticipates enrolling approximately 860 adult patients in a multi-national trial who will be randomized 1:1 to receive either Baxdela or moxifloxacin in a blinded fashion. Study participants will be assessed for clinical response 96 hours after the first dose (primary endpoint), at end of therapy, 5-to-10 days after the last dose, and at a follow-up contact 28 days after the last dose. The study is expected to conclude in 2017.



## About Baxdela

Baxdela (delafloxacin) is an investigational anionic fluoroquinolone antibiotic currently completing Phase 3 clinical development for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI), and in Phase 3 development for hospital-treated community-acquired bacterial pneumonia (CABP). The ABSSSI PROCEED studies (studies 302 (RX-3341-302 (NCT01811732)) and 303 (RX-3341-303 (NCT01984684))) are Phase 3, multicenter, multi-national, randomized, double-blind, active-controlled trials to evaluate Baxdela compared with vancomycin + aztreonam for the treatment of patients with ABSSSI. The CABP Phase 3 program comprises a single randomized, double blind Phase 3 study comparing Baxdela with moxifloxacin for the treatment of patients with CABP. Baxdela is being evaluated in clinical trials in both IV and oral formulations. Baxdela has been designated a Qualified Infectious Disease Product (QIDP) for both ABSSSI and CABP by the U.S. Food and Drug Administration.

## 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 currently in Phase 3 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](http://www.vaterahealthcare.com)) and Malin Corporation plc ([www.malinplc.com](http://www.malinplc.com)) among other private investors. The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit [www.melinta.com](http://www.melinta.com) for more information.

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