



Melinta Therapeutics and Menarini Group Enter into Commercial and Co-Development Agreement for Delafloxacin in 68 Countries

Melinta Retains Rights to Commercialize Delafloxacin as Baxdela in the US

NEW HAVEN, Conn. and FLORENCE, Italy, March 02, 2017 -- [Melinta Therapeutics](#), a privately held company developing novel antibiotics to treat serious bacterial infections, and Menarini Group, an Italian biopharmaceutical group, today announced the signing of a development and commercialization agreement. As part of this agreement, Melinta has granted the Menarini Group exclusive rights to commercialize Delafloxacin (known as Baxdela in the US), an investigational anionic fluoroquinolone, under their own brands in 68 countries in Europe, Asia-Pacific including China, South Korea, and Australia (Japan excluded), and the Commonwealth of Independent States (CIS) including Russia. Under the terms of the collaboration, Melinta will be receiving an upfront payment and near-term development and regulatory milestone payments, as well as sales milestones and royalties from Menarini Group.

Menarini will be responsible for submitting regulatory applications and pursuing pricing approvals for Delafloxacin in the countries being licensed. Currently, the companies expect that a Marketing Authorization Application (MAA) for Delafloxacin would be submitted to the European Medicines Agency (EMA) in the second half of 2017.

Melinta and Menarini have further agreed to co-develop Delafloxacin for additional indications beyond Delafloxacin's initial indication of acute bacterial skin and skin structure infections (ABSSSI), including hospital-treated community-acquired bacterial pneumonia (hCABP). The ongoing Phase 3 clinical study of Delafloxacin in patients with hCABP will continue to enroll patients globally. Going forward, Melinta and Menarini will collaborate in the design and share in the cost of clinical trials for this and other indications.

"We are very pleased to have the Menarini Group as our partner in these major territories. Their strong presence, reputation, and breadth of experience in over 130 countries in Europe, Asia and CIS countries, including in fast-growing markets like China and Russia, will be a significant advantage in driving the global success of Delafloxacin," stated Eugene Sun, MD, CEO of Melinta. "With this agreement and our existing collaborations, we have established commercial partnerships on six continents. Pending approvals in these geographies, we will be well positioned to make Delafloxacin available worldwide."

"This collaboration with Melinta is directly in line with our mission of bringing high-quality pharmaceuticals to patients all over the world," added Dr. Pio Mei, General Manager of The Menarini Group. "We believe that Delafloxacin has an important role to play in the treatment of



severe, life-threatening bacterial infections. We will work with Melinta to bring Delafloxacin to hospitals in Europe, Asia and CIS, and to develop it for additional indications.”

In the US, Melinta will retain rights to Delafloxacin, where the product has completed Phase 3 clinical trials for the treatment of patients with ABSSSI. Melinta submitted New Drug Applications to the FDA for the intravenous and oral formulations of Delafloxacin for this indication in October 2016, and a PDUFA date of June 19, 2017 has been set. Should the FDA approve Delafloxacin for sale in the US, Melinta intends to conduct a commercial launch with a dedicated sales and marketing team.

About Baxdela

Baxdela (delafloxacin) is an investigational anionic fluoroquinolone antibiotic for hospital-treated skin infections, known as acute bacterial skin and skin structure infections (ABSSSI). Baxdela has robust *in-vitro* antimicrobial activity, including activity against methicillin-resistant *Staphylococcus aureus* (MRSA), a major cause of hospital-treated 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 IV and oral Baxdela monotherapy compared with vancomycin plus aztreonam combination therapy 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 plus aztreonam 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 other than co-administration with chelating agents.

Melinta submitted NDAs (New Drug Applications) to the US FDA for the intravenous and oral formulations of Baxdela for the ABSSSI indication in October 2016 which are currently undergoing regulatory review. A PDUFA date of June 19, 2017 has been set by the FDA.

Melinta is also assessing Baxdela in a clinical trial in patients with hospital-treated community-acquired bacterial pneumonia (CABP) and planning to initiate a clinical trial in complicated urinary tract infections (cUTI) in the near future. Baxdela has been designated a Qualified Infectious Disease Product (QIDP) and has been granted fast track designation for community-acquired bacterial pneumonia 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 has submitted NDAs to the FDA for the intravenous and oral formulations of its late-stage investigational antibiotic, Baxdela, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Baxdela is also being studied in Phase 3 clinical development for the treatment of 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.

About the Menarini Group

The Menarini Group is an Italian pharmaceutical company, 19th in Europe out of 5,541 companies, and 39th company in the world out of 21,317 companies, with a turnover of more than 3,4 billion Euro and more than 16,600 employees. The Menarini Group has always pursued two strategic objectives: Research and Internationalisation and is present in the most important therapeutic areas including products for cardiology, gastroenterology, pneumology/antibiotics, diabetology, anti-inflammatory agents/analgesics. With 15 production sites and 6 Research and Development centers, the Menarini Group has a strong presence throughout Europe and Asia, Africa, Central and South America. Menarini's products are available in more than 130 countries worldwide. For further information please visit www.menarini.com

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