Melinta Therapeutics' Topical Radezolid Well Tolerated in Phase 1 Study for Treatment of Acne

NEW HAVEN, Conn., Oct. 10, 2017 (GLOBE NEWSWIRE) -- Melinta Therapeutics, a privately held commercial-stage company developing and commercializing novel antibiotics to treat serious bacterial infections, announced today that a Phase 1 clinical study of topical radezolid for the treatment of mild-to-moderate acne vulgaris has been successfully completed. Melinta and its partner enrolled 10 individuals with grade 3-to-4 acne vulgaris who applied topical radezolid twice daily for four weeks. Results demonstrated that radezolid was well tolerated with minimal systemic absorption.

Acne is caused by the bacterium, *Propionibacterium acnes*, and is one of the most commonly treated skin disorders, affecting up to 50 million Americans. Resistance to antimicrobial treatments for acne has been shown to be as high as 66 percent. A separate *in vitro* study sponsored by Melinta against contemporary (2017) bacterial strains from acne patients that include isolates resistant to commonly used topical antibiotic treatment showed that 38 percent of samples isolated from skin swabs were multi-drug resistant to macrolides, such as erythromycin, lincosamides, such as clindamycin, and tetracyclines. Radezolid, a next-generation oxazolidinone, represents a novel class of antimicrobials to target acne and demonstrated strong *in vitro* activity regardless of the resistance profile of the pathogen, where other agents were not as active against the resistant pathogens.

"The results of the Phase 1 study as well as earlier testing against resistant isolates show that radezolid may have the potential to be an important treatment option for clinicians and their patients," stated Eugene Sun, M.D., Melinta's chief executive officer. "Radezolid is a second-generation oxazolidinone that Melinta designed to have higher affinity to a key ribosomal binding region, which we expect will overcome certain resistance mechanisms. Its favorable PK and safety profiles may make it ideally suited for the treatment of acne, and we're looking forward to exploring its activity in a planned Phase 2 study."

As a next step, a 12-week, randomized, double-blind, vehicle-controlled Phase 2 proof-of-concept study to evaluate the safety and efficacy of radezolid in approximately 48 individuals with moderate-to-severe facial acne vulgaris is anticipated to start by the fourth quarter of 2017. Primary endpoints of interest will include the Investigator's Global Assessment (IGA) (score of "clear" or "almost clear") and the absolute change from baseline of acne lesion count(s) in each treatment group. Safety and tolerability will also be assessed.

About Radezolid
Radezolid is a second-generation oxazolidinone discovered by Melinta scientists using proprietary, structure-based design, to achieve higher ribosomal binding affinity, minimal off-target activity, and a broader spectrum of antimicrobial activity than is currently available in the class. For more information, please visit the company website.

About Melinta Therapeutics
Melinta Therapeutics, Inc. is 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 and better therapeutic solutions. Melinta's lead product is Baxdela, an antibiotic approved by the US FDA for use in the treatment of acute bacterial skin and skin structure

infections (ABSSSI). Melinta is also 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. In August, Melinta announced its entry into a merger agreement with Cempra, Inc. (Nasdaq:CEMP). The company is headquartered in New Haven, CT with offices in Lincolnshire, IL. Visit www.melinta.com for more information.

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