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Vyome Therapeutics begins dosing in Phase2 trial of VB-1953

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VB-1953 is the first bactericidal antibiotic topical gel formulation for treatment of acne vulgaris



Vyome Therapeutics Inc., a clinical-stage specialty pharmaceutical company developing novel medicines for treating skin diseases caused by resistant microbes has announced that it has dosed the first patient in its Phase 2 trial of the Company's

lead clinical candidate, VB-1953, for the treatment of moderate to severe inflammatory acne vulgaris.

VB-1953 is the first bactericidal antibiotic topical gel formulation for treatment of acne vulgaris capable of not only reducing infection due to P. acnes with anti-inflammation action, but also retarding antibacterial resistance.

Venkat Nelabhotla, chief executive officer of Vyome Therapeutics said, “There are about 10 million patients in the US with moderate to severe inflammatory acne who are resistant to the currently-approved bacteriostatic antibiotics. There is an urgent need for a new and effective therapy that yields higher clinical response than what is currently available. With its novel bactericidal and anti-inflammatory mechanisms of action, VB-1953 could potentially meet this unmet need and we look forward to sharing the important results of this trial in early 2020.”

The double-blind, randomized, vehicle controlled, dose ranging Phase 2 study is evaluating the safety and efficacy of VB-1953 topical gel when applied once versus twice daily for 12 weeks in subjects with moderate to severe inflammatory facial acne vulgaris.

The Company plans to enroll up to 480 patients. The primary efficacy endpoint of the study is the absolute change from baseline in inflammatory lesion counts in each treatment arm at Week 12 and the secondary endpointis the proportion of subjects at week 12 achieving an Investigator’s Global Assessment of Inflammatory Acne (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point improvement from baseline.

Dr. Angelo Secci, chief medical officer of Vyome Therapeutics said, “Today, patients who are not responding to current medicines have no option outside of oral systemic acne treatments which are well-known for their potential adverse events. VB-1953 has the potential to not only serve as an effective topical therapy for these patients, but also to delay the onset of resistant bacterial strains, serve as a potent anti-inflammatory agent, and prevent patients from needing systemic acne treatments.”

Vyome’s lead molecule, VB-1953, is a first-in-class topical bactericidal antibiotic clinical drug candidate with a novel mechanism of action that includes inflammation-reducing capabilities as well as the demonstrated ability to treat antibiotic resistant P. acnes strains. VB-1953 is currently being studied in a Phase 2 clinical trial in the United States. In preclinical studies, VB-1953 showed activity against clindamycin-resistant P. acnes bacteria, a low emergence of resistance and the ability to reduce inflammation.

VB-1953 is delivered with a microtechnology gel system that ensures the drug is retained at the site of infection and minimizes systemic exposure. Acne caused by antibacterial-resistant P.acnes currently poses an emerging and unmet need for patients worldwide, with a potential $2B market opportunity in the US alone.