VISUS THERAPEUTICS INITIATES PHASE 2 CLINICAL TRIAL OF BRIMOCHOL FOR THE TREATMENT OF PRESBYOPIA

First Patients Dosed in 30-Day Efficacy and Safety Trial Evaluating Presbyopia-Correcting Eye Drop

SEATTLE – March 25, 2021 – Visus Therapeutics Inc., a clinical-stage pharmaceutical company in pursuit of developing the world’s first presbyopia-correcting eye drop with the potential to last a minimum of eight hours, today announced the commencement of its Phase 2 clinical trial of BRIMOCHOL™ topical ophthalmic solution under investigation for the treatment of presbyopia. Presbyopia is the loss of near vision associated with aging, making it difficult to perform certain tasks like reading fine print. It typically begins when adults are in their 40s, and becomes almost universal by age 50, impacting approximately 123 million adults in the U.S. alone.

BRIMOCHOL is a proprietary pupil-modulating eye drop that combines two well-studied, FDA-approved pharmaceuticals: carbachol (a cholinergic agent) and brimonidine tartrate (an alpha-2 agonist). Together, they produce a “pinhole effect”, which reduces the size of the pupil so that only centrally focused light rays are able to enter the eye, thereby sharpening distant and near images while minimizing side effects. The result is clarity of vision for near tasks like reading or using a smartphone.

“We have designed a robust clinical development program in a diverse population of patients living with presbyopia. By combining the unique properties of carbachol and brimonidine tartrate into one novel eye drop, BRIMOCHOL has the potential to be a meaningful advancement for the category,” said Rhett Schiffman, M.D., M.S., M.H.S.A., co-founder, chief medical officer and head of research and development at Visus Therapeutics. “The dosing of the first patient in the Phase 2 study brings us one step closer to an innovative near vision solution for the millions of patients who suffer from presbyopia.”

“The onset of presbyopia poses a significant and ongoing impact on the quality of life for so many of my patients who struggle with the loss of near vision as they age. BRIMOCHOL has the potential to be a once-daily treatment option for these patients, eliminating reliance on glasses,” said David Wirta, M.D., of the Eye Research Foundation in Newport Beach, Calif., a principal investigator for the BRIMOCHOL trial. “I am enthusiastic about the commencement of this trial and am hopeful that BRIMOCHOL, with its unique mechanism of action, will be able to expand the treatment landscape for patients with presbyopia.”

The Phase 2 clinical trial (NCT04774237) is a double-masked, randomized crossover study designed to evaluate the safety and efficacy of two proprietary formulations of BRIMOCHOL topical ophthalmic solution in patients with emmetropic phakic and pseudophakic presbyopia. The trial is expected to enroll approximately 42 patients. The primary endpoint is the percentage of patients who gained three lines or more in near visual acuity without losing distance vision. Topline data from the Phase 2 trial is expected in mid-2021.

About Visus Therapeutics
Visus Therapeutics is a clinical-stage company in pursuit of developing the world’s first presbyopia-correcting eye drop with the potential to last a minimum of eight hours. With offices in Seattle and Orange County, Calif., its lead clinical candidate is BRIMOCHOL, an eye drop designed to correct the loss of near vision associated with presbyopia. In parallel, Visus Therapeutics is focused on advancing its pipeline of early-stage ophthalmic product candidates. For more information, visit: www.visustx.com and follow us on Twitter (@VisusTx) and on LinkedIn.
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