

VISUS THERAPEUTICS ANNOUNCES FDA ACCEPTANCE OF IND FOR PRESBYOPIA-CORRECTING EYE DROP

Acceptance Clears Path for Initiation of Phase 2 Clinical Trial for BRIMOCHOL

SEATTLE – March 16, 2021 – Visus Therapeutics Inc. (the “Company”), 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 that the U.S. Food and Drug Administration (FDA) has accepted the company’s Investigational New Drug Application (IND) to proceed with the clinical development program for BRIMOCHOL™, the company’s lead investigational asset. BRIMOCHOL, a proprietary combination of carbachol and brimonidine tartrate, is designed to be a once-daily eye drop to correct for the loss of near vision associated with presbyopia. Under this IND, Visus will initiate its planned Phase 2 clinical trial in the U.S. immediately.

“The FDA’s acceptance of the IND for BRIMOCHOL represents an important step forward for Visus Therapeutics and, more importantly, for the estimated 123 million U.S. adults living with presbyopia,” said Ben Bergo, co-founder and chief executive officer of Visus. “We are excited to begin dosing patients in the Phase 2 clinical study, which we believe will validate BRIMOCHOL as a well-tolerated solution that meets patients’ desire for a long-lasting near vision treatment option.”

Six clinical studies have been conducted in more than 200 patients evaluating the safety and efficacy of BRIMOCHOL.¹ These studies demonstrated an average near visual acuity improvement of five lines or more on the Jaeger eye chart, with a duration of a minimum of eight hours post-dose.² The most recent study, published in 2019 in the *International Journal of Ophthalmic Research*, evaluated 57 patients and reported that BRIMOCHOL’s proprietary combination of carbachol and brimonidine delivered sustained improvement in near visual acuity for a minimum of eight hours.² It also showed an average improvement of more than five lines on the Jaeger eye chart and no reports of brow ache or loss in distance vision. Visus has confirmed a 505(b)(2) pathway with the FDA.

About BRIMOCHOL

BRIMOCHOL is an investigational drug designed to be a once-daily eye drop to correct for the loss of near vision associated with presbyopia. BRIMOCHOL is a combination eye drop with a proprietary and patent-protected formulation that combines carbachol (a cholinergic miotic agent) and brimonidine tartrate (an alpha-2 agonist), two well-studied and FDA-approved medicines. Carbachol produces a “pinhole effect”, which reduces the size of the pupil and allows the light rays focused on the retina to enter the eye, thereby sharpening images. The addition of brimonidine to carbachol is designed to provide several benefits, including longer duration of the pinhole effect and a lower incidence of the side effects typically induced by miotic agents.

About Presbyopia

Presbyopia is the loss of near vision associated with aging, making it difficult to perform tasks like reading fine print. It typically begins when adults are in their 40s and becomes almost universal by age 50.³ Presbyopia impacts billions of people globally with approximately 123 million adults affected in the U.S. alone.⁴ Reading glasses are the most common solution for near-vision correction. However, many people find glasses inconvenient and/or prefer not to wear them for aesthetic reasons. Currently, there are no FDA-approved medications for presbyopia.

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](https://twitter.com/VisusTx)) and on [LinkedIn](#).

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Media Contacts:

Eye Care Trade Press:

Michele Gray
Michele_gray@me.com
(917) 449-9250

Business & Biotech Press:

Sierra Smith
sierra@healthandcommerce.com
(408) 540-4296

¹ Data on file.

² Abdelkader Int. J. Ophthalmic Res 2019 September; 5(1): 317-320.

³ US Census data, www.census.gov, accessed 7 September, 2019.

⁴ Market Scope, Global Presbyopia-Correcting Surgery Market Report, April 2012.