



## **Visus Therapeutics Completes Enrollment in BRIO-I, a Phase 3 Clinical Trial of BRIMOCHOL™ PF for the Treatment of Presbyopia**

*Topline Phase 3 data for presbyopia candidate anticipated in Q2, 2023*

**SEATTLE, Wash. and IRVINE, Calif., – March 22, 2023** – Visus Therapeutics Inc., a clinical stage biopharmaceutical company focused on developing multi-targeted ophthalmic therapeutics for the front and back of the eye, today announced it has completed patient enrollment and the last visit has been conducted in BRIO-I, a pivotal Phase 3 trial for its lead asset, BRIMOCHOL™ PF, a preservative-free topical ophthalmic solution for the treatment of presbyopia.

“We are thrilled to have reached this milestone in the BRIO-I study, as part of our Phase 3 program,” said Ben Bergo, co-founder and chief executive officer of Visus Therapeutics. “BRIMOCHOL PF has the potential to be a highly appealing presbyopia correcting eye drop, providing both the duration and tolerability profile presbyopes desire. We look forward to sharing topline results from BRIO-I in Q2, 2023.”

BRIO-I is a double-masked, randomized, multi-center, safety and efficacy study that enrolled emmetropic phakic and pseudophakic presbyopic subjects.

BRIMOCHOL PF is a novel, preservative free, fixed-dose combination of carbachol and brimonidine tartrate that produces a robust and sustained “pinhole effect” by reducing the size of the pupil. This allows only the light rays focused on the retina to enter the eye, thereby sharpening vision. The result is an enhanced and durable clarity of vision for near tasks like reading or using a smartphone, and intermediate tasks such as looking at a computer screen. In addition to increasing the magnitude and duration of carbachol on the pupil in non-clinical and clinical studies, brimonidine is also known to cosmetically whiten the eye.<sup>1</sup>

“BRIO-I is a safety and efficacy study whose primary objective is to evaluate whether a combination drug therapy of carbachol and brimonidine tartrate is superior in improving near vision than each of the two monotherapies dosed individually,” 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. “By demonstrating this so-called contribution-of-elements in this study, Visus would become the first company to meet this FDA-required high bar for approving a combination product for presbyopia in a pivotal phase 3 study. We look forward to presenting our results at upcoming meetings in Q2, 2023.”

### **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.<sup>2</sup> Presbyopia impacts billions of people globally with approximately 128 million adults affected in the U.S. alone.<sup>3,4</sup> Reading glasses are the most common solution for near-vision correction. However, many people find glasses inconvenient or prefer not to wear them for aesthetic reasons.



## About Visus Therapeutics

With offices in Seattle, Wash., and Irvine, Calif., Visus Therapeutics is a clinical stage biopharmaceutical company focused on developing multi-targeted ophthalmic therapeutics for the front and back of the eye. The company is developing novel, pupil-modulating therapeutics designed to correct the loss of near vision associated with presbyopia. In parallel, Visus Therapeutics is advancing its pipeline of early-stage ophthalmic drug candidates engineered to preserve and restore visual function associated with the leading causes of vision loss including cataract and presbyopia, ocular surface and corneal disease, glaucoma, and age-related macular degeneration. For more information, visit [www.visustx.com](http://www.visustx.com) and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

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<sup>1</sup> McLaurin, E., Cavet, M. E., Gomes, P. J., & Ciolino, J. B. (2018). Brimonidine Ophthalmic Solution 0.025% for Reduction of Ocular Redness: A Randomized Clinical Trial. *Optometry and vision science* : official publication of the American Academy of Optometry, 95(3), 264–271.

<sup>2</sup> U.S. Census Bureau. Retrieved September 7, 2019 from <http://www.census.gov>.

<sup>3</sup> Zebardast et al. The Prevalence and Demographic Associations of Presenting Near-Vision Impairment Among Adults Living in the United States. *Am J Ophthalmol*. 2017;174:134-144.

<sup>4</sup> U.S. Census Bureau. Table 9. Washington: Population Division. 2014.