

**Visus Therapeutics Announces Positive Topline Clinical Data
from Phase 3 Pivotal BRIO-I Trial of BRIMOCHOL PF™ for the Treatment of
Presbyopia**

BRIMOCHOL PF, a preservative-free eyedrop, successfully met the pre-specified visual acuity primary endpoints for both the US and EU/UK against its active comparators carbachol and brimonidine.

BRIMOCHOL PF successfully demonstrated “contribution-of-elements,” paving the way for the first, and potentially only, fixed-dose combination topical ophthalmic eyedrop for Presbyopia.

BRIMOCHOL PF achieved highly statistically significant near vision improvements over 8 hours and was well-tolerated.

SEATTLE, Wash. and IRVINE, Calif., – April 20, 2023 – Visus Therapeutics Inc., a clinical-stage pharmaceutical company, focused on developing multi-targeted ophthalmic therapies for indications in the front and back of the eye, today reported positive topline results from its Phase 3 pivotal BRIO-I trial. BRIO-I met the pre-specified primary study endpoints agreed upon with the US-FDA and EMA/MHRA, demonstrating contribution of elements for the once-daily, fixed-dose combination, BRIMOCHOL PF, over both active comparators carbachol and brimonidine monotherapies. BRIMOCHOL PF demonstrated highly statistically significant improvements in near and distance binocular visual acuity at multiple timepoints over carbachol and brimonidine. Clinically and statistically significant reductions in pupil size were also observed out to 10 hours. BRIMOCHOL PF was well-tolerated with no treatment-related serious adverse events. Further details will be presented at upcoming meetings, including [Eyecelerator](#) during the [2023 American Society of Cataract and Refractive Surgery \(ASCRS\) Annual Meeting](#) taking place in San Diego, CA on May 4th.

“Visus Therapeutics is the first and only company to demonstrate contribution-of-elements in a presbyopia pivotal study. We are very grateful to the investigators, their staff, and the study participants for their enormous efforts in this trial,” 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. BRIO-I is a 3-arm, multicenter, randomized, double-masked, crossover safety and efficacy study of BRIMOCHOL PF (carbachol/brimonidine tartrate fixed-dose combination) topical ophthalmic solution vs. carbachol monotherapy topical ophthalmic solution vs. brimonidine tartrate monotherapy topical ophthalmic solution in subjects with emmetropic phakic or pseudophakic presbyopia ([NCT#: NCT05270863](#)). The study enrolled 182 subjects across 15 sites in the United States.

“I am pleased to see that BRIMOCHOL PF was superior to both highly active treatments, carbachol and brimonidine, over a range of timepoints in this study,” said Eric Donnenfeld, M.D., Visus Board of Directors member and Chair of the Company’s Medical Advisory Board. “BRIMOCHOL PF was well-tolerated in a broad presbyopia population with no study subjects discontinuing due to adverse events. If approved, BRIMOCHOL PF has the potential to last a full workday in presbyopia patients not fully served at this time.”

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 50¹. Presbyopia impacts billions of people globally with approximately 128 million adults affected in the U.S. alone^{2,3}. 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 pharmaceutical company focused on developing multi-targeted ophthalmic therapies for indications in both the front and back of the eye formulated in novel, sustained delivery platforms. For more information, visit: www.visustx.com and follow us on [LinkedIn](#), Twitter ([@VisusTx](#)) and [Instagram](#).

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¹ U.S. Census Bureau. Retrieved September 7, 2019, from <http://www.census.gov>.

² 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.

³ U.S. Census Bureau. Table 9. Washington: Population Division. 2014.