



## **Visus Therapeutics Announces Positive Topline Clinical Data from Phase 2 VIVID Study of BRIMOCHOL for the Treatment of Presbyopia**

*Three Proprietary Formulations Achieved a Three-Line Improvement in Binocular Near Visual Acuity, without Losing One Line in Distance Visual Acuity with a Minimum Responder Rate of 83% at One Hour; a Minimum of 35% of Subjects Met the Same Endpoint at 9 Hours*

*Positive Outcomes of Phase 2 VIVID Study Clear Path to Advance to Phase 3 Pivotal Studies*

**SEATTLE – November 30, 2021** – Visus Therapeutics Inc., a clinical-stage pharmaceutical company focused on developing innovative ophthalmic therapies to improve vision for people around the world, today reported positive topline results from VIVID, the company's Phase 2 study of three novel topical ophthalmic formulations under investigation for the treatment of presbyopia. All three investigational candidates studied in VIVID achieved the endpoint of three lines of improvement in binocular near visual acuity without losing one line of distance vision with a minimum responder rate of 83% at one hour. A minimum of 35% of subjects in the study met this same endpoint at nine hours in all three formulations. Additionally, all three formulations were well-tolerated and exhibited favorable safety profiles. Based on these positive outcomes, the company plans to commence Phase 3 pivotal trials shortly.

"We are very encouraged by the VIVID study topline clinical data, which demonstrate that our clinical development program has delivered drug candidates which provide a durable improvement in visual acuity with favorable tolerability and safety profiles," 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. "We know that presbyopia has a profound impact on quality of life for patients. These positive results provide further confidence that we are well positioned to bring to market the longest-lasting eye drop in the presbyopia category, which would be a meaningful breakthrough treatment for these individuals. We are excited to initiate our Phase 3 pivotal trials."

### **VIVID Phase 2 Trial Topline Highlights:**

- In the per protocol population, a minimum of 83% of subjects treated with BRIMOCHOL, BRIMOCHOL F or Carbachol F achieved the endpoint of 3 lines of improvement in binocular near visual acuity under mesopic conditions without losing 1 line of distance vision at 1 hour. A minimum of 82%, 52% and 35% of subjects met this same endpoint at 3, 7 and 9 hours, respectively.
- In key secondary endpoints, BRIMOCHOL and BRIMOCHOL F achieved a mean improvement in binocular near visual acuity of a minimum of 18 ETDRS letters, almost 4 lines, as early as 30 minutes and a minimum of 12 letters at 9 hours.
- BRIMOCHOL, BRIMOCHOL F and Carbachol F were well-tolerated with no unexpected adverse events. Adverse events exceeding 5% included temporary burning and stinging upon instillation, headache and brow ache. No serious adverse events were reported.

"The successful completion of the VIVID study marks an important milestone for Visus Therapeutics," said Ben Bergo, co-founder and chief executive officer at Visus Therapeutics. "In light of the recent



FDA approval of Allergan's Vuity™, the first pharmacologic approved for the treatment of presbyopia, it is truly exciting to see this category come to fruition. We are pleased the VIVID study data exceeded our expectations, demonstrating a clear opportunity to commercialize long-acting miotic formulations."

The VIVID clinical trial ([NCT04774237](#)) was a double-masked, randomized, dose-ranging, multi-center, three-arm crossover study designed to evaluate the safety and efficacy of fixed-dose combinations of carbachol and brimonidine tartrate (BRIMOLCHOL and BRIMOLCHOL F) compared to a similarly formulated preservative-free carbachol. The trial enrolled 85 subjects, ages 45 to 80, with emmetropic phakic and pseudophakic presbyopia at three U.S. sites. The trial was not designed to achieve statistical significance in any of these study populations. Full results from the VIVID study will be presented at future medical meetings.

"These are very encouraging preliminary results for the millions of people living with presbyopia and the eye care professionals who treat them," said Eric D. Donnenfeld, M.D., founding partner of Ophthalmic Consultants of Long Island and Clinical Professor of Ophthalmology at NYU. "Eye drops are emerging as an important new treatment option for correcting age-related loss of near vision. I see tremendous clinical value in a long-acting, preservative-free eye drop that can improve near vision throughout the workday while avoiding the potential toxicity of preservatives. What's really exciting is that these study results demonstrate the potential of drug candidates that can be studied in a larger treatment population."

"Currently, drugstore reading glasses are the most common treatment option for people as they lose their near vision with age. This means that many people aren't getting regular comprehensive eye exams, and as such, more serious eye conditions are going undiagnosed," said David Evans, O.D., an optometrist at Total Eye Care in Memphis, Tenn., and a clinical investigator in the VIVID trial. "The availability of a once-daily, preservative-free eye drop such as those evaluated in the VIVID study could attract millions of people into eye care practices nationwide, creating opportunities to not only improve visual performance but also advance eye health overall for this patient population."

### **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>1</sup> Presbyopia impacts billions of people globally with approximately 128 million adults affected in the U.S. alone.<sup>2,3</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 pharmaceutical company focused on developing innovative ophthalmic therapies to improve vision for people around the world. The company is developing novel miotic formulations for a once-daily eye drop 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 with applications in ocular surface disease, glaucoma and age-related macular degeneration. Additionally, Visus Therapeutics has entered into a worldwide exclusive licensing agreement with DelSiTech Ltd, a leader in advanced, biodegradable, silica-based, controlled-release materials, to develop novel drug delivery technology that can help optimize the clinical benefit of ophthalmic therapies. For more information, visit: [www.visustx.com](http://www.visustx.com) and follow us on [LinkedIn](#), Twitter ([@VisusTx](#)) and [Instagram](#).



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

<sup>2</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>3</sup> U.S. Census Bureau. Table 9. Washington: Population Division. 2014.