

VISUS THERAPEUTICS LAUNCHES AND ANNOUNCES CLINICAL DEVELOPMENT PROGRAM FOR NOVEL PRESBYOPIA EYE DROP

Patent Assets Acquired from Acclaimed Ophthalmologist and Innovator Herb Kaufman, M.D., to Progress to Phase II Studies

Eric Donnenfeld, M.D., Appointed Leader of Clinical Advisory Board, Bringing World-Class Ophthalmology Expertise as Company Moves Into Clinical Development

SEATTLE – September 28, 2020 – Visus Therapeutics Inc. today announced its launch and clinical development program for a novel eye drop designed to restore the loss of near vision associated with presbyopia. Presbyopia is the most common cause of vision impairment among adults¹ and it affects billions globally. Visus' lead product candidate is BRIMOCHOL™, a proprietary formulation that combines two well-studied, FDA-approved pharmaceuticals: carbachol and brimonidine tartrate. Visus recently completed the acquisition of all patent assets underpinning the development of BRIMOCHOL, which is based on pioneering research led by Herb Kaufman, M.D., a celebrated ophthalmologist who is responsible for more than 15 landmark innovations in the field of eye care and beyond.

Five clinical studies have been conducted evaluating the safety and efficacy of BRIMOCHOL. In the most recent clinical study of 57 patients, BRIMOCHOL demonstrated statistically significant improvement in near visual acuity of a 5 Jaeger-line or greater gain, with the effect lasting at least 12 hours. The same study found that BRIMOCHOL was well tolerated with no reports of headache or browache in this proprietary combination.⁴ Phase II trials are slated to commence in early 2021.

“The billions of people globally who suffer from presbyopia struggle with simple, everyday activities – such as reading a menu in a restaurant or using a mobile phone – representing a tremendous unmet need in the eye care segment,” said Ben Bergo, co-founder, president and chief executive officer of Visus Therapeutics. “We are very excited to advance the clinical development program for BRIMOCHOL with the hope of bringing the therapy to market and helping restore near vision for millions of adults globally.”

“The previously published clinical studies and our own extensive non-clinical studies demonstrate that this proprietary formulation supports a robust and extended duration of effect of 8-12 hours^{4,5},” said co-founder Rhett Schiffman, M.D., M.S., M.H.S.A., chief medical officer and head of research and development at Visus Therapeutics. “The data also suggest that, unlike other combination drop candidates in this space, pivotal studies of BRIMOCHOL are expected to demonstrate that the individual drugs will contribute significantly to the overall effect of the combination product on near visual acuity.”

Visus brings deep ophthalmology experience to drive innovation for patients with presbyopia. Dr. Schiffman is a board-certified internist and ophthalmologist and uveitis-trained specialist; and Robert Sambursky, M.D. is a board-certified ophthalmologist with corneal and external disease specialty training. Schiffman previously served as vice president of global drug development and therapeutic area head of ophthalmology at Allergan Inc.; chief medical officer at Neurotech Pharmaceuticals Inc.; and chief medical officer and head of research and development at Envisia Therapeutics Inc., since acquired by Aerie Pharmaceuticals. Sambursky is also chairman of the board of directors and president and chief executive officer of Lumos Diagnostics, previously RPS Diagnostics. RPS Diagnostics and Planet Innovation were early investors for Visus.

Visus also announces the formation of its clinical advisory board, appointing industry veteran Eric Donnenfeld, M.D., as its leader. Dr. Donnenfeld is an internationally recognized ophthalmologist, serving on the editorial board of nine journals and having participated in more than 40 FDA clinical studies. He is the founding partner of Ophthalmic Consultants of Long Island and Connecticut and also serves as Clinical Professor of Ophthalmology at New York University Medical Center. Dr. Donnenfeld is a past president of ASCRS and editor in chief of EyeWorld.

"I am very pleased to partner with the leadership team at Visus Therapeutics as they work to advance their pipeline of ophthalmic therapeutics," said Dr. Donnenfeld. "BRIMOCHOL employs an innovative approach and the pharmacologic treatment of presbyopia would be a significant benefit for patients."

About Presbyopia

Presbyopia is the loss of near vision associated with aging, making it difficult to perform tasks like reading. It typically begins when adults are in their 40s, and becomes almost universal by age 50.² Presbyopia impacts billions of people globally with approximately 123 million adults affected in the U.S. alone.³ While reading glasses are the most common solution, many people find glasses to be inconvenient and a detriment to their appearance. Currently, there are no FDA-approved medications for presbyopia.

About Visus Therapeutics

Visus Therapeutics is a clinical-stage company developing innovative medicines to improve vision for people around the world. With offices in Seattle and Orange County, Calif., its lead clinical candidate is BRIMOCHOL, an eye drop designed to restore 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](#).

¹ <https://www.aao.org/editors-choice/study-reveals-significant-worldwide-burden-from-un>

² US Census data, www.census.gov, accessed 7 September, 2019.

³ Market Scope, Global Presbyopia-Correcting Surgery Market Report, April 2012

⁴ Abdelkader Int. J. Ophthalmic Res 2019 September; 5(1): 317-320

⁵ Abdelkader and Kaufman Eye and Vision (2016) 3:31

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