**Tenpoint Therapeutics Ltd. Submits New Drug Application to U.S. FDA for BRIMOCHOL™ PF for the Treatment of Presbyopia**

*NDA submission includes efficacy and safety data for the first fixed-dose combination therapy from the world's largest and longest study ever conducted in the presbyopia eye drop category*

**LONDON, United Kingdom and SEATTLE, Wash., April 8 2025 –** Tenpoint Therapeutics, Ltd. ("Tenpoint"), a global, clinical-stage biotechnology company focused on developing groundbreaking treatments to rejuvenate vision in the aging eye, today announced that the Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for BRIMOCHOL™ PF for the treatment of presbyopia, an age-related near-vision loss condition impacting approximately two billion people globally and 128 million people in the United States.[1]

"The submission of the U.S. NDA for BRIMOCHOL PF marks a significant milestone for our company," said Henric Bjarke, Chief Executive Officer at Tenpoint Therapeutics. "As we accelerate the build-out of our commercial team in preparation for the anticipated launch in the first half of 2026, we are incredibly proud of the dedication and tireless work that has brought the company to this point. We look forward to collaborating closely with the FDA throughout the NDA review process."

BRIMOCHOL PF offers the potential for a best-in-class product profile, achievable through the unique combination of brimonidine and carbachol in a pupil-modulating eye drop. This combination produces a "pinhole effect," intended to improve the depth of focus and sharpening near and distant images, with the benefit of greater peak efficacy and duration relative to monotherapy alone. This formulation would be the first combination therapy for presbyopia if approved by the FDA.

The NDA submission is supported by positive data from the first pivotal Phase 3 BRIO-I study, which demonstrated the benefit of the combination therapy over the individual components – a requirement for FDA approval of a fixed-dose combination.

In a second vehicle-controlled Phase 3 BRIO-II study, BRIMOCHOL PF achieved all primary and secondary near vision improvement endpoints with statistically significant three-lines or greater improvement in binocular uncorrected near visual acuity (BUNVA) over 8 hours, without the loss of one line or more in binocular uncorrected distance visual acuity (BUDVA). In addition, BRIMOCHOL PF was well-tolerated with no serious treatment-related adverse events observed in the over 70,000 treatment days monitored in the BRIO-II study.

"The NDA submission includes data from the world's largest and longest (12 months) efficacy and safety study in presbyopia, with more than 70,000 dosing days of data. BRIMOCHOL PF demonstrated a very favorable tolerability profile and no reduction in efficacy over the 12-month study duration," said Rhett Schiffman M.D., M.S., M.H.S.A., Chief Medical Officer and Head of Research and Development. "We also observed additional patient benefits beyond near vision improvements such as statistically significant increases in reading speed and significant lower rates of hyperemia (eye redness) compared with carbachol (p=0.001) and importantly, the rate of vitreous detachment was similar to vehicle. The increase in peak effect and duration of BRIMOCHOL PF over carbachol alone[2], along with the decreased incidence of hyperemia[3] and the lower rate of vitreous detachment[4] are all consistent with previously reported mechanisms of action of brimonidine or related compounds."

The FDA will conduct a standard 60-day filing review to assess the completeness and acceptability of the application for formal review.

**About BRIMOCHOL™ PF and BRIO-II Phase 3 Study**

BRIMOCHOL PF is an investigational, preservative-free, once daily eyedrop to correct for the loss of near vision associated with aging. BRIO-II is a 3-arm, multicenter, randomized, double-masked, safety and efficacy study of BRIMOCHOL PF (carbachol/brimonidine tartrate fixed-dose combination) topical ophthalmic solution vs. carbachol monotherapy topical ophthalmic solution vs. a vehicle topical ophthalmic solution in subjects with emmetropic phakic or pseudophakic presbyopia (NCT05135286). The study enrolled 629 subjects across forty-seven sites in the United States.

**About Tenpoint Therapeutics**

Tenpoint Therapeutics Limited is a global, clinical-stage biotech company developing groundbreaking treatments to rejuvenate vision in the aging eye. Its pipeline includes paradigm-shifting treatments for ophthalmic indications with the greatest need and global market potential, including presbyopia, cataracts, and geographic atrophy. Its lead asset, BRIMOCHOL PF, is a novel pupil-modulating therapeutic designed to correct the loss of near vision associated with presbyopia, a condition that afflicts approximately two billion people globally. BRIMOCHOL PF has completed two large Phase 3 pivotal trials (BRIO-I and BRIO-II) and has submitted its NDA to the US FDA. Tenpoint's leadership team includes ophthalmic industry luminaries with track records of successful approvals and commercialization of blockbuster drugs. A privately held company, Tenpoint Therapeutics is backed by AdBio Partners, AlbionVC, British Business Bank (formerly British Patient Capital), Eight Roads, EQT Life Sciences, F-Prime Capital, Hillhouse Capital Management, Qiming Venture Partners USA, Sofinnova Partners, and Wille AG. To learn more, visit tenpointtherapeutics.com and connect on LinkedIn.

**References**


1. Zebardast N, Friedman DS, Vitale S. The prevalence and demographic associations of presenting near-vision impairment among adults living in the United States. *Am J Ophthalmol*. 2018;174:134-144.
2. Verhoeven RS, Burke, J, Schiffman, R. Nonclinical Pharmacokinetics and Pharmacodynamics of Brimochol, a Combination Product for the Treatment of Presbyopia. Investigative Ophthalmology & Visual Science June 2022, Vol.63, 1819 – F0435. https://iovs.arvojournals.org/article.aspx?articleid=2780074
3. Ackerman, S. L., Torkildsen, G. L., Mclaurin, E., & Vittitow, J. L. (2019). Low-dose brimonidine for relief of ocular redness: integrated analysis of four clinical trials. *Clinical and Experimental Optometry*, *102*(2), 131–139. https://doi.org/10.1111/cxo.12846
4. Kubo C, Suzuki R. Involvement of prejunctional alpha 2-adrenoceptor in bovine ciliary muscle movement. J Ocul Pharmacol. 1992;8(3):225-31.


# # #




**Media and Investors**
Andrew Korda or Donna LaVoie
LaVoieHealthScience
tenpoint@lavoiehealthscience.com
617-865-0043

**Ophthalmic Trade Media Relations**
Michele Gray
Gray Communications, LLC
michele@mgraycommunications.com
917-449-9250