Tenpoint Therapeutics Ltd. Announces FDA Approval of YUVEZZI™, the First and Only Combination Eye Drop Approved to Treat Presbyopia

YUVEZZI (carbachol and brimonidine tartrate ophthalmic solution) 2.75%/0.1% is the only dual-agent presbyopia-correcting eye drop intentionally designed to deliver durability, tolerability, and safety

YUVEZZI was studied in two pivotal Phase 3 trials enrolling more than 800 patients, including the world's largest and longest safety study for presbyopia eye drops[1,2]

YUVEZZI achieves miosis from 30-minutes up to 10 hours with one drop daily[1]

LONDON, U.K. and SEATTLE, Wash., January 28, 2026 – Tenpoint Therapeutics, Ltd., a global, commercial biotechnology company focused on developing groundbreaking treatments to improve vision in the aging eye, today announced that the U.S. Food and Drug Administration (FDA) approved YUVEZZI™ (carbachol and brimonidine tartrate ophthalmic solution) 2.75%/0.1%, previously known as BRIMOCHOL™ PF, the first and only dual-agent eye drop for the treatment of presbyopia in adults. Presbyopia, the gradual loss of near vision that typically begins around age 45, affects about two billion people globally and 128 million people in the U.S.[3,4,5] YUVEZZI is expected to be broadly commercially available in the U.S. in Q2 2026.

The FDA approval of YUVEZZI is based on positive data from two Phase 3 studies. The Phase 3 BRIO I study demonstrated a superior benefit of the combination therapy over the individual actives – a requirement for FDA approval of a fixed-dose combination.[1] In the second Phase 3 study, BRIO II, which was vehicle-controlled, YUVEZZI achieved all primary 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).[2] In addition, YUVEZZI was well-tolerated with no treatment-related serious adverse events observed in the more than 72,000 treatment days monitored in BRIO II, the longest safety study (12 months) conducted in presbyopia to-date.[2] The most common side effects of YUVEZZI are headache, impaired vision and temporary eye pain or eye irritation.[6]

Eye redness was not a commonly reported side effect in clinical trials of YUVEZZI. In BRIO I and BRIO II the reports of adverse events of ocular hyperemia (eye redness) were low.[1,2] In BRIO II, the rate of reported adverse events of ocular hyperemia (eye redness) was lower in subjects receiving YUVEZZI (2.8%) than carbochol alone (10.7%).[2]

"The FDA approval of YUVEZZI represents a significant milestone for the millions of people in the U.S. living with presbyopia and its daily frustrations and challenges," said Henric Bjarke, Chief Executive Officer of Tenpoint Therapeutics. "As the first FDA-approved dual-agent eye drop for presbyopia, YUVEZZI leverages the mechanisms of carbachol and brimonidine tartrate to deliver sharp near vision with favorable tolerability. People deserve treatments that not only work but also can fit conveniently into their daily lives, and YUVEZZI brings an innovative new option to the presbyopia category. This approval marks the first groundbreaking therapy for Tenpoint Therapeutics aimed at advancing our mission to bring innovation to the aging eye."

"The impact of presbyopia is often underestimated, and current solutions like glasses, contacts or surgery have fallen short in meeting the real-world needs of people who struggle with close-up tasks," said John Hovanesian, M.D., FACS, of Harvard Eye Associates in Laguna Hills, California. "YUVEZZI introduces a novel approach by combining carbachol and brimonidine tartrate in a single daily eye drop that sharpens near vision and maintains tolerability throughout the day. YUVEZZI was intentionally designed to deliver both efficacy and tolerability, which represents an important step forward in delivering a complete, non-invasive option for people with presbyopia."

“Presbyopia remains a universal and progressive condition that requires individualized management strategies,” said Mile Brujic, OD, FAAO, of Premier Vision Group in Bowling Green, Ohio. “I’m excited that I will be able to offer my patients YUVEZZI™, the first-of-its-kind eye drop well-suited for long-term use. For people seeking a reliable, lifestyle-friendly solution to manage their near vision challenges in aging eyes, YUVEZZI is a valuable and practical advancement.”

“We’ve been working diligently to bring YUVEZZI to the eye care community and to the millions of adults looking for the optimal solution to address their frustration with presbyopia,” said Carol Kearney, Chief Commercial Officer of Tenpoint Therapeutics. “It was important to us that we provide an option that fits seamlessly into active, social and professional lifestyles, and we intentionally designed YUVEZZI to offer the right balance of efficacy, tolerability and ease of use.”

About Presbyopia
Presbyopia is the gradual loss of near vision that typically begins around age 45 and significantly affects aging eyes and quality of life.[3,4,7,8] It is a natural, inevitable part of aging and impacts nearly 128 million people in the U.S. and ~2 billion people worldwide.[3,5] Presbyopia affects the lens’ ability to change shape and focus on close objects.[9] It can also make it difficult to adapt to different levels of ambient illumination, particularly in dim or low-contrast settings.[10,7]

About YUVEZZI™ (carbachol and brimonidine tartrate ophthalmic solution) 2.75%/0.1%
YUVEZZI™ (carbachol and brimonidine tartrate ophthalmic solution) 2.75%/0.1% is a dual-agent eye drop approved by the U.S. Food & Drug Administration (FDA) for the treatment of presbyopia, a condition characterized by the gradual loss of near vision acuity that typically begins after the age of 45.[6,4]

The proposed mechanism of action of this fixed-dose combination of carbachol and brimonidine in presbyopia is pupillary constriction and the creation of a pinhole effect that improves near visual acuity and depth of focus.[6] Carbachol is a cholinergic agent which produces constriction of the iris sphincter and ciliary body. Brimonidine tartrate, an alpha-adrenergic agonist, blocks contraction of the iris dilator muscle and relaxes tonic contraction of the ciliary muscle, enhancing selectivity for the pupil and increasing bioavailability of carbachol in the aqueous humor.[6]

YUVEZZI Indication and Important Safety Information

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YUVEZZI (carbachol and brimonidine tartrate ophthalmic solution) 2.75% / 0.1 is a prescription eye drop for adults with blurry close-up vision due to age.

IMPORTANT SAFETY INFORMATION

Do not use YUVEZZI if you are allergic to any of its ingredients or if you currently have inflammation of the iris (iritis).

Before taking YUVEZZI, tell your doctor if you have depression, low blood pressure, or circulation problems.

YUVEZZI may cause temporary blurry, dim, or dark vision. If you experience this, avoid driving, using machinery, and participating in hazardous activities. Use caution when night driving and in other activities in low light.

Call your doctor right away if you suddenly have flashes of light, floaters, or vision loss.

Do not let the tip of the vial touch your eye, eyelid, or any other surface.

The most common side effects of YUVEZZI are headache, impaired vision, and temporary

eye pain or irritation. These are not all of the possible side effects of YUVEZZI.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Brief Summary for more information.

Please see the full Prescribing Information for YUVEZZI.

About Tenpoint Therapeutics

Tenpoint Therapeutics Ltd. is a global biotechnology company focused on the commercialization of YUVEZZI™ (carbachol and brimonidine tartrate ophthalmic solution) 2.75%/0.1%, the first and only dual-agent eye drop for the treatment of presbyopia, a condition that affects nearly 128 million people in the U.S. and approximately 2 billion people globally.[3,5] By understanding real-world needs and partnering with eye care professionals, Tenpoint is working to bring innovation to the aging eye.

To learn more, visit tenpointtherapeutics.com and connect on LinkedIn.

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[1] Data on file confirmed from the BRIO I study.
[2] Data on file confirmed from the BRIO II study.
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[4] National Eye Institute. Presbyopia. National Eye Institute. December 4, 2024. https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/presbyopia. Accessed January 7, 2026.
[5] Fricke TR, Tahhan N, Resnikoff S, et al. Global Prevalence of presbyopia and vision impairment from uncorrected presbyopia: systematic review, meta-analysis and modelling. Ophthalmology. 2018;125(10):1492–9.
[6] YUVEZZI US Prescribing Information
[7] Mancil GL, Baily IL, Brookman KE, et al. Optometric clinical practice 2024 guideline care of the patient with presbyopia. American Optometric Association; 2011.
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[9] Glasser A, Campbell MCW. Biometric, optical and physical changes in the isolated human crystalline lens with age in relation to presbyopia. Vision Research. 1999;39:1991-2015. doi:10.1016/S0042-6989(98)00283-1. https://www.sciencedirect.com/science/article/pii/S0042698998002831?via%3Dihub.
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