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LENZ Therapeutics Announces Submission of Marketing Authorization Application to European Medicines Agency for VIZZ® for the Treatment of Presbyopia

MAA submission to the European Medicines Agency represents a key regulatory milestone in LENZ's strategy to expand global access to VIZZ

*Submission of MAA in Europe results in the fifth ex-U.S. regulatory submission for*VIZZ

SAN DIEGO, March 10, 2026 (GLOBE NEWSWIRE) -- LENZ Therapeutics, Inc. (Nasdaq: LENZ) today announced that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the review and approval of VIZZ® (aceclidine ophthalmic solution) 1.44%, the first and only aceclidine-based eye drop for the treatment of presbyopia in adults. If approved, the EMA's positive opinion would serve as a foundational step toward making VIZZ available to the millions of Europeans living with age-related blurry near vision. The submission of the MAA in Europe represents the fifth ex-U.S. regulatory submission for VIZZ.

The MAA submission is supported by positive data from three randomized, double-masked, controlled Phase 3 studies (CLARITY trials) conducted in the United States, in which VIZZ achieved all primary and secondary endpoints, demonstrating the ability to improve near vision within 30 minutes and last up to 10 hours. VIZZ was well tolerated with no serious treatment-related adverse events observed in over 30,000 treatment days across all three CLARITY trials.

VIZZ was approved by the U.S. Food and Drug Administration (FDA) in July 2025 and is commercially available in the United States. The EMA submission marks the fifth ex-US submission and represents a significant milestone in LENZ's international expansion strategy to establish VIZZ as a global brand. Presbyopia affects an estimated 1.8 billion people globally, and Europe represents one of the largest markets for vision correction products. LENZ intends to pursue commercialization in Europe through strategic partnerships, complementing partnerships already in place for Greater China, the Republic of Korea and Southeast Asia, Canada, and the Middle East region, and expects to provide further updates as the regulatory review progresses.

"The submission of our Marketing Authorization Application to the EMA is a pivotal milestone for LENZ as we advance our mission to bring VIZZ to patients around the world," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "Europe represents a substantial opportunity, with millions of people affected by presbyopia who

currently lack a convenient pharmacological treatment option. We believe the strong clinical data from our CLARITY program, combined with the favorable safety and tolerability profile of VIZZ, positions us well for a successful regulatory review. We look forward to working with the EMA throughout the review process and continue to advance our partnership discussions necessary to bring VIZZ to Europeans living with presbyopia."

About Presbyopia

Presbyopia is the inevitable loss of near vision associated with aging, impacting the daily lives of nearly all people over the age of 45. As people age, the crystalline lens in their eyes gradually hardens and becomes less able to change shape. This loss of elasticity of the lens reduces the ability of the lens to focus incoming light from near objects onto the retina. Adults over 50 years of age lose, on average, 1.5 lines of near vision every six years. Although the progression of presbyopia is gradual, presbyopes often experience an abrupt change in their daily life as the symptoms become more pronounced starting in their mid-40s, when reading glasses or other corrective aids are suddenly necessary to read text or conduct close-up work. Presbyopia is typically self-diagnosed and self-managed with over-the-counter reading glasses, or managed, after evaluation by an ECP, with prescription reading or bifocal glasses or multifocal contact lenses.

About VIZZ (aceclidine ophthalmic solution) 1.44%

VIZZ (aceclidine ophthalmic solution) 1.44% is a once-daily eye drop developed to restore clear near vision for up to 10 hours. Aceclidine is the sole active ingredient in VIZZ and provides rapid and durable near vision improvement. VIZZ is preservative-free and provided in single-dose vials. VIZZ is a predominantly pupil selective miotic that interacts with the iris with minimal ciliary muscle stimulation. VIZZ causes contraction of the iris sphincter muscle, resulting in a pinhole effect that extends depth of focus to improve vision. For more information, please visit www.VIZZ.com.

VIZZ Indication and Important Safety Information

INDICATION

VIZZ (aceclidine ophthalmic solution) 1.44% is a prescription eye drop used to treat age-related blurry near vision (presbyopia) in adults.

IMPORTANT SAFETY INFORMATION

- Do not use VIZZ if allergic to any of the ingredients.
- To help avoid potential eye injury or contamination of the product, do not allow the vial tip to touch the eye or any surfaces. Discard the opened vial immediately after use.
- Contact lenses should be removed before using VIZZ. After dosing, contact lenses can be reinserted after 10 minutes.
- If using more than one topical eye medication, the medicines should be administered at least 5 minutes apart.
- Temporary dim or dark vision may be experienced after using VIZZ. Do not drive or operate machinery if vision is not clear.

- Seek immediate medical care if sudden onset of flashing lights, floaters, or vision loss is experienced.

ADVERSE REACTIONS

The most common reported adverse reactions of participants were instillation site irritation (20%), dim vision (16%), and headache (13%). Adverse reactions reported in >5% of participants were conjunctival hyperemia (8%) and ocular hyperemia (7%). The majority of adverse reactions were mild, transient, and self-resolving.

For additional information, please see the full Prescribing Information available at www.VIZZ.com/full-prescribing-information.pdf.

About LENZ Therapeutics

LENZ Therapeutics is a pharmaceutical company focused on the commercialization of VIZZ® (aceclidine ophthalmic solution) 1.44%, the first and only FDA-approved aceclidine-based eye drop for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States. LENZ is commercializing VIZZ in the United States and continues to establish licensing partnerships internationally to provide access to VIZZ globally. LENZ is headquartered in San Diego, California. For more information, visit www.VIZZ.com and www.LENZ-tx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of federal securities laws. You can identify forward-looking statements by words such as “may,” “will,” “could,” “can,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “poised,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, but not all forward-looking statements will contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing and outcome of the European Medicines Agency’s review of the Marketing Authorization Application for VIZZ, the potential commercial availability of VIZZ in Europe, LENZ’s mission to bring VIZZ to patients around the world, and plans for commercialization through strategic partnerships. These statements are based on numerous assumptions concerning LENZ, VIZZ, target markets and regulatory agencies and involve substantial risks, uncertainties and other factors that could cause actual results to differ materially from those projected, expressed or implied by these forward-looking statements, including risks related to regulatory approvals, market conditions, and those risk factors described in the section titled “Risk Factors” in our Quarterly Report on Form 10-Q filed for the quarter ended September 30, 2025 and our subsequent filings with the Securities and Exchange Commission. We cannot assure you that the forward-looking statements in this press release or the assumptions upon which they are based will prove to be accurate. The forward-looking statements in this press release are made as of the date of this press release. Except as otherwise required by applicable law, LENZ disclaims any duty to update any forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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