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LENZ Therapeutics Announces MFDS Submission of New Drug Application for LN100 (VIZZ™) in South Korea for the Treatment of Presbyopia

Submission of NDA in South Korea by Lotus Pharmaceutical results in the second ex-U.S. regulatory submission for VIZZ

SAN DIEGO and TAIPEI, Taiwan, Dec. 01, 2025 (GLOBE NEWSWIRE) -- LENZ Therapeutics, Inc. (Nasdaq: LENZ) and Lotus Pharmaceutical Co., Ltd. ("Lotus", TWSW Stock Code: 1795) today announced that Lotus has submitted a New Drug Application (NDA) to the Ministry of Food and Drug Safety (MFDS) for the review and approval of VIZZ™, for the treatment of presbyopia in adults in South Korea. This represents the first submission for approval under the exclusive license and commercialization agreement signed in May 2025 for South Korea and certain countries in Southeast Asia.

The NDA submission was 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 near vision improvement 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. The most common reported adverse reactions of participants were instillation site irritation, dim vision, headache, and eye redness. The majority of adverse reactions were mild, transient and self-resolving.

Under the terms of the licensing and commercialization agreement, LENZ is eligible to receive up to \$125 million in regulatory and commercial milestone payments, as well as tiered, double-digit royalties on future net sales. In addition to South Korea, Lotus has exclusive development, manufacturing, registration and commercialization rights for VIZZ for the treatment of presbyopia in certain countries in Southeast Asia, including Thailand, Philippines, Vietnam, Malaysia, Brunei, Indonesia and Singapore.

Petar Vazharov, Chief Executive Officer of Lotus Pharmaceutical, commented: "We are proud to have completed the MFDS submission for VIZZ in South Korea, a key milestone that reflects the strength of our partnership with LENZ. South Korea is one of the core markets for Lotus, and this filing supports our strategy to expand our current portfolio by leveraging our established commercial footprint and field force. With these capabilities already in place, we can enable an efficient launch that opens new growth avenues with minimal incremental investment. Most importantly, VIZZ has the potential to be a truly life-changing option for millions of South Koreans living with presbyopia, and we are committed to working closely with regulators to bring it to patients as quickly as possible."

“LENZ is committed to collaborating with trusted partners like Lotus Pharmaceutical to expand global access to VIZZ,” said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. “Lotus’ completion of the MFDS filing marks the second submission for VIZZ in Asia, an important step in bringing this therapy to patients worldwide. We’re excited to reach this achievement together and look forward to supporting Lotus as they advance toward commercial availability in South Korea across Southeast Asia.”

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.

About Lotus

Founded in 1966, Lotus (1795: TT) is an international pharmaceutical company with a global presence, focused on commercializing both novel and generic pharmaceuticals to provide patients with better, safer, and more accessible medicines. The company boasts a best-in-class R&D and manufacturing platform in Asia, certified by leading regulatory authorities around the world, including the US FDA, EU EMA, Japan PMDA, China FDA, and Brazil ANVISA. Lotus has established partnerships in nearly every major global market, including the U.S., Europe, Japan, China, and Brazil. The company is currently developing and registering over 100 strategically selected pharmaceutical projects across Asia and the U.S., with more than 250 commercial products. Lotus invests in a diversified portfolio, consisting of high-barrier oncology, complex generics, 505(b)2, NCEs, and biosimilars, through both internal R&D investments and licensing-in partnerships to strengthen its portfolio competitiveness.

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