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LENZ Therapeutics Announces FDA Acceptance of New Drug Application for LNZ100 for the Treatment of Presbyopia

FDA sets Prescription Drug User Fee Act (PDUFA) target date of August 8, 2025

SAN DIEGO, Oct. 21, 2024 (GLOBE NEWSWIRE) -- LENZ Therapeutics, Inc. (Nasdaq: LENZ or “LENZ” or the “Company”), a pre-commercial biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop to improve near vision in people with presbyopia, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company’s New Drug Application (NDA) for LNZ100 for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LNZ100. The FDA noted that it is not planning to hold an advisory committee meeting to discuss this application.

“With the acceptance of our New Drug Application for LNZ100, we are pleased to be one step closer towards potential approval and look forward to continuing to collaborate with the FDA to deliver the first once-daily, well-tolerated and rapid acting eye drop for the treatment of presbyopia to the 128 million individuals living with blurry near vision in the United States,” said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. “Since our public debut in March 2024, we have generated tremendous momentum and demonstrated consistent clinical, regulatory and financial execution, and are focused on transforming LENZ into a robust commercial organization in anticipation of a potential launch as early as the second half of 2025.”

The NDA submission for the treatment of presbyopia is supported by the positive data results from the pivotal Phase 3 CLARITY study. Aceclidine is a new chemical entity in the United States and is not approved for the treatment of presbyopia in any country.

“This is an important milestone as we advance our commercial preparations in anticipation of a potential approval in August 2025,” said Shawn Olsson, Chief Commercial Officer. “With a highly accomplished commercial leadership team in place, we look forward to the continued build-out of our commercial organization with an aim to clearly define the market and establish LNZ100 as the standard of care eye drop for the treatment of presbyopia.”

About LENZ Therapeutics
LENZ Therapeutics is a pre-commercial biopharmaceutical company focused on the development and commercialization of the first and only aceclidine-based eye drop to improve near vision in patients with presbyopia. LENZ’s product candidate, LNZ100 is a

preservative-free, single-use, once-daily eye drop containing aceclidine. LNZ100 was evaluated in the registration-enabling Phase 3 CLARITY study as a potential therapy for the treatment of presbyopia, a condition impacting an estimated 1.8 billion people globally and 128 million people in the United States. The U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 8, 2025 for LNZ100. LENZ is committed to commercializing an ideal pharmaceutical presbyopia solution that enhances vision for “all eyes, all day”. LENZ is headquartered in San Diego, California. For more information, visit: 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 review and potential approval of our NDA by FDA for the potential regulatory approval and commercialization of LNZ100; our plans relating to commercialization, including engagement with key opinion leaders and eye care professionals and the development of commercial capabilities; the size of the market opportunity for LNZ100; the beneficial characteristics of LNZ100 and its expected impact on presbyopes; and expectations regarding shareholder value creation. These statements are based on numerous assumptions concerning the development of LENZ’s product candidates and target markets and involve substantial risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievement to be materially different from the information expressed or implied by these forward-looking statements, including those risk factors described in the section titled “Risk Factors” in our Quarterly Report on Form 10-Q to be filed for the quarter ended June 30, 2024 and our subsequent filings with the SEC. 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 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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