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LENZ Therapeutics Announces NMPA Submission of New Drug Application for LNZ100 in China for the Treatment of Presbyopia

Submission of NDA for LNZ100 in China by CORXEL Pharmaceuticals results in achievement of first milestone due to LENZ under the Development and Commercialization Agreement

SAN DIEGO, July 28, 2025 (GLOBE NEWSWIRE) -- LENZ Therapeutics, Inc. (Nasdaq: LENZ, "LENZ" or the "Company"), a pre-commercial stage 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 CORXEL Pharmaceuticals ("CORXEL") has submitted the New Drug Application (NDA) for LNZ100 to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People's Republic of China (PRC). LENZ licensed the Greater China rights to CORXEL for the development and commercialization of LNZ100 in April 2022.

The NDA submission was supported by positive data from the Phase 3 JX07001 clinical trial of LNZ100 in patients with presbyopia in China. In this Phase 3 safety and efficacy trial, LNZ100 (1.75% aceclidine HCl) achieved the primary endpoint and secondary endpoints, with statistically significant three-lines or greater improvement in Best Corrected Distance Visual Acuity (BCDVA) at near, without losing one-line or more in distance visual acuity.

The submission of the NDA for LNZ100 results in the achievement of the first milestone under the License and Collaboration Agreement with CORXEL (the "License"). Under the terms of the License, LENZ is eligible to receive up to $95.0 million of regulatory and sales milestones, as well as tiered mid single-digit to low double-digit royalties on net sales in Greater China.

"This exciting milestone in our development partnership with CORXEL has come as a result of tremendous collaboration between the teams," said Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics. "This submission was supported by the impressive data generated from the Phase 3 clinical trial of LNZ100 in China, consistent with the data from the CLARITY trial. This is the first regulatory submission outside of the United States, further reinforcing the opportunity for LNZ100 to become a global therapy 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 United States 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 potential of LNZ100 to have best-in-class performance and LNZ100 as a global therapy; the size of the addressable population for LNZ100; expectations regarding the commercial opportunity and beneficial characteristics of LNZ100; and plans and expectations regarding the commercialization of LNZ100 in China or the United States, if approved. These statements are based on numerous assumptions concerning the development of LENZ's products 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 LENZ's Quarterly Report on Form 10-Q filed for the quarter ended March 31, 2025 and in LENZ's subsequent filings with the SEC. LENZ 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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