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LENZ Therapeutics Announces Positive Topline Data from Phase 2 INSIGHT Trial of LNZ100 and LNZ101 to Treat Presbyopia

– Both LNZ100 and LNZ101 Achieved Primary Endpoint of Three-Line or Greater Improvement in Near Visual Acuity, without Losing One Line in Distance Visual Acuity at 1-Hour, 71% and 56% respectively

– Both LNZ100 and LNZ101 Maintained Three-Line or Greater Improvement Significance Compared to Vehicle for All Timepoints Including the Last Measured at 10 hours, 37% and 48% respectively

– Both Formulations Maintained an Average Pupil Size of 1.5 – 2mm for 10 hours

SAN DIEGO--(BUSINESS WIRE)-- LENZ Therapeutics, a privately held late-stage clinical company, today reported positive topline results from its Phase 2 INSIGHT clinical trial of two investigational formulations of aceclidine to treat presbyopia. Both LNZ100 (aceclidine), and LNZ101 (aceclidine + brimonidine) achieved the primary endpoint of three-line or greater improvement in near visual acuity, without losing one-line or more in distance visual acuity at one hour, 71% and 56% of treated subjects respectively, compared to 6% of vehicle-treated. Both LNZ100 and LNZ101 maintained statistical significance of three-line or greater improvement compared to vehicle for all timepoints including the last measured at 10 hours, 37% and 48% respectively. Both formulations maintained an average pupil size of 1.5-2mm for 10 hours which is a biomarker of efficacy. Additionally, patient feedback indicated both formulations were well-tolerated and there were no serious drug related adverse events. Based on these positive outcomes, the company plans to initiate Phase 3 trials shortly.

“We know that the majority of presbyopia patients are looking for a product that is highly effective in improving near vision for their full workday. Our best-in-class results clearly reflect this ideal profile, with 10-hour efficacy, and further extends our potential for category leadership,” said Eef Schimmelpennink, President and CEO of LENZ. “I look forward to our upcoming pivotal trials.”

INSIGHT Phase 2 Trial Topline Highlights:

The INSIGHT trial (https://clinicaltrials.gov/ct2/show/NCT05294328) was a multicenter, double-masked, randomized, crossover, active and vehicle-controlled, safety and efficacy study with a broad study population of 46-73 years of age and refractive error -3.25D SE to +1.5D SE. The trial enrolled 67 subjects, including some patients who had prior vision correction or were pseudophakic. Full results from the INSIGHT trial will be presented at future medical meetings.

– LNZ100 and LNZ101 both achieved their primary endpoint of three-line (15 letters) or greater improvement in near visual acuity without losing one-line (5 letters) or more of distance vision, with a responder rate of 71% for LNZ100 ($p<0.0001$) and 56% for LNZ101 ($p<0.0001$) at one hour post treatment compared to 6% for vehicle, and maintained significance for 10 hours with a responder rate of 37% for LNZ100 ($p<0.0012$) and 48% for LNZ101 ($p<0.0002$) compared to 4% for vehicle. LNZ101 statistically separated from LNZ100 at 9 hours.

– Both achieved the key secondary endpoint of two-line (10 letters) or greater improvement in near visual acuity without losing one-line (5 letters) or more of distance vision, with a responder rate of 86% for LNZ100 and 78% for LNZ101 at one hour post treatment, and 55% and 58% at ten hours post treatment.

– The biomarker of pupil size was maintained in the targeted 1.5 – 2mm range for 10 hours.

– Both formulations demonstrated rapid onset with 73% and 62% three-line or greater improvement within 30 min for LNZ100 and LNZ101 respectively, compared to 8% for vehicle.

Overall, both formulations were well tolerated without drug related serious adverse events observed in any LNZ100 or LNZ101 treated subjects and low rates of mostly mild adverse events. In conjunction with establishing these positive results, the company intends to initiate Phase 3 pivotal trial shortly.

About LNZ100 (aceclidine) and LNZ101 (aceclidine + brimonidine)

Aceclidine is a small molecule acetylcholine receptor agonist that causes pupil contraction, or miosis, creating a pinhole effect that improves near vision. Studies have shown that aceclidine's mechanism of action (MOA) is ideally positioned to create a pinhole pupil effect while avoiding myopic shift. It is crucial to minimize myopic shift as it can significantly impair distance vision for a majority of presbyopes.

Aceclidine's unique pupil selective MOA, in which miosis is decoupled from myopic shift, is expected to allow it to target the broadest patient population.

About LENZ Therapeutics

LENZ Therapeutics is a late-stage clinical company developing innovative ophthalmic pharmaceutical products that improve vision. Its lead programs, LNZ100 and LNZ101, are aceclidine-based eye drops designed to restore the loss of near vision associated with presbyopia. Presbyopia is estimated to impact almost two billion people globally and more than 120 million people in the United States. LENZ is headquartered in San Diego, California, and is backed by venture capital investors, including Versant Ventures, RA Capital Management, and RTW Investments. For more information, visit: LENZ-Tx.com.

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