Lumos Pharma Announces OraGrowthH212 Trial of LUM-201 in PGHD Is Open for Enrollment

June 28, 2021

Single-Center Phase 2 Trial to Study the Pharmacokinetics/Pharmacodynamics (PK/PD) and Unique Pulsatile Mechanism of Action of LUM-201 at Two Dose Levels

AUSTIN, Texas, June 28, 2021 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced today that the OraGrowthH212 Trial, a Phase 2 PK/PD study of the company's lead asset LUM-201 for the treatment of patients with pediatric growth hormone deficiency (PGHD), is open for enrollment.

Lumos Pharma believes an increase in the pulsatile release of endogenous growth hormone (GH) has the potential to produce a substantial improvement in height velocity in PGHD patients. The primary goal of our OraGrowthH212 Trial will be to document PK/PD data showing both a dose-related response and increased pulsatile release of GH in response to LUM-201 in a moderately growth hormone deficient subset of pediatric patients with PGHD. Similar PK/PD data showing a dose-related response and increased pulsatile release of GH was previously documented in Phase 2 studies conducted by Merck in adults and in a small subset of PGHD patients. The OraGrowthH212 Trial is being conducted at the Research Institute of Mother and Child Care, an institute of the University of Chile, at the San Borja Arriaran Clinical Hospital, a specialized pediatric center with the ability to perform the more frequent sample collection and monitoring required for this type of clinical trial.

"We are excited to announce the opening of the OraGrowthH212 Trial" said Rick Hawkins, CEO, President and Chairman of Lumos Pharma. "This study, run in parallel with our Phase 2b OraGrowthH210 Trial, should confirm the unique pulsatile mechanism of action of LUM-201 and its potential for efficacy in moderate PGHD patients. While this trial is not required as part of the regulatory process, we hope that it will provide supportive data for future regulatory filings and commercial marketing efforts."

The study, *A Single-Center, 6-Month, Randomized, Open-Label, Parallel Arm Study of Daily Oral **LUM-201** in Naïve-to-Treatment, Prepubertal Children with Pediatric Growth Hormone Deficiency*, will evaluate the pharmacokinetic (PK) and pharmacodynamic (PD) effects of LUM-201 in 24 PGHD patients randomized to two separate dose cohorts: 1.6 mg/kg/day and 3.2 mg/kg/day. Patients will have their baseline levels of growth hormone secretion measured every ten minutes over a 12-hour period prior to starting their randomized LUM-201 treatment for 6 months. Following 6 months of treatment, patients will again have a 12-hour assessment of growth hormone levels to measure LUM-201's amplification of pulsatile growth hormone secretion. Primary outcome measures are evaluation of augmented growth hormone pulsatility and pharmacokinetics of LUM-201. Safety data and height standard deviation score (SDS) will also be evaluated as secondary outcome measures.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. Lumos Pharma was founded and is led by a management team with longstanding experience in rare disease drug development and received early funding from leading healthcare investors, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), Santé Ventures, and UCB. Lumos Pharma's lead therapeutic candidate is LUM-201, an oral growth hormone stimulating small molecule, currently being evaluated in a Phase 2b clinical trial, the OraGrowthH210 Trial, and a PK/PD clinical trial, OraGrowthH212 Trial, for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an orally administered alternative to daily injections that current PGHD patients endure for many years of treatment. LUM-201 has received Orphan Drug Designation in both the US and EU. For more information, please visit https://lumos-pharma.com/.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Lumos Pharma, Inc. (the "Company") that involve substantial risks and uncertainties. All such statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "forecast," "projected," "guidance," "upcoming," "will," "would," "should," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, the ability of prior research results to forecast the performance of therapeutic agents in the clinic anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; results of operations and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes due to a number of important factors, including the effects of pandemics or other widespread health problems, the outcome of our future interactions with regulatory authorities, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements as discussed in "Risk Factors" and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 and the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and other reports filed with the SEC. The forward-looking statements in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause their views to change. However, while it may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing the Company's views as of any date subsequent to the date of this press release.

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