Lumos Pharma Reaches 50% Randomization Milestone in Phase 2 OraGrowthH210 Trial Evaluating Oral LUM-201 in PGHD

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- Interim Data Anticipated by End of 2022 -

- Interim Data from PK/PD OraGrowthH212 Trial also Anticipated by End of 2022 -

AUSTIN, Texas, April 11, 2022 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced this morning achievement of the 50% randomization milestone for our Phase 2 OraGrowthH210 Trial evaluating orally administered LUM-201 in pediatric growth hormone deficiency (PGHD). Interim data from both the OraGrowthH210 and OraGrowthH212 Trials are anticipated by the end of 2022.

"We are pleased to have reached an important milestone in our trials evaluating oral LUM-201 in PGHD despite the severe challenges posed by conditions from the Covid-19 pandemic worldwide," commented Rick Hawkins, CEO and Chairman of Lumos Pharma. "The pace of screening and enrollment for these trials in recent months has been encouraging, and we look forward to the release of interim data for both trials by the end of 2022. We believe the interim data should provide an early indication of efficacy and safety of oral LUM-201 versus standard of care in PGHD."

The OraGrowthH210 Trial is a multi-site, global trial evaluating orally administered LUM-201 at three dose levels (0.8, 1.6, 3.2 mg/kg/day) against a standard dose of injectable rhGH in approximately 80 subjects diagnosed with idiopathic PGHD, which is less severe than organic PGHD. The objective of this trial is to identify the optimal dose of LUM-201 to be used in a Phase 3 registration trial, based on annualized height velocity from a 6-month dataset, and to prospectively confirm the preliminary validation of our Predictive Enrichment Marker (PEM) strategy. The interim analysis will evaluate the safety and annualized height velocity of the three dose levels of LUM-201 against a standard dose of injectable recombinant human growth hormone (rhGH) in 40 subjects at six months on therapy. The complete set of 6-month, primary outcome data for OraGrowthH210 Trial is anticipated in the second half of 2023.

The OraGrowthH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in up to 24 PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. The objective of the OraGrowthH212 Trial is to confirm prior clinical data demonstrating the amplified pulsatile release of endogenous growth hormone unique to LUM-201 and its potential for this mechanism of action to contribute to its efficacy in PGHD. The primary endpoint for this trial is six months of PK/PD and height velocity data in up to 24 subjects. Interim data on a minimum of 10 subjects is anticipated by the end of 2022.

Lumos Pharma intends to analyze these interim datasets separately and also perform a combined analysis to increase the number of subjects in the top two LUM-201 dose cohorts. This combined interim analysis of approximately 50 subjects from both the OraGrowthH210 and OraGrowthH212 Trials should provide a robust data package from which to obtain an early indication of the potential of oral LUM-201 in PGHD.

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 2 clinical trial, the OraGrowthH210 Trial, and a PK/PD trial, the 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 recombinant growth hormone injections that PGHD patients otherwise 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. 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. A law that, in part, gives us the opportunity to share our outlook for the future without fear of litigation if it turns out our predictions were not correct.

We are passionate about our business - including LUM-201 and the potential it may have to help patients in the clinic. This passion feeds our optimism that our efforts will be successful and bring about meaningful change for patients. Please keep in mind that actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make.

We have attempted to identify forward-looking statements by using words such as "projected," "upcoming," "will," "would," "plan," "intend," "anticipate," "approximate," "expect," "potential," "imminent," and similar references to future periods or the negative of these terms. Not all forward-looking statements contain these identifying words. Examples of forward-looking statements include, among others, statements we make regarding screening and enrollment for both our OraGrowthH210 and OraGrowthH212 Trials progressing well, the timing of interim data readout for OraGrowthH210 and OraGrowthH212 Trials, the timing of primary outcome data readout for our OraGrowthH210 Trial, the potential to expand our LUM-201 platform into other indications, anticipated market reception to our treatment regimen for PGHD and other indications, plans related to initiation and execution of clinical trials; plans related to moving additional indications into clinical development; future financial performance, results of operations, cash position and sufficiency of capital resources to fund our operating requirements through the primary outcome data readout from OraGrowthH210 and OraGrowthH212 Trials, and any other statements other than statements of historical fact.

We wish we were able to predict the future with 100% accuracy, but that just is not possible. In addition to other considerations referenced in this paragraph, the recent conflict between Ukraine and Russia has increased the uncertainty in that region and may impact our business in the future. Our forward-looking statements are neither historical facts nor assurances of future performance. You should not rely on any of these forward-looking statements and, to help you make your own risk determinations, we have provided an extensive discussion of risks that could cause actual results to differ materially from our forward-looking statements in the "Risk Factors" section and elsewhere in Lumos Pharma's Annual Report on Form 10-K for the year ended December 31, 2021, as well as other reports filed with the SEC including our Quarterly Reports on Form 10-Q. All of these documents are available on our website. Before making any decisions concerning our stock, you should read and understand those documents.

We anticipate that subsequent events and developments will cause our views to change. We may choose to update these forward-looking statements at some point in the future, however, we disclaim any obligation to do so. As a result, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

Investor & Media Contact:

Lisa Miller
Lumos Pharma Investor Relations
512-792-5454
ir@lumos-pharma.com

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