



Additional Data on Lumos OraGrowth Trials Presented at International Meeting of Pediatric Endocrinology

March 5, 2023

Oral Presentation Highlighting Data on 15 Subjects from OraGrowth212 Trial Supportive of Conclusions from Interim Data Analysis

Baseline Characteristics of OraGrowth210 Trial Subjects Highlighted in Poster Presentation

AUSTIN, Texas, March 05, 2023 (GLOBE NEWSWIRE) -- [Lumos Pharma, Inc.](https://www.lumos-pharma.com/) (NASDAQ:LUMO), a biopharmaceutical company advancing an oral therapeutic candidate for Pediatric Growth Hormone Deficiency (PGHD) through Phase 2 clinical trials, announced today that additional data from its OraGrowth212 trial was included in an oral presentation of interim results at the 2023 [International Meeting of Pediatric Endocrinology \(IMPE\)](#), held in Buenos Aires, Argentina, March 4-7, 2023. Data from the interim analysis of its OraGrowth210 trial are also being presented as a poster during the conference.

"The additional data presented at IMPE on our OraGrowth212 Trial reinforce the conclusions drawn about the PK/PD profile of LUM-201 from the interim data analysis we conducted last November," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "The data update continued to show a dose-dependent increase of growth hormone pulsatility, correlation of pulsatility with increased height velocity, and a durable response out to 12 months. Now that the OraGrowth210 and OraGrowth212 trials are fully enrolled, we look forward to completing these studies and announcing top line results in the fourth quarter of 2023."

Oral Presentation

Title - *Dose-dependent Increase in GH AUC_{0-12h} with LUM-201 in Idiopathic Pediatric GH Deficiency (iPGHD) from the Interim Analysis Data of the OraGrowth212 Trial*

Lead Author – Fernando Cassorla, M.D., Chief of Pediatric Endocrinology, University of Chile

Date/Time - Sunday, March 5, 3:15 PM – 4:00 PM local time

Slide presentation available in the [Posters & Publications](#) section of Lumos Pharma's website

The OraGrowth212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in 22 treatment-naïve PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. Subjects enrolled in the OraGrowth212 Trial are PEM-positive and, therefore, enriched for responsiveness to LUM-201. In this presentation, results of analysis of 15 subjects were presented. The updated analysis included data on five additional subjects (three in the 1.6 mg/kg treatment arm, two in the 3.2 mg/kg treatment arm) since interim results of the OraGrowth212 Trial were announced in November 2022. Results showed that across the dose range of 1.6 to 3.2 mg/kg/day for 6 months, LUM-201 is well-tolerated and produces dose-dependent and substantial increases in GH AUC_{0-12h}. Results also showed that increased GH pulse amplitude was associated with improved height velocity compared to baseline, and that effects on annualized height velocity were durable through 12 months.

Poster Presentation (Poster #83)

Title - *Baseline Demographics of the OraGrowth210 Trial Studying LUM-201 in Idiopathic Pediatric Growth Hormone Deficiency (iPGHD) Interim Analysis Data (Poster #83)*

Lead Author - Alison Lunsford, M.D., Assistant Professor, Texas Tech Physicians of Amarillo

Date/Time - March 5-7 (Dr. Lunsford present at poster session March 6, 11:45 am-1:45pm local time)

Poster presentation available in the [Posters & Publications](#) section of Lumos Pharma's website

The OraGrowth210 Trial is a multi-site, global Phase 2 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 82 subjects diagnosed with idiopathic (moderate) PGHD. The poster presentation highlighted the results of the interim analysis of data for 41 subjects from the OraGrowth210 Trial. These data showed mean annualized height velocity of 8.6 cm/year at the 1.6 mg/kg/day LUM-201 dose, in line with expectations of growth observed in multiple large historical datasets of this moderate idiopathic PGHD population treated with rhGH. An imbalance in baseline demographic characteristics between the LUM-201 and rhGH arms predicted the disparate growth responses observed across these cohorts. These imbalances, due primarily to two growth outliers in the rhGH cohort, are expected to diminish at full enrollment with a complete dataset of 82 subjects.

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. 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 OraGrowth210 Trial, a PK/PD trial, the OraGrowth212 Trial, and a switch trial, the OraGrowth213 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 subjects 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 progress in our clinical efforts including comments concerning screening and enrollment for our trials, expecting the primary outcome data readout for our trials, 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 the OraGrowtH210 and OraGrowtH212 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. Our forward-looking statements are neither historical facts nor assurances of future performance. Forward-looking statements contained in this announcement are made as of this date and Lumos undertakes no duty to update such information except as required under applicable law. 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.

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Source: Lumos Pharma, Inc.