Lumos Pharma Announces New Analyses of Phase 2 OraGrowthH212 Trial Presented at ENDO 2024

Jun 4, 2024

AUSTIN, Texas, June 04, 2024 (GLOBE NEWSWIRE) -- Lumos Pharma, Inc. (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced today details of new analyses of data from its Phase 2 OraGrowthH212 clinical trial presented in two posters at the *2024 Annual Meeting of the Endocrine Society (ENDO)*, held in Boston, MA, June 1-4, 2024. The posters were presented in parallel sessions on Monday June 3, 2024.

"The new analyses of data from our OraGrowthH212 Trial further characterized LUM-201's unique ability to augment the natural pulsatile secretion of growth hormone, producing comparable growth to injectable rhGH with significantly less exposure to circulating growth hormone," said John C. McKew, PhD, President and Chief Scientific Officer of Lumos Pharma. "The presented results also provide additional support for our planned approach to a placebo-controlled Phase 3 trial of LUM-201 in moderate PGHD, a trial design proposed by the FDA as an appropriate option for oral LUM-201 given its differentiated mechanism as a growth hormone secretagogue."

In the poster MON-111, titled, *Oral LUM-201 Restores Pulsatile Growth Hormone Secretion and Growth Response in Moderate Pediatric Growth Hormone Deficiency (PGHD): Key Discoveries from Phase 2 of OraGrowthH212 Trial* (Cassorla, F, et al) [poster link], investigators evaluated growth hormone pulsatility data obtained at baseline and at six months following treatment with LUM-201.

- Results showed that at six months on LUM-201, a significant increase over baseline in key parameters was observed for the 1.6 mg/kg/day dose. At baseline GH secretion was 0.19 ±0.09 µg/kg/12-hrs; pulsatile GH was 1.17 ±0.66 µg/kg/12-hrs; and total GH was 1.35 ±0.66 µg/kg/12-hrs.
- At 6 months each parameter increased significantly: GH secretion to 0.36 ±0.21 µg/kg/12-hrs, pulsatile GH to 1.8 ±0.74 µg/kg/12-hrs, and total GH to 2.2 ±0.89 µg/kg/12-hrs
- A similar level of increase was observed in the 3.2 mg/kg/day dose cohort
- Investigators combined data from both dose cohorts and conducted a deconvolution analysis on GH secretion. It was determined that at six months GH secretion was 3.3 ±1.8 to 4.4 ±2.1 µg/kg/day compared to 5.0 ±1.3 µg/kg/day derived from published data in normal children, indicating restoration of approximately normal GH secretion by LUM-201.
- Conclusion – at 6 months LUM-201 was able to restore endogenous GH pulsatile secretion to a similar level seen in normal children while also normalizing serum IGF-1 concentrations. Results indicate that by restoring endogenous GH secretion, LUM-201 facilitates growth utilizing a much lower amount of GH than that provided by daily exogenous rhGH. By providing an oral therapy that attains physiological GH profiles, investigational LUM-201 treatment aligns with the fundamental objectives of endocrine therapies, specifically the restoration of normal hormonal homeostasis.

In a late-breaking poster (MON-704) titled, *Growth Response to Oral Growth Hormone Secretagogue LUM-201 in Children with Moderate GH Deficiency (GHD) is Dependent on the Pattern of Pulsatile GH Secretion Stimulated by LUM-201* (Stevens, A, et al), [poster link], investigators evaluated pulsatile GH profiles and growth response to LUM-201.

- Data from OraGrowthH212 pulse assessments at Day 1 (D1) and at 6 months (M6) were analyzed utilizing a univariate Spearman's rank correlations matrix to screen for relationships between D1 characteristics, D1 height velocity, 6M Annualized Height Velocity and interpulse, pulsatile, and total GH secretion at D1 and M6.
- The 12-hour pattern of pulsatile secretion was characterized using Functional Principal Component Analysis (FPCA) to identify dominant modes of variation in the functional data. Subjects were grouped into tertiles based on 6M AHV. The 12-hour profiles were grouped into three 4-hour intervals.
- Results:
    - All parameters increased from D1 to M6
    - D1 pulsatile GH secretion was positively associated with D1 AHV
    - While 6M AHV increased compared to baseline, GH Secretion at D1 and M6 was not apparently correlated with 6M AHV
    - In the FPCA, difference in interquartile range (IQR) for mean GH secretion was highest in 0-4 hrs in subjects in the high and medium AHV tertiles, while subjects with low AHV at 6 months had the highest difference at 8-12 hours
- Conclusions – LUM-201 stimulates significant increases in GH secretion over 6 months in patients with moderate PGHD. The relationship between growth response and both the amount and pattern of pulsatile GH secretion, with the highest growth observed in OraGrowthH212 associated with greatest pulsatile activity early in the 12 hour profile. Restoring GH secretion with LUM-201 in moderate PGHD results in both an increase in the overall amount of GH, and importantly, an alteration of the pattern of the pulse profile, with distinct differences in these patterns between the best and lower responders.

About Lumos Pharma

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare diseases. The Company was founded and is led by a management team with longstanding experience in rare disease drug development. Lumos Pharma's lead therapeutic candidate, LUM-201, is a novel, oral growth hormone (GH) secretagogue, seeking to transform the ~$4.7B global GH market from injectable to oral therapy. LUM-201 is currently being evaluated in multiple Phase 2 clinical studies in Pediatric Growth Hormone Deficiency (PGHD) and 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 the advancement of oral LUM-201 to Phase 3, the potential for LUM-201 to be the first oral therapeutic for PGHD, 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. 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 including risks related to the timing and ability of Lumos Pharma to structure our Phase 3 trial in an effective and timely manner, the ability to initiate and advance a pivotal Phase 3 trial, as well as advance our clinical and corporate strategy in general, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to successfully develop our product candidate, the effects of pandemics, other widespread health problems or military conflicts including the Ukraine-Russia conflict and the Middle East conflict and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements including information in the "Risk Factors" section and elsewhere in Lumos Pharma's Quarterly Report on Form 10-Q for the period ended September 30, 2023, as well as other subsequent reports filed with the SEC. 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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