



Updated Phase 2 OraGrowth Data Presented at ESPE 2024 Demonstrate Sustained Growth on Oral LUM-201 to 24 Months in PGHD and Correlation of Growth to LUM-201's Unique Pulsatile Mechanism of Action

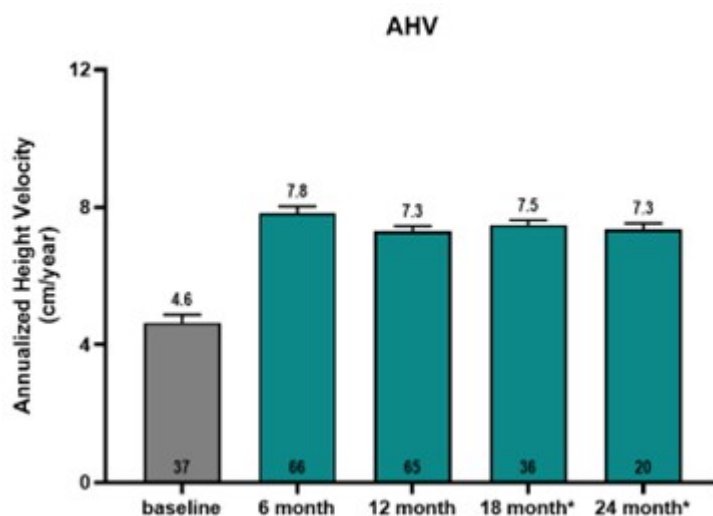
Nov 21, 2024

AUSTIN, Texas, Nov. 21, 2024 (GLOBE NEWSWIRE) -- [Lumos Pharma, Inc.](#) (NASDAQ:LUMO), a clinical-stage biopharmaceutical company focused on therapeutics for rare diseases, announced that new analyses of data from its Phase 2 OraGrowthH210 and OraGrowthH212 clinical trials were presented orally at the [62nd Annual European Society for Paediatric Endocrinology Meeting](#), or ESPE 2024, held November 16-18, 2024 in Liverpool, UK.

"The new analyses and updated data from our Phase 2 OraGrowthH210 and OraGrowthH212 Trials presented at ESPE this week demonstrate sustained growth on LUM-201 in moderate Pediatric Growth Hormone Deficiency (PGHD) to 24 months, as well as the correlation of LUM-201's pulsatile mechanism of action (MOA) to growth," said John C. McKew, PhD, President and Chief Scientific Officer of Lumos Pharma. "We are encouraged by these data and look forward to advancing oral LUM-201 in a Phase 3 clinical trial in moderate PGHD next year."

In the oral presentation of Abstract FC7.6 on Sunday, November 17th, entitled, *Growth, IGF-1 and IGFBP-3 Responses to Oral LUM-201 in OraGrowthH210 and OraGrowthH212 Trials in Pediatric Growth Hormone Deficiency (PGHD) Over 12 to 24 Months on Treatment* (Elzbieta Petriczko, MD, PhD, *et al*) [\[link\]](#), the investigator reviewed updated combined data from the Phase 2 OraGrowthH210 and OraGrowthH212 Trials out to 24 months following treatment with LUM-201.

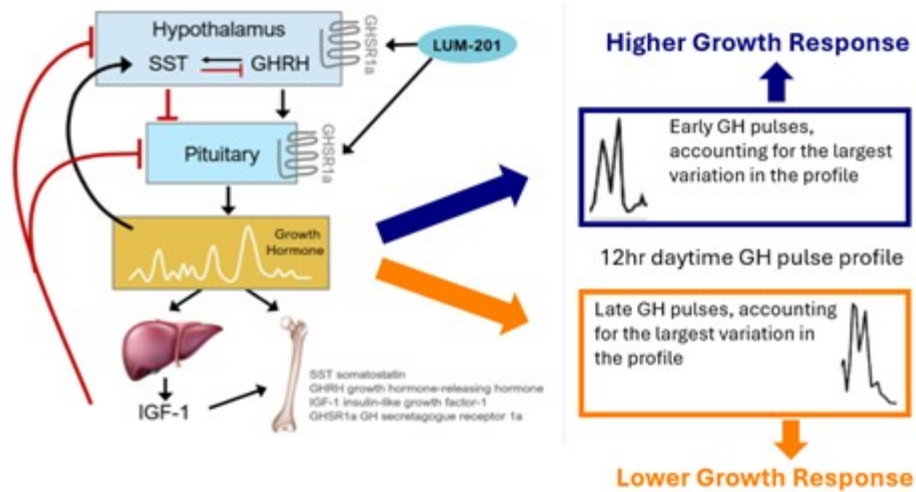
- Results showed that at six months on LUM-201, a significant increase over baseline in Annualized Height Velocity (AHV) was observed for the combined 1.6 and 3.2 mg/kg/day doses. At baseline, AHV was 4.6 cm/yr for 37 subjects for which baseline data were available vs 7.8 cm/yr at 6 months on LUM-201 for 66 subjects.
- Results also showed that growth rates on oral LUM-201 (combined 1.6 and 3.2 mg/kg dose cohorts) were sustained out to 24 months with AHVs of 7.3 (N=65), 7.5 (N=36), and 7.3 (N=20) cm/yr at 12, 18, and 24 months, respectively [graphic below].



- Combined results also demonstrated significant increases in IGF-1 and IGFBP-3 levels from baseline out to 24 months, with IGF-1 increasing from 13.1 (baseline) to 25.5 (12 months) to 29.2 (24 months) nmol/L and IGFBP-3 increasing from 133.5 (baseline) to 179.6 (12 months) to 186.2 (24 months) nmol/L.
- **Conclusions:** LUM-201 shows a significant increase in AHV at 6 months, and the effect continues with a minimal decrease in AHV through 24 months. Compared to historical rhGH (KIGS)¹, LUM-201 has a smaller drop in AHV from 12 months to 24 months. LUM-201 significantly increases IGF-1 and IGFBP-3 levels at 12 months which continues to 24 months. A favorable investigational safety profile has been observed to date.

In the late-breaking oral presentation of Abstract FC15.2 on Monday, November 18th, entitled, *Amount and Pattern of Pulsatile GH Secretion Induced by the Oral Growth Hormone Secretagogue LUM-201 Is Related to Growth and IGF-1 Responses in Moderate Pediatric Growth Hormone Deficiency (PGHD)* (Peter E. Clayton, MD, *et al*) [\[link\]](#), the investigator reviewed data from OraGrowthH212 demonstrating the relationship between pulsatile GH profiles and both the growth and IGF-1 responses to LUM-201 treatment.

- Data from 22 prepubertal children with moderate PGHD from the OraGrowthH212 Trial were evaluated with subjects grouped into tertiles based on 6-month annualized height velocity (AHV).
- Pulsatile growth hormone (GH) pulse assessments at baseline and at 6 months (M6) were characterized using 1) Approximate Entropy (ApEn, scale 0-1) examining degree of orderliness over the whole profile and 2) Functional Principal Component Analysis (FPCA) identifying where within the 12-hour profile, divided into 4-hour periods, the dominant variation occurred.
- Results of 6-month treatment with LUM-201:
 - Pulsatile GH secretion, ApEn, IGF-1 SDS and IGFBP-3 SDS increased from baseline to M6.
 - Greater M6 AHV was associated with an earlier periodicity of augmented pulsatile GH secretion [graphic below].



- **Conclusion:** Both amount and pattern of GH secretion are important for growth and IGF-1 responses to LUM-201.

¹ Ranke et al., 2010 – Pfizer KIGS database rhGH treated cohort of moderate prepubertal GHD children.

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, 2024, 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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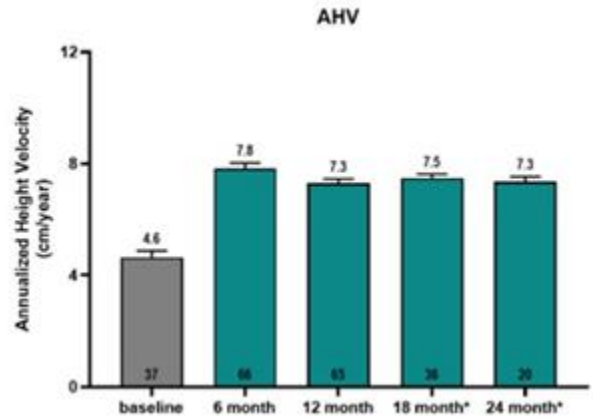
Photos accompanying this announcement are available at
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Source: Lumos Pharma, Inc.



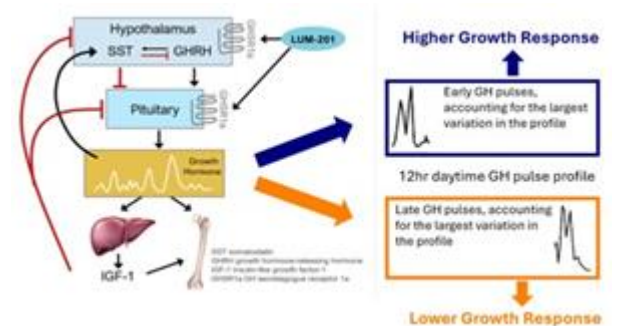
Source: Lumos Pharma, Inc.

ESPE PR - Graphic 1



Graphic 1

ESPE PR - Graphic 2



Graphic 2