UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

> November 7, 2023 Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

001-35342 (State or other jurisdiction of incorporation or organization) (Commission File Number)

42-1491350 (I.R.S. Employer Identification No.)

4200 Marathon Blvd., Suite 200 Austin, Texas 78756 (Address of Principal Executive Offices) (512) 215-2630 Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):
☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	ridding Symbol(s)	rame of each exchange on which registered
Common Stock	LUMO	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On November 7, 2023, Lumos Pharma, Inc. issued a press release titled "Lumos Pharma Announces Topline Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials of LUM-201 in PGHD Met All Primary and Secondary Endpoints."

A copy of the press release and the updated corporate slide deck are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Description

Press Release, dated November 7, 2023, entitled "Lumos Pharma Announces Topline Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials of LUM-201 in PGHD Met All Primary and Secondary Endpoints."

Corporate Slide Deck Exhibit Number 99.1

99.2

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 7, 2023

LUMOS PHARMA, INC., a Delaware corporation

/s/ Richard J. Hawkins Richard J. Hawkins Chief Executive Officer By:

Its:



Lumos Pharma Announces Topline Data from Phase 2 OraGrowtH210 and OraGrowtH212 Trials of LUM-201 in PGHD Met All Primary and Secondary Endpoints

Phase 2 Data Provide Supportive Evidence to Advance Oral LUM-201 to Phase 3

- OraGrowtH210 Results Show LUM-201 Dose of 1.6 mg/kg Achieves Annualized Height Velocities (AHV) of 8.2 cm/yr at 6 Months and 8.0 cm/yr at 12 Months,
 Comparable to Growth Rates for Moderate PGHD Population
- Delta at 6 and 12-month AHV Between Optimal LUM-201 Dose of 1.6 mg/kg and rhGH Comparator Arm is Within the Non-inferiority Margin (< 2 cm/yr) Suggested by FDA for Recent Approvals
- Initial 24-month LUM-201 Data from Combined OraGrowtH210 and OraGrowtH212 Trials Demonstrate a Sustained AHV Effect from Year 1 to Year 2
- Met Pre-specified Primary Endpoint of Validation of Predictive Enrichment Marker (PEM) Test and Secondary Endpoint Demonstrating 100% Reproducibility of PEM-Positive Classification
- OraGrowtH212 Demonstrated That, with Only 20% the GH Concentration of Injectable rhGH, LUM-201 Achieved Expected AHV While Demonstrating the Unique Pulsatile Mechanism of Action of LUM-201^{††}
- No Safety Signal to Date for LUM-201

Company to Host Conference Call Tomorrow Morning at 8:30AM ET

AUSTIN, TX, November 7, 2023 – Lumos Pharma, Inc. (NASDAQ:LUMO) today announced that topline results from its Phase 2 OraGrowtH210 dose-finding trial and its Phase 2 OraGrowtH212 Pharmacokinetic/Pharmacodynamic (PK/PD) trial met all primary and secondary endpoints. Data from the OraGrowtH210 Trial demonstrated annualized height velocity (AHV) on the 1.6 mg/kg dose of orally administered LUM-201 of 8.2 cm/yr at six months and 8.0 cm/yr at 12 months on treatment,* in line with historical data in moderate pediatric growth hormone deficiency (PGHD) patients and within the targeted 2 cm/yr margin of the comparator injectable recombinant growth hormone (rhGH) arm. Data also provided preliminary validation of the predictive enrichment marker (PEM) strategy, with prespecified primary

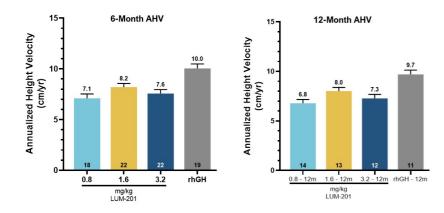
and secondary outcomes met, de-risking our patient selection for our Phase 3 program. Data from the OraGrowtH212 Trial confirmed that LUM-201's unique pulsatile mechanism produces an increase in growth rates while restoring growth hormone secretion and IGF-1 to within normal ranges, with levels substantially below those produced by exogenous injectable rhGH.¹⁺ Additionally, data from a small subset of 10 subjects combined 1.6 and 3.2 mg/kg dosage of LUM-201 in both OraGrowtH210 and OraGrowtH212 trials demonstrated the sustained effectiveness of AHV up to 24 months. Furthermore, the safety profile for LUM-201 remained clean throughout both Phase 2 studies, with no safety concerns identified in either of our Phase 2 trials conducted thus far.

"Results from our OraGrowtH trials have provided us with clear proof of concept that oral LUM-201 has the potential to serve as a viable alternative to injectable therapies in moderately growth hormone deficient patients. Our data indicates that LUM-201 can enhance AHVs in line with established standards for moderate PGHD patients undergoing rhGH therapy, demonstrating a robust and durable response," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "We look forward to discussing these data and finalizing our plans for a Phase 3 pivotal trial with the FDA in our end of Phase 2 meeting anticipated in the first half of 2024."

Renowned pediatric endocrinologist Dr. Ron Rosenfeld, who also serves as the Chairman of our Clinical and Scientific Advisory Board, provided insight on the data, stating, "These findings not only align with historical growth expectations on therapy but also underscore the distinct advantage of LUM-201's unique pulsatile mechanism. Demonstrating the ability to achieve expected growth with oral LUM-201 while exposing patients to only 20% of the growth hormone compared to daily rhGH injections is a significant scientific breakthrough that has the potential to revolutionize the approach to treating children with moderate growth hormone deficiency."

OraGrowtH210 Topline Results Highlights

The OraGrowtH210 trial met its primary objective, with 6-month AHV data of 8.2 cm/yr supporting the 1.6 mg/kg as the optimal dose for a Phase 3 clinical trial.* The 6-month and 12-month AHV on 1.6 mg/kg/day met expectations for growth and were within the targeted 2.0 cm/yr margin for non-inferiority against injectable rhGH cohort.



 $ANCOVA\ Model\ Terms:\ treatment,\ Age\ at\ dose\ 1,\ Sex,\ Baseline\ HT\ SDS,\ Baseline\ BMI\ SDS,\ Baseline\ IGF-1\ SDS,\ LUM-201\ PEM,\ AncovA\ Model\ Terms:\ treatment,\ Age\ at\ dose\ 1,\ Sex,\ Baseline\ HT\ SDS,\ Baseline\ BMI\ SDS,\ Baseline\ IGF-1\ SDS,\ LUM-201\ PEM,\ AncovA\ Model\ Terms:\ The AncovA\ Mod$

Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM

- Dosage at 1.6 mg/kg demonstrates highest LUM-201 AHV at six months and 12 months
- 1.7 cm/yr difference between 1.6 mg/kg LUM-201 dose and rhGH comparator arm at 12 months falls within historical non-inferiority Phase 3 margins
- · LUM-201 AHVs align with historical growth rates of rhGH in patient populations with similar characteristics.
- 12-month AHV data available for 50/81 subjects: Growth rates durable at 12 months

The mean AHVs at 6 months and 12 months observed in the 1.6 mg/kg dose LUM-201 arm were 8.2 cm/yr and 8.0 cm/yr, respectively. These AHVs were in line with the Company's expectations for 8.3-8.6 cm/yr AHV observed after 12 months of rhGH treatment in a moderate PGHD patient population. 1.2.3

The higher than anticipated AHV seen in this moderate PGHD population treated in the rhGH control arm of the OraGrowtH210 Trial was inconsistent with multiple historical trials which predicted growth in the 8.3-8.6 cm/yr range for moderate PGHD¹⁻⁴. This distinctive growth pattern observed in the daily GH arm of this study is likely due to a higher dosage and the presence of outliers. We anticipate that in a larger, more statistically robust Phase 3 trial, the AHV associated with rhGH treatment will align more closely with historical values for the moderate patient population.

The OraGrowtH210 Trial met the prespecified percent responder enrichment providing preliminary validation of the PEM strategy. Additionally, we have achieved a 100% success rate in meeting the predetermined outcome for positive PEM specification classification reproducibility.

OraGrowtH212 Topline Results Highlights

The topline results from the OraGrowtH212 Trial reveal that LUM-201 achieved an expected AHV with only 20% of the growth hormone (GH) concentration observed using injectable rhGH. This outcome was achieved through LUM-201's natural pulsatile mechanism, promoting growth in moderate PGHD subjects that align with historical norms. Notably, LUM-201 raised circulating GH to levels closer to normal physiological ranges, whereas treatment with injectable rhGH has been shown to elevate GH levels to four to five times that of typical healthy children. Furthermore, it's important to highlight that during the first 12 months of LUM-201 treatment, no IGF-1 values exceeded 2 standard deviations from the mean.

Combined 24-Month Data from OraGrowtH210 and OraGrowtH212 Trials

- Eighteen and 24-month growth data were available for 10 subjects from the OraGrowtH210 and OraGrowtH212 Trials who met AHV criteria per protocol at 12 months.
- Combined data from the 1.6 mg/kg and 3.2 mg/kg cohorts of both trials demonstrate sustained AHVs from 12 to 24 months without a considerable decline in growth velocity compared to the previously reported ~20% decline in AHV on rhGH from 12 to 24 months observed in the Pfizer Phase 4 KIGS dataset.³

Safety & Tolerability Highlights

The topline results from both the OraGrowtH210 and OraGrowtH212 trials have shown a clean safety record, characterized by an absence of treatment-related Serious Adverse Events (SAEs), no instances of participants discontinuing treatment due to adverse events (AEs), and the absence of any significant safety concerns in various parameters such as laboratory values, adverse event data, or in electrocardiogram (ECG) readings.

[†] Zadik et al Horm Res 1992

- †† Adapted from data in Albertsson-Wikland et al JCEM 1994; 24h exposures listed reflect absorbance/bioavailability of ~60% of the administered dose.
- * For all OraGrowth Trial AHV values, ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, for graphs HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM

1 Blum et al JES 2021.

² Lechuga-Sancho et al JPEM 2009,

3 Ranke et al JCEM 2010, 4 Bright et al JES 2021

Conference Call and Webcast Details

Date: November 8, 2023 **Time:** 8:30 AM ET

Dial-in: 1-877-407-9716 or 1-201-493-6779 (international)

Conference ID: 13742617

Or Dial-in registration (Available 15 minutes prior to scheduled start time): $\frac{https://callme.viavid.com/viavid/?callme=true\&passcode=13742617\&h=true\&info=company-email&r=true\&B=6}{https://callme.viavid.com/viavid/?callme=true\&passcode=13742617\&h=true\&info=company-email&r=true\&B=6}$

Webcast link: https://viavid.webcasts.com/starthere.jsp?ei=1642841&tp_key=d9efda8a69

Slides are available on the Lumos Pharma website in the "Investors & Media" section under "Events and Presentations" link: https://investors.lumos-pharma.com/events-presentations

A replay of the call will be available approximately two hours after the completion of the call and can be accessed by using the same numbers as above for two weeks following the call.

Virtual KOL Event Planned

The Company plans to host a virtual KOL Event on December 6th to discuss topline results from OraGrowtH210 and OraGrowtH212 trials in greater detail and provide updates on clinical and corporate strategy. Management will be joined by the following three esteemed thought leaders in the field of endocrinology:

- Andrew Dauber, MD, Chief of Endocrinology at Children's National Medical Center, Washington, D.C.
- Fernando Cassorla, MD, Chief of Pediatric Endocrinology at the Institute of Maternal and Child Research, University of Chile
- · Leslie A. Soyka, MD, Chief of Pediatric Endocrinology, UMass Memorial Medical Center; Associate Professor, UMass Chan Medical School, Worcester, MA

Access information regarding the KOL Event will be provided at a later date.

OraGrowtH210 Trial Design

The OraGrowtH210 Trial is a global, multi-site study that assesses the effects of orally administered LUM-201 at three different dose levels (0.8, 1.6, 3.2 mg/kg/day) in comparison to daily injections of recombinant human growth hormone (rhGH) at a dose of $34 \mu g/kg/day$. This trial involves 82 participants diagnosed with moderate Pediatric Growth Hormone Deficiency (PGHD). To enrich the trial population with individuals likely to respond to LUM-201, specific PEM criteria were applied during the screening process. These criteria included having a baseline IGF-1 value above 30 ng/ml and achieving a peak growth hormone value of 5 ng/ml or higher after administering a single 0.8 mg/kg dose of LUM-201 to treatment-naïve PGHD patients. It is important to note that the primary purpose of this study was not to establish efficacy or demonstrate non-inferiority compared to daily GH treatment.

OraGrowtH212 Trial Design

The OraGrowtH212 Trial is a single-site, open-label study designed to assess the pharmacokinetic (PK) and pharmacodynamic (PD) impacts of oral LUM-201. This trial includes up to 24 individuals with no prior treatment for Pediatric Growth Hormone Deficiency (PGHD), who are administered LUM-201 at two different dosage levels,

specifically 1.6 and 3.2 mg/kg/day. Every participant in the OraGrowtH212 Trial met the criteria for Patient PEM positivity, ensuring their potential responsiveness to LUM-201.

About Lumos Dharm

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 ~\$3.4B 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 our Phase 2 data providing supporting evidence to advance oral LUM-201 to Phase 3, clear proof of concept that oral LUM-201 has the potential to serve as a viable alternative to injectable therapies in moderately growth hormone deficient patients, the potential for LUM-201 to enhance AHVs in line with established standards for moderate PGHD patients undergoing rhGH therapy, looking forward to discussing these data and finalizing our plans for a Phase 3 pivotal trial with the FDA in our end of Phase 2 meeting anticipated in the first half of 2024, that this is a significant scientific breakthrough that has the potential to revolutionize the approach to treating children with moderate growth hormone deficiency, data from the OraGrowtH210 Trial supporting the 1.6 mg/kg dose for LUM-201 as the optimal dose for a Phase 3 trial, that this distinctive growth pattern observed in the daily GH arm of this study is likely due to a higher dosage and the presence of outliers, that in a larger, more statistically robust Phase 3 trial, the AHV associated with rhGH treatment will align more closely with historical values for the moderate patient population, 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 continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 meeting with the FDA, the timing and ability of Lumos to raise additional equity capital as needed to fund our Phase 3 Trial, our ability to project future can utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 trial in an effective and timely manner, 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 June 30, 2023, as well as other reports filed with the SEC including our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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 <u>ir@lumos-pharma.com</u>





Forward Looking Statements

This presentation contains forward-looking statements of Lumos Pharma, Inc. that involve substantial risks and uncertainties. All such statements contained in this presentation are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. This 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 plan to have an end-of-phase 2 meeting with the FDA in the first half of 2024 and the anticipated initiation of a Phase 3 program in the second half of 2024, our Phase 2 data providing a clear path to Phase 3 in PGHD, that PEMs enrich trials for patients likely to respond to LUM-201, the expected benefits to LUM-201, 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 continued analysis of data from our LUM-201 Trials, the timing and outcome of our future interactions with regulatory authorities including our end of Phase 2 Trial, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to structure our Phase 3 Trial in an effective and timely manner, the ability to successfully develop our LUM-201 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 June 30, 2023, as well as other reports filed with the SEC including our subsequent Quarterly Reports on Form 8-K. 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 presentation.

Phase 2 Data Provides Clear Path to Phase 3 in PGHD

OraGrowtH210 - Met All Primary and Secondary Endpoints

- ✓ LUM-201 1.6 mg/kg/day dose AHV at 6 months and 12 months were 8.2 cm/yr and 8.0 cm/yr, respectively
 - → Comparable to historical rhGH AHV data in moderate PGHD population
 - → 6 and 12-month AHV within 1.8 cm of the comparator rhGH arm
 - → 1.8 2.0 cm non-inferiority margin has been the historical Phase 3 standard for rhGH approvals
- ✓ Met pre-specified primary endpoint: Preliminary validation of PEM test
- ✓ Met pre-specified secondary endpoint: PEM+ classification 100% reproducible exceeds statistical objective

OraGrowtH212 - Met All Primary and Secondary Endpoints

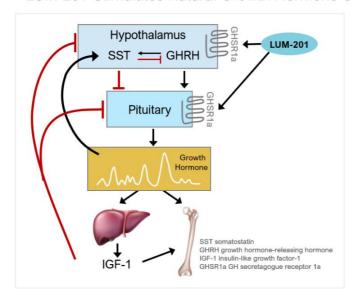
- ✓ LUM-201 restored GH secretion comparable to normal children
- ✓ Increased 6-month AHV materially from baseline
- ✓ LUM-201 normalized IGF-1 SDS values within 6 months of treatment

Secondary Observations – Durable Effect with Favorable Phase 2 Safety

- ✓ Durable effect on AHV at 12 months with 8.0 cm AHV in 1.6 mg/kg/day cohort
- ✓ Initial 24-month data demonstrate more durable effect than rhGH after year-1 treatment
- ✓ Favorable Phase 2 safety profile of LUM-201 in both studies to date
- 3 1AHV = Least Squares Mean Annualized Height Velocity, throughout this presentation AHV values from the OraGrowth studies are based on ANCOVA model (details provided on subsequent slides)



LUM-201 Stimulates Natural Growth Hormone Secretion



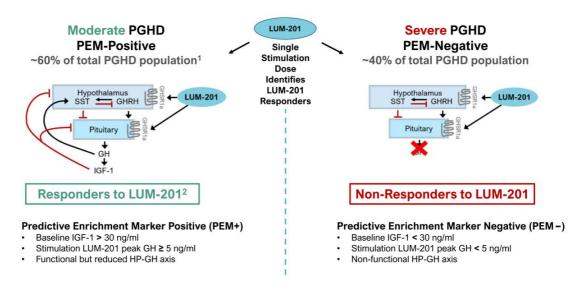
LUM-201 mimics natural release of growth hormone (GH) Different from injections of synthetic GH

- · LUM-201 is an oral GH secretagogue*
- Acts on specific receptors in hypothalamus and pituitary to stimulate release of GH1
- · Increases the amplitude of natural pulsatile GH secretion^{2,3}
- LUM-201 stimulated GH release regulated by natural GH/IGF-1 feedback mechanisms
- · Differentiated mechanism versus exogenous injection of recombinant human growth hormone (rhGH) products

- ¹ Howard 1996 Science ² Nass 2008 Ann Intern Med
- ³ Chapman 1997 J Clin Endocrinol Metab * GH secretagogue = molecule that stimulates the secretion of growth hormone (GH)

PEMs Enrich Trials for Patients Likely to Respond to LUM-201



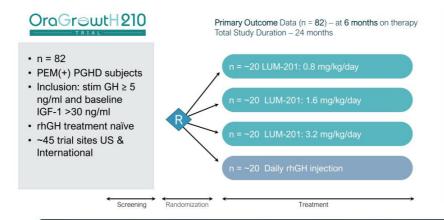


⁵ Blum 2021 JES ² Bright 2021 JES

HP-GH axis - hypothalamic pituitary growth hormone axis



OraGrowtH210 Trial: Phase 2 Trial in Naïve Moderate PGHD



Objectives

Study Objectives:

- Prospectively confirm utility of PEM strategy
- Evaluate reproducibility of PEM classification
- Annualized Height Velocity (AHV)

Goals

 Determine optimal dose for Phase 3

Study not powered to show statistical non-inferiority

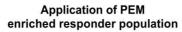
OraGrowtH210 Baseline Demographics

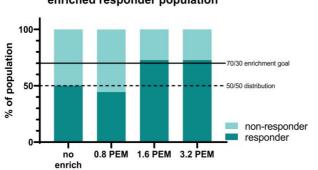
	LUM-201 0.8 mg Mean (SD) N=18	LUM-201 1.6 mg Mean (SD) N=22	LUM-201 3.2 mg Mean (SD) N=22	rhGH Mean (SD) N=19
Age (months)	101.3 (29.2)	95.2 (27.3)	94.5 (21.1)	90.7 (23.7)
Height (cm)	116.4 (12.4)	113.6 (11.0)	113.8 (9.2)	112.9 (10.7)
Height SDS	-2.32 (0.30)	-2.33 (0.54)	-2.29 (0.59)	-2.19 (0.41)
IGF-1 SDS	-1.46 (0.62)	-1.38 (0.61)	-1.39 (0.53)	-1.25 (0.49)
MPH (cm)	165.3 (7.1)	164.9 (7.4)	167.4 (7.7)	169.4 (8.7)
MPH SDS Δ	-1.47 (0.67)	-1.61 (0.68)	-1.87 (0.59)	-1.94 (0.62)
BA Delay (yrs)	1.8 (0.9)	1.9 (0.8)	2.0 (0.9)	1.9 (0.9)
BMI SDS	-0.55 (1.10)	-0.18 (0.87)	-0.57 (0.99)	+0.16 (0.88)

SDS = Standard deviation score MPH = Mid-parental height (Child's target height) MPH SDS delta = (Height SDS) – (MPH SDS) BA = Bone age BMI = Body mass index

OraGrowtH210 Met Primary Statistical Objective: PEM enriches the responder population

lumos





Highlights

- PEM test ensures patients enrolled in the study are capable of secreting GH in response to a single-dose of LUM-201
- PEM-positive criteria:
 - o PGHD patients with baseline IGF-1 >30 ng/ml
 - Peak stimulated GH ≥ 5 ng/ml after a single 0.8 mg/kg dose of LUM-201

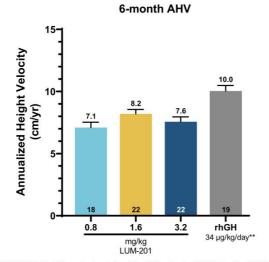
Enrichment strategy demonstrated that >70% of PEM+ subjects met pre-specified target growth in 1.6 and 3.2 mg/kg/day cohorts

OraGrowtH210 Secondary Statistical Objective: PEM test yields highly reproducible results

PEM Test Reproducibility				
Subjects with Positive Agreement on PEM Tests	76/76			
Reproducibility Rate	100%			
95% Confidence Interval	(95.3%, 100%)			

PEM positive classification was 100% reproducible and exceeded pre-specified statistical objective

OraGrowtH210 Met Primary Objective: 6-Month AHV Supports 1.6 mg/kg as Optimal Dose for Phase 3



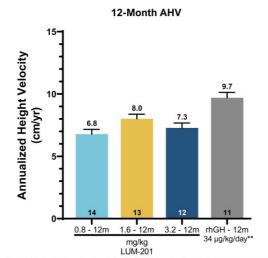
Highlights

- 1.6 mg/kg demonstrates highest LUM-201 AHV at 6 months
- 1.8 cm difference between 1.6 mg/kg LUM-201 dose and rhGH comparator arm

AHV ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM

** Equates to 0.24 mg/kg/wk (approved rhGH dose range: 0.17-0.24 mg/kg/wk for Norditropin)

OraGrowtH210: 12-Month AHV Data Available for 50/81 Subjects Growth Rates are Durable at 12 Months



Highlights

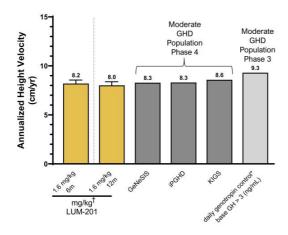
- 1.6 mg/kg best performing LUM-201 cohort
 - o Growth of 8.0 cm comparable to historical 12-month AHV for moderate population
- 1.7 cm difference between 1.6mg/kg and rhGH cohorts
 - o Differences less than 1.8 2.0 cm have been the historical Phase 3 non-inferiority margin for rhGH approvals

AHV ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), Error bars represent the Standard Error of LSM

** Equates to 0.24 mg/kg/wk (approved rhGH dose range: 0.17-0.24 mg/kg/wk for Norditropin)

The N in each cohort represents the number of subjects who have received 12 months of treatment at the time we read out the 6-month primary readout

LUM-201 Growth Comparable to Multiple 12-Month Historical Datasets

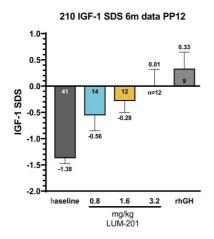


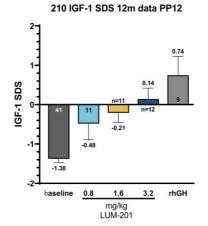
Highlights

- AHVs range from 8.3-9.3 cm/yr in datasets of moderate PGHD patients treated with daily rhGH
- LUM-201 AHVs in line with historical rhGH growth rates in comparable patient populations

[†]ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM), [†]Error bars represent the Standard Error of LSM

^{*}Daily Genotropin control group for Somatrogon Ph3 dosed at 0.034 mg/kg/day (equates to 0.24 mg/kg/wk); subjects were stratified based on GH production during a standard stim test.





Highlights

- LUM-201 normalizes IGF-1 within 6 months
- Durable effect out to 12 months

Bars represent sample mean, and error bars represent Standard Error of the Mean

OraGrowtH210 Summary



- √ All primary and secondary endpoints met
- ✓ LUM-201 AHV's consistent with pre-specified targets from historical benchmarks in moderate PGHD population
- ✓ AHV delta for LUM-201 1.6 mg/kg from comparator daily rhGH arm at 6- and 12-months is within the non-inferiority margin (difference less than 1.8 to 2.0 cm) typically used in Phase 3 pivotal trials for rhGH approvals
- ✓ LUM-201 normalizes IGF-1 SDS within 6 months on treatment
- ✓ Investigational product safety profile remains clean after >1,300 patients treated to date¹
- √ Phase 2 results support advancing to Phase 3 with final design to be confirmed following EOP2 FDA meeting, anticipated in 1H 2024

¹ Includes adult and pediatric subjects from prior Merck studies

EOP2 = End of Phase 2

OraGrowtH212 Trial: PK/PD Trial in Naïve Moderate PGHD

Randomization

Screening

OraGrewtH212

- n = 22
- · Open-label study
- · Moderate PGHD patients
- · rhGH-treatment naïve
- · Dosing to near-adult height
- Single, specialized clinical site in Santiago, Chile
- Q10 minute GH sampling for 12 hours

n = 11 - LUM-201: 1.6 mg/kg/day n = 11 - LUM-201: 3.2 mg/kg/day

Primary Outcome Data (n = 22) – at 6 months on therapy Total Study Duration – Subjects on therapy to near adult height

Objectives

Study Endpoints:

- Assess LUM-201 effect on endogenous GH pulsatility and Annualized Height Velocity (AHV)
- · Evaluate PK/PD in children

Goals

- Confirm prior PK/PD data in adults & subset of Merck 020 trial
- Support future regulatory filings & commercialization

OraGrowtH212 was a single-site trial with a more homogenous patient population than larger international OraGrowtH210 Trial

Treatment

15 PK/PD = Pharmacokinetic / Pharmacodynamic

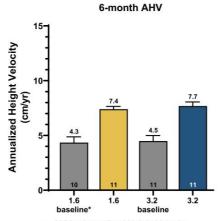
OraGrowtH212 Trial Baseline Demographics

	LUM-201 1.6 mg Mean (SD) N=11	LUM-201 3.2 mg Mean (SD) N=11
Age (months)	99.7 (15.2)	100.9 (21.1)
Height (cm)	116.5 (5.5)	116.6 (9.5)
Height SDS	-2.15 (0.28)	-2.26 (0.38)
IGF-1 SDS	-1.01 (0.64)	-0.85 (0.50)
MPH (cm)	162.6 (7.0)	160.3 (8.7)
MPH SDS Δ	-0.85 (0.53)	-0.73 (0.51)
BA Delay (yrs)	1.7 (0.86)	1.8 (0.96)
BMI SDS	-0.07 (0.85)	0.28 (0.97)

SDS = Standard deviation score MPH = Mid-parental height (Child's target height) MPH SDS delta = (Height SDS) – (MPH SDS) BA = Bone age BMI = Body mass index

OraGrowtH212: Significant Increase in Growth from Baseline AHV at 6 Months





Highlights

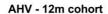
- · AHV at 6 months:
 - o 7.4 in the 1.6 mg/kg arm
 - o 7.7 in the 3.2 mg/kg arm
- · OraGrowtH212 is a single-site study with a seemingly more homogeneous population than those enrolled in the global OraGrowtH210
- AHV = Annualized Height Velocity
- Bars represent sample mean
- Error bars represent SEM

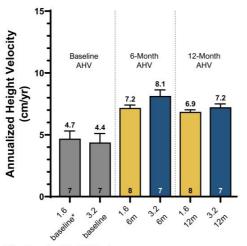
AHV ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS Bars represent Least Squares Mean (LSM),

*Baseline AHV was not measured for one patient in the 1.6 mg/kg cohort.

OraGrowtH212: Significant Growth from Baseline Per Protocol 12-Month Population: 6 and 12-Month AHVs

lumos





Highlights

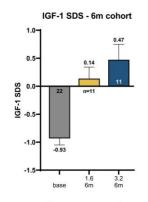
- · Significant increase in growth from baseline
- · Durable effect to 12 months
- · Minimal drop off in AHV between 6 and 12 months
- · No material difference between 2 dose cohorts at 6 or 12 months
- · AHV at 12 months:
 - o 6.9 cm in the 1.6 mg/kg arm
 - o 7.2 cm in the 3.2 mg/kg arm

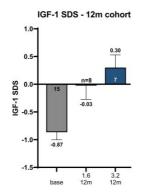
- AHV = Annualized Height Velocity
- Bars represent sample mean
- Error bars represent SEM

AHV ANCOVA Model Terms: treatment, Age at dose 1, Sex, Baseline HT SDS, Baseline BMI SDS, Baseline IGF-1 SDS, LUM-201 PEM, Baseline BA Delay, HT SDS-MPH SDS
*Baseline AHV was not measured for one patient in the 1.6 mg/kg cohort.

OraGrowtH212 Phase 2: IGF-1 SDS LUM-201 Normalizes IGF-1 Level with Durable Effect out to 12 months







Highlights

- LUM-201 normalizes IGF-1 within 6 months
- Durable effect on IGF-1 out to 12 months
- 0 Subjects > 2 SDS between 0 and 12 months

- Bars represent sample meanError bars represent SEMData represent number of pat Data represent number of patients for whom data was available at each timepoint; not all patients had reached 12 months on treatment at time of data pull.

OraGrowtH212: LUM-201 Normalizes GH Concentrations in Moderate PGHD

Time period	Normal healthy (IC-GH [‡])	Untreated GHD (IC-GH [‡])	LUM-201 (baseline GH)*	LUM-201 (treat 6M GH)*	
	Zadik [†]		Zadik [†] N = 22		22
12h (day) μg/kg.12hr	3.3 <u>+</u> 1.3	1.1 <u>+</u> 0.5	1.3	2.6	
24h µg/kg/24hr	5.0 <u>+</u> 1.3	1.4 <u>+</u> 0.5	1.7	3.3 – 4.0	
Ratio 24:12(day)	1.52	1.27	1.27	1.27-1.52	

LUM-201 stimulates an increase in pulsatile secretion of GH approximating normal physiologic levels

[†]IC-GH: integrated concentration of Growth Hormone; data represent mean ± standard deviation
*GH concentrations from the combined 1.6 and 3.2 mg/kg/day cohorts

Notes for clarification of methods:

Similar methodology used for the Zadik manuscript and the OraGrowtH212 Trial for calculation of the total AUC and derivation of secretion rate per kg body weight
Assays for measurement of GH are different between the two studies

OraGrowtH212: LUM-201 Normalizes GH Concentrations in Moderate PGHD

Time period	Normal healthy (IC-GH [‡])	Untreated GHD (IC-GH [‡])	LUM-201 (baseline GH)*	LUM-201 (treat 6M GH)*	Comparator arm rhGH 34 μg/kg/day
Zadik [†]		N =	Albertsson- Wikland ^{††}		
12h (day) μg/kg.12hr	3.3 <u>+</u> 1.3	1.1 <u>+</u> 0.5	1.3	2.6	-
24h µg/kg/24hr	5.0 <u>±</u> 1.3	1.4 <u>+</u> 0.5	1.7	3.3 – 4.0	~20 µg/kg/24hr ^{††}
Ratio 24:12(day)	1.52	1.27	1.27	1.27-1.52	-

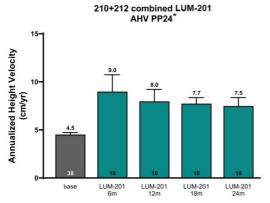
Increasing 24-hour pulsatile secretion, LUM-201 achieves comparable growth to exogenous injectable rhGH, with only 20% of GH concentration levels

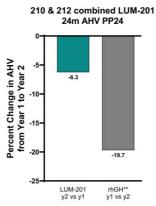
[‡] IC-GH: integrated concentration of Growth Hormone; data represent mean ± standard deviation
*GH concentrations from the combined 1.6 and 3.2 mg/kg/day cohorts
†Zadik et al Horm Res 1992
†† Adapted from data in Albertsson-Wikland et al JCEM 1994; 24h exposures listed reflect absorbance/bioavailability of ~60% of the administered dose

OraGrowtH212 Summary

- √ All primary and secondary endpoints met
- ✓ Increased 6- and 12-month AHV meaningfully from baseline
- ✓ LUM-201 normalized IGF-1 SDS values within 6 months of treatment with durable effect
- ✓ LUM-201 stimulates an increase in pulsatile secretion of GH approximating normal physiologic levels
- ✓ Increasing 24-hour pulsatile secretion, LUM-201 achieves comparable growth to daily exogenous injectable rhGH, with only 20% of GH concentration levels

LUM-201 Data Suggests Greater Durability of Response than rhGH to 24 Months lumos OraGrowtH210 & OraGrowtH212 Combined (1.6 and 3.2 mg/kg LUM-201)





Highlights

- · Preliminary data demonstrate LUM-201 AHV durable to 24 months
- More moderate year 2 AHV decline than rhGH likely due to LUM-201 restoration of GH and IGF-1 to normal levels via pulsatile secretion

AHV values from the OraGrowth studies are based on ANCOVA model (details provided on previous slides)

* At 24 months, data include a subset of subjects from OraGrowtH210 trial who met protocol criteria to continue past 12 months.

** Ranke et.al. 2010 – rhGH treated cohort of moderate GHD children; mean AHV for the moderate GHD cohorts were 8.58 cm/yr in year 1 and 6.89 cm/yr in year 2.

Safety Data from Combined Trials

	PEM	0.8 mg/kg	1.6 mg/kg	3.2 mg/kg	rhGH
	N =129	N =18	N =33	N=33	N =20
Number of AEs	38	59	155	150	54
Subjects with AE (%)	24 (18.6%)	14 (77.8%)	31 (93.9%)	30 (90.9%)	16 (80.0%)
Treatment Related AEs *	7	2	17	20	6
Subjects with Treatment Related AEs (%)	4 (3.1%)	1 (5.6%)	13 (39.4%)	13 (39.4%)	5 (25.0%)
Subjects with SAEs (%)	0 (0%)	#2 (11.1%)	1 (3.0%)	0 (0%)	##1 (5.0%)
Subject with Treatment Related SAEs (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0.0%)

Topline Safety Results

- No meaningful treatment-related Serious Adverse Events (SAEs)
- No drop-outs due to SAEs or AEs
- No meaningful safety signals observed in laboratory values, adverse events data, or in EKG values to date
- * Treatment related AEs in 1.6 and 3.2 groups: Increased appetite (23), Pain in extremity (7), Arthralgia (5), Abdominal pain (1), Transaminases Increased (1)

One subject had SAE between PEM dose and randomized dose

^{##} Subject had SAE between PEM dose and randomized dose

Lumos Pharma Financial Information as of September 30, 2023 $_{Values\ in\ USD}$

Cash, equivalents & short-term investments	\$42.7M
Debt	\$0
Shares Outstanding	7.9M
Cash Use for 4Q 2023	~ \$9.0-\$10.0M
Fiscal Year End	December 31



Cash, cash equivalents, & short-term investments to support operations through 3Q 2024, inclusive of activities related to advancing the PGHD program into Phase 3



Recap Summary and Next Steps

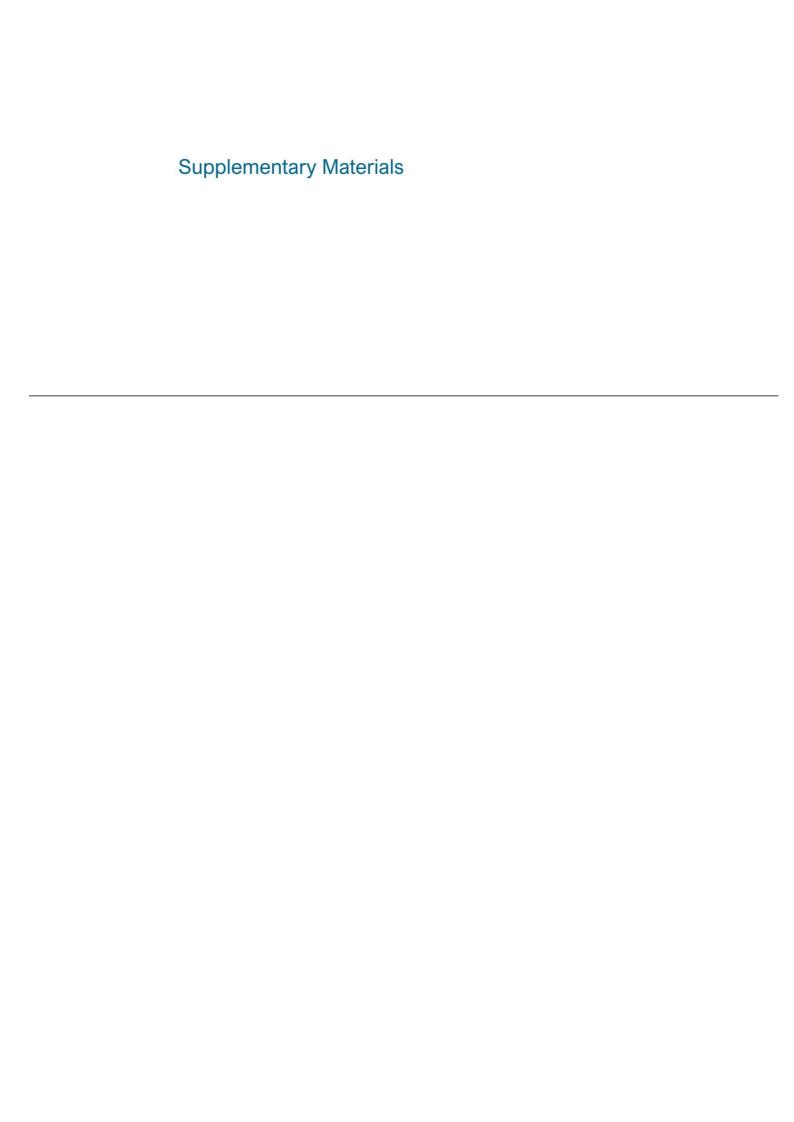
OraGrowtH210 and OraGrowtH212 Phase 2 Clinical Trials

- o Met all primary and secondary endpoints
- o LUM-201 increases pulsatility, restores GH secretion and normalizes IGF-1
- o LUM-201 promotes growth comparable to rhGH with only 20% of GH concentration levels
- Optimal 6-month LUM-201 dose vs rhGH AHV delta (1.8 cm) within historical Phase 3 non-inferiority margins
- Optimal 12-month LUM-201 dose vs historical rhGH AHV delta (~1.3 cm) within historical Phase 3 non-inferiority margins

Considerations for Phase 3 in PGHD

- o Plan to request End-of-Phase 2 meeting with FDA and conduct in 1H 2024
- o Anticipate initiating Phase 3 program in 2H 2024

AHV = Least Squares Mean Annualized Height Velocity, AHV values from the OraGrowth studies are based on ANCOVA model (details provided on previous slides)



Safety Profile at Interim Analysis for OraGrowtH210 Trial

	0.8 mg/kg	1.6 mg/kg	3.2 mg/kg	ALL LUM-201	rhGH 34 mcg/kg
N =	18	22	22	<u>62</u>	20
Number of AEs	59	79	74	212	54
Subjects with AE (%)	14 (77.8%)	20 (90.9%)	19 (86.4%)	53 (85.5%)	16 (80.0%)
Treatment Related AEs (N)	2	2	4	8	6
Subjects with Treatment Related AEs (%)	1 (5.6%)	2 (9.1%)	3 (13.6%)	6 (9.7%)	5 (25.0%)
Subjects with SAEs (%)	#2 (11.1%)	1 (4.5%)	0 (0.0%)	2 (3.2%)	##1 (5.0%)
Subjects with Treatment Related SAEs (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[#]One subject had SAE between PEM dose and randomized dose ##Subject had SAE between PEM dose and randomized dose

Related 210 AEs -

Preferred Term, N (%)	0.8 N=18	1.6 N=22	3.2 N=22	ALL N= 62	rhGH N=20	Comments						
Contusion					1 (5.0)	Grade 1, Recovered by next visit						
Injection Site Bruising					2 (10.0)	Grade 1, Recovered by next visit						
				4.5) 3 (4.8)			0.8	Ongoing				
Increased Appetite (All Grade 1)	1 (5.6)	1 (4.5)	1 (4.5)		2 (10.0)	Duration:	1.6 3.2	1 & 7 months Ongoing				
(All Ordue 1)											rhGH	9, 13 & 15 months
Arthralgia		1 (4.5)	1 (4.5)	2 (3.2)		Both Grade 1, Duration was a few days						
Growing Pains	1 (5.6)			1 (1.6)		Grade 1						
Pain in Extremity			2 (9.1)	2 (3.2)	1 (5.0)	All Grade 1, Intermittent or short duration						

Serious Adverse Events 210 Trial

Serious Adverse Event	System Organ Class	Gr	Study Treatment	Relatedness	Serious Criteria
Product Administration Error	Injury, Poisoning and Procedural Complications	1	NA (occurred prior to receiving any study drug)	<u>Unrelated</u>	Hosp
Dehydration	Metabolism and Nutrition Disorders	3	*PEM (single 0.8 mg/kg)	Unrelated	Hosp
Glycosuria	Renal and Urinary Disorders	1	**PEM (single 0.8 mg/kg)	Unrelated	Hosp
Cartilage Development Disorder	Musculoskeletal and Connective Tissue Disorders	3	0.8 mg/kg/day	<u>Unrelated</u>	Hosp
Pain in Extremity	Musculoskeletal and Connective Tissue Disorders	2	1.6 mg/kg/day	<u>Unrelated</u>	Hosp

^{*} This subject was later randomized to the 0.8mg/kg study arm ** This subject was later randomized to the rhGH arm

There have been no SAEs in the 212 trial to date

Related 212 AEs -

Preferred Term, N (%)	1.6 N=11	3.2 N=11	ALL N=22	Comments		
Abdominal Pain	1 (9.1)		1 (4.5)	Grade 1, Duration: few days		
Transaminases Increased		1 (9.1)	1 (4.5)	Grade 1, Duration: <3 months		
Increased Appetite	11 (100.0)	10 (90.9)	21 (95.5)		9 ongoing	
				19 Grade 1	10 resolved (duration 1-23, avg 9.7 months)	
				2	Grade 2, both ongoing	
Arthralgia	1 (9.1)	2 (18.2)	3 (13.6)	All Grade 1, Duration: < 2 weeks		
Pain in Extremity	2 (18.2)	3 (27.3)	5 (22.7)	All Grade 1, All with duration: < 2 weeks, except or with ongoing intermittent leg pain		

Specific OraGrowtH210 AEs – No meaningful signal safety data available for 82 subjects at interim analysis

	0.8 N=18	1.6 N=22	3.2 N=22	ALL N=62	rhGH N=20
Arthralgia	2 (11.1%)	3 (13.6%)	2 (9.1%)	7 (11.3%)	2 (10.0%)
Myalgia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (15.0%)
Headache	5 (27.8%)	7 (31.8%)	5 (22.7%)	17 (27.4%)	3 (15.0%)
Lethargy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abd. pain	1 (5.6%)	3 (13.6%)	5 (22.7%)	9 (14.5%)	1 (5.0%)
Emesis	0 (0.0%)	1 (4.5%)	3 (13.6%)	4 (6.5%)	3 (15.0%)
Inc. appetite	1 (5.6%)	1 (4.5%)	1 (4.5%)	3 (4.8%)	2 (10.0%)
Hypoglycemia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Orophary. pain	2 (11.1%)	2 (9.1%)	0 (0.0%)	4 (6.5%)	1 (5.0%)



Laboratory Shifts: No meaningful signal 82 subjects

	0.8 mg/kg N=18	1.6 mg/kg N=22	3.2 mg/kg N=22	ALL N=62	rhGH N=20
ALT NI to high	2/17 (11.8%)	5/22 (22.7%)	4/22 (18.2%)	11/61 (18%)	7/20 (35%)
AST NI to high	3/14 (21.4%)	4/21 (19%)	5/22 (22.7%)	12/57 (21.1%)	6/20 (30%)
Bicarb NI to high	0/18 (0%)	0/22 (0.0%)	1/22 (4.5%)	1/62 (1.6%)	0/20 (0%)
Bicarb NI to low	8/18 (44.4%)	6/22 (27.3%)	8/22 (36.4%)	22/62 (35.5%)	5/20 (25%)
Bilirubin NI to high*	4/18 (22.2%)	4/22 (18.2%)	4/22 (18.2%)	12/62 (19.4%)	2/20 (10%)
Calcium NI to low	1/18 (5.6%)	2/21 (9.5%)	4/22 (18.2%)	7/61 (11.5%)	2/20 (10%)
Calcium NI to high	0/18 (0%)	2/22 (9.1%)	0/22 (0.0%)	2/61 (3.3%)	0/20 (0%)
Creatinine NI to low	2/18 (11.1%)	3/22 (13.6%)	2/22 (9.1%)	7/62 (11.3%)	2/20 (10%)
GGT NI to high	2/17 (11.8%)	6/22 (27.3%)	8/22 (36.4%)	16/61 (26.2%)	1/20 (5%)

For the shift to study visit, the denominator is the number of subjects with a non-missing value for the given parameter at baseline and the visit. Baseline is defined as the latest results obtained prior to the first dose of study drug.

* Bilirubin Q2 laboratory normal range high values are lower than most laboratories

Laboratory Shifts

lumos

	0.8 mg/kg N=18	1.6 mg/kg N=22	3.2 mg/kg N=22	ALL N=62	rhGH N=20
Urea nitro NI to low	4/18 (22.2%)	4/21 (19%)	7/22 (31.8%)	15/61 (24.6%)	7/20 (35%)
Urea nitro NI to high	1/18 (5.6%)	0/22 (0%)	1/22 (4.5%)	2/62 (3.2%)	0/20 (0%)
Basophils NI to high	7/17 (41.2%)	12/22 (54.5%)	10/21 (47.6%)	29/60 (48.3%)	4/20 (20%)
Eosinophils NI to high	2/17 (11.8%)	4/22 (18.2%)	3/21 (14.3%)	9/60 (15%)	5/20 (25%)
Hematocrit NI to low	2/18 (11.1%)	0/22 (0.0%)	2/22 (9.1%)	4/61 (6.6%)	0/20 (0%)
Hematocrit NI to high	1/17 (5.9%)	1/22 (4.5%)	2/22 (9.1%)	4/61(6.6%)	0/20 (0%)
Hemoglob. NI to low	4/18 (22.2%)	2/22 (9.1%)	5/22 (22.7%)	11/62 (17.7%)	0/20 (0%)
Lymphoc. NI to low	3/17 (17.6%)	0/21 (0.0%)	1/21 (4.8%)	4/59 (6.8 %)	1/20 (5%)
Lymphoc. NI to high	0/17 (0.0%)	0/22 (0.0%)	2/21 (9.5%)	2/60 (3.3%)	0/20 (0%)

Laboratory Shifts

	0.8 mg/kg N=18	1.6 mg/kg N=22	3.2 mg/kg N=22	ALL N=62	rhGH N=20
Globulin NI to low	6/18 (33.3%)	4/22 (18.2%)	4/22 (18.2%)	14/62 (22.6%)	5/20 (25%)
Glucose NI to high	0/18 (0%)	5/22 (22.7%)	6/22 (27.3%)	11/61 (18%)	0/20 (0%)
Glucose NI to low	0/18 (0%)	0/22 (0.0%)	1/22 (4.5%)	1/62 (1.6%)	0/20 (0%)
Insulin NI to low	2/17 (11.8%)	2/20 (10%)	1/21 (4.8%)	5/58 (8.6%)	0/20 (0%)
Phosphate NI to low	0/18 (0%)	0/22 (0.0%)	1/22 (4.5%)	1/61 (1.6%)	1/20 (5%)
Phosphate NI to high	6/17 (35.3%)	4/22 (18.2%)	7/22 (31.8%)	17/61 (27.9%)	7/20 (35%)
Protein NI to high	0/18 (0%)	1/22 (4.5%)	5/22 (22.7%)	6/62 (9.7%)	1/20 (5%)
Protein NI to low	0/18 (0%)	2/22 (9.1%)	2/22 (9.1%)	4/62 (6.5%)	3/20 (15%)
Potassium NI to high	4/16 (25%)	9/22 (40.9%)	7/22 (31.8%)	20/60 (33.3%)	1/20 (5%)

Laboratory Shifts

	0.8 mg/kg N=18	1.6 mg/kg N=22	3.2 mg/kg N=22	ALL N=62	rhGH N=20
Ery. crp. Hb NI to low	2/17 (11.8%)	2/22 (9.1%)	3/22 (13.6%)	7/61 (11.5%)	2/20 (10%)
Ery. crp. vol NI to low	1/18 (5.6%)	3/21 (14.3%)	3/22 (13.6%)	7/61 (11.5%)	1/20 (5%)
Ery. crp vol NI to high	0/17 (0.0%)	0/22 (0.0%)	0/22 (0.0%)	0/61 (0%)	0/20 (0%)
Monocytes NI to low	3/17 (17.6%)	3/21 (14.3%)	1/21(4.8%)	7/59(11.9%)	1/20(5%)
Monocytes NI to high	3/17 (17.6%)	3/22 (13.6%)	4/21 (19%)	10/60(16.7%)	0/20 (0%)
Neutroph. NI to high	0/18 (0%)	2/22 (9.1%)	2/21 (9.5%)	4/60 (6.7%)	1/20 (5%)
Neutroph. NI to low	3/17 (17.6%)	4/21 (19%)	6/21 (28.6%)	13/59 (22%)	3/20 (15%)
Platelets NI to low	0/18 (0.0%)	0/22 (0%)	1/22 (4.5%)	1/62 (1.6%)	0/20 (0%)
Platelets NI to high	6/17 (35.3%)	5/22 (22.7%)	6/22 (27.3%)	17/61 (27.9%)	0/20 (0%)

Laboratory Shifts: No meaningful signal

	0.8 mg/kg N=18	1.6 mg/kg N=22	3.2 mg/kg N=22	ALL N=62	rhGH N=20
Eryth. NI to high	1/17 (5.9%)	2/22 (9.1%)	2/22 (9.1%)	5/61 (8.2%)	1/20 (5%)
Eryth. NI to low	1/18 (5.6%)	0/22 (0.0%)	0/22 (0.0%)	1/62 (1.6%)	0/20 (0%)
Leukocyt. NI to high	1/17 (5.9%)	2/22 (9.1 %)	2/22 (9.1%)	5/61 (8.2%)	1/20 (5%)
Leukocyt. NI to low	4/17 (23.5%)	4/21 (19%)	2/22 (9.1%)	10/60 (16.7%)	2/20 (10%)