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 14, 2022
Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35342**	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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))

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

Title of each class	Trading Symbol(s)	Name 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).

Emerging growth company ☐

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 14, 2022, Lumos Pharma, Inc., a Delaware corporation (the "Company"), issued a press release announcing interim results from two phase 2 trials evaluating oral LUM-201 for moderate pediatric growth hormone deficiency. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Also on November 14, 2022, the Company is hosting a conference call to discuss the foregoing interim data. A copy of the updated corporate slide deck, a portion of which will be used during the Company's conference call, is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 14, 2022, entitled "Lumos Pharma Announces Encouraging Interim Results from Two Phase 2 Trials Evaluating Oral LUM-201 for Moderate Pediatric Growth Hormone Deficiency."
99.2	Corporate Presentation

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 14, 2022

LUMOS PHARMA, INC.,
a Delaware corporation

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

Lumos Pharma Announces Encouraging Interim Results from Two Phase 2 Trials Evaluating Oral LUM-201 for Moderate Pediatric Growth Hormone Deficiency

- *LUM-201, potentially the first oral medication for PGHD, met expectations in an interim analysis of two Phase 2 trials evaluating growth in Pediatric Growth Hormone Deficiency (PGHD) -*

- *Interim results for approximately 50% enrollment (n=41) of OraGrowtH210 Trial demonstrated a mean annualized height velocity (AHV) of 8.6 cm at six months for 1.6 mg/kg/day LUM-201, in line with 8.3 cm AHV expected from historical database comparisons -*

- *These data further de-risk clinical program and support selection of 1.6 mg/kg/day LUM-201 dose for pivotal Phase 3 trial -*

- *OraGrowtH210 Trial is now ~80% enrolled, and the Company continues to anticipate primary outcome readout with all 80 subjects at six months in 2H 2023 -*

- *KOL event planned for December 6, 2022 -*

- *Conference call today, November 14, 2022 at 8:30AM ET -*

AUSTIN, TX, November 14, 2022 – Lumos Pharma, Inc. (NASDAQ:LUMO), today announced that interim results met expectations for its Phase 2 OraGrowtH210 Trial and Phase 2 Pharmacokinetic/Pharmacodynamic (PK/PD) OraGrowtH212 Trial evaluating oral LUM-201 for subjects with moderate (idiopathic) pediatric growth hormone deficiency (PGHD) who screened PEM-positive utilizing Lumos's predictive enrichment marker (PEM) strategy.

"We are elated that our candidate for the first oral therapeutic for treatment of PGHD, LUM-201, performed as predicted in these moderate (idiopathic) PEM-positive PGHD subjects," said Rick Hawkins, Chairman and CEO of Lumos Pharma. "The observed annualized height velocity of 8.6 cm at 6 months on the 1.6 mg/kg dose of LUM-201 was in line with our prediction of 8.3 cm, which was observed in the PEM-positive moderate naïve-to-treatment PGHD subjects identified from Eli Lilly's large Phase 4 rhGH historical database known as GeNeSIS. These data support advanced planning for a pivotal Phase 3 trial. Additionally, our robust enrollment trends with the OraGrowtH210 Trial now at 80% enrolled, keep us well on track with our previously stated goal of announcing full results from this trial and the OraGrowtH212 Trial in the second half of 2023."

OraGrowtH210 Interim Analysis Highlights at 6 Months

The OraGrowtH210 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) compared to a standard dose of injectable recombinant human growth hormone (rhGH) 34 µg/kg/day in approximately 80 naïve-to-treatment subjects diagnosed with moderate (idiopathic) PGHD. The trial population was enriched for subjects known to be responsive to LUM-201 during screening by applying the specific

PEM cutoffs of a baseline IGF-1 value > 30 ng/ml and a peak growth hormone value of ≥ 5 ng/ml after administering a single dose of 0.8 mg/kg of LUM-201 to treatment-naïve PGHD patients.

The interim analysis was performed after 41 subjects, randomized into four treatment arms of approximately ten subjects, completed six months of treatment. The 6-month annualized height velocity (AHV) on 1.6 mg/kg/day LUM-201 met our expectations for growth. The mean (median)* AHV at six months is shown below for each of the four treatment arms:

- 7.26 (7.71) cm/year in the 0.8 mg/kg/day LUM-201 arm (n=11)
- 8.57 (8.61) cm/year in the 1.6 mg/kg/day LUM-201 arm (n=10)
- 7.77 (8.11) cm/year in the 3.2 mg/kg/day LUM-201 arm (n=10)
- 11.05 (10.48) cm/year in the rhGH arm (n=10)

The mean AHV of 8.6 cm/year at six months observed in the 1.6mg/kg dose arm was in line with the Company's expectations for 8.3 cm/year AHV, which was observed after 12 months of recombinant growth hormone (rhGH) treatment in a moderate naïve-to-treatment PGHD patient population derived from the large 20-year Phase 4 Eli Lilly GeNeSIS database.[1] This was also comparable to the first-year height velocity observed for similar moderate PGHD subjects treated with rhGH in three other large historical databases.[2,3,4]

This unexpected growth was likely due both to the presence of two of the youngest subjects in the rhGH cohort known to show a robust growth response (15.6 and 12.7 cm/yr) and to other imbalances in several baseline characteristics also documented as predictors of greater growth response to rhGH.[1,3,5] The higher than anticipated AHV seen in this moderate PGHD population treated in the rhGH control arm was inconsistent with multiple historical trials in similarly characterized populations, which predicted growth in the 8.3-8.6 cm / year range[1-4]. Baseline characteristics other than age which are predictive of greater growth on therapy include: height (shorter stature), lower height and IGF-1 standard deviation scores (SDS), greater distance from mid-parental height (MPH), and higher body mass index standard deviation score (BMI SDS). Additionally, there was an outlier in the rhGH arm whose AHV was 15.6 cm. The imbalanced baseline parameters of the 1.6 mg/kg LUM-201 arm compared to the rhGH arm are shown in the table below:

Imbalances in Five Baseline Parameters are Predictive of Higher Growth in the rhGH Arm:

Baseline metrics	**1.6 mg LUM-201** Mean (SD) N=10	**rhGH** Mean (SD) N=10
Age in months	99.3 (28.3)	90.3 (26.7)
Height in cm	114.6 (9.6)	111.6 (11.9)
Height SDS	-2.35 (0.62)	-2.29 (0.43)
IGF-1 SDS	-1.17 (0.72)	-1.37 (0.48)
MPH in cm	166.98 (7.15)	168.78 (8.85)
BMI SDS	-0.35 (0.79)	+0.31 (1.05)

We believe the imbalance in age will even out as enrollment progresses since age is a stratification factor. As mentioned earlier, two of the three subjects under five years are in the rhGH cohort and are growth outliers. To date, older subjects are being randomized to the rhGH treatment arm based on the age stratification which would predict a slower growth response to rhGH treatment. With higher enrollment, we believe the imbalance of predictors favoring faster growth is likely to resolve, resulting in greater balance across all cohorts.

OraGrowtH210 Interim Analysis Highlights at Nine and 12 Months

The nine and 12-month interim data available for a subset of the subjects demonstrated the durability of the growth response for LUM-201 at these later treatment intervals, albeit with a smaller number of subjects. The decline in the AHV rate for the rhGH arm was more pronounced over time (11.05 cm/yr at 6 months to 9.93 cm/yr at 12 months) compared to the LUM-201 1.6 mg/kg arm (8.57 cm/yr at six months to 8.14 cm/yr at 12 months).

LUM-201 Demonstrates Durable Growth Rates Out to 12 Months:

OraGrowtH210 AHV	**6 months**		**9 months**		**12 months**	
	cm/year	n	cm/year	N	cm/year	n
0.8 mg/kg/day LUM-201	7.26	11	6.17	5	6.74	4
1.6 mg/kg/day LUM-201	8.57	10	8.48	6	8.14	4
3.2 mg/kg/day LUM-201	7.77	10	6.80	6	6.94	3
34 µg/kg/day rhGH	11.05	10	10.46	7	9.93	4

Recent prior 12-month registration trials for other growth hormone products used a non-inferiority margin of 1.8-2 cm in AHV between the treatment and rhGH arms.

OraGrowtH212 Interim Analysis Highlights

The OraGrowtH212 Trial is a single site, open-label trial evaluating the pharmacokinetic (PK) and pharmacodynamic (PD) effects of oral LUM-201 in up to 24 treatment-naïve PGHD subjects at two dose levels, 1.6 and 3.2 mg/kg/day. Every subject in the OraGrowtH212 Trial was PEM-positive and, therefore, enriched for responsiveness to LUM-201.

The interim analysis of the OraGrowtH212 Trial was performed after ten subjects randomized to one of two LUM-201 treatment arms had completed six months of treatment. The AHV for each arm was comparable to that observed in the OraGrowtH210 Trial. The data also demonstrate the growth is durable out to 12 months, albeit in a more limited number of subjects. This separate study also supports the narrowing of the AHV difference between LUM-201 and rhGH seen in the OraGrowtH210 Trial as subjects approach 12 months on treatment.

LUM-201 in OraGrowtH212 Demonstrates Comparable Growth Rates to OraGrowtH210:

OraGrowtH212	**6 months**		**9 months**		**12 months**	
	cm/year	n	cm/year	n	cm/year	n
1.6 mg/kg/day LUM-201	7.14	5	6.85	4	7.21	2
3.2 mg/kg/day LUM-201	8.60	5	8.00	4	7.78	3

Safety & Tolerability Highlights

We believe LUM-201 will demonstrate a favorable safety profile as data from both OraGrowtH trials to date show comparable safety and tolerability to the rhGH subjects in the trials. There were no treatment-related Serious Adverse Events (SAEs), no drop-outs due to SAE's and no meaningful safety signals observed in either laboratory values, adverse event data, or in electrocardiogram values. The safety data for the OraGrowtH212 Trial is consistent with the data in the OraGrowtH210 Trial.

[*] *Median can be more informative with smaller subject numbers where the mean is distorted by outliers*

[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,* [5] *Yang et.al. Nature Sci Rep 2019*

Conference Call and Webcast Details

Date: November 14, 2022
Time: 8:30 AM ET
Dial-in information: 1-877-407-9716 (U.S.); 1-201-493-6779 (International)
Conference ID: 13733665
Webcast link: https://viavid.webcasts.com/starthere.jsp?ei=1576942&tp_key=000b578e33

Slides will be available at the start of the call through 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 interim results from OraGrowthH210 and OraGrowthH212 trials in greater detail and provide updates on clinical and corporate strategy. Management will be joined by two 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

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

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; a PK/PD trial, the OraGrowthH212 Trial; and a switch trial, the OraGrowthH213 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 the encouraging growth response in our LUM-201 trials, interim data further de-risking the program, the imbalance of predictors in the control arm being expected to resolve and that the imbalance will even out as the enrollment process progresses, progress in our clinical efforts including comments concerning screening and enrollment for our trials, expecting the primary outcome data readout for our trials anticipated developments in 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, our belief that LUM-201 will demonstrate a favorable safety profile 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 including risks related to the final results of our LUM-201 Trials being different than our interim results, the effects of pandemics, other widespread health problems or the Ukraine-Russia conflict, the outcome of our future interactions with regulatory authorities, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to obtain and maintain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the timing and ability of Lumos to raise additional equity capital as needed 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 Annual Report on Form 10-K for the year ended December 31, 2021, as well as other reports filed with the SEC including our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. 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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Lisa Miller

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lumos
PHARMA
Interim Analysis
OraGrowtH210
&
OraGrowtH212
November 14, 2022

Forward Looking Statements

This presentation contains proprietary and confidential information of Lumos Pharma, Inc. ("Lumos," "we," "us" and "our"), and such content should be considered "Confidential Information" and covered by your confidentiality obligations to Lumos. This presentation is made solely for informational purposes, and no representation or warranty, express or implied, is made by Lumos or any of its representatives as to the information contained in these materials or disclosed during any related presentations or discussions.

This presentation contains forward-looking statements of Lumos 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.

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.

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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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make due to a number of important factors, including potential material differences between the interim results of our LUM-201 trials and the final results of the trails which are not known at this time, the effects of pandemics (including COVID-19), other widespread health problems, the Ukraine-Russia conflict, the outcome of our future interactions with regulatory authorities, our ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the ability to obtain the necessary patient enrollment for our product candidate in a timely manner, the ability to successfully develop our product candidate, the timing and ability of Lumos to raise additional equity capital as needed and other risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements. 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 our 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 filed after such Annual Report. 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.

The data contained herein is derived from various internal and external sources. All of the market data in the presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Further, no representation is made as to the reasonableness of the assumptions made within or the accuracy or completeness of any projections or modeling or any other information contained herein. Any data on past performance or modeling contained herein is not an indication as to future performance. 11.12.2022

Investment Highlights

Lead asset targeting children with growth disorders

Novel Oral Rare Disease Asset	• Novel **oral** therapeutic asset, **LUM-201**, for growth hormone deficiency (GHD) disorders • LUM-201 acts within natural endocrine pathway, differentiated from injectable therapies • **Potential to disrupt** significant subset of sizable **injectable market** for GHD
Pipeline in a Product	• Worldwide injectable market for GHD disorders is **$3.4 billion*** • Market for initial oral LUM-201 indication, Pediatric GHD (PGHD), is **$1.2 billion*** • Prior data support potential efficacy of LUM-201 in multiple GHD disorders
Late-stage Trials in PGHD	• Phase 2 OraGrowtH**210** Trial & PK/PD OraGrowtH**212** Trials ongoing • Interim data obtained | Primary outcome data expected 2H 2023 • **Approximately 80% enrolled in Phase 2 OraGrowtH210 Trial**
Solid Financial Position	• Cash balance of **$73.7 million** as of close of **3Q 2022** • Cash runway **into 2Q 2024,** beyond OraGrowtH210 & OraGrowtH212 primary outcome data

PGHD = Pediatric Growth Hormone Deficiency

* USA, Germany, France, Italy, Spain, UK, Japan (Grandview Research, Growth Hormone Market Forecast, 2019)

Interim Analysis: LUM-201 Met Expectations in Idiopathic (PEM+) PGHD

Expected annualized height velocity (AHV) was met

- AHV of 8.6 cm at 6-months on 1.6 mg/kg/day LUM-201, in line with 8.3 cm expected in PEM+ PGHD

Durability of growth response was observed at 9 and 12 months

- LUM-201 AHVs are sustained & converge with rhGH AHVs at 12-month treatment interval

Safety and tolerability profile

- No treatment related SAEs, no trial dropouts due to AEs, and no meaningful safety signal

Evidence of a dose response & Phase 3 dose identified

- Interim safety and efficacy data support selection of 1.6 mg/kg/day for Phase 3

Data support potential for oral LUM-201 to disrupt injectable PGHD market

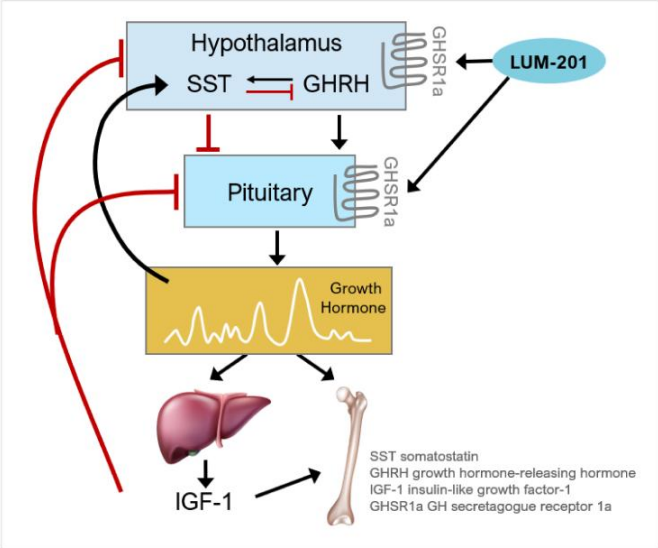
- ~$3.4 billion worldwide GHD market treated by injectable rhGH primed for conversation to oral therapy

SAEs = Serious adverse events AEs = Adverse events

OraGrowtH210 Trial

Phase 2 Trial Evaluating Oral LUM-201 in Moderate PGHD

LUM-201 Stimulates Natural Growth Hormone Secretion



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

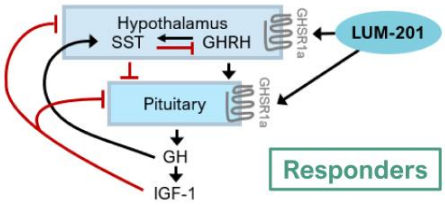
- LUM-201 is an oral GH secretagogue*
- Acts on specific receptors in hypothalamus and pituitary to stimulate release of GH[1]
- Increases the amplitude of natural pulsatile GH secretion[2,3]
- LUM-201 stimulated GH release regulated by natural GH/IGF-1 feedback mechanisms
- Differentiated mechanism 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

~ PEMs = Predictive Enrichment Markers ~
A single dose of LUM-201 can identify likely responders

Moderate (PEM+): Included in Clinical Trials

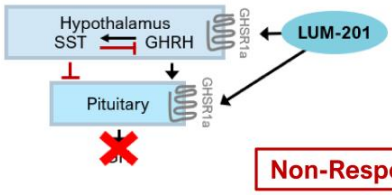


Responders

Moderate (PEM+) = Idiopathic PGHD

Functional but reduced HP-GH axis
- Able to secrete some, but insufficient, GH
- Expected to respond to LUM-201[1]
- Represents ~60% of PGHD patients[2]

Severe (PEM−): Excluded from Clinical Trials



Non-Responders

Severe (PEM−) = Organic PGHD

Non-functional HP-GH axis
- Unable to secrete GH
- Not expected to respond to LUM-201
- Represents ~40% of PGHD patients[2]

(PEM+) PEM-positive = PGHD patients with baseline IGF-1 > 30 ng/ml & stimulated GH ≥ 5 ng/ml
HP-GH axis – hypothalamic pituitary growth hormone axis

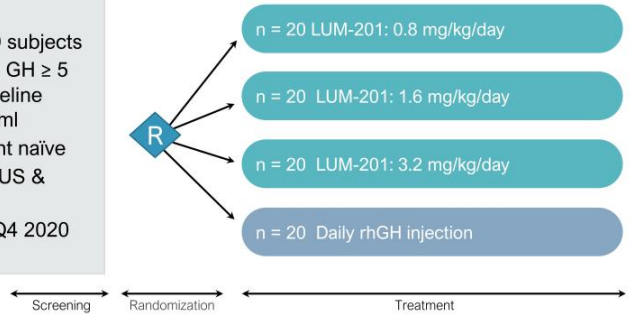
[1] Bright 2021 JES
[2] Blum 2021 JES

OraGrowthH210 Trial: Phase 2 Trial in PGHD

OraGrowthH210 TRIAL

- n = 80
- PEM(+) PGHD subjects
- Inclusion: stim GH ≥ 5 ng/ml and baseline IGF-1 >30 ng/ml
- rhGH treatment naïve
- ~40 trial sites US & International
- Trial opened Q4 2020

Interim Data Analysis (n = **40**) – at **6 months** on therapy
Primary Outcome Data (n = **80**) – at **6 months** on therapy
Total Study Duration – 24 months



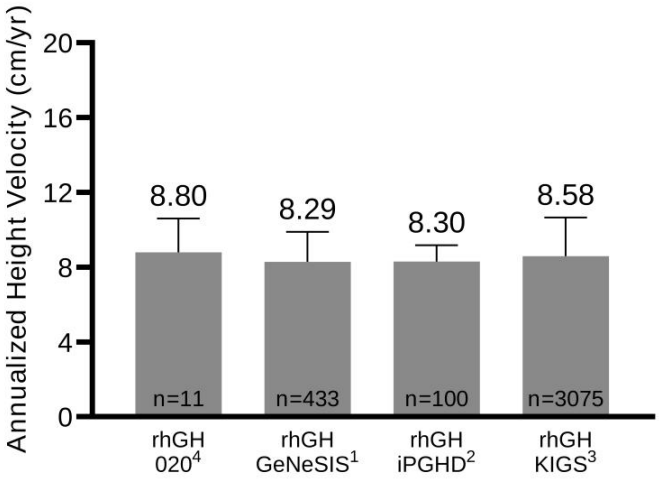
Objectives

Primary Endpoint:
- Annualized Height Velocity (AHV)

Goals:
- Prospectively confirm utility of PEM strategy
- Determine optimal dose for Phase 3

Interim AHV and safety data on 40 subjects at 6 months on therapy announced Nov 14, 2022
Primary outcome data for OraGrowthH210 Trial on 80 subjects anticipated 2H2023

Historical Data for rhGH Growth Rates in Moderate PGHD Patients



Historical Datasets

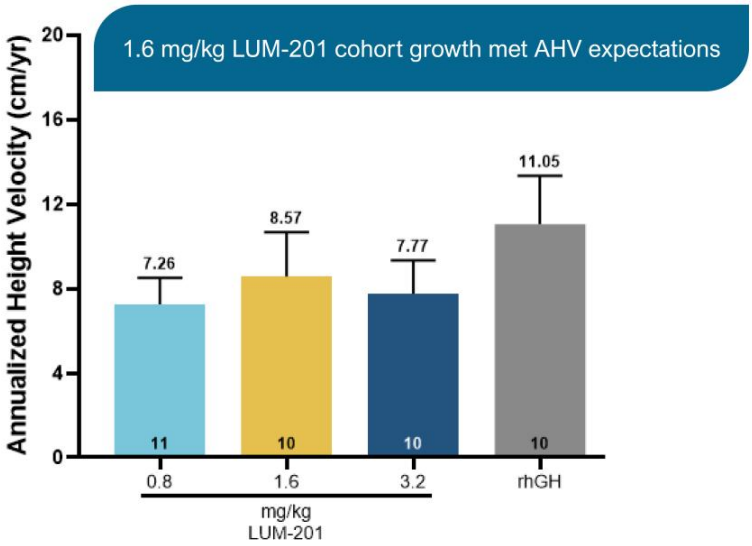
- GeNeSIS[1], iPGHD[2], and KIGS[3] AHV from 12 months of rhGH
- Merck 020[4] AHV from 6 months of rhGH
- These trials set precedent for expected growth on rhGH in moderate PGHD

Prediction

- Prediction for growth in OraGrowthH210 is AHV of ~8.3 cm/yr on both rhGH and LUM-201 based on this historical data

Sources: 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.

OraGrowtH210 Interim Analysis: AHV at 6 Months (41 Subjects)

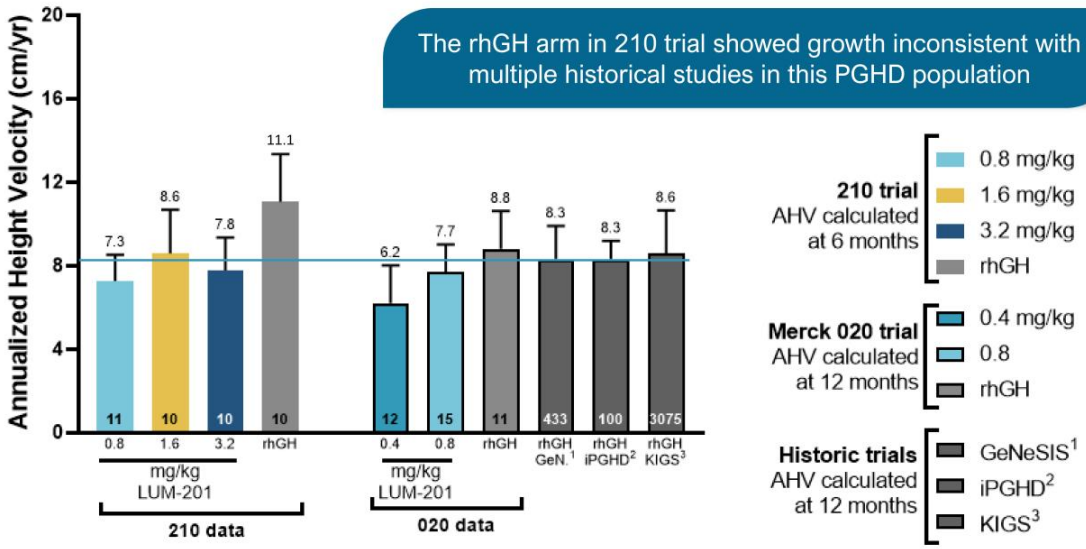


Results

- LUM-201 1.6 mg/kg/day cohort grew 8.6 cm/yr, in line with the expected rate of 8.3 cm/yr based on prior data
- rhGH cohort grew at a much faster rate than expected or previously reported in moderate PGHD population
- Cohort baseline differences predict faster first-year growth in the rhGH arm[1,2]
- The balance between cohorts should continue to improve with further enrollment

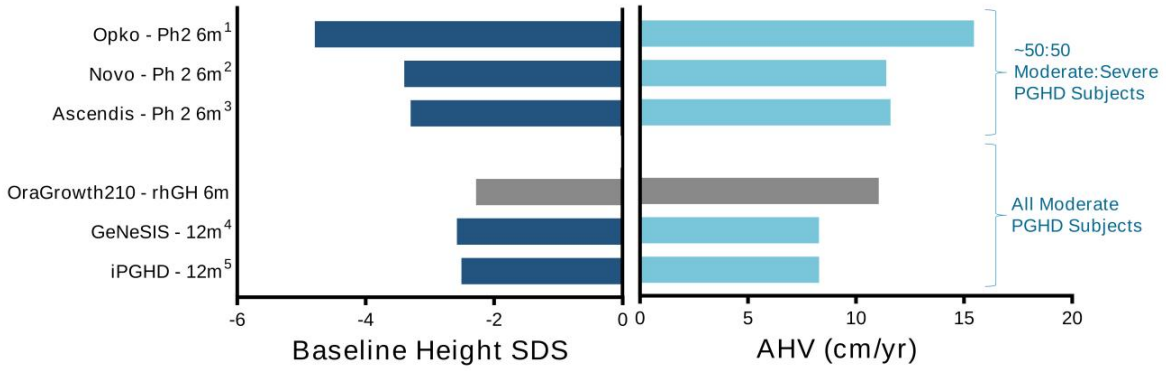
1 Blum et al JES 2021, 2 Ranke et al JCEM 2010

LUM-201 Growth in 210 Trial is Consistent with Historical Precedent



Sources: 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.

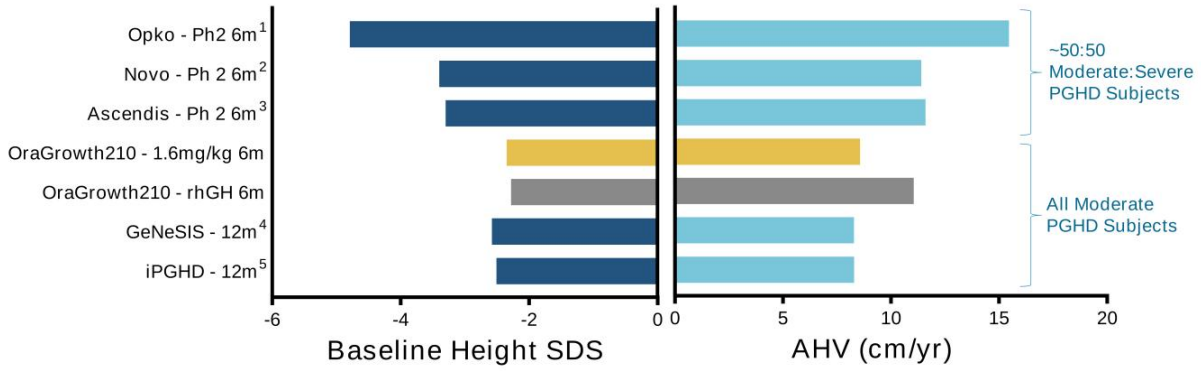
OraGrowtH210 Trial rhGH Cohort Grew More than Historical Norms in Moderate PGHD Patient Population



Unprecedented rhGH growth response in OraGrowtH 210 in moderate PGHD likely due to outlier & small sample size
Expect larger N from fully enrolled dataset to reduce impact of growth outliers

1) Rosenfeld, ENDO 2014 presentation interim analysis, full analysis Zelinska et al JCEM 2017 2) Sävendahl et al JCEM, 2020 3) Chatelain et al JCEM, 2017
4) Blum et al JES 2021 5) Lechuga-Sancho et al JPEM 2009

OraGrowtH210 Trial rhGH Cohort Grew More than Historical Norms in Moderate PGHD Patient Population



Unprecedented rhGH growth response in OraGrowtH 210 in moderate PGHD likely due to outlier & small sample size
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1) Rosenfeld, ENDO 2014 presentation interim analysis, full analysis Zelinska et al JCEM 2017 2) Sävendahl et al JCEM, 2020 3) Chatelain et al JCEM, 2017
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Key Baseline Characteristics that Predict Better AHV With rhGH Treatment of PGHD Patients

Historical data from multiple peer-reviewed scientific publications demonstrate the following metrics as key predictors of first-year growth

- Baseline Age
  - Age is the top predictor of growth on treatment
  - **Younger PGHD subjects grow faster[1]**
- Baseline Height
  - **Shorter stature at baseline predicts greater 1st year growth[2]**
- Baseline IGF-1 SDS
  - **Lower baseline IGF-1 SDS predicts faster growth[3]**
- Baseline Mid-parental height & Delta MPH SDS
  - **Greater mid-parental height and subject Height SDS farther below MPH SDS predicts greater 1st year growth[4]**
- Baseline weight (BMI)
  - **Greater baseline weight (higher BMI) predicts faster growth[5]**

[1] Ranke, et al. Growth Horm & IGF Res (2009) 19:1–11; Lee, et al. Internat J Pediat Endocrin (2011):6; Yang, et al. Nature Sci Rep (2019) 9(1):16181; Blum et al JES (2021); Ranke et al JCEM (2010); Blethen, et al. JCEM (1993 Mar);76(3):574-9; Cho, et al. J Korean Med Sci. (2020 May) 35(19):e151
[2] Ranke, et al. Growth Horm & IGF Rese (2009) 19:1–11; Lee, et al. Intern J Pediat Endocrin (2011):6; Cho, et al. J Korean Med Sci. (2020 May) 35(19):e151; Ranke et al. JCEM (2005) 90(4);1966-1971
[3] Ranke, et al. Growth Horm & IGF Res (2009) 19:1–11; Lee, et al. Internat J Pediat Endocrin (2011):6
[4] Ranke, et al. Growth Horm & IGF Res (2009) 19:1–11; ; Lee, et al. Intern J Pediat Endocrin (2011):6; Cho, et al. J Korean Med Sci. 2020 May 18;35(19):e151
[5] Ranke, et al. Growth Horm & IGF Res (2009) 19:1–11; Lee, et al. Intern J Pediat Endocrin 2011:6; Cho, et al. J Korean Med Sci. 2020 May 18;35(19):e151; Blethen, et al. JCEM (1993 Mar);76(3):574-9; Ranke, et al. JCEM (2005) 90(4);1966-1971; Yang, et al. Nature Sci Rep 2019, 9(1); 16181

OraGrowtH210 Trial Baseline Characteristics – at Interim Data (N=41)

Imbalance in baseline characteristics between rhGH and LUM-201 arms

	LUM-201 0.8 mg Mean (SD) N=11	LUM-201 1.6 mg Mean (SD) N=10	LUM-201 3.2 mg Mean (SD) N=10	rhGH Mean (SD) N=10
Age (months)	95.5 (28.2)	99.3 (28.3)	96.1 (21.7)	90.3 (26.7)
Height (cm)	113.8 (12.6)	114.6 (9.6)	113.8 (8.8)	111.6 (11.9)
Height SDS	-2.31 (0.32)	-2.35 (0.62)	-2.30 (0.48)	-2.29 (0.43)
Max Height SDS	-1.76	-1.66	-1.57	-1.73
IGF-1 SDS	-1.24 (0.573)	-1.17 (0.72)	-1.39 (0.61)	-1.37 (0.48)
Max IGF-1 SDS	-0.3	-0.3	-0.6	-0.7
MPH (cm)	164.47 (6.44)	166.98 (7.15)	166.20 (8.06)	168.78 (8.85)
MPH SDS Δ	1.29 (0.62)	1.76 (0.60)	1.96 (0.83)	1.76 (0.73)
BA Delay (yrs)	1.89 (1.02)	1.91 (0.53)	2.19 (0.86)	1.78 (0.96)
BMI SDS[1]	-0.29 (1.04)	-0.35 (0.79)	-0.70 (0.48)	+0.31 (1.05)

Baseline characteristics for the rhGH arm predict this cohort will show a faster first-year growth rate on treatment than the LUM-201 cohorts [2,3]

[1] Yang, et al. Nature Sci Rep 2019, 9(1); 16181 [2] Blum et al JES 2021, [3] Ranke et al JCEM 2010

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

Baseline Comparison of 1.6mg Arm to Control Arm

	LUM-201 1.6 mg Mean (SD) N=10	rhGH Mean (SD) N=10
Age in months	99.3 (28.3)	90.3 (26.7)
Height in cm	114.6 (9.6)	111.6 (11.9)
Height SDS	-2.35 (0.62)	-2.29 (0.43)
Min Height SDS	-3.90	-3.07
IGF-1 SDS	-1.17 (0.72)	-1.37 (0.48)
Max IGF-1 SDS	-0.3	-0.7
MPH in cm	166.98 (7.15)	168.78 (8.85)
MPH SDS Δ	1.76 (0.60)	1.76 (0.73)
BA Delay in years	1.91 (0.53)	1.78 (0.96)
BMI SDS[1]	-0.35 (0.79)	+0.31 (1.05)
Growth outliers	---	1 @ 15.6 cm/yr

rhGH Anomaly

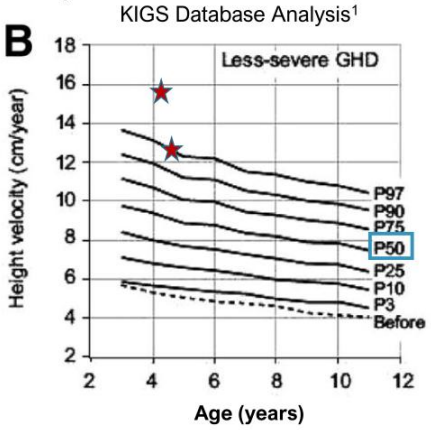
- Key baseline characteristics of rhGH cohort predicted greater growth on treatment than historical norms would suggest
- Significant outlier in rhGH cohort of 15.6 cm/yr AHV
- As trial enrolls more subjects, unprecedented imbalance of predictors of growth will likely converge as seen in our 12-month data

Differences between ~50 and 80% enrollment are significant for rhGH arm

[1] Yang, et al. Nature Sci Rep 2019, 9(1); 16181 [2] Blum et al JES 2021, [3] Ranke et al JCEM 2010
SDS = Standard deviation score MPH = Mid-parental height (Child's target height) MPH SDS delta = SD's from target height BA = Bone age BMI = Body mass index

Growth Outliers in the rhGH Cohort: 2/3 Subjects under 5 Randomized to rhGH

First-year Growth on rhGH for Moderate PGHD
KIGS Database Analysis[1]



★ OraGrowtH210 youngest subjects in rhGH cohort at 6-months AHV

P lines = Percentiles
"Before" line marks height velocity before GH therapy

[1] Ranke, et al 2010 JCEM

OraGrowtH210 Trial Baseline Characteristics – at ~75% Enrollment

Balance improves at ~75% enrollment

	LUM-201 0.8 mg Mean (SD) N=14	LUM-201 1.6 mg Mean (SD) N=15	LUM-201 3.2 mg Mean (SD) N=14	rhGH Mean (SD) N=15
Age (months)	99.1 (28.3)	98.4 (28.6)	92.9 (22.6)	94.1 (23.7)
Height (cm)	115.1 (12.5)	114.6 (11.2)	112.4 (9.2)	113.4 (10.6)
Height SDS	-2.32 (0.3)	-2.31 (0.5)	-2.32 (0.4)	-2.25 (0.4)
Max Height SDS	-1.76	-1.66	-1.57	-1.73
IGF-1 SDS	-1.43 (0.67)	-1.30 (0.67)	-1.35 (0.57)	-1.32 (0.46)
Max IGF-1 SDS	-0.3	-0.3	-0.6	-0.7
MPH (cm)	165.5 (7.1)	164.3 (7.2)	166.1 (7.0)	168.5 (7.9)
MPH SDS Δ	1.43 (0.66)	1.70 (0.54)	1.92 (0.73)	1.75 (0.63)
BA Delay (yrs)	1.89 (1.02)	1.91 (0.53)	2.20 (0.86)	1.68 (0.9)
BMI SDS[1]	-0.47 (1.09)	-0.38 (0.91)	-0.55 (0.79)	+0.14 (1.08)

At ~75% enrollment balance between arms is very good, effect of outliers should be diminished

[1] Yang, et al. Nature Sci Rep 2019, 9(1); 16181 [2] Blum et al JES 2021, [3] Ranke et al JCEM 2010

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

Baseline Comparison of rhGH Arm at N=15 and N=10

	rhGH Mean (SD) N=15	rhGH Mean (SD) N=10
Age in months	94.1 (23.7)	90.3 (26.7)
Height in cm	113.4 (10.6)	111.6 (11.9)
Height SDS	-2.25 (0.4)	-2.28 (0.43)
Max Height SDS	-1.73	-1.73
IGF-1 SDS	-1.32 (0.46)	-1.37 (0.48)
Max IGF-1 SDS	-0.7	-0.7
MPH in cm	168.5 (7.9)	168.78 (8.54)
MPH SDS Δ	1.75 (0.63)	1.76 (0.73)
BA Delay in years	1.68 (0.9)	1.78 (0.96)
BMI SDS[1]	+0.14 (1.1)	+0.31 (1.05)
Growth outliers	?	1 @ 15.6 cm/yr

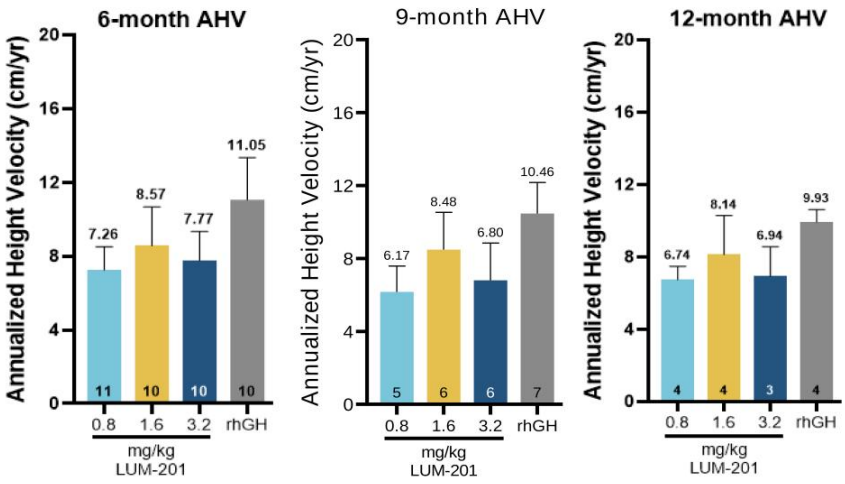
rhGH Anomaly

- Key baseline characteristics of earlier rhGH cohort predicted greater growth on treatment than historical norms would suggest
- Significant outlier in rhGH cohort of 15.6 cm/yr AHV
- As trial enrolls more subjects, baseline predictors of growth converge as seen at ~75% enrollment

Differences between ~50 and ~75% enrollment are significant for rhGH arm

[1] Yang, et al. Nature Sci Rep 2019, 9(1); 16181 [2] Blum et al JES 2021, [3] Ranke et al JCEM 2010
SDS = Standard deviation score MPH = Mid-parental height (Child's target height) MPH SDS delta = SD's from target height BA = Bone age BMI = Body mass index

210 Data: LUM-201 Demonstrates Durable Response to 12 Months



Conclusions

- LUM-201 growth rates consistent from 6 to 12 months
- rhGH growth rates decline more from 6 to 12 months, narrowing the AHV Δ between the arms at 12 months
- A Phase 3 non-inferiority trial is expected to be a 12-month study in a much larger population
- Historically, non-inferiority margin for AHV's in Phase 3 trials was ~2 cm

OraGrowtH212 Trial

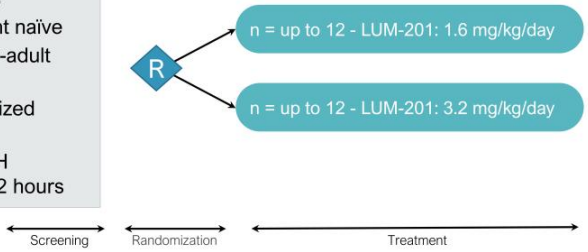
PK/PD Trial Evaluating Oral LUM-201 in PGHD

OraGrowthH212 Trial: Pharmacokinetic / Pharmacodynamic Trial in PGHD

OraGrowthH212 TRIAL

- n = up to 24
- Open-label study
- PGHD patients
- rhGH-treatment naïve
- Dosing to near-adult height
- Single, specialized clinical site
- Q10 minute GH sampling for 12 hours

Interim Data Analysis (**n =10**) – at **6 months** on therapy
Primary Outcome Data (**n = up to 24**) – at **6 months** on therapy
Total Study Duration – subjects on therapy to near adult height



Objectives

Primary Endpoints:

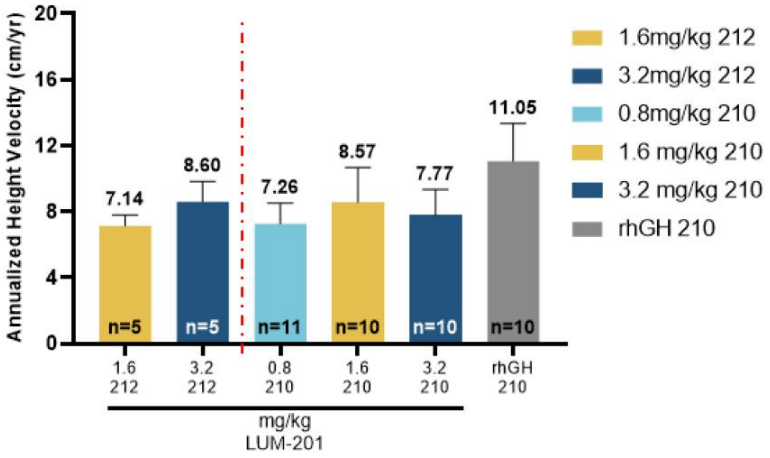
- Assess LUM-201 effect on endogenous GH pulsatility and Annualized Height Velocity (AHV)
- Evaluate PK/PD in children

Goals:

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

Interim AHV and safety data on 10 subjects announced Nov. 14, 2022
Primary outcome data on up to 24 patients anticipated 2H 2023

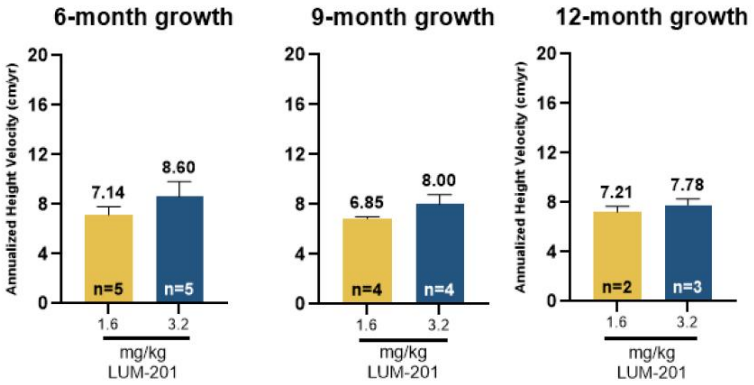
OraGrowthH212 & OraGrowthH210 Comparative AHVs at 6 Months



Conclusions

- OraGrowthH212 Trial results showed a similar growth rate to OraGrowthH210 Trial
- Anticipate fully enrolled datasets and larger N from both trials to strengthen these results
- Anticipate larger Phase 3 trial to further support the LUM-201 growth rate seen in OraGrowthH210 and OraGrowthH212

OraGrowtH212 Data Demonstrate Durable Response

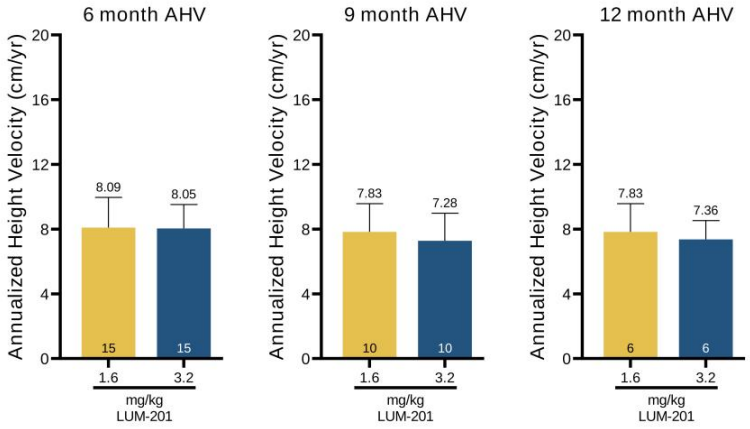


Conclusions

- OraGrowth212 data also demonstrate growth is durable out to 12 months
- This separate study supports the narrowing of the AHV difference seen in the 210 trial as subjects approach 12 months on treatment
- A Phase 3 non-inferiority trial is expected to be a 12-month study in a much larger population

OraGrowthH210 & OraGrowthH212 Interim Data Combined

Annualized Height Velocity for LUM-201
Combined Data from OraGrowthH210 & OraGrowthH212 Trials



Conclusions

- Post-hoc analysis of combined data conducted to determine optimal dose for Phase 3
- Comparable mean AHVs for top 2 LUM-201 doses seen at 6,9, and 12 months
- Combined interim data supports selection of 1.6 mg/kg/day dose for pivotal Phase 3 trial

Safety and Tolerability

Interim Safety and Tolerability Profile

- We believe LUM-201 will demonstrate a favorable safety profile as data from both OraGrowtH trials to date show comparable safety and tolerability to the rhGH subjects in the trials.

- **No meaningful safety signals to date**
  - In laboratory values
  - In Adverse Event (AEs) data
  - In ECGs values

Financials

Lumos Pharma Financial Information as of September 30, 2022

Values in USD

Cash	$73.7M
Debt	$0
Shares Outstanding	8.4M
Cash Use in Q4 2022	$8.5-$9.5M
Fiscal Year End	December 31

Cash balance to support current operations into 2Q 2024,
Beyond primary outcome data readouts for OraGrowtH210 and OraGrowtH212 Trials 2H 2023

Conclusions

Interim Analysis: LUM-201 Met Expectations in Idiopathic (PEM+) PGHD

Expected annualized height velocity (AHV) was met

- AHV of 8.6 cm at 6-months on 1.6 mg/kg/day LUM-201, in line with 8.3 cm expected in PEM+ PGHD

Durability of growth response was observed at 9 and 12 months

- LUM-201 AHVs are sustained & converge with rhGH AHVs at 12-month treatment interval

Safety and tolerability profile

- No treatment related SAEs, no trial dropouts due to AEs, and no meaningful safety signal

Evidence of a dose response & Phase 3 dose identified

- Interim safety and efficacy data support selection of 1.6 mg/kg/day for Phase 3

Data support potential for oral LUM-201 to disrupt injectable PGHD market

- ~$3.4 billion worldwide GHD market treated by injectable rhGH primed for conversation to oral therapy

SAEs = Serious adverse events AEs = Adverse events

Interim Analysis
Supplemental Materials

Safety Profile at Interim Analysis for OraGrowtH210 Trial

66 subjects randomized to date with safety data available for 58 subjects at interim analysis

	PEM Dose*	0.8 mg/kg	1.6 mg/kg	3.2 mg/kg	ALL LUM-201	rhGH 34 mcg/kg
N =	**86**	**14**	**15**	**14**	**43**	**15**
Number of AEs	29	31	45	38	114	21
Subjects with AE (%)	17 (19.8%)	8 (57.1%)	13 (86.7%)	9 (64.3%)	30 (69.8%)	9 (60.0%)
Treatment Related AEs (N)	7	2	1	3	6	3
Subjects with Treatment Related AEs (%)	4 (4.7%)	1 (7.1%)	1 (6.7%)	2 (14.3%)	4 (9.3%)	2 (13.3%)
Subjects with SAEs (%)**	1 (1.2%)**	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

*Subjects that received a single PEM dose during screening and prior to randomization are included in the safety database, not included in ALL LUM-201
**PEM dose SAE deemed not treatment related: Dehydration related to Rotavirus infection acquired between PEM dose & randomization

Specific AEs – No meaningful signal

66 subjects randomized to date with safety data available for 58 subjects at interim analysis

	PEM Dose* N=86	0.8 N=14	1.6 N=15	3.2 N=14	ALL N=43	rhGH N=15
Arthralgia	1 (1.2%)	1 (7.1%)	2 (13.3%)	2 (14.3%)	5 (11.6%)	1 (6.7%)
Myalgia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (20.0%)
Headache	2 (2.3%)	2 (14.3%)	3 (20.0%)	2 (14.3%)	7 (16.3%)	2 (13.3%)
Lethargy	2 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abd. pain	1 (1.2%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	2 (4.7%)	0 (0.0%)
Emesis	2 (2.3%)	1 (7.1%)	1 (6.7%)	1 (7.1%)	3 (7.0%)	1 (6.7%)
Inc. appetite	2 (2.3%)	1 (7.1%)	1 (6.7%)	0 (0.0%)	2 (4.7%)	2 (13.3%)
Hypoglycemia	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Orophary. pain	0 (0.0%)	1 (7.1%)	1 (6.7%)	0 (0.0%)	2 (4.7%)	1 (6.7%)

*Subjects that received a single PEM dose during screening and prior to randomization are included in the safety database, not included in ALL LUM-201

Specific AEs - No meaningful signal

66 subjects randomized to date with safety data available for 58 subjects at interim analysis

	PEM Dose N=86	0.8 N=14	1.6 N=15	3.2 N=14	ALL N=43	rhGH N=15
Asthma	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (2.3%)	0 (0.0%)
Hyperhydrosis	2 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rash	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (7.1%)	2 (4.7%)	0 (0.0%)
Urticaria	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Inj. Site bruising	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Hematuria	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
FT4 decrease	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Urine ketones	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypotension	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

*Subjects that received a single PEM dose during screening and prior to randomization are included in the safety database, not included in ALL LUM-201

Laboratory Shifts: No meaningful signal

*66 subjects randomized to date with safety data available for 58 subjects at interim analysis**

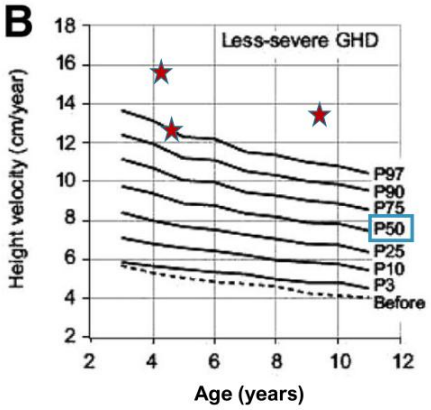
	0.8 mg/kg N=14	1.6 mg/kg N=15	3.2 mg/kg N=14	ALL N=43	rhGH N=15
ALT NI to high	2/12 (16.7%)	1/15 (6.7%)	2/12 (16.7%)	5/39 (12.8%)	5/12 (41.7%)
TAP NI to high	1/12 (8.3%)	0/15 (0.0%)	1/12 (8.3%)	2/39 (5.1%)	5/12 (41.7%)
Bili NI to high	0/13 (0.0%)	0/15 (0.0%)	0/13 (0.0%)	0/41 (0.0%)	0/15 (0%)
Creat. NI to high	0/13 (0.0%)	0/15 (0.0%)	0/13 (0.0%)	0/43 (0.0%)	0/12 (0%)
Gluc NI to high	0/13 (0.0%)	3/15 (20.0%)	1/13 (7.7%)	4/41 (9.8%)	1/12 (8.3%)
Phos. NI to high	3/13 (23.1%)	2/15 (13.3%)	3/13 (23.1%)	8/41 (19.5%)	5/12 (41.7%)
Eos NI to high	2/11 (18.2%)	3/15 (20.0 %)	2/13 (15.4%)	7/39 (17.9%)	3/12 (25.0%)
Gran. NI to low	1/11 (9.1%)	3/15 (20.0%)	4/13 (30.8%)**	8/39 (20.5%)	1/12 (8.3%)
Gran. NI to high	0/11 (0.0%)	1/15 (6.7%)	2/13 (15.4%)**	3/39 (7.7%)	0/12 (0%)

* Percentages calculated based on subjects with both baseline and post-baseline assay data ** Bidirectional shifts diminish any concern

Baseline Characteristics for Top Dose Cohorts in 210 and 212 Studies

	210 1.6 mg/kg N=10	210 3.2 mg/kg N=10	212 1.6 mg/kg N=5	212 3.2 mg/kg N=5
Age (Mos)	99.3	96.1	93.6	91.0
Height SDS	-2.35	-2.30	-1.99	-2.26
IGF-1 SDS	-1.17	-1.39	-1.11	-0.83
Delta MPH	1.76	1.96	0.57	0.70
BA delay yr	1.91	2.19	1.59	1.96
BMI SDS	-0.35	-0.70	0.05	0.66
AHV @ 6 Mos	8.57	7.77	7.14	8.60

Growth Outliers in the rhGH Cohort: 2/3 Subjects under 5 Randomized to rhGH



★ OraGrowtH210 Top growers in rhGH cohort at 6-months AHV outlier

P lines = Percentiles
"Before" line marks height velocity before GH therapy

Ranke, et.al. 2010 JCEM

Ranke Model is the Gold Standard in Growth Prediction for GHD

PHV = 14.55 + [-1.37 X (ln max GH stim)] + (-0.32 X Age) + (0.32 X BWt SDS) + (-0.5457) + (-0.4 X HtSDS-MPH SDS) + (0.29 X Wt SDS)

• Parameter Rank 1st	[-1.37 X (ln max GH stim)]	A measure of how GHD subject is by stim test value
• Parameter Rank 2nd	(-0.32 X Age)	Age at treatment start is a very important predictor
• Parameter Rank 6th	(0.32 X BWt SDS)	Birth weight SDS
• Parameter Rank 5th	(-0.5457)	Dose of rhGH (constant for this trial)
• Parameter Rank 3rd	(-0.4 X HtSDS-MPH SDS)	Measure of how far away from their target height
• Parameter Rank 4th	(0.29 X Wt SDS)	Body weight at start of treatment

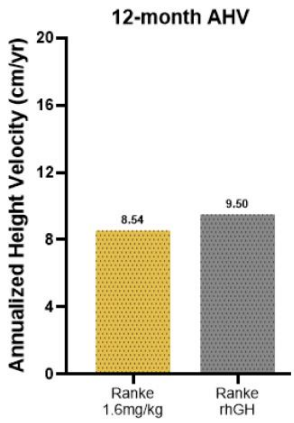
- The model was developed based on mining the KIGS data set of rhGH PGHD treatment data
  - Phase 4 database for Genotropin N= 593 when model developed
  - Developed models to predict 1st, 2nd, 3rd, 4th year growth

Growth for both rhGH and LUM-201 1.6 mg/kg cohorts was predicted using Ranke models

Ranke et al JCEM 1999 | PHV = Predictive Height Velocity | Age = Baseline Age | BWt = Birth Weight | Wt = Weight at Start of Treatment | SDS = Standard Deviation Score

What does Ranke Model Predict about Growth in our Trial Cohorts?

Growth predicted using baseline characteristics of subjects enrolled in OraGrowthH210



Ranke Model

- Our assessment is that the key baseline characteristics, particularly age, between cohorts are enough to bias the rhGH cohort towards more growth at 50% enrollment
- Ranke model agrees with our baseline demographic assessment

Fully enrolling each cohort should balance out ages because age is one of the stratification factors for the trial

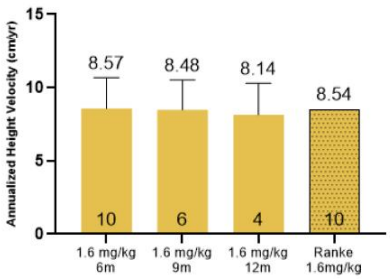
Ranke et al JCEM 1999

What does Ranke Model Predict about Growth in our Trial Cohorts?

Growth predicted using baseline characteristics of subjects enrolled in OraGrowthH210

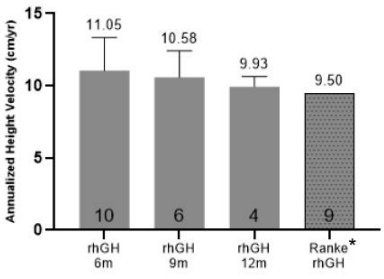
1.6 mg/kg Cohort

Annualized Height Velocity: Ranke-predicted vs observed



rhGH Cohort

Annualized Height Velocity: Ranke-predicted vs observed



Fully enrolling each cohort should minimize the impact of growth outliers

Key Observations

- 1.6 mg/kg cohort is aligned with Ranke model predictions at all time points
- rhGH cohort grows faster than predicted likely due to outliers
- The main growth outlier in rhGH arm has not made it to 12 months yet and is not included in 12-month AHV
- Trial is stratified by age: First 10 rhGH subjects were younger; Second 10 subjects should be older
- rhGH AHV declines more rapidly over time than does LUM-201 AHV

Ranke et al JCEM 1999

* rhGH cohort Ranke analysis conducted with n=9 from data pull prior to availability of full interim dataset


lumos
PHARMA
Additional
Supplemental Materials
42

Management – Significant Clinical Development and Commercial Experience

Richard Hawkins
Chairman & CEO
Developed Growth Hormone (GH) Receptor Antagonist for Acromegaly at Sensus (sold to Pfizer). Built one of the first contract recombinant protein manufacturing facilities (Covance Biotechnology). Founder of Pharmaco, a pioneer in the contract research organization sector (merged with PPD).

David Karpf, MD
Chief Medical Officer
Adjunct Clinical Professor, Endocrinology, Stanford University School of Medicine. Former VP, Clinical Development at Ascendis Pharma; projects include long-acting TransCon GH and PTH injectables, among other compounds. Prior biotech CMO. Clinical R&D leadership roles at Roche and Merck.

Aaron Schuchart, MBA
Chief Business Officer
Former CBO of Aeglea BioTherapeutics, former leadership roles in Business Development, Strategy, and Finance at Coherus Biosciences, Novartis Diagnostics/Grifols, and Amgen.

John McKew, PhD
President & Chief Scientific Officer
Prior VP of Research at aTyr Pharma – led team advancing protein-based therapeutics for rare diseases. Former Scientific Director, NIH - National Center for Advancing Translational Science (NCATS) and Therapeutics for Rare and Neglected Diseases (TRND). Director level, Wyeth Research Genetics Institute.

Lori Lawley, CPA
Chief Financial Officer
Former SVP, Finance and Controller at Lumos Pharma. Previously, SVP, Finance and Member of the Office of the CEO of NewLink Genetics. Prior to that, Senior Manager in Assurance Services at Ernst and Young.

Pisit "Duke" Pitukcheewanont, MD
VP Global Clinical Dev & Medical Affairs
Pediatric endocrinologist and Professor, Clinical Pediatrics, Keck School of Medicine, USC. Incoming President, Human Growth Foundation. Former VP Medical Affairs and VP Global Medical Ambassador & Medical Education at Ascendis Pharma; project: long-acting TransCon GH. Former Advisory Board member at Pfizer, Ipsen, Alexion, Ultragenyx, Pharmacia, Serono, and others.

LUM-201 Program Pipeline

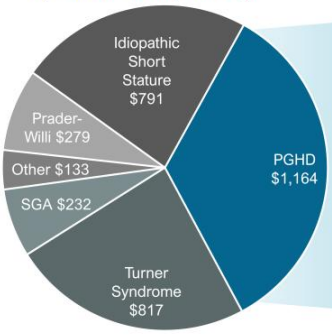
	Study	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (Ibutamoren) In PGHD	Phase 2	OraGrowtH210 TRIAL				Ongoing Phase 2 trial: Interim analysis obtained Primary outcome data 2H 2023
	Long-term extension	OraGrowtH211 TRIAL				Proposed long-term extension study for OraGrowtH Trials
	PK/PD trial	OraGrowtH212 TRIAL				Ongoing PK/PD trial: Interim analysis obtained Primary outcome data 2H 2023
	Switch trial	OraGrowtH213 TRIAL				Switch trial evaluating LUM-201 in subjects from rhGH arm of OraGrowtH210 Trial: Ongoing
LUM-201 In NAFLD	Phase 2 pilot trial	MGH pilot trial				Pilot trial initiated by Mass Gen Hospital (MGH) evaluating LUM-201 in NAFLD: Prescreening

Lumos Pharma is evaluating additional indications for LUM-201 for Phase 2 studies

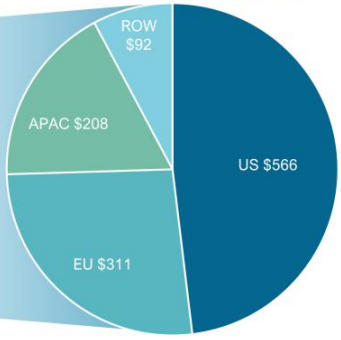
PGHD Pediatric Growth Hormone Deficiency NAFLD Non-Alcoholic Fatty Liver Disease MGH Massachusetts General Hospital

PGHD is ~35% of the $3.4B Pediatric Recombinant Growth Hormone Market

2018 Global rhGH Sales $3.4B*
(Values below in $millions)



2018 Sales of rhGH for PGHD $1.2B*
(Values below in $millions)



- Pediatric rhGH market projected to grow ~8% per year*
- Well characterized market with established reimbursement mechanisms
- Current SOC consists of daily injectables; expected to convert to weekly injectables
- **Pediatric rhGH market appears primed for conversion to oral therapy**

*Grandview Research, hGH Market, 2018, excludes Adult Growth Hormone Deficiency

Market Research: Daily Oral Therapeutic Preferred Over Weekly Injectable

Consideration	Market Research Findings[1]
Unmet Need	Non-injectable (oral) therapy; Less frequent administration of injectable therapy
Preference	Vast majority of physicians & caregivers surveyed prefer daily oral tablet over weekly injectable
MOA	Favorable impression regarding LUM-201 affecting natural physiology vs bolus rhGH treatment
Treatment Decisions	Collaborative between physicians and caregivers
Payer Decisions	Price policies in place for category – small molecule COGS should provide attractive margins

Interview Question:
If a daily oral secretagogue and a weekly rhGH injectable product were both FDA-approved and available for use, which product would you prefer?

[1] Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights. Physicians N = 20. Caregivers N = 9.

Pediatric Growth Hormone Deficiency (PGHD) – Conversion from Injection to Oral

PGHD

- **Inadequate secretion of growth hormone during childhood**
- Majority of cases are idiopathic
- Slower physical growth
- Negative effect on metabolic processes
- Incidence ≈ 1:3500[1]

Current Treatment

- **Injectable therapies are only options**
- Daily, subcutaneous injections of recombinant human growth hormone (rhGH) represent standard of care
- Weekly rhGH injections are entering the market

Unmet Need

- **Standard treatment is ~2,500 daily injections over multi-year period**
- Injections can be painful and burdensome
- Missed doses lead to suboptimal growth[2,3]
- Initial market research supports oral therapy vs weekly injections

An established market is now primed for the first oral alternative

[1] GlobalData EpiCast Report for Growth Hormone Deficiency Epidemiology forecast to 2026
[2] Rosenfeld 2008 Endocrine Practice
[3] Cutfield 2011 PLOS ONE

Significant Prior Clinical Experience with LUM-201 – Both Pediatric and Adult

- Multiple trials were conducted by Merck prior to Lumos acquisition of LUM-201 in July 2018
- Six large-scale adult studies (n ~1,000)
  - In every adult indication, IGF-1 and/or GH levels were meaningfully increased from baseline by LUM-201 treatment
- Three clinical trials in pediatric patients (n ~200)
  - Phase 1 Study 019 – Pharmacokinetics/Pharmacodynamics
  - Phase 2 Study 020 – Patients naïve to treatment
  - Phase 2 Study 024 – Patients previously treated with rhGH
- No significant safety concerns were identified in any of the studies

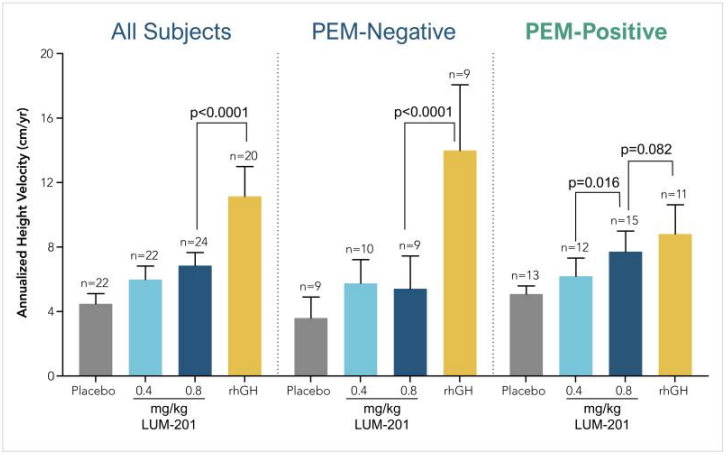
Lumos conducted post-hoc analysis of Study 020

- Established definition of "PEM-positive" patients as those with a functional but reduced HP-GH axis
- Revealed striking efficacy differential in PEM-positive patients, that will serve as basis for future trials
- Data strongly support potential for improved efficacy at higher doses
- Analysis generated IP for use of LUM-201 in PGHD and other growth hormone deficiency indications

Study 020 Post-Hoc Analysis: PEM-Positive Patients Responsive to LUM-201

PEM = Predictive Enrichment Marker

- Naïve PGHD, Study 020[1]
  - N=68; three arms
  - Placebo patients switched to rhGH at 6 months
  - Annualized growth shown for each arm
- PEM-positive subset:
  - LUM-201 0.8 mg/kg not statistically different from rhGH
  - Dose response: 0.8 mg/kg statistically superior to 0.4 mg/kg



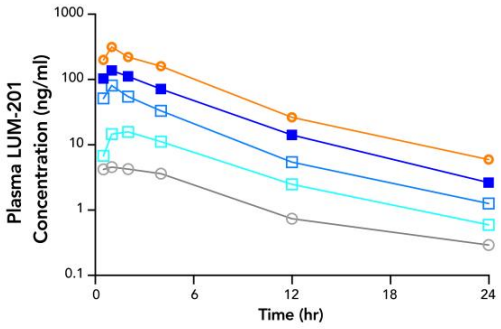
Expect prospective inclusion of only PEM(+) patients and higher doses to improve response to LUM-201

[1] Bright 2021 JES

PK/PD: Evidence of a PK and PD Dose Response in Healthy Volunteers

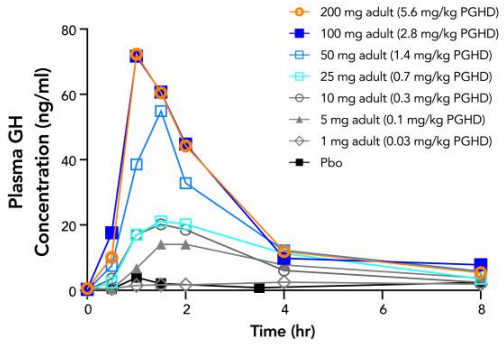
Pharmacokinetics

Dose response to 5.6 mg/kg PGHD dose equivalent*



Pharmacodynamics

PD plateau possible ≥ 2.8 mg/kg PGHD dose equivalent*



Higher LUM-201 doses produce higher plasma concentrations of LUM-201 & GH up to PD plateau
PD curve shows potential for LUM-201 doses in OraGrowthH210 Trial to produce greater GH response

Merck Study 001 in healthy adult subjects, results based on single LUM-201 dose administered

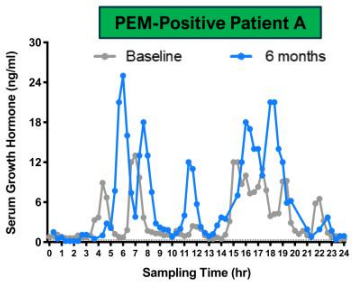
*Dose equivalence is based on AUC

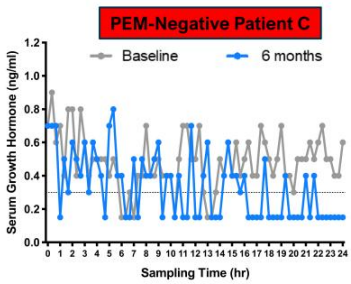
PK/PD Data Show LUM-201 Pulsatile MOA & Potential Efficacy in PGHD Patients

LUM-201 substantially increased GH secretion & height velocity in PEM+ PGHD patients at 6 months on therapy

		PEM Positive				PEM Negative	
		Patient A		Patient B		Patient C	
		Baseline	6months	Baseline	6months	Baseline	6months
	IGF-1 (ng/ml)	182	231	53	72	17	15
Q20m 24h GH	Mean (ng/ml)	3.4	6.3	1.0	1.3	0.5	0.3
	AUC (ng*hr/ml)	75.5	137.3	17.6	25.0	4.9	3.4
	Height Velocity (cm/yr)	3.7	7.9	3.5	8.9	1.1	1.8

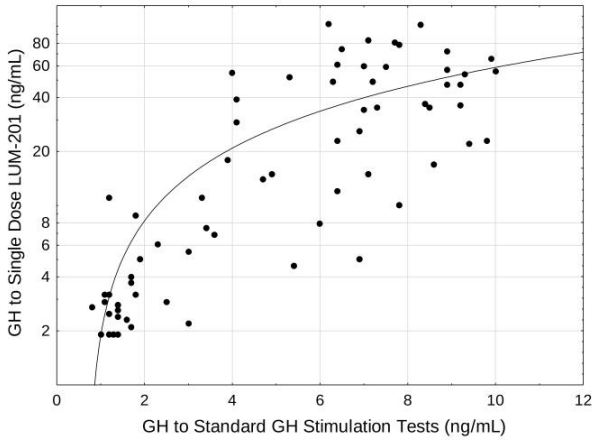
PGHD patients administered 0.8 mg/kg/day LUM-201 for 6 months*





* Merck Study 020 patient subset. Cassorla, F.

More GH Released from LUM-201 Stim than from Standard Stim Test Agents



68 children with growth hormone deficiency

All had 2 standard GH stimulation tests
- Standard test agents: arginine, clonidine, l-dopa, glucagon, insulin

All had a single dose of LUM-201 stim test

Data presented at the 2021 Annual Meeting of The Endocrine Society and published online in the journal, Hormone Research in Paediatrics, March 2022

Exclusivity and Barriers with Orphan Designation and IP

Orphan Drug Designation received in US and EU for GHD in 2017

With potential pediatric extensions, LUM-201 is eligible for:

- 12 years market exclusivity in EU *
- 7.5 years market exclusivity in USA*

Plan to seek Orphan Drug Designation in Japan

Intellectual Property – Patent granted for "Detecting & Treating GHD"

Use of LUM-201 in PGHD and other GHD indications based on PEM strategy

Patents for LUM-201 in GHD with protection through 2036

- Patents granted in US, Australia, EU, Israel, Japan, S. Korea, Hong Kong and Ukraine
- Additional applications pending in multiple jurisdictions

Applications for LUM-201 in NAFLD being prosecuted in multiple jurisdictions

* From date of approval GHD = Growth Hormone Deficiency NAFLD = Non-alcoholic fatty liver disease

Study of Oral LUM-201 in Non-Alcoholic Fatty Liver Disease (NAFLD)
Mass General Investigator-Initiated Phase 2 Pilot Trial

lumos PHARMA

MGH Initiated Phase 2 Pilot Trial[#]

- n = 10
- Adult NAFLD subjects with relative GH/IGF-1 deficiency
- Open-label
- Single-site pilot study
- 6-month dosing

Currently prescreening subjects[##]

Study Duration – 6 months

n = 10 – LUM-201 at dose level of 25 mg/day

Objectives

Primary Objective:

- Determine changes in intra-hepatic lipid content, inflammation, and potentially fibrosis resulting from LUM-201 induced GH augmentation compared to historical placebo-treated controls

Massachusetts General Hospital (MGH) initiated pilot study of oral LUM-201 in NAFLD
Prescreening subjects

Principal Investigator: Laura Dichtel, MD, Assistant Professor, Massachusetts General Hospital
As of August 9, 2022

LUM-201 Deal Terms

Partner	Upfront Payment	Development Milestones*	Sales Milestones* Worldwide	Sales Royalties, Combined
Ammonett	$3.5M	$17M first indication $14M second indication	$55M	10% to 12%, subject to standard generic erosion reductions
Merck	N/A	$14M first indication $8.5M second indication	$80M	

*Milestone figures are maximum, may be less depending on development stage achieved and total net sales up to $1B