

**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 15, 2023
Date of Report (date of earliest event reported)

LUMOS PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-35342
(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))

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.

Lumos Pharma, Inc. (the "Company") is providing an updated corporate slide deck which is attached hereto as Exhibit 99.1 and incorporated herein by reference. The slide deck contains additional information regarding the Company's topline data from its Phase 2 OraGrowthH210 and OraGrowthH212 Trials of LUM-201 in PGHD which met all primary and secondary endpoints.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Corporate Slide Deck	Description
99.1		

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 15, 2023

LUMOS PHARMA, INC.,
a Delaware corporation

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



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 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 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, any statements regarding potential enrollment timelines, 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 September 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 presentation.

11.14.2023

<p>Novel Oral Rare Disease Asset</p>	<ul style="list-style-type: none"> Novel oral therapeutic asset, LUM-201, for growth hormone deficiency (GHD) disorders LUM-201 acts within natural endocrine pathway, differentiated from injectable therapies 	
<p>Pipeline in a Product</p>	<ul style="list-style-type: none"> Worldwide injectable market for GHD disorders is \$3.4 billion, excluding China* Market for Pediatric GHD (PGHD), initial oral LUM-201 indication, is \$1.2 billion* 	
<p>Late-stage Trials in PGHD</p>	<ul style="list-style-type: none"> Topline data from two Phase 2 OraGrowth Trials in PGHD met all endpoints Growth on 1.6 mg/kg LUM-201 in line with historical benchmarks and expectations Ph 2 data provided preliminary validation of PEMs to identify likely LUM-201 responders** 	
<p>Program Advancement</p>	<ul style="list-style-type: none"> End-of-Phase 2 meeting with FDA anticipated 1H 2024 to review Phase 3 program Initiation of Phase 3 trial anticipated 2H 2024 	
<p>Solid Financial Position</p>	<ul style="list-style-type: none"> Cash balance of \$42.7 million as of close of 3Q 2023 Cash runway through 3Q 2024 	

Potential for **1st oral therapeutic** to disrupt injectable market for GHD

PGHD = Pediatric Growth Hormone Deficiency

* USA, Germany, France, Italy, Spain, UK, Japan (Grandview Research, Growth Hormone Market Forecast, 2019), China GHD market estimated at \$1 billion.

** PEM (Predictive Enrichment Marker) strategy consists of screening for PEM+ PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201



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).



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).



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.



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



Pisit "Duke" Pitukchewanont, MD
SVP Global Clinical Development and Medical Affairs
Pediatric endocrinologist and Professor, Clinical Pediatrics, Keck School of Medicine, USC. 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, others.



Peter Clayton, MD, PhD
Senior Medical Advisor and CSAB Member
Professor of Child Health and Paediatric Endocrinology, University of Manchester. Prior member of Councils of GH Research Society, Society for Endocrinology UK, and European Society of Paediatric Endocrinology. Served as Chair of ESPE Corporate Liaison Board. Authored over 300 publications on clinical and scientific aspects of paediatric endocrinology.



Michael Thorner, MB, BS, DSC
VP Endocrine Sciences
Endocrinologist. Former Chairman of Dept of Endocrinology & Metabolism, Director Clinical Research Center at University of Virginia. Led research group investigating GH secretion regulation. Discovered GH releasing hormone. Instrumental in early studies of LUM-201 (MK-0677). Pioneered use of dopamine agonist drugs for prolactin secreting pituitary tumors.

LUM-201 Program Pipeline

	Study	Pre-Clinical	Phase 1	Phase 2	Phase 3	Status
LUM-201 (Ibutamoren) in Moderate PGHD*	Dose-finding trial	OraGrowthH210 TRIAL				Phase 2 Topline Data: Primary and secondary endpoints met (Nov 2023)
	Long-term extension	OraGrowthH211 TRIAL				Long-term extension study for OraGrowth Trials: Ongoing enrollment of patients from Phase 2 trials
	PK/PD trial	OraGrowthH212 TRIAL				Phase 2 Topline Data: Primary and secondary endpoints met (Nov 2023)
	Switch trial	OraGrowthH213 TRIAL				Switch trial evaluating LUM-201 in subjects from rhGH arm of OraGrowthH210 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: Enrolling

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

* PGHD Pediatric Growth Hormone Deficiency **NAFLD Non-Alcoholic Fatty Liver Disease

***Trial supported by prior data evaluating rhGH in NAFLD: (ENDO 2022) JES, Volume 6, Issue Supplement_1, November-December 2022, Page A525, and JES, June 2023.

What is PGHD?

Inadequate secretion of growth hormone during childhood

- Majority of cases are moderate
- Slower physical growth
- Negative effect on metabolic processes
- Incidence \approx 1:3500¹

Current Treatment

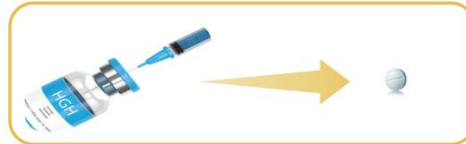
Injectable therapies are only options

- 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**

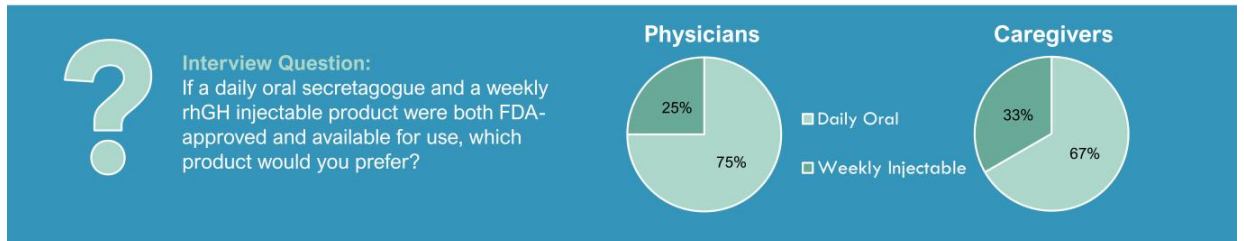


An established market is now primed for the **first oral** alternative

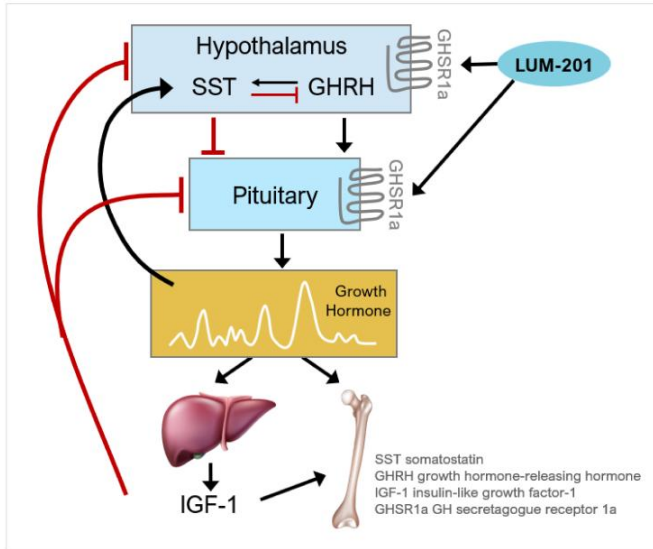
¹ GlobalData EpiCast Report for Growth Hormone Deficiency Epidemiology forecast to 2026
² Rosenfeld 2008 Endocrine Practice
³ Cutfield 2011 PLOS ONE

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



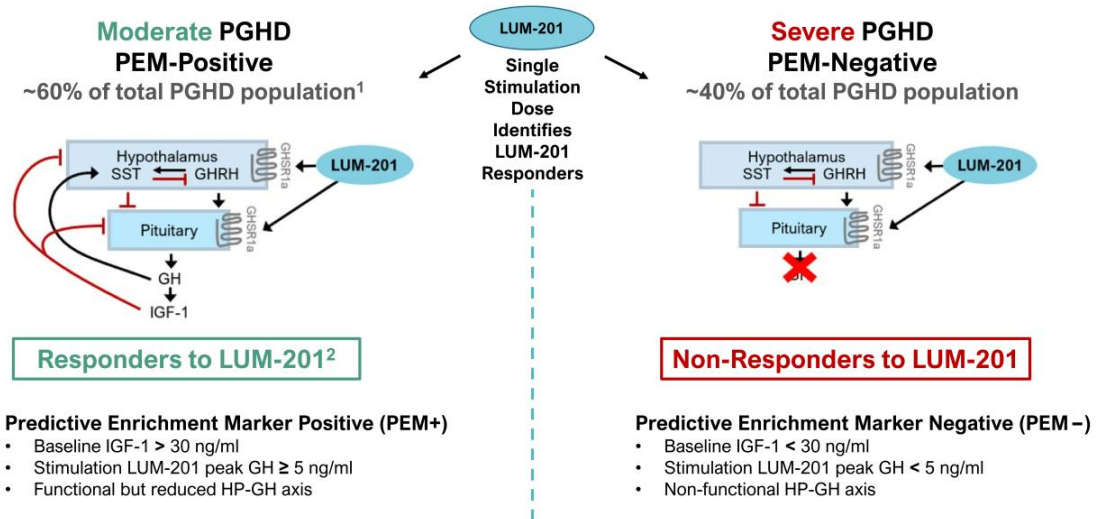
LUM-201 Stimulates Natural Growth Hormone Secretion



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} normalizing GH levels after 6 months on therapy⁴
- 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 ⁴ Supported by Lumos Pharma Topline Phase 2 Data * GH secretagogue = molecule that stimulates the secretion of growth hormone (GH)

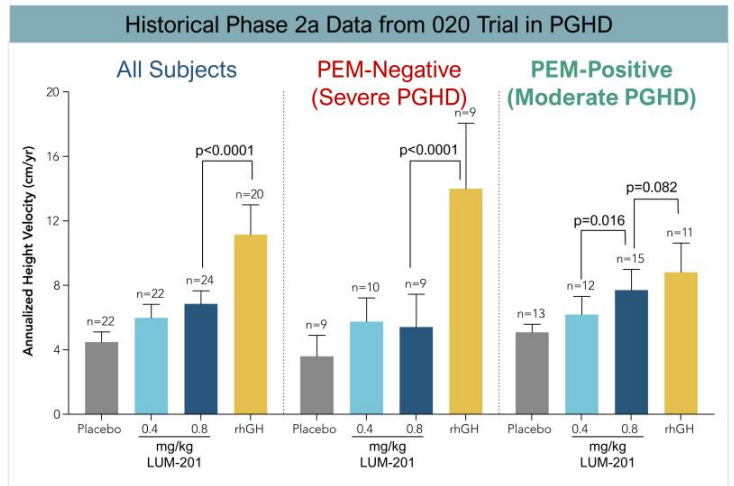


¹ Blum 2021 JES ² Bright 2021 JES HP-GH axis – hypothalamic pituitary growth hormone axis

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

PEM = Predictive Enrichment Marker

- Multiple LUM-201 trials conducted by Merck
 - In ~1000 adults – for sarcopenia, other
 - GH/IGF-1 raised from baseline by LUM-201
 - In ~200 children – for PGHD
- Naïve PGHD, Study 020¹
 - N=68; three arms
 - Placebo patients switched to rhGH at 6 mos.
 - 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

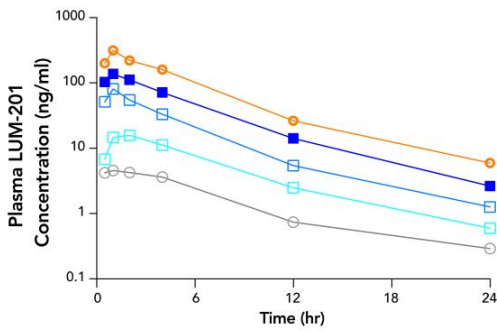


Expect prospective inclusion of only PEM(+) patients and higher doses to improve response to LUM-201

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

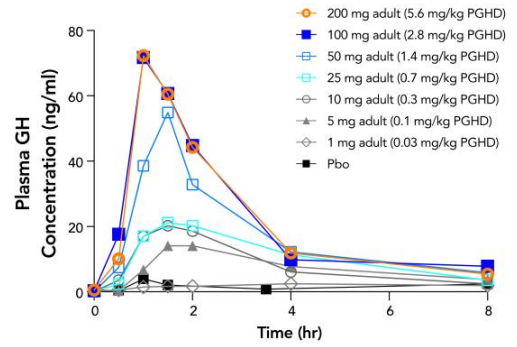
Pharmacokinetics

Dose response to 5.6 mg/kg PGHD dose equivalent*



Pharmacodynamics

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



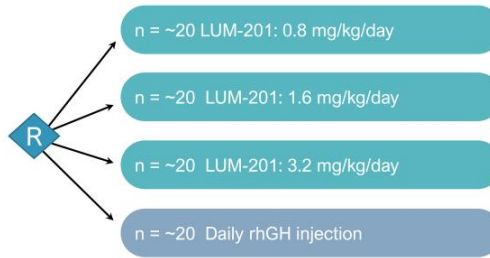
Higher LUM-201 doses produce higher plasma concentrations of LUM-201 & GH up to PD plateau
 PD curve shows potential for LUM-201 doses in OraGrowthH210 Trial to produce greater GH response

OraGrowthH210 Trial: Phase 2 Trial in Naïve Moderate PGHD

OraGrowthH210 TRIAL

- n = 82
- PEM(+) PGHD subjects
- Inclusion: stim GH \geq 5 ng/ml and baseline IGF-1 $>$ 30 ng/ml
- rhGH treatment naïve
- ~45 trial sites US & International

Primary Outcome Data (n = 82) – at 6 months on therapy
Total Study Duration – 24 months



Objectives

Study Objectives:

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

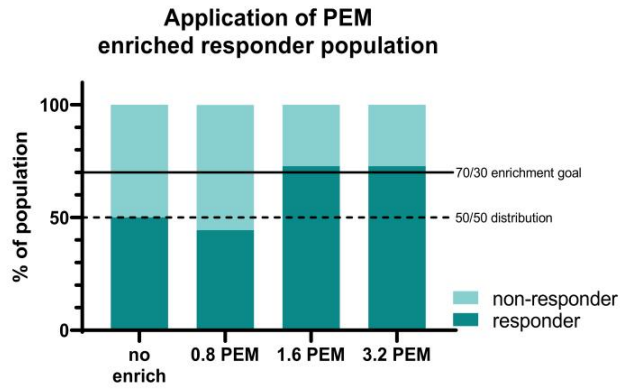
Goals:

- Determine optimal dose for Phase 3

Study not powered to show statistical non-inferiority

	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



Highlights

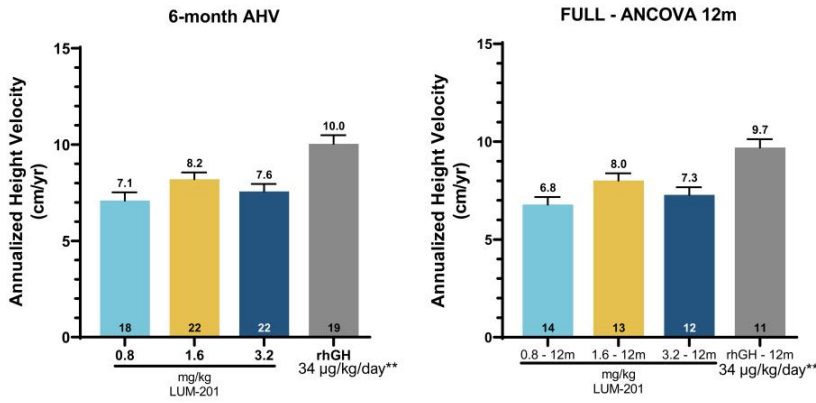
- PEM test ensures patients enrolled in the study are capable of secreting GH in response to a single-dose of LUM-201
- PEM-positive criteria:
 - PGHD patients with baseline IGF-1 >30 ng/ml
 - Peak stimulated GH \geq 5 ng/ml after a single 0.8 mg/kg dose of LUM-201

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

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

OraGrowthH210 Met Primary Objective:
6 and 12-Month AHV Data Support 1.6 mg/kg as Optimal Dose for Phase 3



Highlights

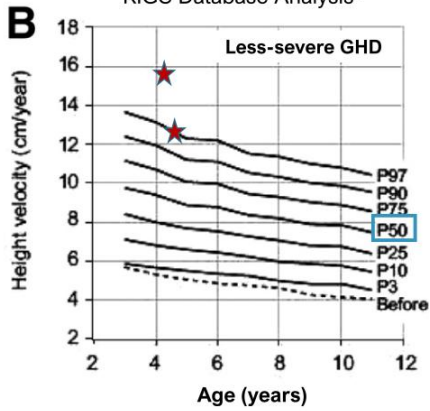
- 1.6 mg/kg best performing LUM-201 cohort
 - Growth of 8.0 cm comparable to historical 12-month AHV for moderate population
- 1.7 cm difference between 1.6mg/kg and rhGH cohorts at 12 months
 - Differences less than 1.8 – 2.0 cm have been the historical Phase 3 non-inferiority margin for rhGH approvals

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

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

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

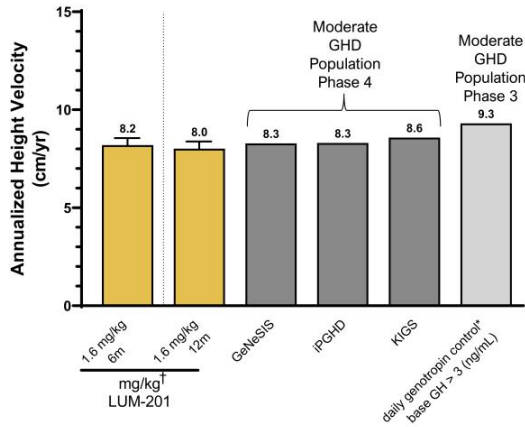
First-year Growth on rhGH for Moderate PGHD
KIGS Database Analysis¹



★ OraGrowth210 youngest subjects in rhGH cohort at 6-months AHV grew well beyond expectations

Analysis of Pfizer's KIGS database of moderate PGHD¹:

- P lines = Percentiles of expected growth on rhGH for moderate PGHD based on age started on therapy
- "Before" line marks height velocity before GH therapy

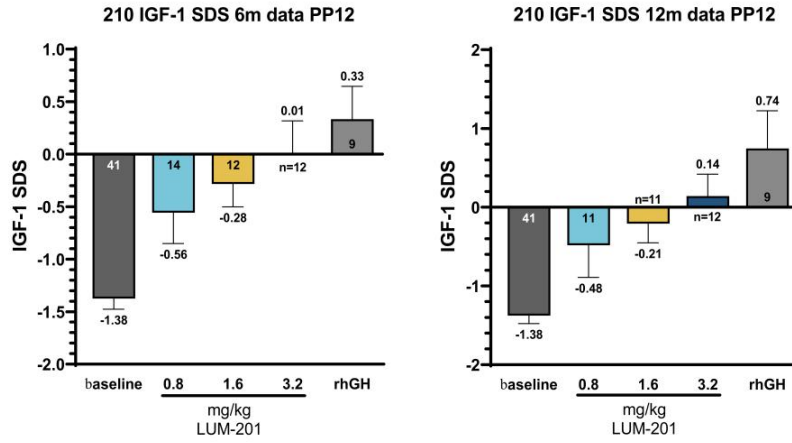


Highlights

- 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 Somatrogen 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

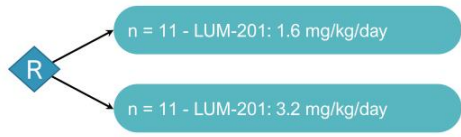
Bars represent sample mean, and error bars represent Standard Error of the Mean

- ✓ 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

OraGrowthH212
TRIAL

- 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

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:

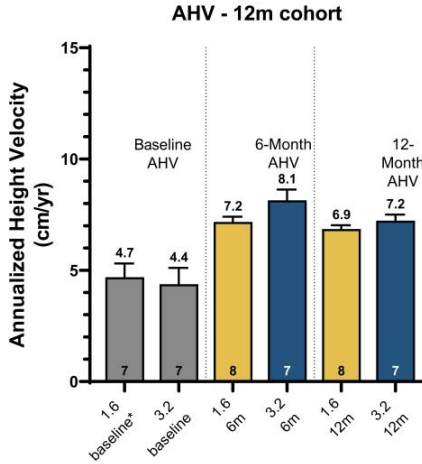
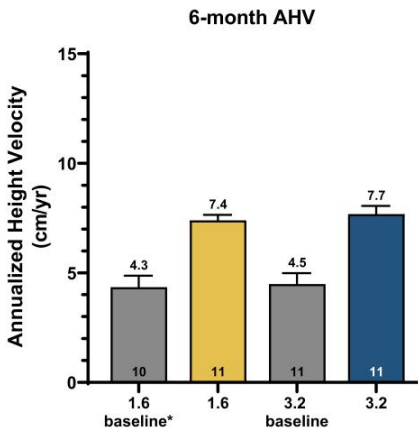
- Confirm prior PK/PD data in adults & subset of Merck 020 trial
- Support future regulatory filings & commercialization

OraGrowthH212 was a single-site trial with a more homogenous patient population than larger international OraGrowthH210 Trial

	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

OraGrowthH212: Significant Increase in Growth from Baseline AHV at 6 Months



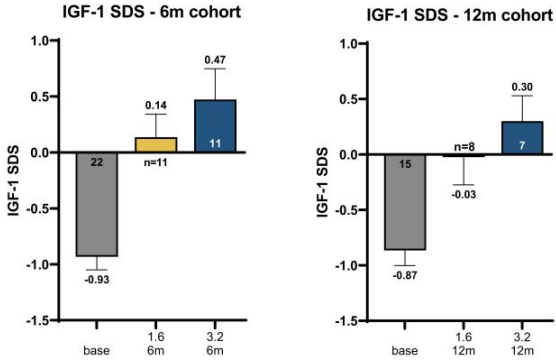
Highlights

- 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 = 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).

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



- Bars represent sample mean
- Error bars represent SEM
- 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.

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

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 = 22		Albertsson-Wikland ^{††}
12h (day) µg/kg.12hr	3.3 ± 1.3	1.1 ± 0.5	1.3	2.6	-
24h µg/kg/24hr	5.0 ± 1.3	1.4 ± 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

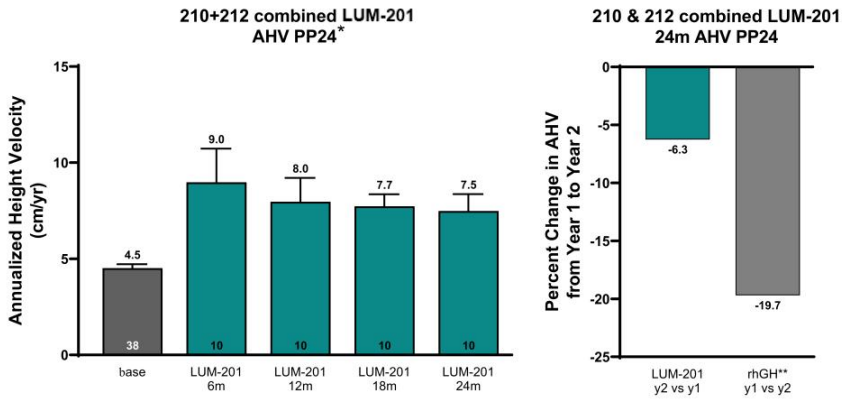
^{*}GH concentrations from the combined 1.6 and 3.2 mg/kg/day cohorts

[†]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

- ✓ 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 PHARMA OraGrowthH210 & OraGrowthH212 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 OraGrowthH210 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

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

OraGrowthH210 and OraGrowthH212 Phase 2 Clinical Trials

- Met all primary and secondary endpoints
- LUM-201 increases pulsatility, restores GH secretion and normalizes IGF-1
- LUM-201 promotes growth comparable to rhGH with only 20% of GH concentration levels
- AHV* delta between optimal 1.6 mg/kg LUM-201 dose and rhGH comparator arm at 6 and 12-months was within historical Phase 3 non-inferiority margins

Considerations for Phase 3 in PGHD






- Plan to request End-of-Phase 2 meeting with FDA and conduct in 1H 2024
- Anticipate initiating Phase 3 program in 2H 2024
- Phase 3 enrollment is estimated to span 12-18 months from first patient dosed**

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

** This estimated enrollment timeline is based on recent peer PGHD registrational trial enrollment timelines and the absence of simultaneous PGHD trials during our planned enrollment period. This enrollment timeline is subject to change dependent upon the EOP2 meeting with the FDA and other factors.

Investment Thesis
Lead asset targeting children with growth disorders

REVISED:
 Aaron Summary Slide
 w/ Lisa's edits

Attractive Market Opportunity	<ul style="list-style-type: none"> Daily oral expected to be well received in GH markets Market research supports rapid conversation to oral and potential expansion opportunities* 	
Novel Asset with Unique MOA	<ul style="list-style-type: none"> Novel MOA takes advantage of natural physiology Orphan Drug Designation in US/EU and issued patents in major markets 	
Clear Proof of Concept	<ul style="list-style-type: none"> PEM strategy de-risks patient selection, identifying likely LUM-201 responders** Phase 2 trials met all primary and secondary endpoints Consistent PK/PD and attractive safety profile to date in > 1,300 subjects studied 	
Focused Execution	<ul style="list-style-type: none"> End-of-Phase 2 meeting with FDA anticipated 1H 2024 to review Phase 3 program Initiation of Phase 3 trial anticipated 2H 2024 	
Solid Financial Position	<ul style="list-style-type: none"> Cash balance of \$42.7 million as of close of 3Q 2023 Cash runway through 3Q 2024 	

Potential for **1st oral therapeutic** to disrupt injectable market for GHD

* Initial Primary Research of PGHD Market conducted for Lumos by Triangle Insights

** PEM (Predictive Enrichment Marker) strategy consists of screening for PEM+ PGHD patients = Baseline IGF-1 > 30 ng/ml & Peak stimulation GH ≥ 5 ng/ml from single oral dose of LUM-201

Additional Analyses of Phase 2 Data

	0.8 mg/kg	1.6 mg/kg	3.2 mg/kg	ALL LUM-201	rhGH 34 mcg/kg
N =	18	22	22	62	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

AE = Adverse Event
SAE = Severe Adverse Event

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
Increased Appetite (All Grade 1)	1 (5.6)	1 (4.5)	1 (4.5)	3 (4.8)	2 (10.0)	0.8 mg Ongoing
						1.6 mg 1 & 7 months
						3.2 mg Ongoing
						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 Event	System Organ Class	Gr	Study Treatment	Relatedness	Serious Criteria
Product Administration Error	Injury, Poisoning and Procedural Complications	1	NA <i>(occurred prior to receiving any study drug)</i>	<u>Unrelated</u>	Hosp
Dehydration	Metabolism and Nutrition Disorders	3	*PEM (single 0.8 mg/kg)	<u>Unrelated</u>	Hosp
Glycosuria	Renal and Urinary Disorders	1	**PEM (single 0.8 mg/kg)	<u>Unrelated</u>	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 OraGrowthH212 Trial to date

Related OraGrowthH212 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)	19 Grade 1
				9 ongoing
				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 one with ongoing intermittent leg pain

Specific OraGrowthH210 AEs – No meaningful signal
 Safety data available for 82 subjects at interim analysis, October 2023

	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

	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%)

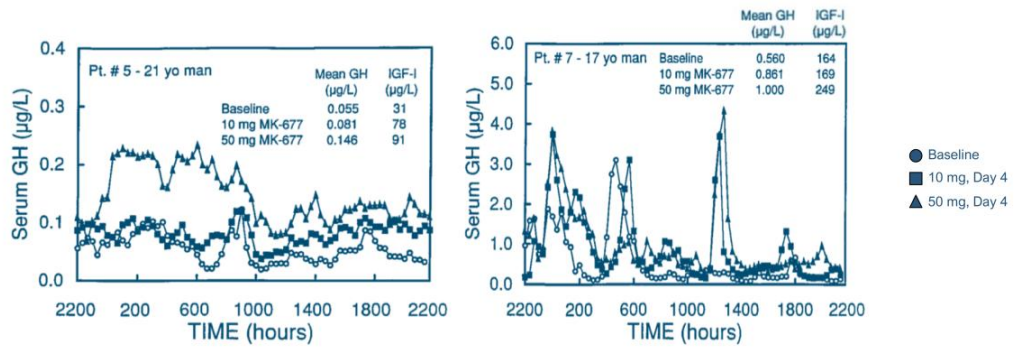
Laboratory Shifts: No meaningful signal

	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%)

Supplementary Materials

Historical Data Show LUM-201 Augments Growth Hormone (GH) Pulsatility and Increases Circulating IGF-1

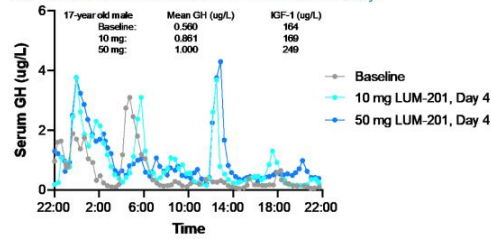
- Adults with GH deficiency
- Individual subjects
- Representative 24-hour GH profiles on Day 4 of treatment



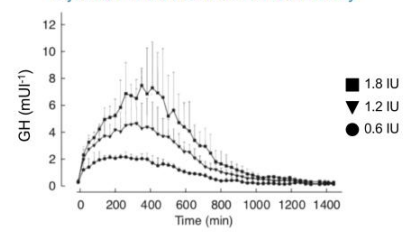
Historical Data Demonstrate Differentiated MOA of LUM-201 vs rhGH LUM-201 Augments Growth Hormone (GH) Pulsatility in GHD Adults

- Adults with GH deficiency
- LUM-201 augments endogenous GH pulses
- rhGH is administered as single, daily bolus doses

24h GH profile following oral LUM-201 administration in an adult with GH deficiency¹



24h PK profile following subcutaneous rhGH injection in adults with GH deficiency²

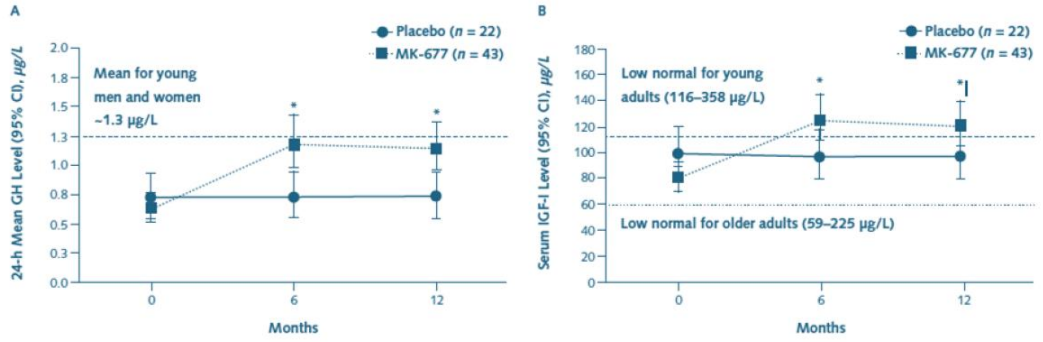


Potential to achieve non-inferior growth from smaller GH AUC via LUM-201 pulsatile delivery vs rhGH bolus administration

¹ Adapted, Chapman 1997 J Clin Endocrinol

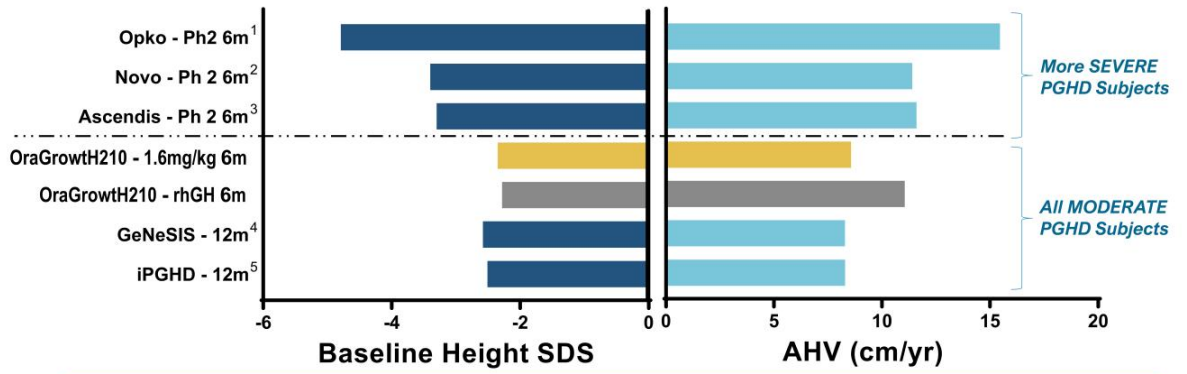
² Janssen 1999 Br J Clin Pharmacol (Genotropin)

Historical Data Show LUM-201 Effects Are Durable in Healthy Elderly



LUM-201 mediated increases in serum GH and IGF-1 are sustained over 1 year of treatment

Interim OraGrowth210 Data (November 2022): rhGH Cohort Grew More than Historical Norms in Moderate PGHD Patient Population



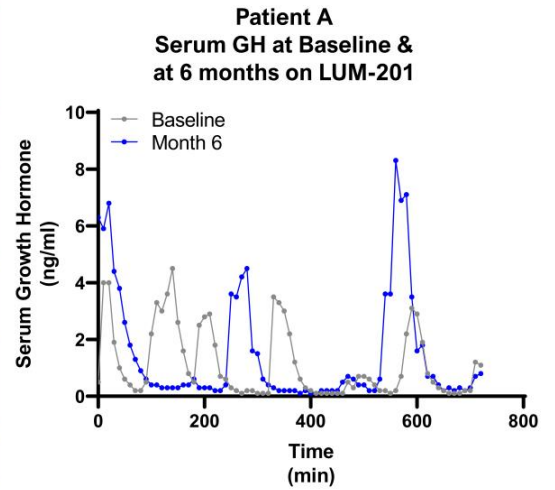
Unprecedented rhGH growth response in OraGrowth 210 in moderate PGHD at ~50% enrollment likely due to outlier & small sample size
 Expect larger N from fully enrolled OraGrowth210 Trial to reduce impact of growth outliers

SDS = Standard Deviation Score

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

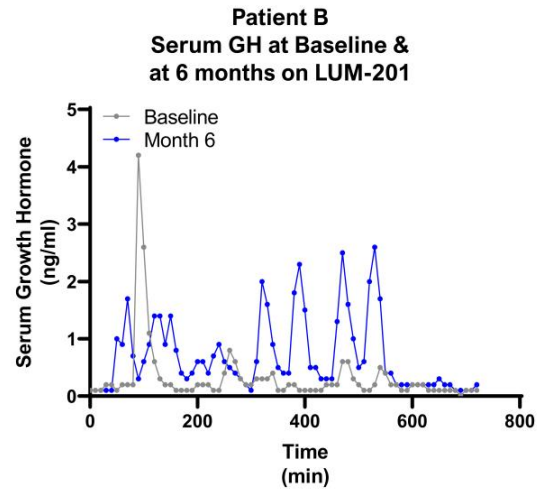
		Baseline	6 months LUM-201 3.2 mg/kg/d
	IGF-1 (ng/ml)	179	289
	% change from baseline**		61%
Q10m 12h GH	AUC ₀₋₁₂ (ng*hr/ml)	798.8	1064.1
	% change from baseline**		33%
	Height velocity (cm/yr)	5.6	7.9

**Percent change from baseline calculated as: (6mo value – baseline value) / (baseline value)



	Baseline	6 months LUM-201 3.2 mg/kg/d
IGF-1 (ng/ml)	48	111
	% change from baseline**	131%
Q10m 12h GH	AUC ₀₋₁₂ (ng*hr/ml)	481.8
	% change from baseline**	91%
Height velocity (cm/yr)	4.4	9.4

**Percent change from baseline calculated as: (6mo value – baseline value) / (baseline value)



Dose of LUM-201		1.6 mg/kg (n = 8)		3.2 mg/kg (n=7)	
		baseline	6 mo	baseline	6 mo
mean GH conc (ng/ml)	Median	1.04	1.22	0.47	1.36
	95% CI	0.51-1.59	0.81-1.93	0.25-1.17	0.49-3.02
GH AUC _{0-12h}	Median	758.6	894.0	343.8	992.3
	95% CI	376.4-1161	587.1-1411	182.0-854.9	357.3-2207

Conclusions

- Increases in GH AUC₀₋₁₂ are driven primarily by increased amplitude of GH pulses to generate increases in height velocity
- Number of GH pulses is unchanged from baseline to 6 months of treatment
- The 3.2 mg/kg cohort started with lower GH secretion at baseline than the 1.6 mg/kg cohort

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 faster¹**
- Baseline Height
 - **Shorter stature at baseline predicts greater 1st year growth²**
- Baseline IGF-1 SDS
 - **Lower baseline IGF-1 SDS predicts faster growth³**
- Baseline Mid-parental height & Delta MPH SDS
 - **Greater mid-parental height and subject Height SDS farther below MPH SDS predicts greater 1st year growth⁴**
- Baseline weight (BMI)
 - **Greater baseline weight (higher BMI) predicts faster growth⁵**

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 Res (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

Ranke Model is the Gold Standard in Growth Prediction for GHD

$$\text{PHV} = 14.55 + [-1.37 \times (\ln \text{ max GH stim})] + (-0.32 \times \text{Age}) + (0.32 \times \text{BWt SDS}) + (-0.5457) + (-0.4 \times \text{HtSDS-MPH SDS}) + (0.29 \times \text{Wt SDS})$$

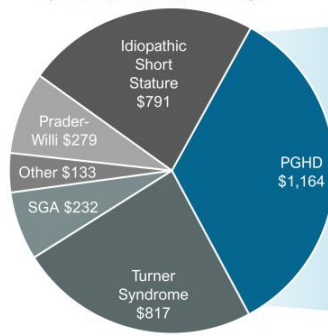
- Parameter Rank 1st [-1.37 X (ln max GH stim)] A measure of how GHD subject is by stim test value
- Parameter Rank 2nd (-0.32 X Age) Age at treatment start is a very important predictor
- Parameter Rank 6th (0.32 X BWt SDS) Birth weight SDS
- Parameter Rank 5th (-0.5457) Dose of rhGH (constant for this 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

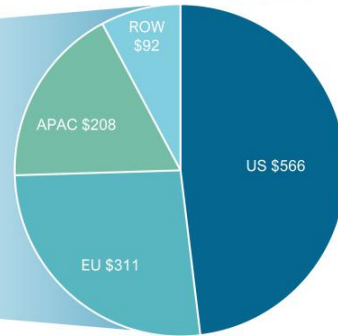
Growth for both rhGH and LUM-201 1.6 mg/kg cohorts was predicted using Ranke models

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

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

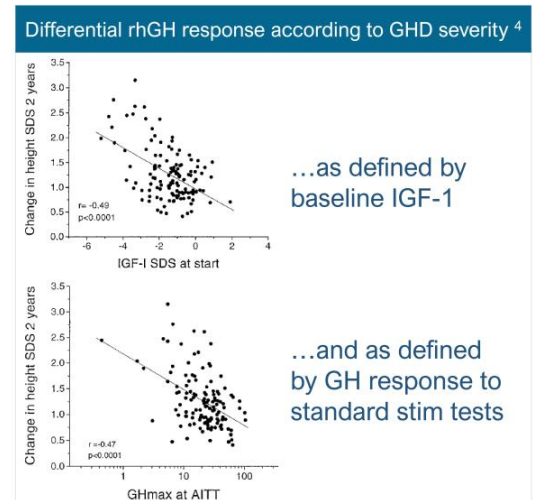


2018 Sales of rhGH for PGHD \$1.2B*
(Values below in \$millions)



- 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**

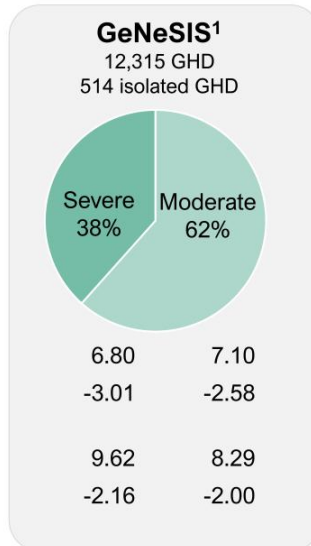
- Well established in the literature:
 - A wide range of severity in GHD¹
 - Variability in responses to GH therapy
 - Severely GH deficient patients exhibit greater growth response to rhGH compared to moderately deficient patients¹
- Several prediction models attempt to explain variability and optimize GH treatment²
 - Multiple factors may contribute
 - GH response to standard stimulation tests is most important predictor of first year growth response to rhGH in PGHD in one analysis³
 - Inclusion of baseline IGF-1 strengthened model⁴
- Recent publications
 - Baseline IGF-1 and GH response to standard stimulations tests are independent predictors of growth when patients are treated with rhGH⁵
 - Moderate GHD represents ~60% of total PGHD population⁵



PEM Segmentation Aligns With Patients' Differentiated Baseline Characteristics

Baseline | Chronological age (y)
Height SDS

rhGH | Height velocity (cm/y)
Height SDS



Conclusions

Analysis of 20-yr multinational database for Eli Lilly's rhGH:

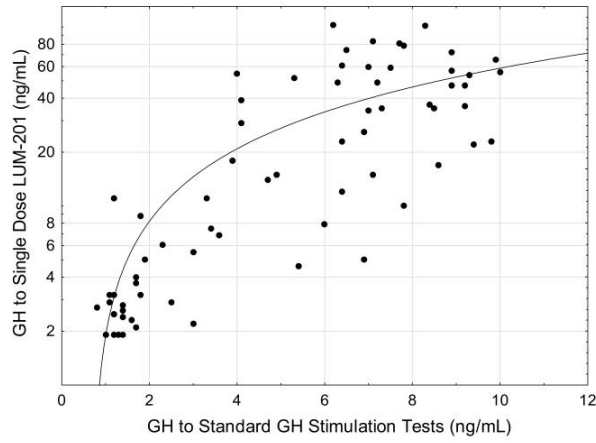
Illustrates PGHD population can be segmented by severity

- Segmentation achieved using PEMs (markers) IGF-1 and peak GH to stimulation tests
- Moderate and Severe PGHD have distinct characteristics

Lumos PEMs applied to GeNeSIS show Moderates ~60% of PGHD

- Likely LUM-201 responders
- Moderate²: LUM-201 PEMs baseline IGF > 30 ng/ml and stim GH ≥ 5 ng/ml

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

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

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 enrolling 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: Enrollment ongoing

Principal Investigator: Laura Dichtel, MD, Assistant Professor, Massachusetts General Hospital

Trial supported by prior data evaluating rhGH in NAFLD: (ENDO 2022) JES, Volume 6, Issue Supplement_1, November-December 2022, Page A525

