# NEWLINK GENETICS
# *and*
# LUMOS PHARMA MERGER

***Focused on Developing Therapies to Treat Rare Diseases***

NewLink GENETICS

lumos PHARMA

September 30, 2019

# LEGAL DISCLAIMER

Additional Information and Where to Find It

In connection with the proposed transaction, NewLink Genetics Corporation ("NewLink") will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed transaction. The definitive proxy statement will be mailed to NewLink's stockholders in connection with the proposed transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at www.sec.gov, on NewLink's website at www.newlinkgenetics.com or by contacting NewLink Investor Relations at 515-598-2555.

Participants in the Solicitation

NewLink and Lumos Pharma, Inc. ("Lumos") and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from NewLink stockholders in connection with the proposed transaction. Information about NewLink's directors and executive officers and their ownership of NewLink's securities is set forth in NewLink's proxy statement for its 2019 Annual Meeting of Stockholders, which was filed with the SEC on April 5, 2019, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of such filing. Other information regarding the proposed transaction, including information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the proxy statements described above and other relevant materials to be filed with the SEC when they become available. These documents are or will be available free of charge at the SEC's web site at www.sec.gov and from other sources indicated above.

# FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among others, statements about NewLink's financial guidance for 2019 and beyond; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; plans related to moving additional indications into clinical development; NewLink's future financial performance, impact of management changes, organizational restructuring, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; statements about NewLink's expectations regarding the capitalization, resources and ownership structure of the combined company; NewLink's expectations regarding the sufficiency of the combined company's resources to fund the advancement of any development program or the completion of any clinical trial; statements about the potential benefits of the transaction; the expected completion and timing of the transaction and other information relating to the transaction, and any other statements other than statements of historical fact.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink Genetics makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this presentation represent NewLink's views as of the date of this presentation. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this presentation.

# We are focused on the *extraordinary*

Our goal is to bring novel therapies to people with rare diseases.

# MANAGEMENT WELCOME

Richard Hawkins
CEO

John McKew, PhD
CSO

Carl Langren
CFO

Eugene Kennedy, MD
CMO

**Experienced management team with significant clinical development and commercial experience**

**Richard Hawkins –** CEO of Lumos Pharma, developer of growth hormone (GH) agonists for use in acromegaly at Sensus (sold to Pfizer). Built one of the first contract recombinant protein manufacturing facility (Covance Biotechnology). Co-founded Pharmaco, a contract research organization (merged with PPD).

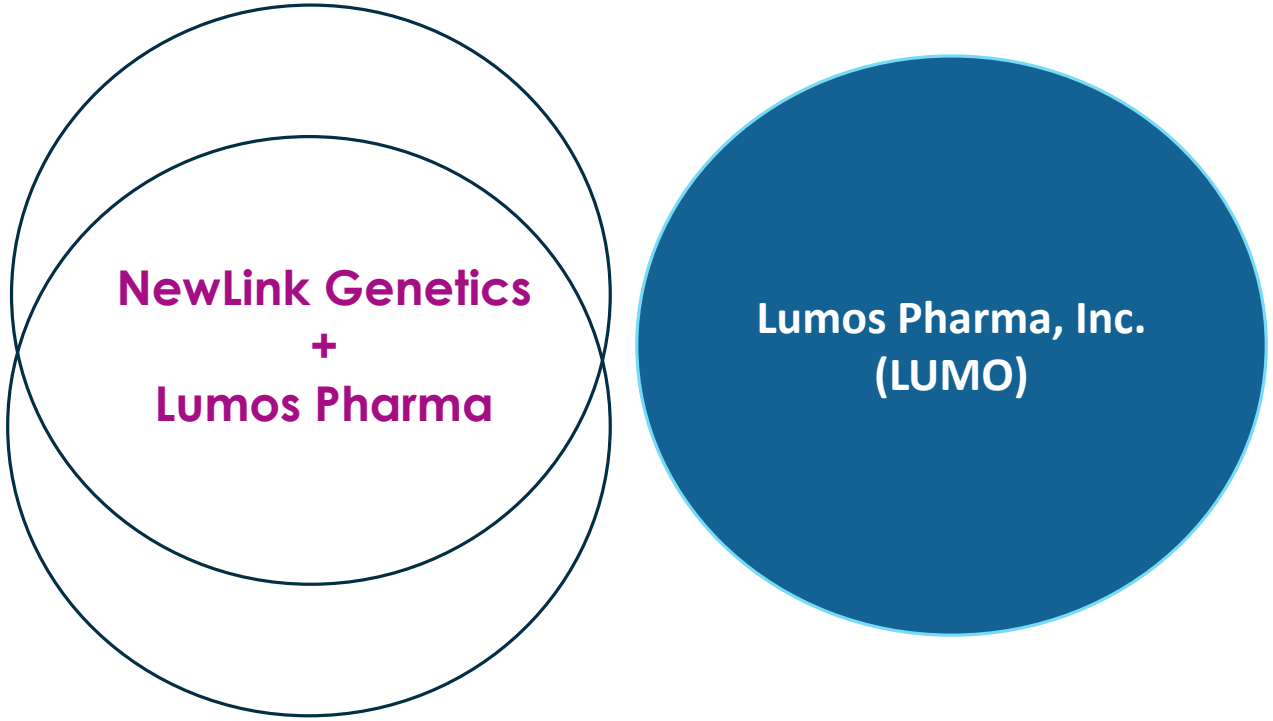
**John McKew –** CSO of Lumos Pharma, former Scientific Dir, NIH - National Center for Advancing Translational Science (NCATS) and Therapeutics for Rare and Neglected Diseases (TRND). Dir. level, Wyeth Research Genetics Institute.

**Carl Langren –** CFO of NewLink Genetics, former CFO of BioProtection Systems, Housby Mixer Group, Equity Dynamics, Inc., and Tax Manager with McGladrey Pullen & Co.

**Eugene Kennedy -** CMO of NewLink Genetics, former Assoc. Professor of Surgery and Chief of the Section of Pancreaticobiliary Surgery Thomas Jefferson University (Philadelphia), former faculty Johns Hopkins Hospital.

# TRANSACTION SUMMARY

Post merger, NewLink Genetics and Lumos Pharma stockholders are each expected to own approximately 50% of the combined company. The combined company will effect a reverse stock split. NewLink Genetics is expected to be renamed “Lumos Pharma, Inc.” and to trade on the Nasdaq under “LUMO.”




- **Company expected to be led by Rick Hawkins, CEO**
- **Board of Directors expected to include current NewLink Genetics and Lumos Pharma directors and mutually agreed designee**
- **Late-stage orphan drug program**
- **Projected pro forma combined cash of ~$80 million at 2019 year end**, excluding ongoing severance and restructuring obligations
- **Projected average cash use of $6.5-$7.5 million per quarter in 2020**, ongoing operating spend, exclusive of any restructuring charges and severance costs
- **Located in Austin, TX and Ames, IA**

# SIGNIFICANT HIGH-QUALITY INVESTORS

Lumos Pharma brings to the merger strong, well-recognized healthcare investors

- Well-known healthcare venture investors:
  **NEA and Santé Ventures**
- Large healthcare investors that participate in public and private markets:
  **Deerfield Management and a fund managed by Blackstone Life Sciences**
- Large pharma representatives:
  **Roche Venture Fund and UCB**

NewLink Genetics' largest stockholder with ~21% ownership has agreed to support merger

# POST-MERGER STRATEGIC PRIORITIES

**Initial focus will be on initiation of Phase 2b trial of LUM-201 (ibutamoren) for pediatric growth hormone deficiency (PGHD)**

**Build pipeline through strategic acquisitions of assets focusing on rare diseases**

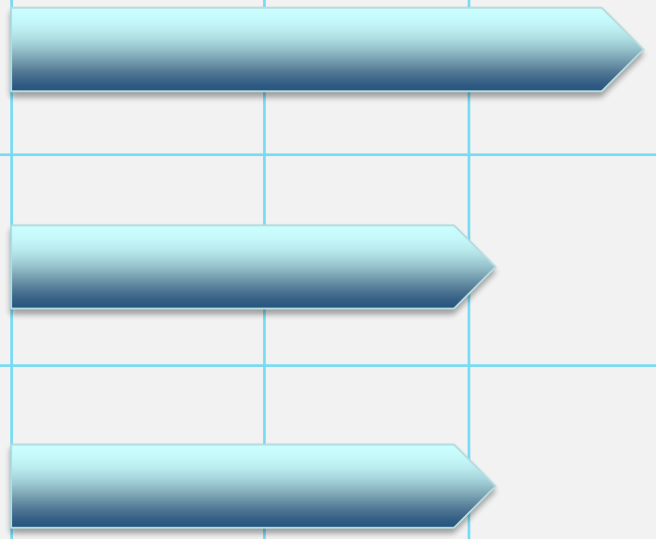
## LUM-201: Oral secretagogue candidate for PGHD

- Established regulatory path – planned Phase 2b expected to start mid-2020
- Potential to address 50-60%[1] of total PGHD patients
- Significant market opportunity, well-proven value through industry peers

1. Lumos Pharma data on file

# LUM-201 PROGRAM PIPELINE

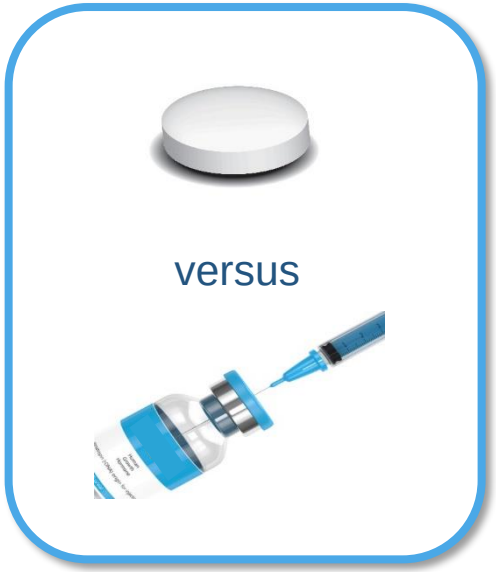
| Product Candidate | Orphan Indication | Preclinical | Phase I | Phase II | Phase III | Status |
|---|---|---|---|---|---|---|
| Ibutamoren (LUM-201) | Pediatric Growth Hormone Deficiency (PGHD) | | | | | Phase 2b – expected to initiate mid-2020 |
| | Turner Syndrome | | | | | Ongoing clinical planning for Phase 2 trial, timing dependent on PGHD data |
| | Children Born Small for Gestational Age (SGA) | | | | | Ongoing clinical planning for Phase 2 trial, timing dependent on PGHD data |



- Combined company plans to look for acquisitions and collaborations to expand pipeline beyond LUM-201

# PGHD AND STANDARD OF CARE

- PGHD occurs due to **inadequate secretion of growth hormone** by the pituitary gland during childhood
- PGHD can be either **hereditary or acquired**, although the majority of cases have unknown causes (**idiopathic**)
  - Lack of physical growth is the most obvious manifestation; but numerous metabolic processes are also affected
- PGHD Incidence in the U.S. – approximately 1 in 3500 children[1]
- Standard of care consists of **daily, subcutaneous injections** of recombinant human growth hormone (rhGH)
  - Can be painful, potentially leading to missed doses and sub-optimal growth[2, 3]
  - ~2500 injections over years of treatment




- Robust, established market primed for an oral alternative

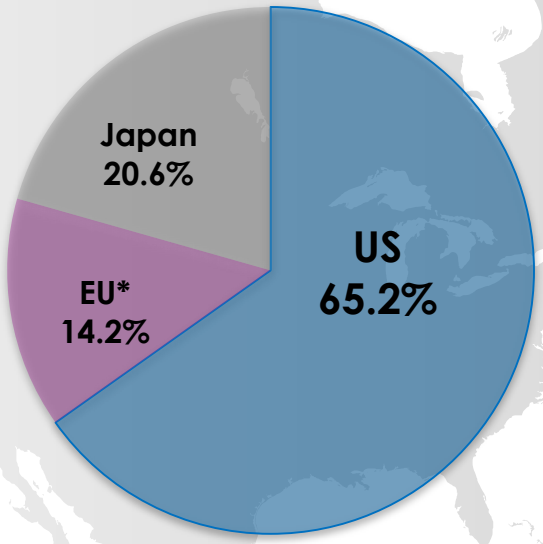

1. GlobalData EpiCast Report for Growth Hormone Deficiency Epidemiology forecast to 2026
2. Rosenfeld, R., et al *Compliance and Persistence in Pediatric and Adult Patients Receiving Growth Hormone Therapy,* Endocrine Practove, 2008, 14(2), 143-154
3. Cutfiled, W. S. et al *Non-Compliance with Growth Hormone Treatment in Children Is Common and Impairs Linear Growth, PLOS ONE 6(1): e16223. https://doi.org/10.1371/journal.pone.0016223*

# PEDIATRIC GROWTH HORMONE DEFICIENCY MARKET ANALYSIS

Global rhGH sales for pediatric patients with growth hormone deficiency (PGHD) reached **$1.12 Billion** in 2016 in major markets[1]

- **Expected CAGR for global PGHD sales is 3.5% leading to a projected market size of $1.58 Billion[1] in 2026**
- **US accounted for 65.2% of global sales of rhGH for PGHD in 2016**

**Global Sales Distribution of rhGH for PGHD in 2016 in the major markets[1]**




*Germany, France, Italy, Spain, and UK

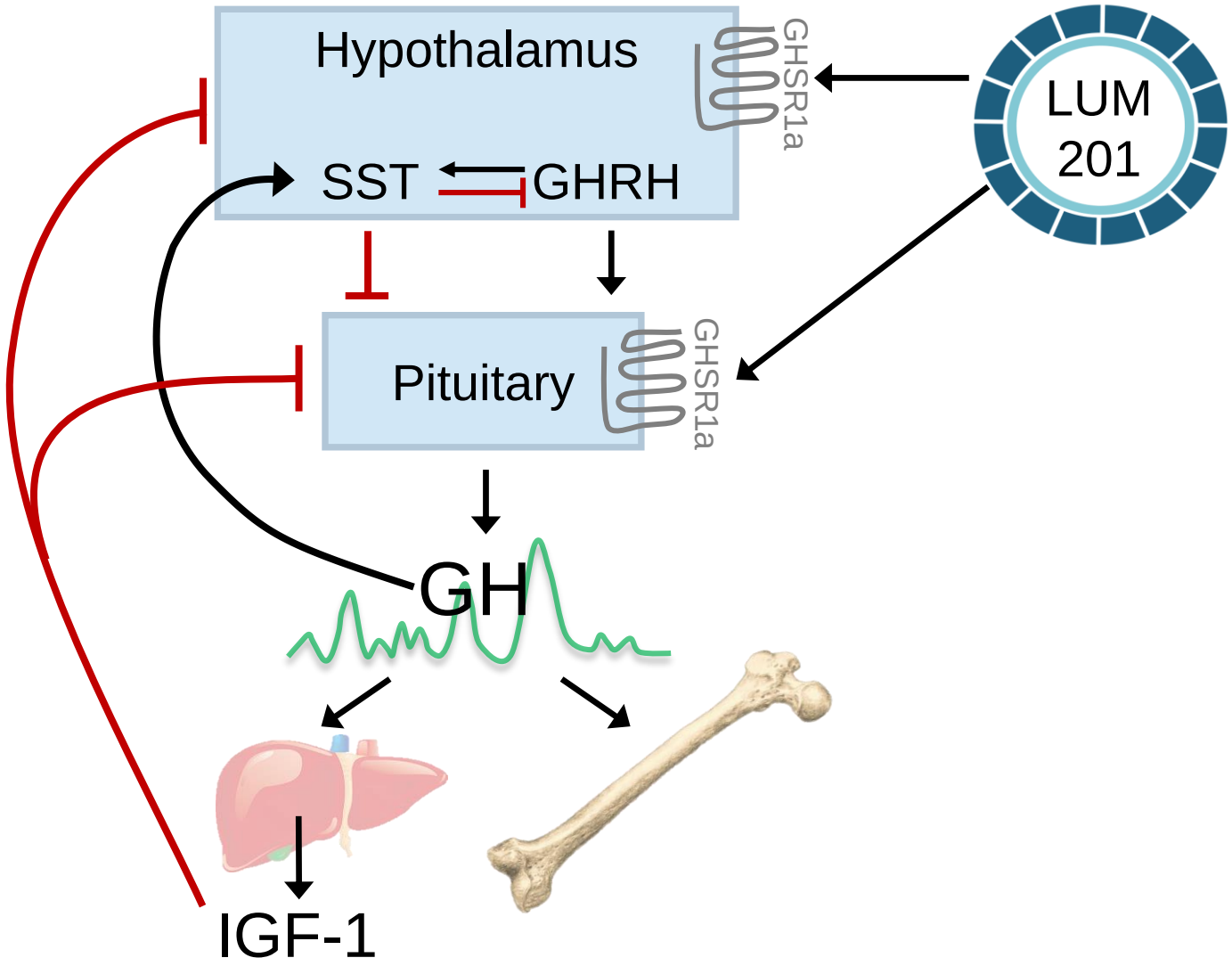
1. Global Data Opportunity Analyzer: Growth Hormone Deficiency Opportunity Analysis and Forecasts to GDHC069POA Published: May 2017

# ESTABLISHED VALUE PROPOSITION AND REGULATORY PATH

| Vision | Targeted Patients | Near-term Clinical Milestone |
|---|---|---|
| **LUM-201, if approved, has the potential to become the world's first oral growth hormone secretagogue to treat PGHD and other rare growth disorders.**<br><br>**Aim to supplant a prolonged treatment regimen of frequent injections (current standard of care).** | **Predictive enrichment markers (PEM) are planned to be employed to optimize the targeted patient population for trials and treatment.**<br><br>**Addressable patients represent 50-60% of PGHD population.**[1]<br><br>**Other potential pediatric endocrine indications identified.** | **Phase 2b trial planned for mid-2020.** |

1. Lumos Pharma data on file

# LUM-201: MECHANISM OF ACTION




- Oral LUM-201 is a ***growth hormone (GH) secretagogue***
- Acts as an agonist of GH Secretagogue Receptor (GHSR1a) to stimulate GH release[1]
- LUM-201 has been observed to ***increase the amplitude of endogenous pulsatile GH secretion***[2, 3]
- LUM-201's stimulatory effect is regulated by GH/IGF-1 feedback

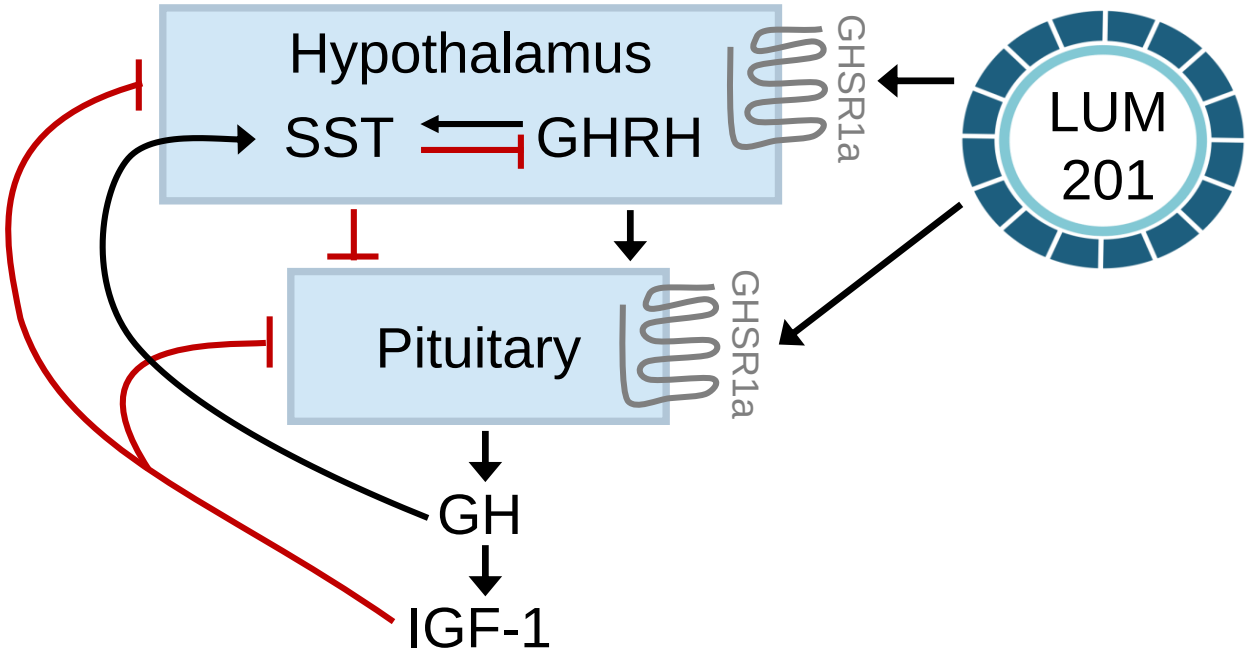

1. Howard 1996 Science
2. Nass 2008 Ann Intern Med
3. Chapman 1997 J Clin Endocrinol Metab


SST = somatostatin
IGF-1 = insulin-like growth factor-1

GHRH = growth hormone-releasing hormone
GHSR1a = GH secretagogue receptor 1a

# TARGETED PGHD POPULATION

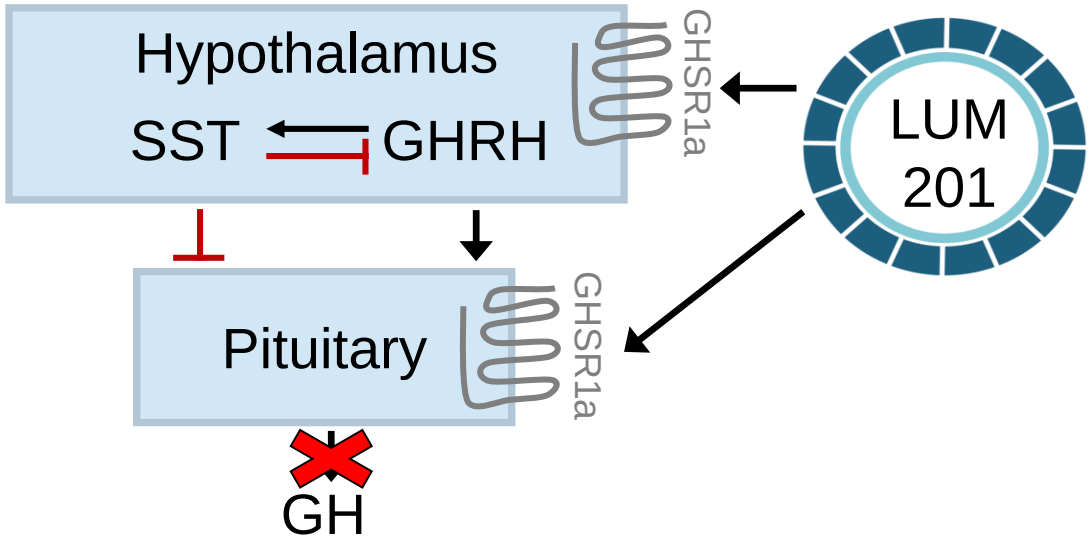
## PEM-Positive: Included




### Functional but reduced HP-GH axis

- Able to secrete some, but insufficient, GH
- Expected to respond to LUM-201
- Represents 50-60% of PGHD patients[1]

## PEM-Negative: Excluded




### Non-functional HP-GH axis

- Unable to secrete GH
- Not expected to respond to LUM-201
- Represents 40-50% of PGHD patients

**Predictive Enrichment Markers (PEM)**

- GH response to a single LUM-201 dose and baseline IGF-1 has the potential to distinguish these two populations

HP-GH = hypothalamic-pituitary-growth hormone

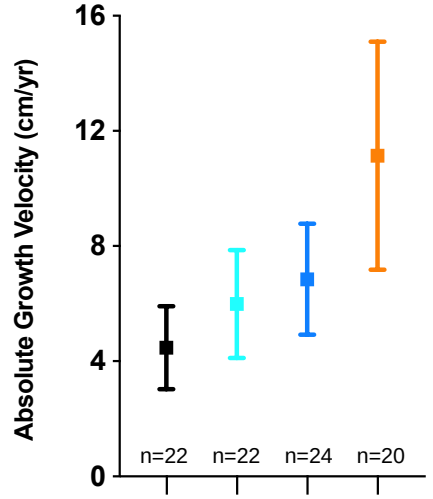
1. Lumos Pharma data on file

# POST-HOC: PREDICTIVE ENRICHMENT MARKERS AT WORK

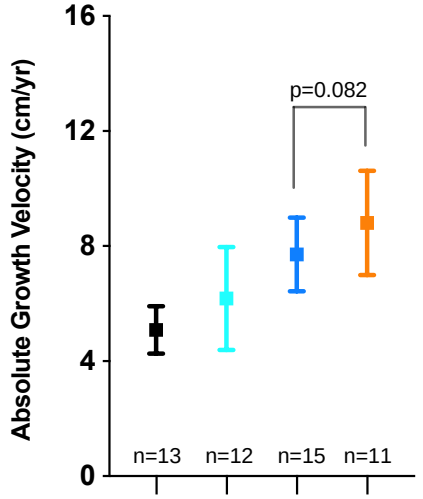
## Absolute Growth

means and SD

### All Subjects



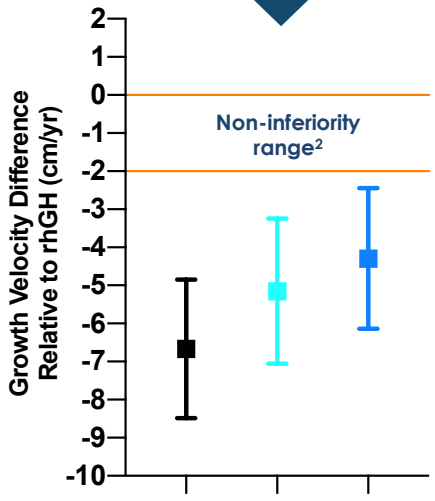

### PEM-Positive

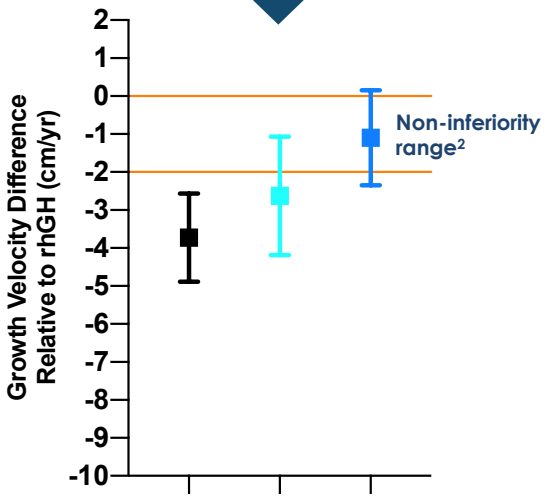



## Relative Growth: **non-inferiority analysis**

[growth velocity in rhGH minus growth velocity in test group]

means of the difference and 95% CI




- Naïve PGHD patients, 020 trial
  - Data from first 6 months prior to formulation change[1]
- LUM-201 0.8 mg/kg not statistically different from rhGH but insufficient to meet FDA requirements for non-inferiority[2]
- Lumos expects **prospective application of PEMs** and **higher doses** to improve response and meet statistical non-inferiority margin

- Placebo
- LUM-201 0.4 mg/kg/d
- LUM-201 0.8 mg/kg/d
- rhGH 42 mcg/kg/d

1. A formulation change occurred 6 months into dosing of this trial and was also used for subsequent PGHD trials, resulting in substantially lower exposure of LUM-201. Data on file.
2. A 2 cm non-inferiority (NI) range was agreed to by the FDA for multiple recent long-acting GH studies. Lumos has not yet agreed to a NI window with the FDA.

# PRIOR CLINICAL EXPERIENCE IN PGHD WITH LUM-201

- Prior PGHD trials
  - Conducted prior to Lumos acquisition of LUM-201 in July 2018
  - 3 clinical trials in pediatric population explored safety and efficacy
    - Phase 1 Trial 019 – PK, Phase 2 Trial 020 – Naïve, Phase 2 Trial 024 – Previously rhGH treated
  - No significant safety concerns were identified
  - Formulation change midway through Trial 020 reduced bioavailability of the drug and confounded data
  - Phase 2 trials were discontinued after interim analysis of Trial 024
- Scientifically-driven post-hoc analysis enabled (Trial 020):
  - Definition of PEM-positive patients, with PEM status planned to be used as an inclusion criteria in future trials

- Growth response in prior trials (highest dose tested) suggests potential improved efficacy at a higher dose

# CLINICAL DEVELOPMENT OUTLINE FOR PGHD

- Proposed Phase 2b PGHD clinical trial design
  - PEM-enabled patient selection
  - Three dose levels of LUM-201 (0.8, 1.6, 3.2 mg/kg)
  - Positive control arm of daily rhGH injections
  - 6-month dosing
  - 20 subjects per arm
  - Treatment-naïve, age-matched cohorts
- Extension trial - move all subjects to most efficacious Phase 2 dose

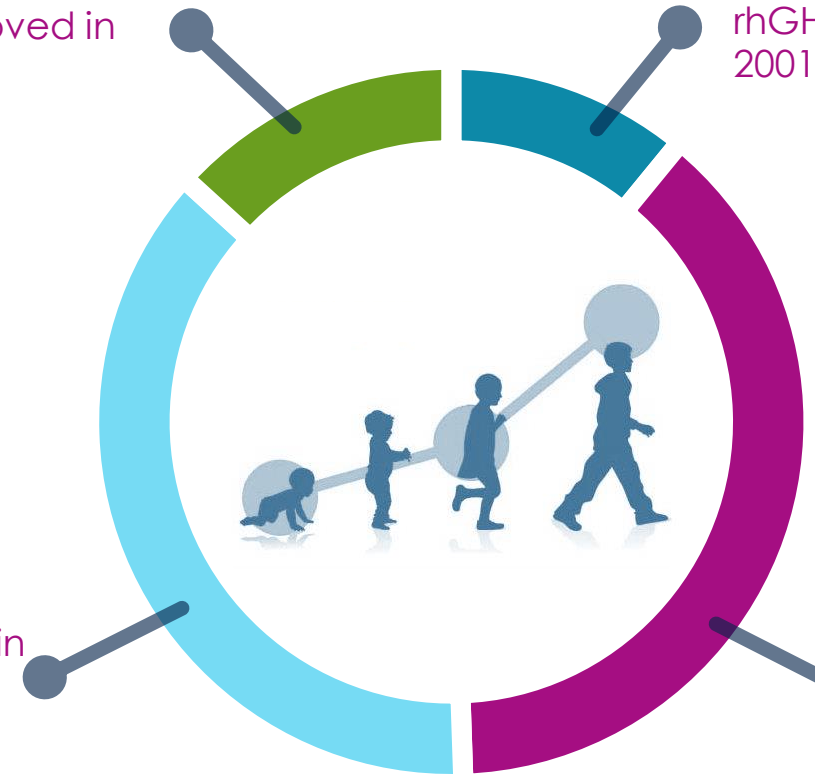
- Primary outcome measure: annualized growth height velocity

# LUM-201: OTHER POTENTIAL RARE ENDOCRINE DISORDERS

Beyond PGHD, Lumos also plans to investigate LUM-201 for other rare endocrine disorders, for which rhGH has been approved

**Prader-Willi Syndrome**
rhGH FDA approved in 2000

**Small for Gestational Age**
rhGH FDA approved in 2001



**Idiopathic Short Stature**
rhGH FDA approved in 2003

**Turner Syndrome**
rhGH FDA approved in 1996

- Significant opportunities with established regulatory pathways

Source: GARD- Genetic and Rare Diseases Information Center

# ORPHAN DESIGNATION AND IP

- Orphan Drug Designation received in US and EU for GHD in 2017
  - With potential pediatric extensions, eligible for 12 years exclusivity in EU and 7.5 years in US.
  - Plan to seek designation in Japan
- Intellectual Property
  - “Detecting and Treating Growth Hormone Deficiency"
    - Use of LUM-201 in PGHD
    - US Patent issued with expiration in 2036
    - Patent applications filed in multiple other countries

# LUM-201 SUMMARY

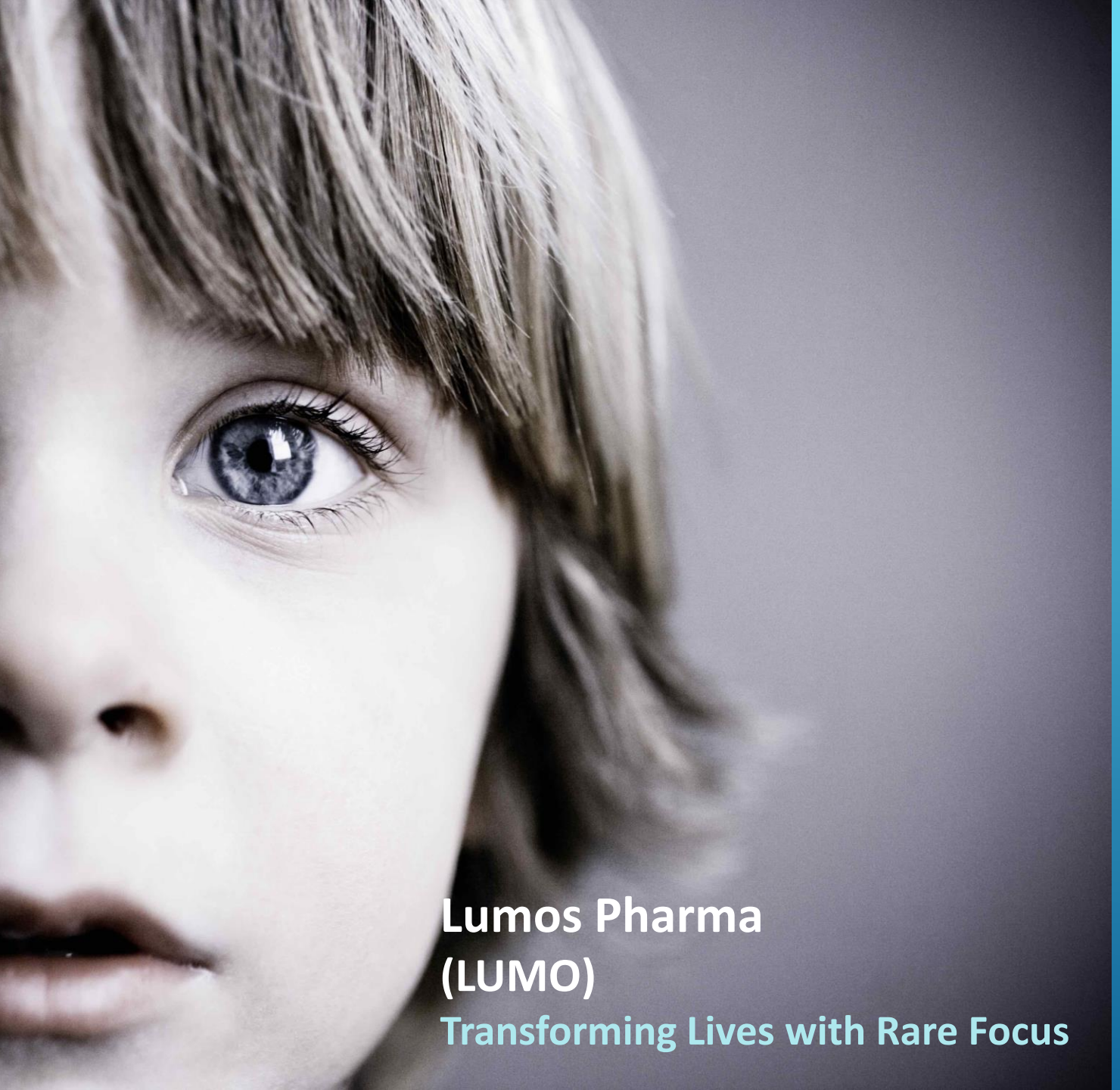
## If approved, potential to be the first oral growth hormone secretagogue therapy for PGHD

- Established regulatory path – Phase 2b in PGHD anticipated to start mid-2020
- Clinical data supports target engagement and safety
  - ~ 1,200 subjects dosed including ~150 PGHD patients
  - Predictive enrichment markers (PEM) identify appropriate patient population
- Orphan drug designation received in US and EU
- Phase 2 ready compound for potential trials in other pediatric endocrine indications

# SECURE PRO FORMA CASH POSITION

- Combined pro forma cash balance at year-end 2019 projected to be ~ $80M, excluding costs to right-size the combined organization
- Spending after merger expected to be an average of $6.5-$7.5M per quarter in 2020, excluding restructuring charges and severance costs
- Financial position expected to support the combined company through the readout of the planned Phase 2b clinical trial
- May receive non-dilutive financing if FDA approves partnered Ebola vaccine V920
  - FDA accepted the biologics license application for V920 on September 17, 2019[1] and the Prescription Drug User Fee Act (PDUFA), or target action date, was set for March 14, 2020
  - An FDA approval of this vaccine would trigger the issuance of a priority review voucher (PRV) in which NewLink holds a substantial financial interest

1. Merck press release, September 17, 2019




- Merger offers opportunity to develop therapeutics for the rare disease community
- LUM-201: Potential to improve upon treatment paradigm in established and sizeable market
- Strong balance sheet and streamlined operations expected to provide substantial runway
- Management team with deep experience in rare disease and clinical development