

# Eiger BioPharmaceuticals to Focus on Metabolic Diseases with Avexitide; David Apelian Takes Helm as CEO

- Prioritizing resources to advance avexitide in hyperinsulinemic hypoglycemia indications
- Active discussions underway with potential partners to advance late-stage virology programs
- Reduction in workforce executed to align with focus on avexitide; extends cash runway to Q4 2024
- David Apelian, MD, PhD, MBA, appointed CEO
- Live conference call and webcast at 8:30 am ET today

Palo Alto, Calif., June 29, 2023 -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare diseases, today announced that following an extensive portfolio prioritization review, the Company will focus its development efforts on advancing avexitide in hyperinsulinemic hypoglycemia indications. The Company will continue to commercialize Zokinvy<sup>®</sup> (lonafarnib) for the treatment of Hutchinson-Gilford progeria syndrome and processing-deficient progeroid laminopathies. In addition, Eiger is evaluating strategic partnering options for its virology assets, lonafarnib and peginterferon lambda. A 25% reduction in workforce, a reduction in out-of-pocket spending related to its hepatitis delta (HDV) development program and its existing term loan are expected to extend the Company's cash runway into the fourth quarter of 2024. The Company also announced that it has appointed David Apelian, MD, PhD, MBA, who has served as interim Chief Executive Officer since December 2022, as the Company's next CEO.

"Today's environment necessitates prudent and strategic evaluation of how to advance our promising and diverse pipeline in order to develop potential breakthrough medicines for patients and to drive stockholder value," said David Apelian, MD, PhD, MBA, CEO of Eiger. "After a thorough examination of our programs, we are deploying our resources toward recognizing the compelling potential of avexitide in metabolic diseases. Our initial focus will be on post-bariatric hypoglycemia, or PBH , where we see the highest revenue potential, have demonstrated proof-of-concept in Phase 2 clinical trials, and have FDA alignment on Phase 3 endpoints, sample size, and study design. In the future, we also intend to develop avexitide for congenital hyperinsulinism as a second indication. We plan to provide further guidance next quarter on the progress of our business development efforts for our virology assets, as well as definitive plans for the PBH Phase 3 study initiation and key study milestones."

Dr. Apelian continued, "For our other late-stage assets, lonafarnib and peginterferon lambda, we believe the strength of our data and alignment on a regulatory path with FDA make them attractive to potential collaborators. We are actively engaged in discussions with potential partners."

"David has embraced his role as CEO, which was a natural transition given his proven tenure with Eiger as a board member and previous Chief Operating Officer," said Thomas Dietz, PhD, non-executive Chairman of the Board. "David's extensive clinical development and regulatory experience gained from working at large

pharmaceutical and biotechnology companies, combined with his strategic vision and previous leadership roles at Eiger, make him the right choice to lead Eiger."

## **Current Pipeline**

# Avexitide for Post-Bariatric Hypoglycemia (PBH)

- A large orphan disease with a growing population; caused by complications in bariatric surgery
- Prevalence of approximately 180,000 in the US and approximately half that in the EU
- Avexitide is the only drug in development for PBH with Breakthrough Therapy designation
- FDA alignment on pivotal Phase 3 study endpoints, sample size, and design

## Avexitide for Congenital Hyperinsulinism

- An ultra-rare, life-threatening, pediatric disorder of persistent hypoglycemia that results in irreversible brain damage in up to 50% of children
- Breakthrough Therapy designation from FDA
- Rare Pediatric Disease designation

# Zokinvy® (lonafarnib) for Progeria and Processing-Deficient Progeroid Laminopathies

• First quarter 2023 net product revenue of \$4.1 million; full year 2022 net product revenue of \$12.7 million

## **Partnering Opportunities**

#### Lonafarnib-Based Regimens for HDV

- First-in-class, oral prenylation inhibitor
- Phase 3 *D-LIVR* study complete; presented at EASL 2023 in Vienna, Austria
  - Week 48 primary endpoint achieved in both lonafarnib arms vs PBO (1.9%) (N=407)
    - Composite response rate in oral arm = 10.1% (p=0.0044)
    - Composite response rate in combination arm = 19.2% (p<0.0001)
  - 24-week post-treatment data demonstrate that both lonafarnib arms showed a statistically significant difference in composite response rate compared to placebo (N=338)
    - Composite response rate in oral arm = 14.2% (p<0.0001)
    - Composite response rate in combination arm = 26.4% (p<0.0001)
    - HDV RNA BLQ response rate in oral arm = 6.1% (p=0.168)
    - HDV RNA BLQ response rate in combination arm = 22.7% (p<0.0001)
- Pre-NDA meeting with FDA supportive of potential path to approval for oral and combination therapy

## Peginterferon Lambda

- First-in-class, well-tolerated interferon
- Potential to be interferon of choice in antiviral combination therapies
- Phase 3 LIMT-2 study of peginterferon lambda monotherapy fully enrolled next month
- Potential for edevelopment in HDV, HBV, respiratory diseases such as COVID and influenza, as well as other virology indications.

#### **Conference Call Details**

The live and replayed webcast of the call will be available through the company's website at www.eigerbio.com. To participate in the live call by phone, dial (866) 524-3160 (U.S.) or (412) 317-6760 (International). The webcast will be archived and available for replay for at least 90 days after the event.

#### About Dr. David Apelian

Dr. Apelian has 23 years of clinical development and regulatory experience with large pharmaceutical and biotechnology companies, including nearly six years in senior management, advisory and Board roles at Eiger. He has served as the Company's interim CEO since December 2022. He had previously served as the Company's Chief Operating Officer and Executive Medical Officer starting in 2018, responsible for heading the company's R&D, Medical and Regulatory Affairs operations. Following his departure from that position in 2019, he has served as a Senior Clinical Advisor and board member at Eiger. Dr. Apelian was also the founding CEO of BlueSphere Bio. In addition, Dr. Apelian was Executive Vice President and Chief Medical Officer of Achillion Pharmaceuticals, Inc. where he was responsible for creating portfolio strategy and managing the company's clinical development programs. Earlier in his career, he held senior management positions at GlobeImmune, Bristol-Myers Squibb, and Schering Plough. Dr. Apelian has extensive experience in chronic HCV, chronic HBV, immune oncology and rare diseases.

#### About Post-Bariatric Hypoglycemia

Post-bariatric hypoglycemia (PBH) and other forms of hyperinsulinemic hypoglycemia (HH) after gastrointestinal surgeries are characterized by exaggerated secretion of glucagon-like peptide-1 (GLP-1) after meals, dysregulated secretion of insulin, and a rapid drop in blood sugar. Hypoglycemia typically occurs one to three hours after meals and is often accompanied by symptoms of brain glucose starvation (neuroglycopenia), such as blurred vision, confusion, speech difficulty and incoordination.

Severe hypoglycemia events can result in serious outcomes such as loss of consciousness, falls, seizures, and motor vehicle accidents, putting patients at risk for death and disability. Recurrent hypoglycemia events can have serious implications on quality of life, including heightened fear of hypoglycemia and reduced functionality, such as ability to work, drive and independently perform activities of daily living.

PBH is an orphan disease caused by complications in bariatric surgery with a prevalence of approximately 180,000 in the US and approximately half that in the EU.

#### **About Avexitide**

Avexitide is an investigational, first-in-class glucagon-like peptide-1 receptor (GLP-1r) antagonist in development for the treatment of post-bariatric hypoglycemia (PBH) and congenital hyperinsulinism (HI). Avexitide has been granted Breakthrough Therapy designation for both PBH and HI.

Because avexitide binds to the GLP-1r on pancreatic beta cells and prevents GLP-1r signaling, it works upstream of beta cell insulin secretion to reduce dysregulated insulin secretion and the occurrence of hypoglycemia. By addressing underlying disease mechanisms, avexitide may offer a targeted approach to treating hypoglycemia in patients with hyperinsulinemic hypoglycemia, including PBH and HI. Eiger has developed a novel formulation of avexitide for subcutaneous injection.

## **About Eiger**

Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for are diseases. Eiger's lead product candidate, avexitide, is a well characterized, first-in-class GLP-1

antagonist for the treatment of post-bariatric hypoglycemia (PBH) and congenital hyperinsulinism (HI). Avexitide is the only drug in development for PBH with Breakthrough Therapy designation from the FDA.

For additional information about Eiger and its clinical programs, please visit <u>www.eigerbio.com</u>.

#### Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, prospective products, preclinical and clinical pipelines, regulatory objectives, business strategy and plans and objectives for future operations, are forward-looking statements. Forward-looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the timing of our ongoing and planned clinical development; our ability to identify, pursue and enter into partnering opportunities for our virology assets; the sufficiency of our cash, cash equivalents and investments to fund our operations into fourth quarter of 2024, including the scope and impact of any savings from our workforce reduction and cash conservation efforts; the revenue potential of avexitide in post-bariatric hypoglycemia and congenital hyperinsulinism; our ability to finance, independently or through collaborations, the continued advancement of our development pipeline; and the potential for success of any of our products or product candidates. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including additional applicable risks and uncertainties described in the "Risk Factors" section in Eiger's Ouarterly Report on Form 10-Q for the quarter ended March 31, 2023 and Eiger's subsequent filings with the SEC. The forward-looking statements contained in this press release are based on information currently available to Eiger and speak only as of the date on which they are made. Eiger does not undertake and specifically disclaims any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

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