Sentynl Therapeutics Announces Global Acquisition of Zokinvy® (Lonafarnib) for Treatment of Hutchinson-Gilford Progeria Syndrome from Eiger BioPharmaceuticals

Sentynl, a Zydus Group company, receives worldwide proprietary rights to Zokinvy, adding to portfolio of biopharmaceuticals for rare and ultra-rare diseases

Zokinvy is approved in the U.S. (2020), European Union and Great Britain (2022), and Japan (2024) for the treatment of progeria, a collection of ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients

Solana Beach, CA, Ahmedabad, India, and Palo Alto, CA – May 3, 2024 — Sentynl Therapeutics, Inc. (Sentynl), a U.S.-based biopharmaceutical company wholly-owned by Zydus Lifesciences, Ltd. (Zydus Group), and Eiger BioPharmaceuticals, Inc. (OTC: EIGRQ), a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases, today announced the closing of the sale of Eiger's Zokinvy® (lonafarnib) program to Sentynl.

Zokinvy is the first and only treatment approved by the U.S. Food and Drug Administration (FDA) to target the cause and symptoms of progeria, also known as Hutchinson-Gilford progeria syndrome (HGPS) and processing-deficient progeroid laminopathies (PDPL), in young people 12 months of age and older. Collectively known as progeria, HGPS and PDPL are ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients. Following its U.S. approval in 2020, Zokinvy secured approval in the European Union and Great Britain (2022) and in Japan (January 2024).

Speaking on the acquisition, Dr. Sharvil Patel, Managing Director of Zydus Lifesciences, said, "This acquisition marks an important milestone in growing our portfolio of medicines for rare and orphan diseases, which can have devastating consequences if left untreated. We are focused on supporting patients to live healthier and more fulfilled lives. The acquisition of Zokinvy directly furthers this mission, as it has a demonstrated meaningful impact on young patients and their families."

"It is an honor to add Zokinvy to our portfolio of products that have a tangible impact on the lives of rare disease patients, whose needs are too often unmet or overlooked," said Matt Heck, President & Chief Executive Officer of Sentynl. "We are firmly committed to provide best-in-class global access to Zokinvy and are eager to serve the patients and their families affected by progeria. We are grateful to Eiger and The Progeria Research Foundation for their dedicated effort to develop and secure availability of this life-changing product."

"We are pleased to complete this agreement with Sentynl, given our shared commitment to supporting patients of life-threatening, rare conditions with high unmet medical needs," said David Apelian, MD, PhD, MBA, CEO of Eiger. "We thank The Progeria Research Foundation for their continued support of Zokinvy."

Audrey Gordon, President and Executive Director of The Progeria Research Foundation (PRF), added, "Without Zokinvy therapy, children with progeria die of the same heart disease that affects millions of normally aging adults, but by an average age of 14.5 years old. Zokinvy gives these beautiful children longer, healthier lives. Since we first launched PRF in 1999, we have achieved tremendous progress in global awareness, breakthrough research, and treatment of progeria. We are thankful for our successful partnership with Eiger, and are excited to now join forces with Sentynl in our journey to continue advancing the research and treatment of this syndrome, with the ultimate goal to find the cure."

As previously disclosed by Eiger, on April 1, 2024, Eiger and its direct subsidiaries filed voluntary petitions for relief under chapter 11 of Title 11 of the United States Code (Chapter 11 Cases) in the United States Bankruptcy Court for the Northern District of Texas (Bankruptcy Court). On April 17, 2024, following the completion of the auction held as part of the Eiger's court-supervised sale process, Sentynl was designated the winning bidder with a final bid during the auction of a base price in the amount of $46.1 million less a credit in the amount of $0.9 million for the termination fee resulting in a net base price in the amount of $45.2 million, subject to certain purchase price adjustments, including a reduction of $100,000 per diem if the sale closed after April 24, 2024. At a hearing held on April 23, 2024, the Bankruptcy Court approved the sale to Sentynl, with the sale closing on May 3, 2024. Under the terms of the acquisition, Sentynl acquired global rights to Zokinvy and will be responsible for its manufacture and commercialization.

For questions on continued access to Zokinvy, please contact the Sentynl Cares support team at 1-888-251-2800 Monday-Friday, 8 am-8 pm ET. For inquiries after hours, follow the recorded instructions.

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About Progeria
Collectively known as progeria, Hutchinson-Gilford progeria syndrome and progeroid laminopathies are ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients.

HGPS is caused by a point mutation in the LMNA gene, yielding the farnesylated aberrant protein, progerin. Progeroid laminopathies are genetic conditions of accelerated aging caused by a constellation of mutations in the LMNA and/or ZMPSTE24 genes yielding farnesylated proteins that are distinct from progerin.[4,5]

Without Zokinvy therapy, children with HGPS commonly die of the same heart disease that affects millions of normally aging adults (arteriosclerosis), by an average age of 14.5 years. Disease manifestations include severe failure to thrive, scleroderma–like skin, global lipodystrophy, alopecia, joint contractures, skeletal dysplasia, global accelerated atherosclerosis with cardiovascular decline, and debilitating strokes.[3]

About Zokinvy (lonafarnib)
Zokinvy is a first-in-class disease-modifying agent that blocks the accumulation of defective progerin and progerin-like proteins which leads to cellular instability and premature aging in children and young adults with progeria. Zokinvy has demonstrated a statistically significant survival benefit in children and young adults with HGPS.[1,4]

The most commonly reported adverse reactions were gastrointestinal (vomiting, diarrhea, nausea), and most were mild or moderate (Grade 1 or 2) in severity. Many progeria patients have received continuous Zokinvy therapy for more than 10 years.[1,2]

Zokinvy is FDA approved for the treatment of patients 12 months of age and older with a genetically confirmed diagnosis of Hutchinson-Gilford progeria syndrome or a processing-deficient progeroid laminopathy associated with either a heterozygous LMNA mutation with progerin-like protein accumulation or a homozygous or compound heterozygous ZMPSTE24 mutation.

For Important Safety Information and prescribing information for Zokinvy in the U.S., please visit www.zokinvy.com.

Eiger licensed exclusive worldwide rights to lonafarnib for the treatment of H-G progeria from MSD, the tradename of Merck & Co., Inc, Rahway, N.J., USA. MSD provided lonafarnib free of charge for clinical studies supported by the PRF and waived royalty and milestone obligations on lonafarnib from Sentynl for people living with the condition.

Eiger and AnGes entered into an exclusive distribution agreement for the treatment of HGPS and PDPL indications, Zokinvy (Lonafarnib), in Japan on May 10, 2022. In March 2023, the Ministry of Health, Labour and Welfare designated Zokinvy as an orphan drug.

About Sentynl Therapeutics
Sentynl Therapeutics is a U.S.-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. The company was acquired by the Zydus Group in 2017. Sentynl's experienced management team has previously built multiple successful pharmaceutical companies. With a focus on commercialization, Sentynl looks to source effective and well-differentiated products across a broad spectrum of therapeutic areas to address unmet needs. Sentynl is committed to the highest ethical standards and compliance with all applicable laws, regulations and industry guidelines. For more information, visit https://sentynl.com.

About Zydus Group
Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group has a significant presence in cancer related therapies and offers a wide range of solutions with cytotoxic, supportive & targeted drugs. The group employs over 26,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more information, visit https://www.zyduslife.com/zyduslife/.

About Eiger Biopharmaceuticals
Eiger is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic 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. On April 1, 2024, Eiger and its direct subsidiaries filed the Chapter 11 Cases in the Bankruptcy Court.

Eiger's securityholders are cautioned that trading in Eiger's securities during the pendency of the Chapter 11 Cases is highly speculative and poses substantial risks. Trading prices for Eiger's securities may bear little or no relationship to the actual recovery, if any, by holders thereof in the Chapter 11 Cases. Accordingly, Eiger urges extreme caution with respect to existing and future investments in its securities. In particular, Eiger expects that its securityholders could experience a significant or complete loss on their investment, depending on the outcome of the Chapter 11 Cases.

About The Progeria Research Foundation
The Progeria Research Foundation (PRF) was established in 1999 by the family of Sam Berns, a child with Progeria. Within four years of its founding, the PRF Genetics Consortium discovered the Progeria gene, a collaboration led by Dr. Francis Collins, Acting Science Advisor to the President of the United States and former Director of the National Institutes of Health (NIH). PRF has funded and co-coordinated all Zokinvy associated clinical trials for Progeria and Progeroid Laminopathies, conducted at Boston Children's Hospital, and supports scientists who conduct Progeria research worldwide. PRF's International Patient Registry includes over 393 children with Progeria in 72 countries. PRF is the only non-profit organization solely dedicated to finding treatments and the cure for Progeria and its aging-related conditions, including heart disease. The organization fills a void, putting these children and Progeria at the forefront of scientific efforts. For more information and to support PRF's mission, please visit www.progeriaresearch.org.

Note Regarding Forward-Looking Statements of Eiger

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 the continued commercialization and manufacturing of Zokinvy, the outcome of the Chapter 11 Cases, business strategy and plans and objectives for future operations, are forward-looking statements. 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 Quarterly Report on Form 10-K for the year ended December 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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