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IN THE UNITED STATES BANKRUPTCY COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

In re:	Chapter 11
EIGER BIOPHARMACEUTICALS, INC., *et al.*[1]	Case No. 24-80040 (SGJ)
	(Jointly Administered)
Debtors.	

PROGERIA RESEARCH FOUNDATION'S RESPONSE (A) IN OPPOSITION TO EIT PHARMA, INC., FORMERLY KNOWN AS EIGER INNOTHERAPEUTICS, INC.'S EMERGENCY MOTION TO CONFIRM TERMS OF LONAFARNIB/LAMBDA SALE ORDER AND (B) IN SUPPORT OF SENTYNL THERAPEUTICS, INC.'S MOTION (I) TO ENFORCE THE ZOKINVY SALE ORDER AND (II) FOR CONTEMPT AGAINST EIGER INNOTHERAPEUTICS, INC.

[1] The Debtors in these chapter 11 cases, together with the last four digits of each Debtor's federal tax identification number, are: Eiger BioPharmaceuticals, Inc. (1591); EBPI Merger Inc. (9986); EB Pharma LLC (8352); Eiger BioPharmaceuticals Europe Limited (N/A); and EigerBio Europe Limited (N/A). The Debtors' service address is 2100 Ross Avenue, Dallas, Texas 75201.

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Progeria Research Foundation ("**PRF**"), submits this response in objection to *EIT Pharma, Inc., Formerly Known as Eiger InnoTherapeutics, Inc.'s Emergency Motion to Confirm Terms of Lonafarnib/Lambda Sale Order*, filed on March 24, 2025 (the "**Emergency Motion**") (Docket No. 787) and in support of *Sentynl Therapeutics, Inc.'s Motion (I) to Enforce the Zokinvy Sale Order and (II) for Contempt Against Eiger Innotherapeautics, Inc.*, filed on March 7, 2025 (the "**Motion to Enforce**") (Docket No. 779), and respectfully states as follows:

RESPONSE

1. As PRF has made clear since the outset of the chapter 11 cases of Eiger BioPharmaceuticals, Inc. ("**Eiger Bio**" and, together with its debtor affiliates, the "**Debtors**"), PRF's sole interest in these chapter 11 cases is to ensure the safe and continuous supply of Zokinvy to Progeria patients around the world.[2] This goal also aligned with the Debtors' stated intentions in filing for bankruptcy on April 1, 2024: "(1) to ensure stability and continuity in the provision of life-saving drugs for patients, including children, worldwide and (2) to institute a sale process designed to maximize the value of all the Debtors' assets for the benefit of all the Debtors' stakeholders."[3] [redacted]

[2] *See* April 3, 2024 Hearing Tr., 22:21–25, 23:1–25, 24:1–25, 25:1–20.

[3] *Declaration of David Apelian in Support of the Chapter 11 Petitions and First Day Pleadings* (Docket No. 19, ¶ 7).

[4] *Order (I) Approving the Sale of the Debtors' Zokinvy Assets, (II) Authorizing Assumption and Assignment of Certain Executory Contracts and Unexpired Leases Related Thereto, and (III) Granting Related Relief* (Docket No. 162) (the "**Zokinvy Sale Order**").

[5] *Revised Order (I) Authorizing the Sale of the Lonafarnib and Lambda Assets Free and Clear of Liens, Claims, Encumbrances, and Other Interests, (II) Authorizing the Assumption and Assignment of Executory Contracts and Unexpired Leases, (III) Granting the Purchaser the Protections Afforded to a Good Faith Purchaser, (IV) Approving Purchaser Protections in Connection with the Sale of the Lonafarnib and Lambda Assets, and (V) Granting Related Relief* (Docket No. 558) (the "**Lonafarnib Sale Order**").

[redacted]

2. As the Court may recall, PRF is a 501(c)(3) charitable organization based in Peabody, Massachusetts. It was co-founded in 1999 by Audrey Gordon and her sister and brother-in-law, Drs. Leslie Gordon (a research scientist) and Scott Berns, whose child Sam was diagnosed with Progeria and passed away in 2014 at age 17. PRF's mission is simple: "To discover treatments and the cure for Progeria and its aging-related disorders, including heart disease."

3. Progeria, or Hutchinson-Gilford Progeria Syndrome, is a fatal premature aging disease caused by a single DNA base mutation, resulting in a toxic protein (progerin) which is expressed in nearly every cell of the body. It is an ultra-rare disease with a 1 in 20,000,000 prevalence. As of March 31, 2025, PRF had identified 149 living patients residing in 51 countries, speaking 37 languages, including approximately fifteen Progeria patients in the US. Progeria is typically diagnosed in children between nine months and four years of age. The symptoms and complications of Progeria include heart failure and stroke, growth failure, premature heart disease,

skin tightness, loss of body fat and hair, and joint stiffness and mobility issues. Progeria patients are cognitively normal and exhibit age-appropriate intelligence, energy and behavior. Without treatment, clinical studies have shown that Progeria patients die at an average age of 14.5 years.

4. Zokinvy was the first—and is currently the only—drug in the world approved to treat Progeria. The active ingredient in Zokinvy is lonafarnib, a drug initially developed by the pharmaceutical company Merck Sharp & Dohme Corp. ("**Merck**") for cancer. Merck licensed the lonafarnib molecule to Eiger Bio for use in treating Progeria under a written license agreement in 2010. In September 2012, the results of the first-ever Progeria clinical drug trial demonstrated that lonafarnib was an effective treatment for Progeria. Notably, all trial participants experienced significant improvements in weight gain, bone structure, and most importantly, the cardiovascular system.[6] Lonafarnib was approved by FDA for the treatment of Progeria in November 2020 under the brand name Zokinvy and has been shown to provide an estimated 4.3 years of additional life, or a 30% increase in lifespan, and improved quality of health to Progeria patients.

5. PRF was integral in isolating the cause of Progeria and, later, in funding and conducting studies of children with Progeria to demonstrate lonafarnib's effectiveness. Because PRF was the owner of the clinical data showing the safety and effectiveness of lonafarnib and the owner of the only two patents regarding the use of lonafarnib for Progeria, Eiger Bio could not file an application for approval with United States Food and Drug Administration (the "**FDA**") for commercialization without PRF. In order to facilitate the manufacture of lonafarnib for treatment of Progeria, PRF licensed its data and patents to Eiger Bio pursuant to a Collaboration and Supply Agreement entered into in 2018 (the "**CSA**" and, as amended and restated in 2024, the "**ARCSA**") so that Eiger Bio could submit an application to regulatory authorities for approval. In exchange,

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[6] Leslie B. Gordon et al., *Clinical Trial of a Farnesyltransferase Inhibitor in Children with Hutchinson-Gilford Progeria Syndrome*, 109 Proc. Nat'l Acad. Sci. 16395, 16666–71 (2012).

Eiger Bio agreed to, among other things, manufacture Zokinvy and provide PRF with free Zokinvy for clinical trials through at least June 20, 2031.[7] With PRF's consent—which was required in order for Eiger Bio to assign the ARCSA—Eiger Bio assigned all of its rights and obligations under the ARCSA (with certain modifications) to Sentynl in connection with the sale of the Zokinvy assets to Sentynl.

[redacted]

[7] The ARCSA specifies that Eiger will continue to supply product for clinical trials until "a minimum of June 20, 2031."

[8] *See Reply in Support of Motion for Allowance of Administrative Expense Claim of Sentynl Therapeutics, Inc.* (Docket Nos. 800, 801, ¶ 14).

[redacted]

8. The dispute that EIT has raised in its Emergency Motion and in its communications with Lonza and Corden as to who purchased or licensed what rights or assets under the respective Sale Orders is, at its core, a contractual dispute that can be reduced to monetary damages. Although EIT would have this Court believe otherwise, it has provided no evidence to support its claims that it is positioned to urgently bring lonafarnib to market as a treatment for the hepatitis delta virus ("**HDV**").[9] [redacted]

[9] EIT has represented to this court that "EIT's development of Lonafarnib [for HDV] is currently on track for accelerated approval: EIT plans to submit a new drug application to the FDA and is targeting Lonafarnib's commercial launch in 2026." *See* Emergency Motion, ¶ 2. However, it appears that after the 2022 completion of the Phase III HDV study of surrogate endpoints, FDA told Eiger Bio that additional outcomes studies would be required for approval of lonafarnib in HDV and that an accelerated approval was not possible. *See* Phil Taylor, *Eiger Wields Axe as FDA Sets High Bar for Hepatitis Drug*, PHARMAPHORUM (June 30, 2023), https://pharmaphorum.com/news/eiger-wields-axe-fda-sets-high-bar-hepatitis-drug. The National Institute of Health's database of all current clinical trials, clinicaltrials.gov, discloses that from 2022 until the present neither

(. . . footnote continued on following page . . .)

[redacted]

10. The relief sought by EIT in its Emergency Motion is not appropriate for the reasons set forth in Sentynl's supplemental response filed on April 11, 2025 at Docket No. 810. [redacted] *See Young v. Higbee Co.,* 324 U.S. 204, 214, 65 S. Ct. 594, 599, 89 L. Ed. 890 (1945) ("Courts of bankruptcy are courts of equity and exercise all equitable powers unless prohibited by the Bankruptcy Act."); *Pepper v. Litton,* 308 U.S. 295, 307–08, 60 S. Ct. 238, 246, 84 L. Ed. 281 (1939) ("[I]n the exercise of its equitable jurisdiction the bankruptcy court has the power to sift the circumstances surrounding any claim to see that injustice or

Eiger Bio or any other entity has commenced a clinical study of lonafarnib for HDV with the morbidity and mortality endpoints specifically requested by FDA. Registration of such a clinical trial is required under 42 C.F.R. 11.24.

unfairness is not done in administration of the bankrupt estate."); *Matter of Fabricators, Inc.*, 926 F.2d 1458, 1464 (5th Cir. 1991) ("[The bankruptcy court's] equitable powers allow a bankruptcy court to produce fair and just results 'to the end that fraud will not prevail, that substance will not give way to form, that technical considerations will not prevent substantial justice from being done.'") (quoting *Pepper v. Litton,* 308 U.S. at 305); *In re Graves*, 212 B.R. 692, 695 (B.A.P. 1st Cir. 1997) ("Bankruptcy courts as courts of equity have the power to look through the form to the substance of a transaction and may fashion new remedies where those in law are inadequate."); *see also* 11 U.S.C. 105(a) ("The court may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title.").

11. For the reasons set forth herein, EIT's Emergency Motion should be denied and the Court should fashion relief similar to the proposed form of order filed by Sentynl at Docket No. 809, Ex. A, [redacted] PRF reserves all rights against any and all parties, including the right to supplement this response, and to raise additional objections, including to the Settlement Agreement, at a later date.

Dated: April 15, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on April 15, 2025, I caused a copy of the foregoing Motion to be served by the Electronic Case Filing System for the United States Bankruptcy Court for the Northern District of Texas and to be emailed to the following parties.

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