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

In re:

EIGER BIOPHARMACEUTICALS, INC., et al.¹

Debtors.

Chapter 11

Case No. 24-80040 (SGJ)

(Jointly Administered)

DEBTORS' EMERGENCY MOTION FOR ENTRY OF AN ORDER (I) AUTHORIZING THE DEBTORS TO PROVIDE PRF WITH UP TO A FIVE-MONTH SUPPLY OF ZOKINVY, AND (II) GRANTING RELATED RELIEF

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.



Emergency relief has been requested. Relief is requested not later than 1:30 p.m. prevailing Central Time on May 7, 2024.

If you object to the relief requested or you believe that emergency consideration is not warranted, you must appear at the hearing if one is set, or file a written response prior to the date that relief is requested in the preceding paragraph. Otherwise, the Court may treat the pleading as unopposed and grant the relief requested.

A hearing will be conducted on this matter on May 7, 2024 at 1:30 p.m. in Courtroom #1, 14th Floor, Earle Cabell Federal Building, 1100 Commerce Street, Suite 1254, Dallas, Texas, 75242.

You may participate in the hearing either in person or by an audio and video connection.

Audio communication will be by use of the Court's dial-in facility. You may access the facility at 1.650.479.3207. Video communication will be by the use of the Cisco WebEx platform. Connect via the Cisco WebEx application or click the link on Judge Jernigan's home page. The meeting code is 479 393 582. Click the settings icon in the upper right corner and enter your name under the personal information setting.

Hearing appearances must be made electronically in advance of electronic hearings. To make your appearance, click the "Electronic Appearance" link on Judge Jernigan's home page. Select the case name, complete the required fields and click "Submit" to complete your appearance.

The debtors and debtors in possession in the above-captioned chapter 11 cases (collectively, the "Debtors") state as follows in support of this motion:²

Relief Requested

1. The Debtors seek entry of an order, substantially in the form attached hereto as **Exhibit A**: (a) authorizing, but not directing, the Debtors to provide the Progeria Research Foundation with, at the Debtors' discretion, up to a five-month supply of Zokinvy; and (b) granting related relief.

Jurisdiction and Venue

2. The United States Bankruptcy Court for the Northern District of Texas (the "Court") has jurisdiction over this matter pursuant to 28 U.S.C. § 1334. This matter is a core proceeding pursuant to 28 U.S.C. § 157(b). The Debtors confirm their consent, pursuant to rule

A detailed description of the Debtors and their business, and the facts and circumstances supporting this motion and the Debtors' chapter 11 cases, are set forth in greater detail in the *Declaration of David Apelian in Support of Chapter 11 Petitions and First Day Pleadings* [Docket No. 19] (the "First Day Declaration"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the First Day Declaration.

7008 of the Federal Rules of Bankruptcy Procedure (the "<u>Bankruptcy Rules</u>"), to the Court's entry of a final order in connection with this motion.

- 3. Venue is proper pursuant to 28 U.S.C. §§ 1408 and 1409.
- 4. The bases for the relief requested herein are sections 105(a) and 363 of title 11 of the United States Code (the "Bankruptcy Code").

Background

- 5. The Debtors are a commercial-stage biopharmaceutical company focused on the development of innovative therapies for hepatitis delta virus ("<u>HDV</u>") and other serious diseases. All of the Debtors' rare disease programs have FDA Breakthrough Therapy designation.
- 6. On April 1, 2024 (the "Petition Date"), each Debtor filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code. The Debtors are operating their business and managing their property as debtors in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. These chapter 11 cases have been consolidated for procedural purposes only and are being administered jointly. No party has requested the appointment of a trustee or examiner in these cases, and no statutory committee has been appointed.

Preliminary Statement

7. The Debtors filed these chapter 11 cases for two primary reasons: (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. The Debtors received approval to pursue the sale of their rights to the drug known as "Zokinvy" (the "Zokinvy Sale Transaction"). As has been previously presented to the Court, Zokinvy is the only approved treatment for a life-threatening disease—progeria—which affects children. While the Zokinvy Sale Transaction is designed and intended to, among other things, ensure a smooth transition of the product and

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continued, uninterrupted supply of the drug to patients, the Debtors make the instant motion in an abundance of caution to avoid any disruption resulting from unanticipated issues. Accordingly, the Debtors request authority to provide, in their discretion, up to a five-month supply of Zokinvy to the Progeria Research Foundation (the "PRF").

- 8. As has been highlighted during the Debtors' first day hearing and in the media,³ the continuing provision of Zokinvy to children with progeria is without question a matter of life and death. Zokinvy is the only known treatment for progeria, and may increase the life of a child with progeria by approximately four years. The Debtors are unwilling to allow any disruption to the Zokinvy supply. In light of the uncertainty of the closing timeline for the Zokinvy Sale Transaction, however, the Debtors are seeking the relief requested herein to ensure that no such disruption transpires. If, however, the Zokinvy Sale Transaction closes prior to a hearing on this motion, the Debtors will withdraw the current motion.
- 9. The Debtors provide Zokinvy to PRF at no cost, so the request herein requires no cash outlay and does not impact the Debtors', or any purchaser's, revenue. Instead, the authority requested herein is simply a timing request—the Debtors seek authority to provide supply of Zokinvy contemporaneously with the closing of the Zokinvy Sale Transaction, supply that, in any event, would have been provided to PRF eventually. The children and families that depend on Zokinvy should not bear any risk, and the relief requested herein removes any risk that they could be impacted by the Debtors' sale process.

See, e.g., Editorial Board, Requiem for Eiger Biopharmaceuticals, WALL ST. J.: OPINION (April 7, 2024, 2:51 PM), https://www.wsj.com/articles/eiger-biopharmaceuticals-bankruptcy-drugs-pharma-food-and-drug-administration-7ce52b88.

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The Amended and Restated Collaboration and Supply Agreement

- 10. Hutchinson-Gilford progeria syndrome ("HGPS") and progeroid laminopathies ("PL"), collectively known as "progeria," are ultra-rare and rapidly fatal genetic conditions causing accelerated aging in children. Patients with progeria experience accelerated cardiovascular disease from the buildup of defective progerin or progerin-like protein in cells and most patients die before reaching 15 years old.
- 11. After the groundbreaking discovery of the progeria gene in 2003, PRF began an intense study of the so-called "progerin" gene. Historically, the only treatment options for progeria included supportive care and therapies directed towards the complications arising from the disease. In 2006, however, PRF's research bore significant fruit with the discovery that farnesyltransferase inhibitors ("FTIs") blocked the buildup of the defective progerin protein, effectively paralyzing the progression of progeria.
- 12. Lonafarnib is an orally bioavailable, first-in-class FTI originally developed by Merck & Co. ("Merck") that the Debtors have an exclusive license to develop and commercialize. On May 15, 2018, the Company entered into a Collaboration and Supply Agreement with PRF (the "Supply Agreement"), pursuant to which the parties agreed to collaborate with respect to the development and pursuit of regulatory approval of lonafarnib to reduce the risk of mortality of progeria. Under the Supply Agreement, the Debtors are also obligated to provide PRF with an exclusive supply of lonafarnib for use in clinical trials and non-clinical research in progeria.
- 13. In November 2020, the Company received FDA approval for the use lonafarnib to treat progeria. Sold under the brand name "Zokinvy," the medication is the first and only product on the market that has received FDA approval for the treatment of progeria. Studies have shown

that with Zokinvy, the average lifespan of a child with progeria was extended by at least 2.5 years, with a 60% reduction in risk of mortality.⁴

- 14. On February 29, 2024, the Debtors and PRF entered into an Amended and Restated Collaboration and Supply Agreement to confirm the Debtors' exclusive right to commercialize Zokinvy for the treatment of progeria, subject to the terms and conditions of the agreement (the "Amended and Restated Supply Agreement").
- 15. According to the terms of the A&R Supply Agreement, the Debtors supply PRF with Zokinvy to patients enrolled in PRF's clinical trials who do not have another reliable or operational source of Zokinvy. *See* A&R Supply Agreement § 9(a). Prior to delivery of the drug, PRF notifies the Debtors of the amount of relevant patient needs. *See id*.
- 16. Here, PRF has requested assurance that the Debtors have the authority to provide, in the Debtors' discretion, advance shipments of Zokinvy in order to cover patients' needs for the next five months. Specifically, PRF is seeking enough product to cover patients who are scheduled for clinical treatment trial visits at Boston Children's Hospital between the date hereof and the end of August 2024. The Debtors believe that they have the authority to provide shipments of Zokinvy to PRF as an ordinary course transaction, but respectfully seek the Court's authority out of an abundance of caution.

Basis For Relief Requested

17. A debtor may use property of the estate in the ordinary course of business without notice or a hearing. 11 U.S.C. § 363(c). Under section 363(b) of the Bankruptcy Code, a debtor may also, in the exercise of its sound business judgment and after notice and hearing, use property of the estate outside of the ordinary course of business. 11 U.S.C. § 363(b). The Fifth Circuit has

See About Zokinvy, https://www.zokinvy.com/hcp/about-zokinvy#efficacy (last visited Apr. 16, 2024).

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held that debtors must articulate a "business justification" for using, selling, or leasing property outside of the ordinary course of business. *See, e.g., In re ASARCO, L.L.C.*, 650 F.3d 593, 601 (5th Cir. 2011) ("[F]or the debtor-in-possession or trustee to satisfy its fiduciary duty to the debtor, creditors, and equity holders, there must be some articulated business justification for using, selling, or leasing the property outside the ordinary course of business.") (quoting *In re Continental Air Lines*, 780 F.2d 1223, 1226 (5th Cir. 1986)). "The business judgment standard in section 363 is flexible and encourages discretion." *In re ASARCO, L.L.C.*, 650 F.3d at 601.

Section 105(a) of the Bankruptcy Code gives the Court vast equitable powers to 18. "issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a); see also In re Davis, 170 F.3d 475, 492 (5th Cir. 1999) ("The basic purpose of § 105 is to assure the bankruptcy courts power to take whatever action is appropriate or necessary in aid of the exercise of its jurisdiction.") (internal quotations omitted). Further, determining the appropriate method for carrying out the provisions of the Bankruptcy Code is left to the discretion of the court. See In re Rojas, No. 07-70058, 2009 WL 2496807, at *7 (Bankr. S.D. Tex. Aug. 12, 2009) ("Section 105 does not require a court to use the least restrictive means to carry out the requirements of the Code. Section 105(a) of the Bankruptcy Code does not say that the Court's authority is limited to orders or judgments necessary to carry out the Code. Rather, Congress explicitly added to the statute deferential, discretionary language with 'or appropriate.'") (quoting 11 U.S.C. § 105(a)). The Court is given these vast equitable powers to ensure that the Debtors are "not unduly denied benefits" provided to them under the Bankruptcy Code. In re Exquisito Servs., Inc., 823 F.2d 151, 155 (5th Cir. 1987); see also Bird v. Crown Convenience (In re NWFX, Inc.), 864 F.2d 588, 590 (8th Cir. 1988) ("The overriding consideration in bankruptcy . . . is that equitable principles govern.").

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19. Here, the Debtors' performance under the A&R Supply Agreement is a reasonable exercise of their business judgment. The A&R Supply Agreement is a critical component of the contemplated restructuring—one of the Debtors' goals in these chapter 11 cases is to institute a sale process designed to maximize the value of all of the Debtors' assets for the benefit of the Debtors' stakeholders. As discussed further in the First Day Declaration and the Bid Procedures Declaration,⁵ the Debtors intend to sell the Zokinvy assets to the best and highest bidder, but the A&R Supply Agreement bestows on PRF certain rights over any sublicense, sale or transfer of the Zokinvy assets. Regardless of what rights PRF has with respect to the Zokinvy assets, PRF's request to obtain an advance supply of Zokinvy goes beyond the sale process. Maintaining goodwill with PRF and honoring any obligations related to the A&R Supply Agreement is important, but the Debtors' commitment to the lives of the children that rely on Zokinvy rises far above such obligations.

20. The continuity of this life-saving treatment for children diagnosed with progeria is, simply, more important than the Zokinvy Sale Transaction. The Debtors are the *sole* providers of lonafarnib to PRF. The requested supply will be utilized to treat children traveling to Boston for clinical treatment trial visits that have been planned for months. These children and their hopeful families have already coordinated travel plans and accommodations and are anticipating receiving this potentially life-saving treatment. With no alternative access to Zokinvy, these clinical treatment trial visits are the only opportunity these patients have to receive treatment. If the

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The "Apelian Bid Procedures Declaration" refers to the Declaration of David Apelian in Support of the Debtors' Motion for Entry of an Order (I)(A) Approving the Bid Procedures; (B) Authorizing the Debtors to Select Sentynl Therapeutics, Inc. as the Stalking Horse Purchaser & Approving Bid Protections; (C) Approving the Bid Protections Relating to the Remaining Assets Stalking Horse Purchaser(s), if any; (D) Establishing Bid Deadlines, Auction(s), and Sale Hearing(s); (E) Approving the Form and Manner of Sale Notice; (F) Approving Assignment and Assumption Procedures; (G) Approving the Form and Manner of Potential Assumption and Assignment Notice; (II)(A) Authorizing the Sale of the Assets Free and Clear; and (B) Approving the Assumption and Assignment of Designated Contracts; and (III) Granting Related Relief [Docket No. 25].

Debtors are unable to provide such lonafarnib, PRF would be unable to provide treatment and the patients—the children—would face significant harm.

21. The Debtors believe that they are empowered to provide PRF with, in the Debtors' discretion, up to a five-month supply of Zokinvy as a transaction in the ordinary course of business, but out of an abundance of caution, respectfully seek the Court's authority to provide any advance supplies of Zokinvy.

Waiver of Bankruptcy Rule 6004(a) and 6004(h)

22. The Debtors request that the Court enter an order providing that notice of the relief requested herein satisfies Bankruptcy Rule 6004(a) and that the Debtors have established cause to exclude such relief from the fourteen-day stay period under Bankruptcy Rule 6004(h), which is necessary to implement the relief requested in this motion.

Reservation of Rights

23. Nothing contained herein or any action taken pursuant to relief requested is intended to be or shall be construed as (a) an admission as to the amount of, basis for, or validity of any claim against a Debtor entity under the Bankruptcy Code or other applicable nonbankruptcy law; (b) a waiver of the Debtors' or any party in interest's rights to dispute any claim or interest on any grounds; (c) a promise or requirement to pay any claim; (d) a waiver of the Debtors' or any other party in interest's rights under the Bankruptcy Code or any other applicable law; (e) an implication or admission that any particular claim is of a type specified or defined in this motion or any order granting the relief requested in this motion or a finding that any particular claim is an administrative expense claim or other priority claim; (f) a request for or approval to assume, adopt, or reject any agreement, contract, program, policy, or lease under section 365 of the Bankruptcy Code; or (g) an admission as to the validity, priority, enforceability, or perfection of any lien on, security interest in, or other encumbrance on property of the Debtors' estates. Likewise, if the

Court grants the relief sought herein, any payment made pursuant to the Court's order is not intended to be and should not be construed as an admission to the validity of any claim or a waiver of the Debtors' or any party in interest's rights to subsequently dispute such claim.

Notice

24. The Debtors will provide notice of this motion to the following: (a) the U.S. Trustee for the Northern District of Texas; (b) the holders of the thirty (30) largest unsecured claims against the Debtors (on a consolidated basis); (c) Innovatus Life Sciences Lending Fund I, LP, as agent to the Debtors' secured lenders, and counsel thereto; (d) the United States Attorney's Office for the Northern District of Texas; (e) the Food and Drug Administration; (f) the Internal Revenue Service; (g) the United States Securities and Exchange Commission; (h) the state attorneys general for the states in which the Debtors conduct business; (i) PRF; and (j) any party that has requested notice pursuant to Bankruptcy Rule 2002. No other or further notice is needed in light of the nature of the relief requested.

[Remainder of page intentionally left blank.]

The Debtors respectfully request entry of the order granting the relief requested herein and granting such other relief as the Court deems appropriate under the circumstances.

Dated: May 1, 2024

Dallas, Texas

SIDLEY AUSTIN LLP

/s/ Thomas R. Califano

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Proposed Attorneys for the Debtors and Debtors in Possession

Certificate of Service

I certify that on May 1, 2024, I caused a copy of the foregoing document to be served by the Electronic Case Filing System for the United States Bankruptcy Court for the Northern District of Texas.

/s/ Thomas R. Califano

Thomas R. Califano

Exhibit A

Proposed Order

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

In re:

EIGER BIOPHARMACEUTICALS, INC., et al.¹

Debtors.

Chapter 11

Case No. 24-80040 (SGJ)

(Jointly Administered)

ORDER (I) AUTHORIZING THE DEBTORS TO PROVIDE PRF WITH A UP TO A FIVE MONTH SUPPLY OF ZOKINVY AND (II) GRANTING RELATED RELIEF

Upon the motion ("<u>Motion</u>")² of the debtors and debtors in possession in the above-captioned chapter 11 cases (collectively, the "<u>Debtors</u>"), for entry of an order (this "<u>Order</u>") (a) authorizing, but not directing, the Debtors to provide the Progeria Research Foundation ("<u>PRF</u>") with up to a five-month supply of Zokinvy; and (b) granting related relief, each as more fully set forth in the Motion; and upon consideration of the First Day Declaration; and this Court

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.

² Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the Motion.

having jurisdiction over this matter pursuant to 28 U.S.C. § 1334; and this matter being a core proceeding within the meaning of 28 U.S.C. § 157(b)(2); and the Court being able to issue a final order consistent with Article III of the United States Constitution; and venue of this proceeding and the Motion in this district being proper pursuant to 28 U.S.C. §§ 1408 and 1409; and appropriate notice of and opportunity for a hearing on the Motion having been given; and the relief requested in the Motion being in the best interests of the Debtors' estates, their creditors and other parties in interest; and the Court having determined that the legal and factual bases set forth in the Motion establish just cause for the relief granted herein; and after due deliberation and sufficient cause appearing therefor, it is

HEREBY ORDERED THAT:

- 1. The Motion is GRANTED as set forth herein.
- 2. The Debtors are authorized, but not directed, to provide PRF with, in the Debtors' discretion, up to a five-month supply of Zokinvy.
- 3. Notwithstanding anything to the contrary herein, any payment to be made by the Debtors pursuant to the authority granted herein shall be subject to and in compliance with any orders entered by the Court authorizing the Debtors' use of cash collateral and/or any budget in connection therewith.
- 4. Notice of the Motion as provided therein shall be deemed good and sufficient notice of such Motion, and the requirements of Bankruptcy Rule 6004(a) and the Bankruptcy Local Rules are satisfied by such notice.
- 5. Notwithstanding Bankruptcy Rule 6004(h), the terms and conditions of this Order shall be immediately effective and enforceable upon its entry.

- 6. The Debtors are authorized to take all such reasonable actions necessary to effectuate the relief granted in this Order in accordance with the Motion.
- 7. This Court retains exclusive jurisdiction with respect to all matters arising from or related to the implementation, interpretation, and enforcement of this Order.

END OF ORDER

Submitted By:

SIDLEY AUSTIN LLP

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