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Counsel for Sentynl Therapeutics, Inc.

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

In re:

EIGER BIOPHARMACEUTICALS, INC., *et al.*<sup>1</sup>

Debtors.

Chapter 11

Case No. 24-80040 (SGJ)

(Jointly Administered)

# SENTYNL THERAPEUTICS, INC.'S (I) RESPONSE TO EIT PHARMA, INC., FORMERLY KNOWN AS EIGER INNOTHERAPEUTICS, INC.'S EMERGENCY MOTION TO CONFIRM TERMS OF LONAFARNIB/LAMBDA SALE ORDER AND (II) REQUEST FOR STATUS CONFERENCE PURSUANT TO 11 U.S.C. § 105(d)

<sup>&</sup>lt;sup>1</sup> 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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Sentynl Therapeutics, Inc. ("<u>Sentynl</u>"), objects to the emergency Motion,<sup>2</sup> which is grossly deficient, and should be denied for several reasons. Instead of granting EIT's improper request for declaratory judgment, Sentynl requests a status conference under 11 U.S.C. § 105(d) to avoid unfair advantage or prejudice and provide guidance on scheduling of multiple interrelated, previously-filed motions, namely:

- (i) The Motion for Allowance of Administrative Expense Claim of Sentynl Therapeutics, Inc. ("Admin Claim"),<sup>3</sup> attached as Exhibit A;
- (ii) Sentynl Therapeutics, Inc. 's (I) Motion to Enforce the Zokinvy Sale Order and (II) for Contempt Against Eiger InnoTherapeutics, Inc. ("Motion to Enforce"),<sup>4</sup> attached as Exhibit B; and
- (iii) the present Motion.

In support thereof, Sentynl respectfully states as follows:

# EMERGENCY CONSIDERATION IS INAPPROPRIATE

1. There was no effort to confer before filing the Motion<sup>5</sup> and no evidentiary basis

exists for emergency consideration.<sup>6</sup> The key premises of the Motion are untrue:

<sup>&</sup>lt;sup>2</sup> EIT Pharma, Inc., Formerly Known as Eiger InnoTherapeutics, Inc.'s Emergency Motion to Confirm Terms of Lonafarnib/Lambda Sale Order (the "Motion"). Docket No. 787.

<sup>&</sup>lt;sup>3</sup> Docket No. 729.

<sup>&</sup>lt;sup>4</sup> Docket Nos. 779, 781. Docket Nos. 779 and 781 are identical. However, motions to enforce and motions for contempt must be filed as separate docket entries under ECF requirements.

<sup>&</sup>lt;sup>5</sup> EIT made no attempt to confer on the Motion in violation of the Procedures for Complex Cases in the Northern District of Texas and Local Bankruptcy Rules. Instead, counsel for EIT emailed a statement that "shortly, EIT will be filing a motion to confirm the terms of the sale order and APA as it relates to Corden inventory purchased by EIT." That is not a good faith attempt to confer.

<sup>&</sup>lt;sup>6</sup> The Motion attaches no competent declaration or other evidence and Sentynl objects to evidence when is has not been afforded the opportunity for discovery, as discussed later.

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- (i) EIT or Eiger Inno<sup>7</sup> is not a "leading manufacturer of Lonafarnib;"<sup>8</sup>
- (ii) Lonafarnib is not an FDA-approved "treatment of HDV;"<sup>9</sup>
- (iii) Lonafarnib is not a "life-saving drug for the treatment of HDV;"<sup>10</sup>
- (iv) Lonafarnib is not the only treatment available to HDV patients, or even an approved treatment;<sup>11</sup> and
- (v) EIT confirmed to Sentynl as early as April 2024, that Sentynl acquired all the existing lonafarnib raw materials located with Corden (and Lonza).

2. Unlike EIT, Sentynl requires lonafarnib raw materials to manufacture and sell Zokinvy®, a life-extending drug used to treat patients with Progeria, a pediatric, fatal rare disease, a drug that requires the subject precursors and reference materials soon (lest real world supply chains be disrupted). To procure the required precursors and reference materials, Sentynl filed its Motion to Enforce and began conferring on expedited discovery. Without any attempt to confer, the Motion was filed to undermine *that* contested matter (as well as Sentynl's efforts to collect from the Debtors on account of various breaches of the Zokinvy APA through prosecution of the Admin Claim). Because Sentynl cannot obtain the precursors for Zokinvy® with EIT seeking to frustrate the supply chain (as discussed in the Motion to Enforce and Admin Claim), Sentynl asks

<sup>&</sup>lt;sup>7</sup> EIT Pharma, Inc., formerly known as Eiger InnoTherapeutics, Inc. ("<u>EIT</u>" or "<u>Eiger Inno</u>").

<sup>&</sup>lt;sup>8</sup> Motion ¶ 2. EIT has not manufactured Lonafarnib. EIT has merely acquired contracts from Debtor Eiger BioPharmaceuticals, Inc. ("<u>Eiger Bio</u>").

<sup>&</sup>lt;sup>9</sup> Motion ¶ 2. Lonafarnib is not a treatment for HDV, let alone "a life-saving treatment."<sup>9</sup> Lonafarnib it is not approved by the FDA to treat HDV. It is not the standard of care for treatment of HDV. Sentynl is not aware of any human patient currently being treated with Lonafarnib for HDV. Lonafarnib for HDV will have to clear a "high bar" before it is approved to treat HDV. https://pharmaphorum.com/news/eiger-wields-axe-fda-sets-high-bar-hepatitis-drug.

<sup>&</sup>lt;sup>10</sup> Motion  $\P$  6. Lonafarnib is not a life-saving drug for the treatment of HDV. It has not saved any lives. At most, it has the *potential* to be a *treatment* for HDV if it is ever approved for that purpose

<sup>&</sup>lt;sup>11</sup> Motion  $\P$  6.

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for a status conference and expedited discovery, lest its real-world human patients be deprived of an FDA-approved life-extending drug.

# EVEN IF AN EMERGENCY EXISTED, AN ATTEMPT TO CONFER WOULD LIKELY HAVE RESOLVED THE DOUBLE-SALE ISSUE

3. The Motion is a tactical move to avoid first addressing the pending Motion to Enforce and Admin Claim, by misrepresenting EIT's motives while presenting an ersatz dispute. The "double-sold" reference samples were technically never sold to EIT, because the Debtor could not sell again what it had previously sold to Sentynl. That is apparently conceded by the Motion and was acknowledged long ago in prior negotiations. The entire Motion could stop there. But it does not. Why?

4. As background, Schedule 2.1(h) to the Lonafarnib APA contains two (2) tables, an *Inventory* table and a *Reference Material* table confirming that the vast majority (if not all) inventory and reference samples were previously sold to Sentynl (the "Zokinvy Buyer" referenced in the column labeled "Transferred to Zokinvy Buyer (Grams)").<sup>12</sup> As explained in paragraphs 17-20 of the Motion to Enforce, the Lonafarnib APA only purports to retain for EIT 50 grams from each of the raw material lots listed in rows 3-12 under the *Reference Material* section of Schedule 2.1(h) to the Lonafarnib APA to the extent not previously sold. Turning Schedule 2.1(h) on its head, EIT alleges in the Motion that the only "reference materials" conveyed to Sentynl were "50 grams of 'reference materials,"<sup>13</sup> which is refuted by the plain language used in Schedule 2.1(h) that the vast majority (if not all) *Reference Material* was "Transferred to Zokinvy Buyer":

<sup>&</sup>lt;sup>12</sup> A copy of Schedule 2.1(h) to the Lonafarnib APA is attached hereto as <u>Exhibit C</u>.

<sup>&</sup>lt;sup>13</sup> See Motion  $\P$  24.

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# Reference Material

	Raw Material Lot	Current On-hand in kilos	Gram Conversion	Retained by Eiger (Grams) as reference materials	Transferred to Zokinvy Buyer (Grams)
1	LONAFARNIB SDD 29.1 Kg 00-0120 Retest Patheon US Only	29.1	29,100	50	29,050
2	LONAFARNIB SDD 54.9 Kg 00-0332 Retest Patheon Global	54.9	54,900	50	54,850
3	YGK BP1515-LT 91.6 Kg 203002 Retest Corden US Only	91.6	91,600	50	91,550
4	YGK BP1515-LT 120.0 Kg 203003 Retest Corden US Only	120	120,000	50	119,950
5	YGK BP1515-LT 84.3 Kg 222004 Retest Corden Global	84.3	84,300	50	84,250
6	YGK BP1515-LT 118.8 Kg 228005 Retest Corden Global	118.8	118,800	50	118,750
7	GLS BP1515-JJ 18.8 Kg 11693 Retest Corden Global	18.8	18,800	50	18,750

9 (	Corden Global GLS BP1515-JJ 59.9 Kg GLS-J-20210201 Retest Corden Global	59.9	59,900	50	59,850
	GLS BP1515-JJ 300 Kg GLS-J-20221201 10/27/2024 Corden Global	300	300,000	50	299,950
1	BP1515-WA Stage 1 0.6 Kg BO2210B22B Retest Corden Global	0.6	600	50	550
1	BP1515-Y Stage 2 46.6 Kg BO2210B023 Retest Corden Global	46.6	46,600	50	46,550
1	Lonafarnib API 17.9 Kg BO2011B901 Retest Lonza Bend US Only	17.9	17,900	50	17,850

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5. Further making mountains of molehills, EIT concedes that the sale order could not sell what had already been sold to Sentynl,<sup>14</sup> as shown in Schedule 3.3(a) to the Zokinvy APA, attached as <u>Exhibit D</u>. Likewise, there should be no dispute regarding the *Inventory* also in Schedule 2.1(h) to the Lonafarnib APA because those products are in the possession of Patheon, not Corden, as shown in the seventh column under the *Inventory* section. Sentynl does not claim to own any other reference material or inventory in Corden's possession other than the materials and inventory specifically acquired pursuant to the Zokinvy APA. The present Motion thus appears to be pretext – generating a non-dispute as a tactical move to secure a seemingly innocuous trojan horse ruling from this Court, which would then be used offensively by EIT in connection with the Motion to Enforce.

# <u>THE REQUESTED DECLARATORY RELIEF WOULD CREATE MORE PROBLEMS</u> <u>THAN IT WOULD RESOLVE</u>

6. EIT's request for the Court to "make *clear* to all parties and for all time, that the language in the Lonafarnib/Lambda Sale Order and the Lonafa[r]nib APA is *clear*, and that the assets and contracts listed therein, and subject thereto were sold, transferred and assigned to EIT"<sup>15</sup> is unnecessary, impermissible, and prejudicial. Is this an advisory opinion? A declaratory judgment? An effort to get the Court to read its misleading statement of facts before the Motion to Enforce is filed? What, exactly, would the Court issue to "grant" this relief?

7. The Motion appears to request an advisory opinion if the Court is opining on "making something clear" about what happens if a third party does not deliver on a disputed

<sup>&</sup>lt;sup>14</sup> See Proposed Order Granting Motion ¶ 2 ("Pursuant to the terms of the Lonafarnib/Lambda Sale Order and the Lonafarnib APA, EIT purchased all Inventory, as defined in section 2.1(h) of the Lonafarnib APA, which, for clarity and the avoidance of doubt, includes any such inventory in the possession of CordenPharma International *that was not previously purchased by Sentynl.*") (emphasis added).

<sup>&</sup>lt;sup>15</sup> Motion  $\P$  21 (emphasis added).

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contractual obligation. The Motion appears to request an impermissible declaratory judgment<sup>16</sup> to resolve a declaration of the rights of the parties but not actually enforce an order. The Motion premises these requests on inaccurate facts (*e.g.*, despite what the Motion suggests, lonafarnib is not an approved treatment for HDV). The Lonafarnib APA states it does not convey material already sold to Sentynl, as discussed in Sentynl's Motion to Enforce. EIT appears to concede it does not own the material previously sold. Yet, the existing Motion to Enforce and Admin Claim *did* join the critical issues between the parties – frustration of the Zokinvy® supply chain. Accordingly, this Court should deny the request but hold a status hearing on the supply chain motion – the Motion to Enforce.

#### **REQUEST FOR STATUS CONFERENCE**

8. In contrast to the Motion, Sentynl and EIT have made repeated efforts to confer on discovery, on timing, and the relevant disputes under the Motion to Enforce. The parties seek a timeline for discovery deadlines, conferences, and an evidentiary hearing on the Sentynl's Motion to Enforce (and even a mediation). The parties made progress on a timeline, and the Court "shall hold such status conferences as are necessary to further the expeditious and economical resolution of the case." 11 U.S.C. § 105(d).

9. As the Motion requests relief before 9:30 a.m. on March 31, 2025, and given the interrelatedness of the Admin Claim and Motion to Enforce (which could reduce the amounts claimed by Sentynl under the Admin Claim), and the present Motion, a status conference should be held in lieu of, or at least before, any hearing on the Motion. At the status conference, the parties must confer at least one day *before* that conference and submit an agreed plan. At the status conference, the Court can then provide guidance on this dispute.

<sup>&</sup>lt;sup>16</sup> A declaratory judgment requires an adversary proceeding, if the Court has jurisdiction and does not abstain. FED. R. BANKR. P. 7001(9).

# **RESERVATION OF RIGHTS**

10. Because this was filed suddenly and without conferring Sentynl must reserve claims

and rights against any person and the right to supplement or correct this Response.

Dated: March 25, 2025

Respectfully submitted,

# PILLSBURY WINTHROP SHAW PITTMAN LLP

By: /s/ Hugh M. Ray, III

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Counsel for Sentynl Therapeutics, Inc.

# **CERTIFICATE OF SERVICE**

I certify that, on March 25, 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.

*Counsel for EIT* GOODWIN PROCTOR LLP Kizzy Jarashow kjarashow@goodwinlaw.com David Chen davidchen@goodwinlaw.com

*Counsel for the Liquidating Trustee* PORZIO, BROMBERG & NEWMAN, P.C. Warren J. Martin Jr. WJMartin@pbnlaw.com Rachel A. Parisi RAParisi@pbnlaw.com

Associate General Counsel for Lonza Lara Crow lara.crow@lonza.com

Counsel for EIT **GRAY REED** Jason S. Brookner jbrookner@grayreed.com Emily F. Shanks eshanks@grayreed.com

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MCKOOL SMITH, PC John J. Sparacino jsparacino@mckoolsmith.com S. Margie Venus mvenus@mckoolsmith.com Travis E. DeArman tdearman@mckoolsmith.com

# General Counsel for Corden

Naoki Takei naoki.takei@cordenpharma.com **Richard Janovjak** richard.janovjak@cordenpharma.com

> /s/ Hugh M. Ray, III Hugh M. Ray, III

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# **EXHIBIT A**

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Counsel for Sentynl Therapeutics, Inc.

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

In re:

EIGER BIOPHARMACEUTICALS, INC., *et al.*<sup>1</sup>

Chapter 11

Case No. 24-80040 (SGJ)

Debtors.

(Jointly Administered)

MOTION FOR ALLOWANCE OF ADMINISTRATIVE EXPENSE CLAIM OF SENTYNL THERAPEUTICS, INC.

Sentynl Therapeutics, Inc. ("Sentynl"), submits its Motion for Allowance of Administrative

Expense Claim (the "Motion"), and in support thereof would respectfully show the Court as

follows:

<sup>&</sup>lt;sup>1</sup> 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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#### PRELIMINARY STATEMENT

1. On April 24, 2024, this Court approved Sentynl's purchase of Zokinvy – the only known life extending treatment for progeria, a rare and fatal genetic condition – for \$45,200,000.<sup>2</sup> As a condition to closing of the Zokinvy Asset Purchase Agreement,<sup>3</sup> the parties executed and delivered the Sublicense Agreement.<sup>4</sup> Debtor Eiger Biopharmaceuticals, Inc. ("<u>Eiger Bio</u>"), is in the process of breaching the Sublicense Agreement and effectively preventing Sentynl from manufacturing the drug and fulfilling its regulatory obligations, which could lead to Sentynl's inability to deliver Zokinvy to patients who depend on it to extend their lives. To make matters worse, the breach is for the apparent benefit of non-debtor Eiger InnoTherapeutics, Inc. ("<u>Eiger Inno</u>"), the purchaser of the estate's remaining Lonafarnib Assets and Lambda Assets and an entity being run by one of Eiger Bio's former founding members.<sup>5</sup>

2. As a result of Eiger Bio's post-petition breach, Sentynl is entitled to an allowed administrative expense up to the amount of the Zokinvy Purchase Price.<sup>6</sup>

<sup>&</sup>lt;sup>2</sup> See 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] ("Zokinvy Sale Order").

<sup>&</sup>lt;sup>3</sup> That certain Asset Purchase Agreement by and between Sentynl Therapeutics, Inc., as Purchaser, and Eiger BioPharmaceuticals, Inc., as Seller, Dated March 31, 2024, annexed as Exhibit 1 to the Zokinvy Sale Order, and as from time to time amended in accordance with the Zokinvy Sale Order or further order of this Court, including by the First Amendment to the Zokinvy Asset Purchase Agreement attached to the Zokinvy Sale Order ("Zokinvy Asset Purchase Agreement").

<sup>&</sup>lt;sup>4</sup> That certain *Sublicense Agreement, dated as of the Closing Date, by and among Purchaser and the Seller,* substantially in the form attached to the Zokinvy Asset Purchase Agreement as Exhibit E [filed under seal pursuant to order at Docket No. 188].

<sup>&</sup>lt;sup>5</sup> The manufacturing and regulatory issues described below arose shortly after Eiger Inno's acquisition closed on September 3, 2024 but several months after Sentynl's acquisition closed on May 3, 2024 and Sentynl initiated discussions with Lonza and IQVIA. See Notice of Closing of Lonafarnib/Lamba Sale Transaction [Docket No. 616]; Notice of Closing of Zokinvy Sale Transaction [Docket No. 214].

<sup>&</sup>lt;sup>6</sup> Separately, the Liquidating Trust has acknowledged and recognized the estate's commitment to satisfy up to an amount of \$3,161,245 in connection with the payment of a rebate claim owing to the French government. Such acknowledgment and agreement obviates the need for Sentynl to include such amount in the calculation of its administrative expense claim requested herein.

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## **JURISDICTION**

3. The United States Bankruptcy Court for the Northern District of Texas (the "<u>Court</u>") has jurisdiction over this matter pursuant to 28 U.S.C. §1334 and the order of referral of the United States District Court for the Northern District of Texas. This matter is a core proceeding pursuant to 28 U.S.C. §157, and this Court may enter a final order consistent with Article II of the United States Constitution.

# **BACKGROUND**<sup>7</sup>

# A. Lonza Bend MSA

4. Bend Research, Inc., a Lonza Company ("Lonza Bend"), provides spray dried dispersion services that are critical to the manufacturing process for the Zokinvy product. The services occur in the middle of the manufacturing process and supply chain for the Zokinvy product and are thus critical to supply of the product. Sentynl does not have any previously existing relationship with Lonza Bend, nor has Sentynl identified an alternative service provider for such services.

5. During the negotiation of the acquisition of the Zokinvy Assets, Sentynl requested Eiger Bio to assign to Sentynl certain key manufacturing and supply agreements, such as the *Commercial Manufacturing Services and Supply Agreement with Lonza Bend, dated October 9, 2019* (the "Lonza Bend MSA"). Eiger Bio informed Sentynl on multiple occasions that Eiger Bio could not assign the Lonza Bend MSA and certain other contracts to Sentynl because Eiger Bio needed to retain them to be able to facilitate a sale of the remaining Lonafarnib Assets.

<sup>&</sup>lt;sup>7</sup> The Motion was intentionally expedited by agreement with the Liquidating Trustee. Copies of the underlying documentation and communications are available to interested parties. In advance of any hearing on the Motion, Sentynl will supplement the record with all evidentiary documentation of the facts referenced herein.

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6. Under the Sublicense Agreement, Eiger Bio agreed that certain agreements, including the Lonza Bend MSA were, "Retained Agreements," which are subject to special treatment. Importantly, Eiger Bio is obligated to use reasonable efforts not to assign the Lonza Bend Agreement in a manner that adversely affects Sentynl's rights under the Sublicense Agreement or ability to "Commercialize" Zokinvy.<sup>8</sup> Additionally, Eiger Bio has represented and warranted to Sentynl that the Lonza Bend MSA, as one of the "Retained Agreements," was one of the agreements necessary for the manufacture and commercialization of Zokinvy.<sup>9</sup>

7. In connection with Eiger Bio's proposed sale of the remaining Lonafarnib Assets to Eiger Inno, Sentynl learned that Eiger Bio agreed to assign many contracts to Eiger Inno that Eiger Bio had told Sentynl were not assignable or would not be assigned. One of those contracts was the Lonza Bend MSA. Sentynl informed Eiger Bio that it wanted those agreements assigned to Sentynl, given the prior communications from Eiger Bio that those agreements were not assignable or were not going to be assigned and given their critical importance to Sentynl's ability to manufacture and commercialize Zokinvy, but Eiger Bio and Eiger Inno refused that request.

8. Sentynl has sought to negotiate a new contract with Lonza Bend, using its best reasonable efforts, as contemplated by the Zokinvy Asset Purchase Agreement. Despite initial engagement and exchange of draft agreements, Lonza Bend has delayed negotiations, which Sentynl is informed and believes is likely the result of an intervention by or on behalf of Eiger Inno.

9. Importantly, the Lonza Bend MSA is scheduled to be formally assigned to Eiger Inno in early November 2024 (on the six month anniversary of the closing of the Zokinvy Asset

<sup>&</sup>lt;sup>8</sup> See Section 3.7 of the Sublicense Agreement.

<sup>&</sup>lt;sup>9</sup> See Sections 11.2(j) and 11.2(w) of the Sublicense Agreement.

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Purchase Agreement). The Lonza Bend MSA contains an exclusivity clause in Section 2.8 that provides Lonza Bend will not manufacture or supply the product to or for any other person other than Customer (soon to be Eiger Inno). If the Lonza Bend MSA is assigned to Eiger Inno, Sentynl is informed and believes that Eiger Inno may attempt to enforce that exclusivity clause to the detriment of Sentynl and those impacted with progeria who rely on a continuous supply of therapy.

10. If Eiger Bio proceeds with assigning the Lonza Bend MSA to Eiger Inno with the exclusivity provision in place or with any other provisions that are adverse to Sentynl, then Eiger Bio will be in breach of its covenants and obligations to Sentynl under the Zokinvy Asset Purchase Agreement.

## B. <u>Regulatory Obligations</u>

11. Zokinvy's status as a commercial progeria therapeutic, approved by the FDA, MHRA, EMA, Japan, and Israel, places significant and important regulatory filing obligations on Sentynl, including the operation and maintenance of the global safety database, and periodic reporting obligations under such as Development Safety Update Reports ("<u>DSUR</u>"), the next of which is due to regulatory authorities on November 29, 2024.

12. Pursuant to the Zokinvy Asset Purchase Agreement and the Sublicense Agreement, Sentynl has acquired and/or licensed from Eiger Bio all data and "Regulatory Information" necessary for Sentynl to commercialize Zokinvy.

13. To aid in the process of transferring from Eiger Bio to Sentynl the data from the global safety database and ensure that the upcoming DSUR filing is timely made, the Liquidating Trustee engaged Rich Franco as a consultant to coordinate among Eiger Bio, Eiger Inno and Sentynl for the preparation of the upcoming DSUR filing and other related coordination efforts. Eiger Bio, Eiger Inno, and Sentynl met on October 15, 2024 to allocate responsibilities for certain

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safety data elements of the DSUR to representatives of the three companies. Mr. Franco agreed to receive and compile data elements from each group for the next DSUR.

14. The next morning, Mr. Franco communicated to Sentynl that he was unable to fulfill those responsibilities because Leen Kawas, Managing General Partner of an investor in Eiger Inno, complained to the Liquidating Trustee and demanded that Eiger Inno be in charge of pharmacovigilance matters, such as the DSUR, because Eiger Inno had assumed contracts with IQVIA, which is a third party that has provided services related to the maintenance and use of the global safety database for Zokinvy. This demand was made even though the marketing authorization of Zokinvy from the European Union had not formally transferred yet from Eiger Bio to Sentynl, and so Eiger Bio was technically responsible for the filing at the time. The marketing authorization of Zokinvy has since transferred to Sentynl and as a result Sentynl is now the official holder of marketing authorization of Zokinvy from the European Union and has the corresponding regulatory obligations. However, due to what Sentynl is informed and believes to be Eiger Inno's problematic engagement to date, Sentynl will not be able to meet its upcoming regulatory obligations unless Eiger Inno cooperates with Sentynl and Eiger Bio as previously proposed and Eiger Inno does not attempt to prevent IQVIA from transferring the applicable data from the global safety database to Sentynl. As discussed above, Sentynl acquired rights to that data and "Regulatory Information," and it should be transferred to Sentynl under the terms of the Zokinvy Asset Purchase Agreement.

15. Additionally, Eiger Bio has failed to fulfill obligations under the transaction documents in regard to safety databases and pharmacovigilance. For example, Eiger Bio is obligated to transfer to Sentynl all relevant information sufficient for Sentynl to comply with its obligations to regulatory authorities and investigators regarding adverse events that have been

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observed during any clinical trials conducted with the Licensed Progeria Product or Licensed Product prior to the Effective Date. The agreements also invest Sentynl with the responsibility for maintaining a safety database for the Licensed Progeria Product.<sup>10</sup> The parties are also obligated to enter into a separate written pharmacovigilance agreement with respect to the Licensed Progeria Products and other Licensed Products to enable the parties to fulfill their respective regulatory reporting obligations. Finally, Eiger Bio is obligated to perform specific transition activity services related to pharmacovigilance scheduled for the benefit of Sentynl.

### **BASIS FOR RELIEF**

16. Section 503(b)(1)(A) of the Bankruptcy Code provides, in relevant part, that "[a]fter notice and a hearing, there shall be allowed administrative expenses, other than claims allowed under Section 502(f) of this title, including . . . the actual, necessary costs and expenses of preserving the estate . . . ." The claimant seeking administrative expenses bears the burden of proof. *Toma Steel Supply, Inc. v. TransAmerican Nat. Gas Corp. (In re TransAmerican Nat. Gas Corp.)*, 978 F.2d 1409, 1416 (5th Cir. 1992).

17. "[T]o qualify as an 'actual and necessary cost' under section 503(b)(1)(A), a claim against the estate must have arisen post-petition and as a result of actions taken by the trustee [or debtor-in-possession] that benefitted the estate." *Matter of Whistler Energy II, L.L.C.*, 931 F.3d 432, 441 (5th Cir. 2019) (quoting *Total Minatome Corp. v. Jack/Wade Drilling, Inc. (In re Jack/Wade Drilling, Inc.)*, 258 F.3d 385, 387 (5th Cir. 2001)). The benefit does not, however, "have to be substantial" to qualify. *See In re Women First Healthcare, Inc.*, 332 B.R. 115, 121 (Bankr. D. Del. 2005).

<sup>&</sup>lt;sup>10</sup> See Section 5.3(c) and Schedule 5.3(c) of the Sublicense Agreement.

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18. Breach of a post-petition agreement may give rise to an administrative expense claim. *See In re Finevest Foods, Inc.*, 159 B.R. 972, 981 (Bankr. M.D. Fla. 1993) ("The Court finds that debtor breached the warranty contained in § 4.1.7(a) of the asset purchase agreement and that claimant is entitled to an administrative expense claim in the amount of \$306,223.00."); *In re Wildwood Villages, LLC*, 2022 Bankr. LEXIS 1466 (Bankr. M.D. Fla. Jan. 21, 2022) (debtor developer's post-petition breach of a covenant to provide recreational facilities gave rise to an administrative claim).

19. "The claimant bears the burden of proving by a preponderance of the evidence that its claim qualifies as an administrative expense." *In re Krisu Hosp., LLC*, No. 19-20347-rlj11, 2021 Bankr. LEXIS 788, at \*10 (Bankr. N.D. Tex. Mar. 26, 2021) (quoting *In re Acis Cap. Mgmt., L.P.*, 604 B.R. 484, 517 (N.D. Tex. 2019)).

20. Here, there can be no credible argument that Eiger Bio's (1) forthcoming assignment of the Lonza Bend MSA to Eiger Inno and (2) acquiescence to Eiger Inno's control of regulatory matters, do not adversely and materially affect Sentynl's rights under the Sublicense Agreement and its ability to commercialize Zokinvy and fulfill its regulatory obligations. Such actions constitute material breaches of the Zokinvy Asset Purchase Agreement and Sublicence Agreement by Eiger Bio and are compensable as an administrative expense. Because these breaches frustrate the entire purpose of the Zokinvy Asset Purchase Agreement and Sublicense Agreement and continued production and therefore commercialization of Zokinvy, the most important goal of this entire bankruptcy case to ensure patients with progeria can continue to receive treatment, Sentynl should be allowed an administrative expense in an amount up to the Zokinvy Purchase Price.

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### **RESERVATION OF RIGHTS**

In filing this Motion, Sentynl does not waive any claims it may have against Eiger
 Inno.

# **CONCLUSION**

WHEREFORE, Sentynl respectfully requests that this Court enter an order, substantially

in the form attached hereto as Exhibit A, allowing Sentynl an administrative expense claim against

the Debtors' respective estates for in the amount up to the full \$45,200,000 paid under the Zokinvy

Asset Purchase Agreement and such other and further relief as is just and necessary.

Dated: November 1, 2024

Respectfully submitted,

# PILLSBURY WINTHROP SHAW PITTMAN LLP

By: /s/ L. James Dickinson

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Counsel for Sentynl Therapeutics, Inc.

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# **Certificate of Service**

I certify that on November 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.

> <u>/s/ L. James Dickinson</u> L. James Dickinson

Case 24-80040-sgj11 Doc 790-2 Filed 03/25/25 Entered 03/25/25 20:15:14 Desc Exhibit B Page 1 of 36

# EXHIBIT B

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Counsel for Sentynl Therapeutics, Inc.

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

In re:

Chapter 11

EIGER BIOPHARMACEUTICALS, INC., *et al.*<sup>1</sup>

(Jointly Administered)

Case No. 24-80040 (SGJ)

Debtors.

# SENTYNL THERAPEUTICS, INC.'S MOTION (I) TO ENFORCE THE ZOKINVY SALE ORDER AND (II) FOR CONTEMPT AGAINST EIGER INNOTHERAPEUTICS, INC.

<sup>&</sup>lt;sup>1</sup> 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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# TO THE HONORABLE STACEY G. C. JERNIGAN, CHIEF JUDGE OF THE UNITED STATES BANKRUPTCY COURT FOR THE NORTHERN DISTRICT OF TEXAS:

Sentynl Therapeutics, Inc. ("Sentynl"), submits this Motion (I) to Enforce the Zokinvy Sale

Order and (II) for Contempt Against Eiger InnoTherapeutics, Inc. (the "Motion"), and respectfully

requests entry of an order enforcing the Zokinvy Sale Order<sup>2</sup> by:

- enjoining non-debtor Eiger InnoTherapeutics, Inc. (n/k/a EIT Pharma, Inc.)
  ("Eiger Inno"), from enforcing the exclusivity provision in the Lonza Bend MSA<sup>3</sup> against third-party Lonza<sup>4</sup> (or any affiliate) or taking any other actions that would prevent Lonza (or any applicable affiliate) from providing products, materials, services, data, information, or know-how to Sentynl in connection with the manufacture, supply, or commercialization of Zokinvy;
- (ii) authorizing and directing third-party Lonza to immediately provide Sentynl data and information, on an ongoing basis, associated with existing Zokinvy inventories purchased by Sentynl under the Zokinvy APA;<sup>5</sup>
- (iii) enjoining Eiger Inno from pursuing or entering any agreement or taking any other actions that would prevent third-party Corden Pharma Colorado ("<u>Corden</u>") (or any affiliate) from providing products, materials, services, data, information, or know-how to Sentynl in connection with the manufacture, supply, or commercialization of Zokinvy;
- (iv) authorizing and directing third-party Corden to immediately provide Sentynl data and information, on an ongoing basis, associated with existing Zokinvy inventories purchased by Sentynl under the Zokinvy APA;
- (v) enjoining Eiger Inno from challenging Sentynl's rights to the existing Zokinvy inventories purchased by Sentynl under the Zokinvy APA in any manner whatsoever, which continue until all ongoing regulatory requirements with respect to these inventories have been satisfied;

<sup>&</sup>lt;sup>2</sup> 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] ("Zokinvy Sale Order").

<sup>&</sup>lt;sup>3</sup> That certain Commercial Manufacturing Services and Supply Agreement, by and between Eiger BioPharmaceuticals Inc. and Bend Research, Inc., dated October 9, 2019 (the "Lonza Bend MSA").

<sup>&</sup>lt;sup>4</sup> Bend Research, Inc. ("<u>Lonza</u>").

<sup>&</sup>lt;sup>5</sup> That certain Asset Purchase Agreement by and between Sentynl Therapeutics, Inc., as Purchaser, and Eiger BioPharmaceuticals, Inc., as Seller, Dated March 31, 2024, annexed as Exhibit 1 to the Zokinvy Sale Order, and as from time to time amended in accordance with the Zokinvy Sale Order or further order of this Court, including by the First Amendment to the Zokinvy Asset Purchase Agreement attached to the Zokinvy Sale Order ("Zokinvy <u>APA</u>").

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- (vi) ordering Eiger Inno to show cause why it should not be held in contempt of Court for interfering with Sentynl's commercialization rights in violation of the Zokinvy Sale Order; and
- (vii) awarding monetary sanctions against Eiger Inno to compensate Sentynl for prosecuting Eiger Inno's contemptible conduct.

In support, Sentynl submits the Declaration of Michael G. Hercz, Esq. in Support of Sentynl Therapeutics, Inc.'s Motion (I) to Enforce the Zokinvy Sale Order and (II) for Contempt Against Eiger InnoTherapeutics, Inc. (the "Hercz Decl."), which is attached as <u>Exhibit 1</u> to the Appendix accompanying this Motion and which is incorporated by reference herein, and respectfully represents as follows:

## **INTRODUCTION**

1. Almost a year ago, the Debtors petitioned this Court for relief "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."<sup>6</sup> The events that immediately followed were, by all accounts, of tremendous benefit to those patients and stakeholders. Sentynl purchased the Zokinvy Assets,<sup>7</sup> which fulfilled those goals by providing stability and continuity for progeria patients and \$45.2 million to the Debtors' estate. Positive developments for the estate's stakeholders continued when Amylyx Pharmaceuticals, Inc. purchased the Avexitide Assets.<sup>8</sup>

<sup>&</sup>lt;sup>6</sup> Declaration of David Apelian in Support of the Chapter 11 Petitions and First Day Pleadings [Docket No. 19 ¶ 7].

<sup>&</sup>lt;sup>7</sup> As defined in the Zokinvy Sale Order [Docket No. 162 ¶ 9].

<sup>&</sup>lt;sup>8</sup> See Order (I) Approving the Sale of the Debtors' Avexitide Assets, (II) Authorizing Assumption and Assignment of Certain Executory Contracts and Unexpired Leases Related Thereto, and (III) Granting Related Relief [Docket No. 376].

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2. Then, with the benefit of knowing exactly what the Debtors already sold and the rights that Sentynl obtained, Dr. Jeffrey Glenn, a former founder and insider of Debtor Eiger BioPharmaceuticals, Inc. ("<u>Eiger Bio</u>"),<sup>9</sup> formed an entity that was confusingly named Eiger InnoTherapeutics, Inc. (as defined above, "<u>Eiger Inno</u>"),<sup>10</sup> to purchase the Debtor's remaining Lonafarnib Assets.<sup>11</sup> Following entry of the Lonafarnib Sale Order, as previously raised before the Court,<sup>12</sup> non-debtor Eiger Inno proceeded to interfere with Sentynl's rights and disrupt the stability and continuity of Zokinvy.

3. Although the issues in the Sentynl Admin Claim that relate to IQVIA have been resolved generally, the Lonza exclusivity issue remains, new issues relating to materials and services provided by Corden have emerged recently, and efforts to obtain a consensual resolution out-of-court have run their course. Consequently, Sentynl must now turn to the Court as a last resort for relief to prevent Eiger Inno from continuing to deprive Sentynl of its rights, interfere

<sup>&</sup>lt;sup>9</sup> Jeffrey S. Glenn, MD, PhD, served as a member of privately-held Eiger BioPharmaceuticals, Inc.'s ("Private Eiger") Board of Directors since his appointment in 2008 until the completion of the Private Eiger's business combination with Celladon Corporation in March 2016, with the surviving entity changing its name to Eiger BioPharmaceuticals, Inc. (the "Merger"). Dr. Glenn, a Professor of Medicine at Stanford University School of Medicine, served on the Board through his resignation on April 1, 2024.

Declaration of Michael Shanahan in Support of Confirmation of the Fourth Amended Joint Plan of Liquidation of Eiger Biopharmaceuticals, Inc. and Its Debtor Affiliates Pursuant to Chapter 11 of the Bankruptcy Code [Docket No. 609 ¶ 19.a] (footnote citations omitted).

<sup>&</sup>lt;sup>10</sup> Eiger Inno was not formed under the *Fifth Amended Joint Plan of Liquidation of Eiger Biopharmaceuticals, Inc. and Its Debtor Affiliates*, but the startup appears to be something of a successor to Eiger Bio, benefiting from the goodwill of the Debtors' name, without compensation to the estate. Eiger Inno was formed under Delaware law on or about April 9, 2024. Eiger Inno has since changed its name to EIT Pharma, Inc. Its principal address is 11620 Wilshire Blvd, Ste 350, Los Angeles, CA 90025, the same address as Propel Bio Management LLC, and two of three of Eiger Inno's board members are managing partners at Propel Bio. *See* https://eitpharma.com/; https://www.propelbio.com/propel-team/.

See 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").

<sup>&</sup>lt;sup>12</sup> See Motion for Allowance of Administrative Expense Claim of Sentynl Therapeutics, Inc. [Docket No. 729] (the "<u>Sentynl Admin Claim</u>").

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with third party relationships necessary to manufacture and commercialize Zokinvy, interfere with Sentynl's ability to meet its regulatory obligations with respect to Zokinvy, and jeopardize the stability and continuity of Sentynl's supply of Zokinvy to progeria patients who depend on it to extend their lives.

# **BACKGROUND**

# A. <u>Sentynl's Acquisition of Zokinvy</u>

4. On April 24, 2024, this Court entered the Zokinvy Sale Order finding (i) Sentynl "is a 'good faith purchaser' . . . within the meaning of section 363(m) of the Bankruptcy Code . . . and, as such, is entitled to all the protections afforded thereby;"<sup>13</sup> and (ii) the transaction should be consummated in a manner that will "avoid any disruption to the patients who depend on Zokinvy to treat progeria, a rare and fatal genetic condition that may result from continued uncertainty about the future of the Transferred Assets."<sup>14</sup>

5. The FDA-approved and commercialized Zokinvy product, and the unapproved and pre-commercialization Lonafarnib for Hepatitis Delta Virus ("<u>HDV</u>") product, both use the same the active pharmaceutical ingredient ("<u>API</u>") and Drug Product Intermediate, also referred to as Spray Dried Dispersion ("<u>SDD</u>"), and thus depend upon the same limited set of suppliers for the API and SDD.<sup>15</sup> This supply chain limitation was not an issue for the Debtors, who owned both products, to allocate materials and services.

6. As a condition to closing of the Zokinvy APA, Sentynl and Eiger Bio entered into the Sublicense Agreement. <sup>16</sup> Under the Sublicense Agreement, certain agreements were

<sup>&</sup>lt;sup>13</sup> See Zokinvy Sale Order ¶ R.

<sup>&</sup>lt;sup>14</sup> See Zokinvy Sale Order ¶ K.

<sup>&</sup>lt;sup>15</sup> Hercz Decl.  $\P$  4.

<sup>&</sup>lt;sup>16</sup> That certain *Sublicense Agreement, dated as of the Closing Date, by and among Purchaser and the Seller,* substantially in the form attached to the Zokinvy APA as Exhibit E [filed under seal pursuant to the order at Docket No. 188] (the "<u>Sublicense Agreement</u>").

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designated as "<u>Retained Agreements</u>" and made subject to special treatment in order to, on the one hand, facilitate the subsequent sale of the Debtors' remaining Lonafarnib Assets, while, on the other hand, protecting Sentynl's ability to manufacture, supply, and "Commercialize"<sup>17</sup> Zokinvy as contemplated in the Zokinvy APA.<sup>18</sup>

7. This delicate balance was struck to allow the Debtors to monetize residual assets for the benefit of their estates, while providing protection to Sentynl against subsequent harm by prohibiting Eiger Bio from assigning the Retained Agreements in a manner that would or reasonably could adversely affect Sentynl's ability to Commercialize Zokinvy and supply patients who depend on it to extend their lives.<sup>19</sup> This balance was necessary because, *inter alia*, Sentynl was informed by Eiger Inno of potential purchasers of the Lonafarnib Assets.<sup>20</sup> Sentynl was specifically advised by Eiger Bio's general counsel of the potential for a third party purchaser to improperly use the Lonafarnib Assets (including the Retained Agreements) to interfere with Sentynl's use and enjoyment of the Zokinvy Assets it purchased "free and clear."<sup>21</sup> Sentynl even considered bidding on and purchasing the Lonafarnib Assets to eliminate this risk, but at the time Sentynl was satisfied that the Zokinvy Sale Order (and the agreements approved thereunder) provided sufficient protections necessary to prevent such interference.<sup>22</sup> Importantly, despite the fact Sentynl could have acquired the Lonafarnib Assets, Sentynl did not want to acquire the Lonafarnib Assets and then "shelve" the related HDV program, because Sentynl did not think that

<sup>&</sup>lt;sup>17</sup> See Section 1.6 of the Sublicense Agreement ("<u>Commercialization</u>' means, with respect to Licensed Product, any and all activities directed to the marketing, promotion, distribution, offering for sale and selling such product, importing and exporting such product for sale, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall also include Commercialization Studies. 'Commercialize' has a correlative meaning.").

<sup>&</sup>lt;sup>18</sup> See Section 3.7 of the Sublicense Agreement.

<sup>&</sup>lt;sup>19</sup> Hercz Decl. ¶ 5; Section 3.7 of the Sublicense Agreement.

<sup>&</sup>lt;sup>20</sup> Hercz Decl.  $\P$  6.

<sup>&</sup>lt;sup>21</sup> Hercz Decl.  $\P$  7.

<sup>&</sup>lt;sup>22</sup> Hercz Decl. ¶ 8.

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was fair to HDV patients that could potentially benefit from such a program in the future even if the likelihood of FDA approval is uncertain at this stage.<sup>23</sup> This decision was based on the apparently false assumption that a subsequent purchaser would not violate this Court's orders.<sup>24</sup>

## B. <u>Eiger Inno's Interference with Sentynl's Manufacturing of Zokinvy</u>

8. One of the Retained Agreements described above is the Lonza Bend MSA pursuant to which Zokinvy SDD is manufactured.<sup>25</sup> Debtor Eiger Bio represented and warranted to Sentynl that the Lonza Bend MSA is necessary for the manufacture, supply, and Commercialization of Zokinvy,<sup>26</sup> as the services rendered thereunder are not currently available through any other supplier.<sup>27</sup> Importantly, Sentynl cannot transfer SDD manufacturing to another entity without major risk of a supply outage, which would jeopardize progeria patients, and without incurring significant cost.<sup>28</sup> The transfer of technology (*i.e.*, process and methods) to a new manufacturing facility is not guaranteed to result in supply, and there is limited amount of raw materials to utilize.<sup>29</sup> Sentynl cannot both transfer the technology and manufacture for patients in the near term.<sup>30</sup> Moreover, certain data relating to existing inventory of Zokinvy that Sentynl purchased from Eiger Bio under the Zokinvy APA is required to be obtained by Sentynl from Lonza for Sentynl to deliver such medication to patients under applicable regulations.<sup>31</sup> Critical to the relief

<sup>&</sup>lt;sup>23</sup> Hercz Decl.  $\P$  9.

<sup>&</sup>lt;sup>24</sup> Hercz Decl. ¶ 10.

<sup>&</sup>lt;sup>25</sup> Hercz Decl. ¶ 11.

<sup>&</sup>lt;sup>26</sup> See Sections 11.2(j) and 11.2(w) of the Sublicense Agreement.

<sup>&</sup>lt;sup>27</sup> Hercz Decl.  $\P$  12.

<sup>&</sup>lt;sup>28</sup> Hercz Decl. ¶ 13.

<sup>&</sup>lt;sup>29</sup> Hercz Decl. ¶ 14.

<sup>&</sup>lt;sup>30</sup> Hercz Decl. ¶ 15.

<sup>&</sup>lt;sup>31</sup> Hercz Decl.  $\P$  16.

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requested herein, the terms of the Sublicense Agreement *preclude* assignment of the Lonza Bend MSA in a manner that adversely affects Sentynl's ability to Commercialize Zokinvy.<sup>32</sup>

9. Eiger Inno caused a dispute to arise, which delayed the assignment of the Lonza Bend MSA in connection with the sale of Lonafarnib Assets to Eiger Inno, because the Lonza Bend MSA contains an exclusivity clause in Section 2.8 that provides Lonza will not manufacture or supply the product to or for any person other than "Customer," which is now Eiger Inno.<sup>33</sup> Sentynl attempted, over numerous months, to negotiate an arrangement permitting a direct relationship between Sentynl and Lonza with respect to services and materials required to Commercialize Zokinvy, however, Eiger Inno refused to allow such direct relationship and failed to articulate a justifiable reason for doing so.<sup>34</sup> Unsurprisingly, Lonza is now unwilling to negotiate a direct agreement with Sentynl, although Sentynl believes Lonza would promptly do so to ensure the quality, safety, and continuity of the long term supply of Zokinvy to progeria patients if Lonza had certainty it would not have any liability for breaching the Lonza Bend MSA by engaging with Sentynl.<sup>35</sup>

10. The Lonza Bend MSA was ultimately assigned to Eiger Inno, over Sentynl's strong and consistent protest, pursuant to a surprise settlement agreement between the Liquidating Trustee and Eiger Inno effective December 18, 2024 (the "<u>Settlement Agreement</u>"),<sup>36</sup> attached to the

<sup>&</sup>lt;sup>32</sup> See Section 3.7 of the Sublicense Agreement ("Eiger will use reasonable efforts to not, and to ensure that its Affiliates do not (i) sell, assign, transfer, convey, deliver or otherwise divest its interests in any of the Retained Agreements to a Third Party in a manner that adversely affects, or would reasonably be expected to adversely affect, Sublicensee's rights or obligations under this Agreement or Sublicensee's ability to Commercialize the Licensed Progeria Product.").

<sup>&</sup>lt;sup>33</sup> Hercz Decl. ¶ 17.

<sup>&</sup>lt;sup>34</sup> Hercz Decl. ¶ 18. Contrary to the Liquidating Trustee's assertion [Docket No. 777 ¶ 13], Sentynl understood the importance of Lonza in the manufacturing of Zokinvy and began negotiating an MSA with Lonza in the third quarter of 2024. See Exhibits 2 and 3 to the Appendix.

<sup>&</sup>lt;sup>35</sup> Hercz Decl. ¶ 19.

<sup>&</sup>lt;sup>36</sup> Hercz Decl.  $\P$  20.

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Appendix as <u>Exhibit 4</u>. Sentynl was blindsided by the Settlement Agreement, which was signed the same week that Co-Counsel to the Official Committee of Equity Security Holders of Eiger BioPharmaceuticals, Inc., *et al.* advised Sentynl that assignment was not imminent.<sup>37</sup>

11. Sentynl is not a party to the Settlement Agreement, nor is Sentynl a third-party beneficiary under the Settlement Agreement. Eiger Inno understands Sentynl does not agree to its terms. <sup>38</sup> The Settlement Agreement purports to resolve Sentynl's concerns regarding the exclusivity clause by requiring Eiger Inno (not Lonza directly) to supply Sentynl with the materials necessary to manufacture and supply Zokinvy.<sup>39</sup> However, by preventing Lonza from directly supplying Sentynl, this arrangement positions Eiger Inno as an unnecessary intermediary, with ample opportunity to exert leverage over Sentynl, which materially and adversely impacts Sentynl's ability to Commercialize Zokinvy.<sup>40</sup> Lonza refuses to transfer any materials, data, information, or know-how to Sentynl, or to enter into any direct contract with Sentynl, without an agreement with all parties.<sup>41</sup> Additionally, Eiger Inno does not have the capability to act as an intermediary in the manufacturing process because it does not meet the regulatory requirements necessary for it to do so.<sup>42</sup>

12. Notwithstanding the assignment of the Lonza Bend MSA to Eiger Inno, Sentynl owns or has rights to Required Data and Information in Lonza' possession,<sup>43</sup> which Sentynl

<sup>&</sup>lt;sup>37</sup> Hercz Decl. ¶ 21. An email from counsel for the Liquidating Trustee confirms that Sentynl was indeed blindsided by the Settlement Agreement. See <u>Exhibit 5</u> to the Appendix.

<sup>&</sup>lt;sup>38</sup> Hercz Decl.  $\P$  22.

<sup>&</sup>lt;sup>39</sup> Hercz Decl. ¶ 23.

<sup>&</sup>lt;sup>40</sup> Hercz Decl.  $\P$  24.

<sup>&</sup>lt;sup>41</sup> Hercz Decl. ¶ 25.

<sup>&</sup>lt;sup>42</sup> Hercz Decl.  $\P$  26.

<sup>&</sup>lt;sup>43</sup> Lonza and Corden each possess some or all of the following data and information related to Zokinvy: (i) executed batch records from all lots that are not expired; (ii) stability data (protocols, reports, raw lab data); (iii) product specific quality events (deviations, change controls, out-of-specifications, corrective and preventive actions); (iv) process validation protocols and reports; (v) method validation protocols and reports; (vi) control strategy (... footnote continued on following page...)

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acquired under the Zokinvy APA.<sup>44</sup> Sentynl must receive the Required Data and Information from Lonza in order to Commercialize Zokinvy, meet its regulatory obligations, and ensure that there are no product quality issues that could affect patients.<sup>45</sup> In order for Sentynl to meet its regulatory obligations with respect to materials that were manufactured or processed by Lonza, Sentynl also needs to enter into a customary quality agreement with Lonza.<sup>46</sup> Attached to the Appendix as **Exhibit 6** is a list of the various documents that comprise Required Data and Information, with details regarding the category of information, the type of document, an explanation as to why it is required and an explanation as to when it is required, in each case with respect to Sentynl's ability to manufacture and Commercialize Zokinvy and to meet its regulatory obligations with respect to Zokinvy.

# C. <u>Eiger Inno's Interference with Sentynl's Regulatory Obligations</u>

13. Corden is a contract development and manufacturing organization that has historically manufactured the API used in Zokinvy.<sup>47</sup> Eiger Bio contracted with Corden for such manufacturing services related to Zokinvy.<sup>48</sup> None of the Corden agreements were assigned to Sentynl as part of the Zokinvy APA or related transaction documents despite Sentynl's requests that they be assigned to Sentynl, given Sentynl's need to ensure uninterrupted supply of Zokinvy

<sup>(</sup>critical process parameters and critical quality attributes development); (vii) method development protocols and reports; (viii) process development protocols and reports; and (ix) annual product reports (collectively, the "<u>Required Data and Information</u>").

<sup>&</sup>lt;sup>44</sup> See, e.g., Sublicense Agreement Sections 2.1 (License Grant), 3.2 (Transition Activities), 3.5 (Transfer of Regulatory Information), 5.1 (Regulatory Filings Transfer), 7.2 (Transfer of Manufacturing Technology), and 15.12 (Further Actions).

<sup>&</sup>lt;sup>45</sup> Hercz Decl. ¶ 27.

<sup>&</sup>lt;sup>46</sup> Hercz Decl. ¶ 28.

<sup>&</sup>lt;sup>47</sup> Hercz Decl. ¶ 29.

<sup>&</sup>lt;sup>48</sup> Hercz Decl. ¶ 30.

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to progeria patients.<sup>49</sup> Instead, like the Lonza Bend MSA, Corden agreements were assigned to Eiger Inno.<sup>50</sup> As with the Lonza Bend MSA, the Corden agreements were classified as "Retained Agreements" under the Zokinvy APA, which as noted above are contracts that were not to be assigned if such assignment is or reasonably could be adverse to Sentynl's ability to manufacture and Commercialize Zokinvy.<sup>51</sup> Notwithstanding the assignment of the Corden agreements to Eiger Inno, Sentynl owns or has rights to Required Data and Information in Corden's possession, which Sentynl acquired under the Zokinvy APA.<sup>52</sup> Sentynl must receive the Required Data and Information from Corden to Commercialize Zokinvy and meet its regulatory obligations.<sup>53</sup> In order for Sentynl to meet its regulatory obligations with respect to materials that were manufactured or processed by Corden, Sentynl also needs to enter into a customary quality agreement with Corden to obtain Lonafarnib-specific audit rights necessary to ensure the products manufactured in compliance with Good Manufacturing Practices (GMP) requirements.<sup>54</sup> The various documents that comprise Required Data and Information that Sentynl believes are or should be in Corden's possession are included in the list attached to the Appendix as **Exhibit 6**.

14. In mid-December 2024, Sentynl's Director of Technical Operations requested batch records from Corden to meet regulatory requirements and other commercial purposes.<sup>55</sup> On December 23, 2024, Corden's Sr. Director, Sales & Key Account Management, in response to

<sup>&</sup>lt;sup>49</sup> Hercz Decl. ¶ 31. As with Lonza, Sentynl immediately understood the importance of Corden in the manufacturing of Zokinvy and began negotiating an MSA with Corden in the third quarter of 2024. The first version of the draft Commercial Manufacturing and Supply Services Agreement between Sentynl and Corden was dated September 18, 2024, though the draft is not attached due to Corden's "confidential" designation.

<sup>&</sup>lt;sup>50</sup> Hercz Decl.  $\P$  32.

<sup>&</sup>lt;sup>51</sup> Hercz Decl. ¶ 33.

<sup>&</sup>lt;sup>52</sup> See, e.g., Sublicense Agreement Sections 2.1 (License Grant), 3.2 (Transition Activities), 3.5 (Transfer of Regulatory Information), 5.1 (Regulatory Filings Transfer), 7.2 (Transfer of Manufacturing Technology), and 15.12 (Further Actions).

<sup>&</sup>lt;sup>53</sup> Hercz Decl.  $\P$  34.

<sup>&</sup>lt;sup>54</sup> Hercz Decl. ¶ 35.

<sup>&</sup>lt;sup>55</sup> Hercz Decl. ¶ 36.

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such request, directed the Sentynl representative to "speak first with Eiger InnoTherapeutics," even though Sentynl owns or has rights to that data held by Corden.<sup>56</sup> That same day Sentynl's General Counsel responded and noted that Corden and Sentynl have been working together since at least October 2024 on a master services agreement to cover services rendered by Corden on behalf of Sentynl.<sup>57</sup> Sentynl also noted that the batch records requested are for drug substance lots previously manufactured and actively being used in clinical and commercial Zokinvy finished drug product batches, which were purchased pursuant to the Zokinvy APA.<sup>58</sup> Corden replied that "it has become known to Corden that the Master Services Agreement from Eiger had been assigned to Eiger InnoTherapeutics. Calls with respective counsel may be required to sort out a contractual path forward but in meantime talking to [Eiger Inno] should be your starting point."59 Corden later emphasized its position, more forcefully, that it would not directly engage with Sentynl, not even to enter a confidential disclosure agreement that would allow Sentynl to share the documents necessary to prove Sentynl's rights to the data.<sup>60</sup> Further, Corden refuses to release any of Sentynl's Transferred Inventory until evidence is shown to them that conclusively proves Sentynl's ownership.<sup>61</sup>

15. The Corden MSA assigned to Eiger Inno does not contain an exclusivity provision that would prevent Corden from having direct discussions with Sentynl and ultimately having a direct contractual relationship with Sentynl.<sup>62</sup> To Sentynl's knowledge, Corden has not entered a

<sup>&</sup>lt;sup>56</sup> Hercz Decl. ¶ 37.

<sup>&</sup>lt;sup>57</sup> Hercz Decl. ¶ 38.

<sup>&</sup>lt;sup>58</sup> Hercz Decl. ¶ 39.

<sup>&</sup>lt;sup>59</sup> See <u>Exhibit 7</u> to the Appendix.

<sup>&</sup>lt;sup>60</sup> See <u>Exhibit 8</u> to the Appendix.

<sup>&</sup>lt;sup>61</sup> See <u>Exhibit 8</u> to the Appendix.

<sup>&</sup>lt;sup>62</sup> That certain Master Services Agreement between Eiger BioPharmaceuticals, Merck Sharpe & Dohme Corporation, and CordenPhama Colorado. Corden's organizational name on file with the Delaware Secretary of State has a space between "Corden" and "Pharma," however it is the same entity that entered the foregoing Master Services Agreement.

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new Corden MSA with Eiger Inno containing an exclusivity provision.<sup>63</sup> However, Corden stopped negotiating a direct master services agreement with Sentynl to manufacture the API required to Commercialize Zokinvy.<sup>64</sup> In other words, no manufacturing of the API for the Zokinvy product is currently underway to replenish the existing inventory of API that is currently being consumed, which places the continuous supply of product to progeria patients at risk.<sup>65</sup>

16. Considering the foregoing, in January 2025, Sentynl turned to the Liquidating Trustee for assistance in addressing Eiger Inno's improper intervention and obstruction of the transfer of Required Data and Information from Corden to Sentynl and the future manufacture of API for the Zokinvy product.<sup>66</sup> Despite some effort by the Liquidating Trustee, little to no progress has been made.<sup>67</sup> Corden still refuses to negotiate directly with Sentynl with respect to a master services agreement with Sentynl, presumably at the request or instruction of Eiger Inno.<sup>68</sup> This obstruction has serious consequences, including preventing Sentynl from meeting regulatory requirements, ensuring product quality, maintaining an uninterrupted supply of drug product, and ultimately safeguarding progeria patients.<sup>69</sup>

## D. Potential Double-Sale of Existing Inventory of Raw Materials

17. Complicating matters further, the Lonafarnib APA purports to retain quantities of certain "Reference Material" that were previously purchased by Sentynl under the Zokinvy APA. Reference material is a manufacturing term of art.<sup>70</sup> Reference material is used to test against new

<sup>&</sup>lt;sup>63</sup> Hercz Decl.  $\P$  40.

<sup>&</sup>lt;sup>64</sup> Hercz Decl.  $\P$  41.

<sup>&</sup>lt;sup>65</sup> Hercz Decl.  $\P$  42.

<sup>&</sup>lt;sup>66</sup> Hercz Decl. ¶ 43.

<sup>&</sup>lt;sup>67</sup> Hercz Decl. ¶ 44.

<sup>&</sup>lt;sup>68</sup> Hercz Decl. ¶ 45.

<sup>&</sup>lt;sup>69</sup> Hercz Decl. ¶ 46.

<sup>&</sup>lt;sup>70</sup> Hercz Decl. ¶ 47.

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materials to ensure that a manufacturing process produced the desired properties in new materials.<sup>71</sup> Testing against new materials is required for API and SDD to satisfy certain regulatory requirements, and to safeguard product quality and patient safety.<sup>72</sup>

18. The Lonafarnib Sale Order states that the Lonafarnib APA is attached as Exhibit A, but it is not. The Lonafarnib APA filed at Docket No. 490-1 includes certain Inventory (as defined therein) among the Transferred Assets (as defined therein) transferred from Eiger Bio to Eiger Inno under the Lonafarnib APA. The Inventory includes certain Raw Materials and Inventory listed in Schedule 2.1(h) of the Lonafarnib APA. Schedule 2.1(h) was not filed on the docket and is attached to the Appendix as **Exhibit 9**. The two rightmost columns under Raw Materials in Schedule 2.1(h) are labeled "Retained by Eiger (Grams) as reference materials" and "Transferred to Zokinvy Buyer (Grams)." Rows 3-12 under Raw Materials in Schedule 2.1(h) specify Reference Material in the possession of Corden. Rows 13-14 under Raw Materials in Schedule 2.1(h) specify Reference Material in the possession of Lonza.

19. The Zokinvy Sale Order defines Transferred Inventory by reference to the Sublicense Agreement.<sup>73</sup> Schedule 3.3(a) of the Sublicense Agreement, attached to the Appendix as **Exhibit 10**, list Transferred Inventory in two categories: Finished Goods and Raw Materials. Under the Raw Materials category, there is no reference to any retained materials, and the amounts of Raw Materials specified in Schedule 3.3(a) to the Sublicense Agreement under the Zokinvy APA are equal to the sum of the two rightmost columns under Raw Materials specified in Schedule 2.1(h) to the Lonafarnib APA . In other words, the Reference Materials purported to be transferred

<sup>&</sup>lt;sup>71</sup> Hercz Decl.  $\P$  48.

<sup>&</sup>lt;sup>72</sup> Hercz Decl. ¶ 49.

<sup>&</sup>lt;sup>73</sup> Docket No. 162 at 68 of 112.

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to Eiger Inno are inaccurate and purport to transfer materials to Eiger Inno that were already sold to Sentynl "free and clear."<sup>74</sup>

20. For avoidance of doubt, Sentynl does not seek to hinder Eiger Inno in its efforts to attempt to develop and commercialize its pre-commercialization Lonafarnib for the Hepatitis Delta Virus (HDV) product and is willing to work with Eiger Inno in order to provide small quantities of Reference Materials to Eiger Inno.<sup>75</sup> However, Eiger Inno cannot, now or in the future, use any claimed but inaccurate rights to the Reference Material, which was acquired by Sentynl "free and clear," as a basis to interfere with Sentynl's rights to Commercialize Zokinvy.

#### **RELIEF REQUESTED**

21. Eiger Inno has already demonstrated a willingness to withhold critical pharmacovigilance data reporting and database access in violation of Sentynl's rights under the Sublicense Agreement.<sup>76</sup> In doing so, Eiger Inno, knowingly endangered the safety of progeria patients and prevented ongoing patient side effects from being reported.<sup>77</sup> Worse still, one of the managing partners of Eiger Inno, Leen Kawas, during two separate phone calls with Sentynl, tacitly threatened to withhold pharmacovigilance data for the specific purpose of exerting leverage in negotiations.<sup>78</sup> These actions cast an unwelcome shadow over the "Bambi" image this Court envisioned at the first day hearing.<sup>79</sup> Although – after countless hours of wholly unnecessary

<sup>&</sup>lt;sup>74</sup> Hercz Decl. ¶ 50.

<sup>&</sup>lt;sup>75</sup> Hercz Decl. ¶ 51.

<sup>&</sup>lt;sup>76</sup> See Motion for Allowance of Administrative Expense Claim of Sentynl Therapeutics, Inc. [Docket No. 729] at paragraphs 11-15.

<sup>&</sup>lt;sup>77</sup> Hercz Decl. ¶ 52.

<sup>&</sup>lt;sup>78</sup> Hercz Decl. ¶ 53

<sup>&</sup>lt;sup>79</sup> Has there ever been more of a Bambi in Chapter 11? And I don't mean to be . . . flippant, but let me be honest. We used to have a judge in this District, God rest his soul, he's been gone, and he used to be very suspicious of every debtor and ask a lot of tough questions. And another judge said to him once, you're always suspicious. But sometimes the debtor is Bambi. And, you know, I would say very rarely do we have a Chapter 11 debtor who's Bambi. But this may be it.

Transcript of April 3, 2024 Hearing on First Day Motions at 144:20-145:5 [Docket No. 108].

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negotiation – this pharmacovigilance data issue appears to have been resolved, the Lonza exclusivity issue, the Corden Transferred Inventory issue, and the Corden and Lonza data and future manufacturing issues have not.<sup>80</sup>

22. Given Eiger Inno's conduct to date, the Court should foreclose any possibility of Eiger Inno undermining or circumventing the Zokinvy Sale Order by ultimately controlling the output of Zokinvy though its intermediary positions with Lonza and Corden or by preventing Sentynl from fulfilling the regulatory obligations necessary to safely deliver existing batches of Zokinvy to progeria patients. Accordingly, Sentynl respectfully requests a "comfort order" for Lonza and Corden, substantially in the form attached hereto as **Exhibit A**, prohibiting Eiger Inno from challenging rights to the Transferred Inventory purchased by Sentynl "free and clear" under the Zokinvy APA; enabling a direct supplier relationship between Sentynl and Lonza; enabling a direct supplier relationship between Sentynl and Corden; permitting Corden and Lonza each to manage Sentynl's Transferred Inventory at Sentynl's sole direction; permitting Corden and Lonza each to transfer the Required Data and Information to Sentynl free from interference by Eiger Inno; permitting Corden and Lonza each to enter into any customary commercial agreements necessary for Sentynl to meet its regulatory obligations with respect to Zokinvy (such as a quality agreement); permitting Corden and Lonza each to freely negotiate an MSA with Sentynl regardless of any MSA with Eiger Inno; and safeguarding both the short term and long term stability of the supply of Zokinvy.

23. Sentynl also requests the Court to order Eiger Inno to show cause why its actions do not violate the Zokinvy Sale order, and in the absence of such showing, award compensatory monetary sanctions against Eiger Inno.

<sup>&</sup>lt;sup>80</sup> Hercz Decl. ¶ 54.

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#### **JURISDICTION**

24. The Court has inherent jurisdiction to consider this matter pursuant to 28 U.S.C.

§§ 157 and 1334 and retained jurisdiction under the Zokinvy Sale Order.<sup>81</sup>

#### **BASIS FOR RELIEF**

## A. <u>This Court's Authority to Enforce the Zokinvy Sale Order Is Without</u> <u>Question</u>

25. Section 105(a) of the Bankruptcy Code provides in relevant part that "[t]he court

may issue any order, process, or judgment that is necessary or appropriate to carry out the

provisions of this title." The Fifth Circuit interprets section 105(a) liberally. See Feld v. Zale

Corp. (In re Zale Corp.), 62 F.3d 746, 760 (5th Cir. 1995) (citing Momentum Mfg. Corp. v. Emp.

Creditors Comm. (In re Momentum Mfg. Corp.), 25 F.3d 1132, 1136 (2d Cir.1994)).

26. There is abundant authority supporting the proposition that a bankruptcy court has inherent core authority under section 105(a) to enforce its own orders, including confirmation orders and sale orders.<sup>82</sup>

<sup>&</sup>lt;sup>81</sup> This Court retained jurisdiction to enforce and Sentynl has standing to seek to enforce the terms of the Zokinvy Sale Order, Zokinvy APA, and Transaction Documents. *See* Zokinvy Sale Order ¶¶ 33-34.

<sup>82</sup> See, e.g., Universal Oil Ltd. v. Allfirst Bank (In re Millenium Seacarriers, Inc.), 419 F.3d83, 97 (2d Cir. 2005) ("Bankruptcy courts retain jurisdiction to enforce and interpret their own orders") (citing Luan Inv. S.E. v. Franklin 145 Corp. (In re Petrie Retail, Inc.), 304 F.3d 223, 230(2d Cir. 2002)); Taggart v. Lorenzen, 139 S. Ct. 1795, 1801 (2019) ("In our view, [sections 524(a) and 105] authorize a court to impose civil contempt sanctions when there is no objectively reasonable basis for concluding that the creditor's conduct might be lawful under the discharge order."); Rosellini v. U.S. Bankruptcy Court (In re Sanchez), 941 F.3d 625, 628 (2d Cir. 2019) ("We therefore hold that bankruptcy courts, like Article III courts, possess inherent sanctioning powers."); In re Cano, 410 B.R. 506 (Bankr. S.D. Tex. 2009) ("Courts have used § 105 to remedy violations of confirmed plans. A bankruptcy court's authority under § 105 to enforce its own orders cannot be reasonably questioned."); In re Palmaz Scientific Inc., 562 B.R. 331 (Bankr. W.D. Tex. 2016) ("This Court has subject matter jurisdiction to interpret the Plan and determine whether continuation of the Respondent's litigation would violate the Plan, Confirmation Order, and permanent injunction provided therein . . . Further, the Court always has jurisdiction to clarify and enforce its own orders."); In re Johns Manville Corp., 97 B.R. 174, 180 (Bankr. S.D.N.Y. 1989) (holding that a "bankruptcy court retains post-confirmation jurisdiction to interpret and enforce its own orders in aid of their proper execution"); In re Cont'l Airlines, Inc., 236 B.R. 318, 325 (Bankr. D. Del. 1999) ("In the bankruptcy context, courts have specifically, and consistently, held that the bankruptcy court retains jurisdiction, inter alia, to enforce its confirmation order."); In re Allegheny Health Educ. & Rsch. Found., 383 F.3d 169, 176 (3d Cir. 2004) ("we hold that the bankruptcy court correctly determined that the suit was a core proceeding because it required the court to interpret and give effect to its previous sale orders"); Travelers Indem. Co. v. (... footnote continued on following page ... )

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## B. <u>The Settlement Agreement Constitutes a Collateral Attack on the Zokinvy</u> <u>Sale Order</u>

27. Parties that did not object to or appeal the Zokinvy Sale Order are not permitted to challenge its terms. *See In re Vista Marketing Grp. Ltd.*, 2014 WL 1330112, at \*5 (Bankr. N.D. Ill. Mar. 28, 2014) ("Sale orders, such as this Sale Order, are final, appealable orders, and once the time for appeal has expired, a party to the sale proceeding cannot collaterally attack it.") (citing *Precision Indus., Inc. v. Qualitech Steel SBQ, LLC*, 327 F.3d 537, 543 (7th Cir. 2003)); *United Student Aid Funds, Inc. v. Espinosa*, 559 U.S. 260 (2010) (foreclosing the possibility of an after-the-fact attack on a confirmed plan by a party that never objected or appealed).

28. Eiger Inno has participated in and benefited from the proceedings in these bankruptcy cases but did not object to or appeal the Zokinvy Sale Order. Thus, it cannot challenge the terms of the Sublicense Agreement that preclude assignment of the Lonza Bend MSA or the Corden MSA in a manner that adversely affects Sentynl's ability to Commercialize Zokinvy, which it has now done by taking assignment of both and hindering business with each service provider, transactions Sentynl expressly opposed as adverse to is ability to Commercialize Zokinvy.

29. Although the Settlement Agreement feigns compliance with the Sublicense Agreement under the section entitled "Inno's Obligation to Supply Sentynl," there is absolutely no principled reason for Sentynl to remain at the mercy of a startup company that has no approved products and no infrastructure for access to the same materials and services that Eiger Inno utilizes in the possible future manufacture and supply of its own products and absolutely no doubt that this intermediary arrangement will result in further disputes and litigation if and when "complications"

*Bailey*, 557 U.S. 137, 151 (2009) ("Bankruptcy Court plainly had jurisdiction to interpret and enforce its own prior orders").

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inevitably arise. Similarly, there is absolutely no principled reason why Eiger Inno should be permitted to hold the Required Data and Information hostage and prevent Sentynl from delivering existing or future batches of Zokinvy manufactured by Corden. Such ongoing actions put existing and future progeria patients at real risk of losing access to the only approved therapy to treat progeria, which appears to be driven primarily by the pursuit of riches by an entity led by Eiger Bio's former insiders and founders in search of a speculative indication of Lonafarnib for Hepatitis Delta Virus (HDV). These actions also put Sentynl at significant financial risk, including an inability to meet contractual commitments to the Progeria Research Foundation (PRF), Merck, ex-US distributors, licensors, and vendors that require certain minimum volumes.

## C. <u>The Settlement Agreement Imposes Problematic Obligations on Eiger Inno</u>

## 30. It does not take an industry expert to recognize the shortcomings of the existing

arrangement.

Inno hereby agrees that, for so long as Inno and/or its affiliates are party to the Lonza (Bend) Contract and Section 2.8 thereof is effective and in force, at Sentynl's request, Inno shall supply Sentynl with bulk finished drug product intermediate containing the Molecule that Lonza (Bend) manufactures for Inno under the Lonza (Bend) Contract (the "Material") solely for use with Zokinvy for the treatment of Progeria, which shall continue to be manufactured in accordance with the terms of the Lonza (Bend) Contract, at Inno's cost of manufacturing the Material plus a reasonable markup to compensate Inno for related overhead (such markup to be consistent with arms-length, market rate markups in the industry for similar supply arrangements), such that Sentynl is in substantially no worse position in obtaining its requirements of the Material for use with Zokinvy for the treatment of Progeria had Sentynl been able to contract directly with Lonza (Bend).

Settlement Agreement at 2.

31. *First*, the Settlement Agreement imposes an obligation on Eiger Inno to supply materials to Sentynl, but only for use with Zokinvy, apparently entitling Eiger Inno to audit the use of materials it supplies to Sentynl. *Second*, to determine the price of the materials sold to Sentynl, Eiger Inno is obligated to conduct an overhead cost analysis and an industry market rate

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markup analysis – on a one-of-a-kind material – to tack on to its own costs. Third, Eiger Inno is obligated to somehow undertake a hypothetical analysis to determine whether Sentynl would be in a substantially worse position than it would be if it could contract directly with Lonza but prescribes no manner for doing so. The Settlement Agreement does not prescribe the manner in which any of these analyses are to be conducted, does not specify who bears the cost for this exercise or how much markup leaves Sentynl in a substantially worse position, and does not provide for any involvement from Sentynl in the analysis process. *Fourth*, the Food and Drug Administration (FDA) expects Sentynl, as sponsor of approved and commercialized products, to enter into direct agreements with its contract manufacturing organizations so that it can provide critical oversight and control over production to ensure product quality, efficacy and patient safety. There is no industry-recognized role for a "contract manufacturing organization intermediary," and, moreover, Eiger Inno does not have the quality systems, qualified personnel or infrastructure required to meet Good Manufacturing Practices (GMP) standards for overseeing the manufacture of Lonafarnib API or SDD for commercial use. Thus, Sentynl could not rely on Eiger Inno to conduct all of the necessary regulatory product quality, safety, and efficacy oversight measures, including, but not limited to, oversight of quality control release and stability testing, quality assurance batch record review and batch release, investigation of product quality issues and potential recalls, and regular audits of vendors in the supply chain. What could possibly go wrong?

32. Eiger Inno, were it acting in a commercially reasonable manner, would welcome being relieved of this headache. The simple fact that Eiger Inno would readily agree to accept such obligations immediately and before it has any infrastructure or quality systems whatsoever – instead of simply allowing Sentynl to contract directly with Lonza – should be enough for the Court to infer Eiger Inno's *actual* intent for maintaining its intermediary position.

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#### D. <u>Sentynl Should Be Permitted to Contract Directly with Corden and Lonza</u>

33. Sentynl does not request the Court to nullify the Settlement Agreement, nor does it seek consent rights to any assignment of the Lonza Bend MSA through a modification of the Zokinvy Sale Agreement.<sup>83</sup> The simplest solution to resolve this matter is a narrow injunction prohibiting Eiger Inno from (i) enforcing the exclusivity clause in the Lonza Bend MSA against Lonza and (ii) pursuing or obtaining any agreement that would prevent Corden or Lonza from providing manufacturing services and materials to Sentynl, thus facilitating the ability for direct relationships between Sentynl and Lonza and between Sentynl and Corden to be negotiated among the respective parties and short-circuit this untenable situation.

34. Bankruptcy courts may enter injunctions as may be necessary or appropriate to effectuate or prevent the frustration of orders that it has previously issued, including sale orders.<sup>84</sup> The Court should do so here and prevent Eiger Inno's desire to hamstring Sentynl and frustrate the purpose of this Court's orders and the primary goal of this bankruptcy case, *i.e.*, to protect the quality, safety, and continuity of the long term supply of Zokinvy to progeria patients.

<sup>&</sup>lt;sup>83</sup> Under FED. R. CIV. P. 60(b)(6) and FED. R. BANKR. P. 9024, a bankruptcy court may modify its sale order to prevent manifest injustice. *See In re Strudel Holdings LLC*, 656 B.R. 404 (Bankr. S.D. Tex. 2024).

See, e.g., In re Chiron Equities, LLC, 552 B.R. 674, 696-97 (Bankr. S.D. Tex. 2016) (enjoining a non-debtor shareholder of chapter 7 debtor limited liability company from prosecuting estate claims that had been sold pursuant to a sale order); *Matter of PFO Glob., Inc.*, 26 F.4th 245, 253 (5th Cir. 2022) (bankruptcy court had jurisdiction to pause state court litigation controlled by a prior order); *In re E. Orange Gen. Hosp., Inc.*, 587 B.R. 53, 75 (D.N.J. 2018) (affirming bankruptcy court's barring claims against purchaser on motion to enforce sale order); *In re CTE 1 LLC*, No. 19-30256 (VFP), 2024 WL 2349620, at \*10 (Bankr. D.N.J. May 21, 2024) (granting motion to enforce sale order and precluding discovery against purchaser on successor liability claims); *In re Old Carco LLC*, 593 B.R. 182, 189 (Bankr. S.D.N.Y. 2018) (barring claims, in part, on grounds that they are enjoined under terms of the sale order); *Cent. W. Virginia Energy Co. v. Wheeling-Pittsburgh Steel Corp.*, 245 Fed. Appx. 415, 426 (6th Cir. 2007) (affirming bankruptcy court enjoinment of creditor from reducing the amount of coal it suppled under assignments).

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## E. <u>Corden and Lonza Should Turnover the Required Data and Information on</u> <u>an Ongoing Basis Without Any Involvement from Eiger Inno</u>

35. Eiger Inno cannot credibly argue that Sentynl did not acquire the rights to the Required Data and Information under the Zokinvy Sale Order, which provides that "[a]ll Persons that are presently or on the Closing Date may be in possession of some or all of the Transferred Assets are directed to surrender possession of such Transferred Assets to the Purchaser as of the Closing Date."<sup>85</sup> Additionally, the "terms and provisions of the Amended Zokinvy Stalking Horse APA, the Transaction Documents, the Bid Procedures Order, and this Zokinvy Sale Order shall be binding in all respects . . . upon any and all third parties . . . ."<sup>86</sup> Thus, regardless of the assignment of the Corden or Lonza agreements to Eiger Inno, Corden and Lonza are each obligated to deliver the property to which Sentynl is entitled. This obligation is ongoing because new data is generated every time the stability of product already on the market is tested, which continues for years after the product is released for sale. If, at any point, stability fails, Sentynl must investigate and determine the implications to patient safety and, if the product is determined unsafe, issue a recall.

36. Sentynl seeks an order compelling Corden and Lonza to turnover the Required Data and Information – property that it acquired and is entitled to under the Zokinvy APA – without any further interference from Eiger Inno. Ordering the turnover of property acquired pursuant to a bankruptcy court's sale order is an appropriate enforcement mechanism. *See Matter of RE Palm Springs II, L.L.C.,* 106 F.4th 406, 413 (5th Cir. 2024) (affirming bankruptcy court's interpretation and enforcement of sale order through an order for construction company to turnover materials and equipment related to partially completed hotel project). The Court should do so here and

<sup>&</sup>lt;sup>85</sup> Zokinvy Sale Order ¶ 11.

<sup>&</sup>lt;sup>86</sup> Zokinvy Sale Order ¶ 22.

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prevent Eiger Inno from needlessly jeopardizing the quality and safety of existing batches of API for Zokinvy.

# F. <u>Eiger Inno Should Be Ordered to Show Cause Why Its Actions Are Not</u> <u>Violations of the Zokinvy Sale Order</u>

37. Section 105(a) expressly authorizes bankruptcy courts to "issue any order . . . necessary or appropriate to carry out the provisions" of Title 11 or to take any action or make any "determination necessary or appropriate to enforce or implement court orders or rules, or to prevent an abuse of process." 11 U.S.C. § 105(a); *see also Placid Refining Co. v. Terrebonne Fuel and Lube, Inc. (In re Terrebonne Fuel & Lube, Inc.)*, 108 F.3d 609, 613 (5th Cir. 1997) (holding that a bankruptcy court has the power under section 105 to issue sanctions, including civil contempt proceedings, in order to carry out the provisions of the Bankruptcy Code). Notably, a finding of bad faith is not required pursuant to 11 U.S.C. § 105, only a finding of violation of a court order.

38. "*Taggart* applies broadly to orders entered in Chapter 11 proceedings ....." *In re Fieldwood Energy LLC*, No. 20-33948, 2024 WL 4173048, at \*16 (Bankr. S.D. Tex. Sept. 12, 2024) "Under *Taggart*, three elements must be proven for a court to hold a party in contempt: '(1) the party violated a definite and specific order of the court requiring him to ... refrain from performing ... particular ... acts; (2) the party did so with knowledge of the court's order; and (3) there is no fair ground of doubt as to whether the order barred the party's conduct." *In re McKinney*, No. 21-50046-RLJ11, 2022 WL 1632156, at \*2 (Bankr. N.D. Tex. Apr. 28, 2022) (citing *In re City of Detroit, Mich.*, 614 B.R. 255, 265 (Bankr. E.D. Mich. 2020)). "But 'a party's subjective belief that she was complying with an order ordinarily will not insulate her from civil contempt if that belief was objectively unreasonable." *Id.* at \*3 (citing *Taggart v. Lorenzen*, 587

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U.S. 554, 561 (2019)). This standard is easily met here for Eiger Inno's violations of the Zokinvy Sale Order.

39. Eiger Inno violated Section 3.7 of the Sublicense Agreement (and therefore violated the Zokinvy Sale Order) by taking assignment of the Lonza MSA. To provide cover, and without any disclosure to Sentynl until the ink was dry, Eiger Inno entered the Settlement Agreement, but the Settlement Agreement is no remedy for this violation of a Court order. Sentynl never consented to and actively opposed any intermediary position for Eiger Inno. Sentynl was deliberately excluded from its negotiation and is not a party to or third-party beneficiary under the Settlement Agreement. There was no principled reason to exclude Sentynl and contrive this indirect contractual arrangement. Rather, the Settlement Agreement confirms Eiger Inno's knowledge of the Zokinvy Sale Order's prohibition and leaves no fair ground of doubt as to whether the Zokinvy Sale Order barred the assignment. The same is true for the assignment of the Corden MSA and whatever actions Eiger Inno has taken to cause Corden to believe that it cannot contract with Sentynl or transfer data directly to Sentynl without Eiger Inno's approval. Accordingly, Eiger Inno should be ordered to show cause why it should not be found in contempt.

## G. <u>Sentynl Requests Attorneys' Fees and Costs for Prosecuting Eiger Inno's</u> <u>Violations of the Zokinvy Sale Order</u>

40. If Eiger Inno fails to show that it has not violated this Court's orders, Sentynl is

entitled to monetary compensatory sanctions for Eiger Inno's violations of the Zokinvy Sale Order.

[C]ivil contempt sanctions may not have the primary purpose of punishing the contemnor or vindicating the authority of the court. Rather, they must be remedial, and for the benefit of the complainant.

That means civil contempt sanctions must be calculated either to (1) coerce the contemnor into compliance with a court order or (2) compensate another party for the contemnors violations. . . . Contempt sanctions imposed for compensatory purposes are civil only if they are based upon evidence of complainants actual loss.

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*Matter of Highland Capital Mgmt., L.P.*, 98 F.4th 170, 174–75 (5th Cir. 2024) (citations and quotations omitted, alterations adopted).

41. Here, civil contempt sanctions in the form of attorney's fees and costs for Sentynl are appropriate remedial sanctions against Eiger Inno for months of interference with the manufacture and supply of Zokinvy and rights Sentynl acquired under the Zokinvy Sale Order.

42. Following the resolution of any contempt proceeding, Sentynl is prepared to submit a motion for attorneys' fees and costs to enable the Court to conduct a lodestar analysis or otherwise apply the *Johnson* factors. *See In re Pilgrim's Pride Corp.*, 690 F.3d 650, 656 (5th Cir. 2012) ("[A]fter calculating the lodestar, bankruptcy courts retain[] the discretion to adjust the lodestar upwards or downwards to reflect their consideration of the Johnson factors."); *In re Cahill*, 428 F.3d 536, 539 (5th Cir. 2005) ("the bankruptcy court did not abuse its discretion by using the precalculated lodestar amount . . . because it properly applied the . . . Johnson factors to the specific facts of the case, setting forth a reasoned analysis and providing reasons why the lodestar amount did not need to be adjusted"); *Johnson v. Georgia Highway Express*, 488 F.2d 714 (5th Cir. 1974) ("the novelty and difficulty of the questions" involved in the case is a factor in the determination of a reasonable fee).

#### **RESERVATION OF RIGHTS**

43. In filing this Motion, Sentynl does not waive any claims it may have against Eiger Inno or the claim it has asserted against the Debtor's estate in Sentynl's Admin Claim. Sentynl further reserves all rights, claims, defenses, and remedies, including, without limitation, the right to amend, modify, or supplement this Motion.

WHEREFORE, Sentynl respectfully requests that this Court grant the relief requested herein and such other and further relief as is just and necessary. A proposed form of order is attached as **Exhibit A** for the Court's use and consideration.

Dated: March 7, 2025

Respectfully submitted,

## PILLSBURY WINTHROP SHAW PITTMAN LLP

By: /s/ L. James Dickinson

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-and-

Joshua D. Morse Four Embarcadero Center, 22nd Floor San Francisco, CA 94111-5998 Tel: (415) 983-1202 joshua.morse@pillsburylaw.com

Counsel for Sentynl Therapeutics, Inc.

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## **CERTIFICATE OF CONFERENCE**

Pursuant to L.B.R. 7007-1(b), I certify that I conferred with David Chen, counsel for Eiger Inno, by telephone on March 7, 2025 regarding the Motion. Eiger Inno disagrees that its actions violated the Zokinvy Sale Order and is opposed to the relief sought in the Motion.

<u>/s/ Joshua D. Morse</u> Joshua D. Morse

## **CERTIFICATE OF SERVICE**

I certify that, on March 7, 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.

<u>Counsel to Eiger Inno</u> GOODWIN PROCTOR LLP Kizzy Jarashow kjarashow@goodwinlaw.com Maggie Wong mwong@goodwinlaw.com David Chen davidchen@goodwinlaw.com

<u>Counsel for the Liquidating Trustee</u> PORZIO, BROMBERG & NEWMAN, P.C. Warren J. Martin Jr. WJMartin@pbnlaw.com Rachel A. Parisi RAParisi@pbnlaw.com

<u>Associate General Counsel for Lonza</u> Lara Crow lara.crow@lonza.com <u>Counsel for the Liquidating Trustee</u> MCKOOL SMITH, PC John J. Sparacino jsparacino@mckoolsmith.com S. Margie Venus mvenus@mckoolsmith.com Travis E. DeArman tdearman@mckoolsmith.com

## General Counsel for Corden

Naoki Takei naoki.takei@cordenpharma.com

> <u>/s/ James Dickinson</u> L. James Dickinson

# 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.*<sup>1</sup>

Debtors.

Chapter 11

Case No. 24-80040 (SGJ)

(Jointly Administered)

# ORDER GRANTING SENTYNL THERAPEUTICS, INC.'S MOTION TO ENFORCE <u>THE ZOKINVY SALE ORDER AND SETTING SHOW CAUSE HEARING</u>

Upon consideration of Sentynl Therapeutics, Inc.'s Motion (I) to the Enforce Zokinvy Sale

Order and (II) for Contempt Against Eiger InnoTherapeutics, Inc. (the "Motion"),<sup>2</sup> all objections

thereto, all proceedings before the Court, and after due deliberation and sufficient cause appearing

therefor, it is hereby:

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Capitalized terms used but not defined herein have the meanings ascribed to them in the Motion.

#### Case 24-80040-sgj11 Doc 799-2 Filed 03/25/25 Entered 03/25/25 20:32:13 Desc Exhibit Ex

**ORDERED** that Eiger Inno is prohibited and enjoined from enforcing the Section 2.8 of the Lonza Bend MSA against Lonza or its affiliates or taking any other action that would prevent Lonza or any applicable affiliate from providing products, materials, services, data, information, or know-how to Sentynl in connection with the manufacture, supply, or commercialization of Zokinvy; and it is further

**ORDERED** that Eiger Inno is prohibited and enjoined from pursuing or entering any agreement or taking any other actions that would prevent Corden or any affiliate from providing products, materials, services, data, information, or know-how to Sentynl in connection with the manufacture, supply, or commercialization of Zokinvy; and it is further

**ORDERED** that Eiger Inno is prohibited and enjoined from challenging Sentynl's rights to the existing Zokinvy inventories purchased by Sentynl under the Zokinvy APA in any manner whatsoever, and those rights shall continue until all ongoing regulatory requirements with respect to these inventories have been satisfied; and it is further

**ORDERED** that Lonza and Corden are each authorized and directed to immediately provide Sentynl data, information, and know-how associated with existing Zokinvy inventories purchased by Sentynl under the Zokinvy APA on an ongoing basis; and it is further

**ORDERED** that Eiger Inno is prohibited and enjoined from interfering with the turnover of Required Data and Information from Lonza and Corden to Sentynl in any manner whatsoever; and it is further

**ORDERED** that Eiger Inno shall show cause why it should not be held in contempt of Court for interfering with Sentynl's commercialization rights in violation of the Zokinvy Sale Order at a hearing to be held at \_\_\_\_\_ (CT) on \_\_\_\_\_, 2025; and it is further

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# Case 24-80040-sgj11 Doc 799-2 Filed 03/25/25 Entered 03/25/25 20:32:13 Desc Exhibit Explicit Explicit

ORDERED that this Court shall retain jurisdiction over any and all matters arising from

or related to the implementation or interpretation of this Order.

# ### END OF ORDER ###

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# EXHIBIT C

# Case 24-80040-sgj11 Doc 790-3 Filed 03/25/25 Entered 03/25/25 20:15:14 Desc Exhibit C Page 2 of 3

Invento	ry			<u>.</u>			
Use	Description	Quantity	Unit	Lot	Exp Date	Location(s)	Notes:
HDV	SZ 4 WHITEOP CAPSULE Shell	7.2	Kg	7202096	09/28/2026	Patheon	Imprinted "LNF 25" Capsule Shells for 25mg HDV
HDV	SZ 4 WHITEPOX CAPSULE Shell	72.0	Kg	7206089	04/19/2027	Patheon	Imprinted "LNF 25" Capsule Shells for 25mg HDV
HDV	SZ 4 WHITEOP CAPSULE Shell	33.7	Kg	7208817	08/25/2027	Patheon	Imprinted "LNF 25" Capsule Shells for 25mg HDV
HDV	LNF 25MG BULK	71.3	Kg	CNBMK	8/31/2026	Patheon	25mg PPQ1 (~480,000 Capsules)

# Schedule 2.1(h) Raw Materials and Inventory

## **Reference Material**

	Raw Material Lot	Current On-hand in kilos	Gram Conversion	Retained by Eiger (Grams) as reference materials	Transferred to Zokinvy Buyer (Grams)
1	LONAFARNIB SDD 29.1 Kg 00-0120 Retest Patheon US Only	29.1	29,100	50	29,050
2	LONAFARNIB SDD 54.9 Kg 00-0332 Retest Patheon Global	54.9	54,900	50	54,850
3	YGK BP1515-LT 91.6 Kg 203002 Retest Corden US Only	91.6	91,600	50	91,550
4	YGK BP1515-LT 120.0 Kg 203003 Retest Corden US Only	120	120,000	50	119,950
5	YGK BP1515-LT 84.3 Kg 222004 Retest Corden Global	84.3	84,300	50	84,250
6	YGK BP1515-LT 118.8 Kg 228005 Retest Corden Global	118.8	118,800	50	118,750
7	GLS BP1515-JJ 18.8 Kg 11693 Retest Corden Global	18.8	18,800	50	18,750

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8	GLS BP1515-JJ 9.9 Kg GLS-J-20210201 Retest Corden Global	9.9	9,900	50	9,850
9	GLS BP1515-JJ 59.9 Kg GLS-J-20210201 Retest Corden Global	59.9	59,900	50	59,850
10	GLS BP1515-JJ 300 Kg GLS-J-20221201 10/27/2024 Corden Global	300	300,000	50	299,950
11	BP1515-WA Stage 1 0.6 Kg BO2210B22B Retest Corden Global	0.6	600	50	550
12	BP1515-Y Stage 2 46.6 Kg BO2210B023 Retest Corden Global	46.6	46,600	50	46,550
13	Lonafarnib API 17.9 Kg BO2011B901 Retest Lonza Bend US Only	17.9	17,900	50	17,850
14	Lonafarnib API 43.1 Kg BO2210B024 2/28/2026 Lonza Bend Global	43.1	43,100	50	43,050

Case 24-80040-sgj11 Doc 790-4 Filed 03/25/25 Entered 03/25/25 20:15:14 Desc Exhibit D Page 1 of 4

# EXHIBIT D

# Case 24-80040-sgj11 Doc 790-4 Filed 03/25/25 Entered 03/25/25 20:15:14 Desc Exhibit D Page 2 of 4

# Schedule 3.3(a)

# **Transferred Inventory**

#### FINISHED GOODS

Description	Quantity	Unit	Lot	Exp Date	Location(s)	Notes:
50mg BS - US/Clin	3355	Ea.	CKFDX	5/31/2027	Patheon	Britestock 30ct - Only for use in Zokinvy US/TR/IL + all Clinical and MAP
50mg BS - US/Clin	237	Ea.	CHHMC	11/30/2025	Patheon	Britestock 30ct - Only for use in Zokinvy US/TR/IL + all Clinical and MAP
75mg BS - US/Clin	1880	Ea.	CKFDY	5/31/2027	Patheon	Britestock 30ct - Only for use in Zokinvy US/TR/IL + all Clinical and MAP
75mg BS - US/Clin	34	Ea.	CHHMD	11/30/2025	Patheon	Britestock 30ct - Only for use in Zokinvy US/TR/IL + all Clinical and MAP
50mg BS Global	3354	Ea.	CSGBG	1/31/2028	Patheon	Britestock 30ct - For global use, all demand types
75mg BS Global	1326	Ea.	CSGBK	1/31/2028	Patheon	Britestock 30ct - For global use, all demand types
Clinical Label 50mg	497	Ea.	Multi	11/30/2025	Fisher+Sciensus+Clinigen	Clinical Label 30ct - For global use Clincial Studies and MAP
Clinical Label 75mg	470	Ea.	Multi	11/30/2025	Fisher+Sciensus+Clinigen	Clinical Label 30ct - For global use Clincial Studies and MAP
US TR IL Zokinvy 50mg	165	Ea.	CKFDZ	11/30/2025	McKesson	US Zokinvy Commercial for use anywhere that accepts the US SKU
US TR IL Zokinvy 75mg	390	Ea.	CKFFB	11/30/2025	McKesson	US Zokinvy Commercial for use anywhere that accepts the US SKU
US TR IL Zokinvy 75mg	73	Ea.	CNCPZ	11/30/2025	McKesson	US Zokinvy Commercial for use anywhere that accepts the US SKU
DE Zokinvy 50mg	49	Ea.	CMXTG	11/30/2024	Sciensus	DE Zokinvy Commercial for use anywhere that accepts the DE SKU
DE Zokinvy 75mg	6	Ea.	CMXTH	11/30/2024	Sciensus	DE Zokinvy Commercial for use anywhere that accepts the DE SKU
DE Zokinvy 50mg	120	Ea.	CSFCY	1/31/2027	Sciensus	DE Zokinvy Commercial for use anywhere that accepts the DE SKU
DE Zokinvy 75mg	120	Ea.	CSFCZ	1/31/2027	Sciensus	DE Zokinvy Commercial for use anywhere that accepts the DE SKU
FR Zokinvy 50mg	120	Ea.	CSDWX	1/31/2027	Sciensus	FR Zokinvy Commercial for use anywhere that accepts the FR SKU
FR Zokinvy 75mg	120	Ea.	CSDXB	1/31/2027	Sciensus	FR Zokinvy Commercial for use anywhere that accepts the FR SKU
UK Zokinvy 50mg	120	Ea.	CSFDB	1/31/2027	Patheon	UK Zokinvy Commercial for use anywhere that accepts the UK SKU
UK Zokinvy 75mg	120	Ea.	CSFDC	1/31/2027	Patheon	UK Zokinvy Commercial for use anywhere that accepts the UK SKU
US Zokinvy 50mg Non-Rev	26	Ea.	CNCPY	11/30/2025	Clinigen	US Zokinvy Commercial for use anywhere that accepts the US SKU
US Zokinvy 50mg Non-Rev	6	Ea.	CGGVC	9/30/2024	Clinigen	US Zokinvy Commercial for use anywhere that accepts the US SKU
US Zokinvy 50mg Non-Rev	150	Ea.	CKFDZ	11/30/2025	Clinigen	US Zokinvy Commercial for use anywhere that accepts the US SKU
US Zokinvy 75mg Non-Rev	147	Ea.	CHSMY	9/30/2024	Clinigen	US Zokinvy Commercial for use anywhere that accepts the US SKU
US Zokinvy 75mg Non-Rev	35	Ea.	CGGVD	9/30/2024	Clinigen	US Zokinvy Commercial for use anywhere that accepts the US SKU

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#### **RAW MATERIALS**

LONAFARNIB SDD	29.1	Kg	00-0120	Retest	Patheon	US Only
LONAFARNIB SDD	54.9	Kg	00-0332	Retest	Patheon	Global
UK Zokinvy 50mg	120	Ea.	CSFDB	1/31/2027	Patheon	UK Zokinvy Obselete but usable for Transpo Studies
UK Zokinvy 75mg	120	Ea.	CSFDC	1/31/2027	Patheon	UK Zokinvy Obselete but usable for Transpo Studies
YGK BP1515-LT	91.6	Kg	203002	Retest	Corden	US Only
YGK BP1515-LT	120.0	Kg	203003	Retest	Corden	US Only
YGK BP1515-LT	84.3	Kg	222004	Retest	Corden	Global
YGK BP1515-LT	118.8	Kg	228005	Retest	Corden	Global
GLS BP1515-JJ	18.8	Kg	11693 GLS-J-	Retest	Corden	Global
GLS BP1515-JJ	9.9	Kg	20210201 GLS-J-	Retest	Corden	Global
GLS BP1515-JJ	59.9	Kg	20210201 GLS-J-	Retest	Corden	Global
GLS BP1515-JJ	300	Kg	20221201	10/27/2024	Corden	Global
BP1515-WA Stage 1	0.6	Kg	BO2210B22B	Retest	Corden	Global
BP1515-Y Stage 2	46.6	Kg	BO2210B023	Retest	Corden	Global
Lonafarnib API	17.9	Kg	BO2011B901	Retest	Lonza Bend	US Only
Lonafarnib API	43.1	Kg	BO2210B024	2/28/2026	Lonza Bend	Global

# Schedule 3.3(b)

#### **Storage Agreements**

See Schedule 3.3(a) for locations of transferred materials.

- Master Services Agreement with Clinigen Healthcare Ltd dated April 26, 2018
- Master Services Agreement with Fisher Clinical Services, Inc. dated May 6, 2016 (Retained Agreement per Schedule 3.7)
- Master Manufacturing Services Agreement with Patheon, Inc. dated January 9, 2020 (Retained Agreement per Schedule 3.7)