

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 20, 2016

Eiger BioPharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36183
(Commission
File Number)

33-0971591
(IRS Employer
Identification No.)

350 Cambridge Avenue, Suite 350
Palo Alto, California
(Address of principal executive offices)

94306
(Zip Code)

Registrant's telephone number, including area code: (650) 272-6138

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On April 20, 2016, Eiger BioPharmaceuticals, Inc. (the “**Company**”) and Bristol-Myers Squibb Company (“**BMS**”) entered into a License Agreement (the “**License Agreement**”) and a Common Stock Purchase Agreement (the “**Purchase Agreement**”).

Under the License Agreement, BMS granted the Company an exclusive, worldwide, license to research, develop, manufacture, and sell products containing the proprietary BMS molecule known as PEG-interferon Lambda-1a (the “**Licensed Product**”) for all therapeutic and diagnostic uses in humans and animals. The Company is responsible for the development and commercialization of the Licensed Product at its sole cost and expense. The License Agreement requires the Company to make an upfront payment of \$2 million in cash and issue \$3 million in Company common stock and includes development and regulatory milestone payments totaling \$61 million and commercial sales milestones of up to \$128 million. The Company is obligated to pay BMS annual net sales royalties in the range of mid-single to mid-double digits, depending on net sales levels. In addition, if the Company grants a sublicense, the Company is obligated to pay BMS a portion of the sublicensing income received.

The License Agreement will continue in effect on a country-by-country basis for so long as the Company owes royalty payments to BMS under the License Agreement. The royalty term extends on a country-by-country basis for the longer of a specified number of years after first commercial sale, regulatory exclusivity or the period of exclusivity under the licensed patents. Both parties have the right to terminate the agreement for the other party’s uncured material breach of the License Agreement. BMS also has the right to terminate the License Agreement if Eiger fails to meet certain specified diligence obligations, is insolvent or challenges the patents licensed under the License Agreement. In addition, Eiger has the right to terminate the agreement without cause at any time after completion of a specified clinical milestone.

The Purchase Agreement provides for the sale and issuance of 157,587 shares of common stock of the Company at a price per share of \$19.04 and an aggregate purchase price of approximately \$3,000,000 and grants BMS certain registration rights with respect to the shares of common stock delivered, and BMS has agreed to certain trading and other restrictions with respect to the shares purchased.

The foregoing description is only a summary of certain provisions of the License and Purchase Agreements and is qualified in its entirety by the terms of the License Agreement and Purchase Agreement, copies of which (with certain portions subject to confidential treatment) will be filed with the Quarterly Report on Form 10-Q for the period ended June 30, 2016.

Item 3.02. Unregistered Sales of Equity Securities.

The information under Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 3.02.

Item 7.01 Regulation FD Disclosure.

The Company is furnishing the Lambda Product Background and Plans Presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use from time to time in connection with discussing the Licensed Product with investors.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered “filed” or incorporated by reference therein.

Item 8.01. Other events.

On April 20, 2016, the Company issued a press release announcing the Company’s entry into the License Agreement. A copy of the press release is attached hereto as Exhibit 99.2 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Reference is made to the Exhibit Index included with this Current Report on Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Eiger BioPharmaceuticals, Inc.

Dated: April 20, 2016

By: /s/ James Welch
James Welch
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Lambda Product Background and Plans.
99.2	Press release issued on April 20, 2016.

Building a Franchise in HDV

Sarasar[®] (lonafarnib)

Pegylated Interferon Lambda-1a



Forward-Looking Statements

This presentation and the oral commentary contain “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements. These forward-looking statements include terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “contemplate,” “intend,” “target,” “project,” “should,” “plan,” “expect,” “predict,” “could,” “potentially” or the negative of these terms. Forward looking statements are our current statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned clinical development, the timing of and our ability to initiate or enroll clinical trials, and our ability to make regulatory filings and obtain and maintain regulatory approvals for Sarasar, PEG IFN Lambda and our other product candidates, our intellectual property position, the potential safety, efficacy, reimbursement, convenience clinical and pharmaco-economic benefits of our product candidates, commercial opportunities, including potential market sizes and segments, our ability to commercialize, expectations regarding clinical trial data and FDA outcomes, our results of operations, cash needs, spending of the proceeds from this offering, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

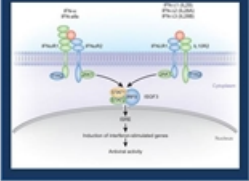
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PEG IFN Lambda

The Next Frontier in Interferon Therapy

Journal of
Interferon & Cytokine
Research



Interferon-Lambda: A New Addition to an Old Family

The discovery and initial description of the interferon- λ (IFN- λ) family in early 2003 opened an exciting new chapter in the field of IFN research. There are 3 IFN- λ genes that encode 3 distinct but highly related proteins denoted IFN- λ 1, - λ 2, and - λ 3. These proteins are also known as interleukin-29 (IL-29), IL-28A, and IL-28B, respectively. Collectively, these 3 cytokines comprise the type III subset of IFNs. They are distinct from both type I and type II IFNs for a number of reasons, including the fact that they signal through a heterodimeric receptor complex that is different from the receptors used by type I or type II IFNs. Although type I IFNs (IFN- α/β) and type III IFNs (IFN- λ) signal via distinct receptor complexes, they activate the same intracellular signaling pathway and many of the same biological activities, including antiviral activity, in a wide variety of target cells. Consistent with their antiviral activity, expression of the IFN- λ genes and their corresponding proteins is inducible by infection with many types of viruses. Therefore, expression of the type III IFNs (IFN- λ s) and their primary biological activity are very similar to the type I IFNs. However, unlike IFN- α receptors which are broadly expressed on most cell types, including leukocytes, IFN- λ receptors are largely restricted to cells of epithelial origin. The potential clinical importance of IFN- λ as a novel antiviral therapeutic agent is already apparent. In addition, preclinical studies by several groups indicate that IFN- λ may also be useful as a potential therapeutic agent for other clinical indications, including certain types of cancer.

- *First developed by Zymogenetics*
 - *Clinical Development into Phase 2 in early 2000's*
- *Proposed benefit: improved safety and tolerability vs PEG IFN α*
- *Target indication: HCV*
- *Acquired by Bristol-Myers Squibb in 2010*
- *Greater than 3,000 patients in 17 clinical trials*
 - *Phase 2 and Phase 3 studies in HCV and HBV*
- *Discontinued following advent of all oral HCV combinations*

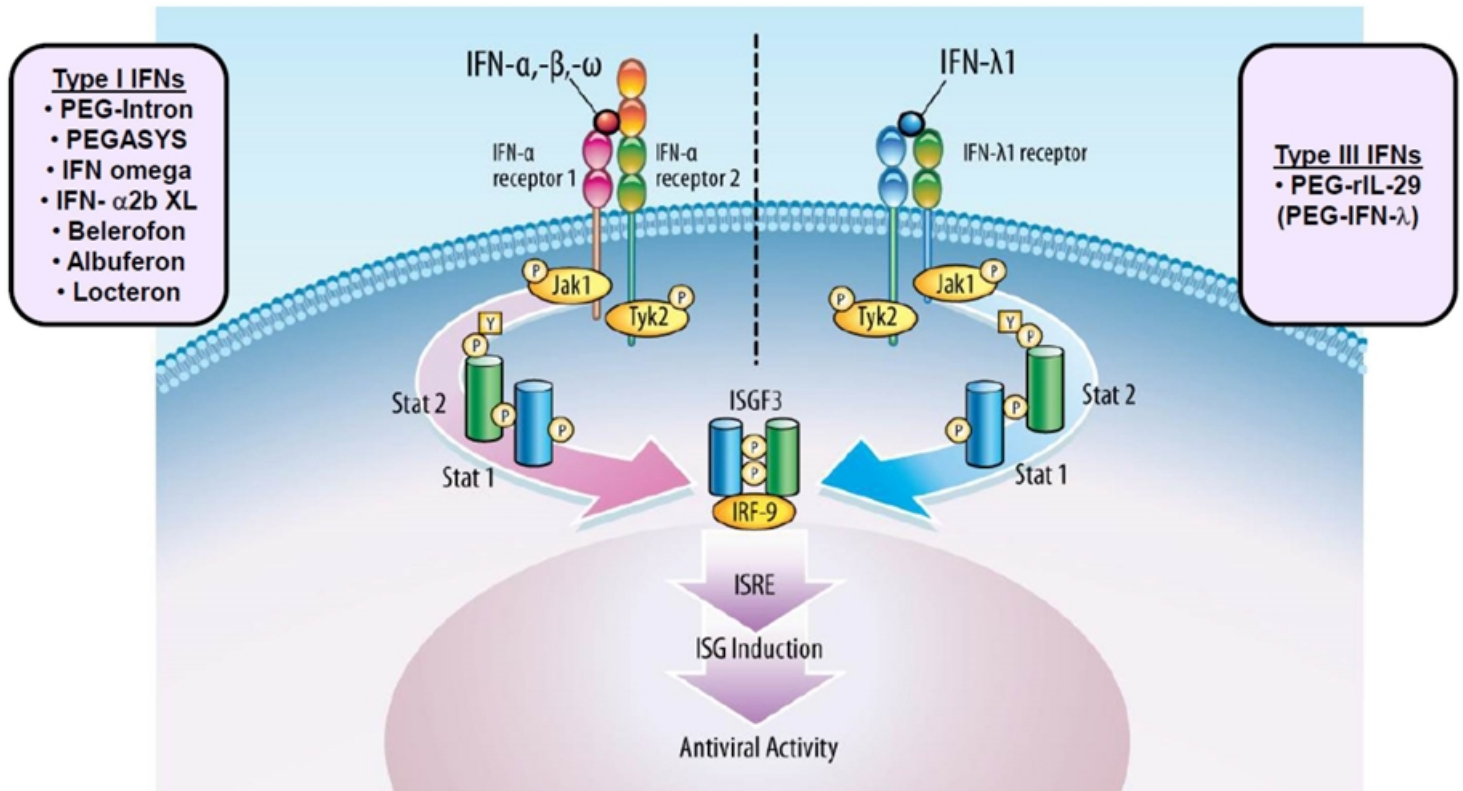
PEG IFN Lambda

A targeted interferon for HDV

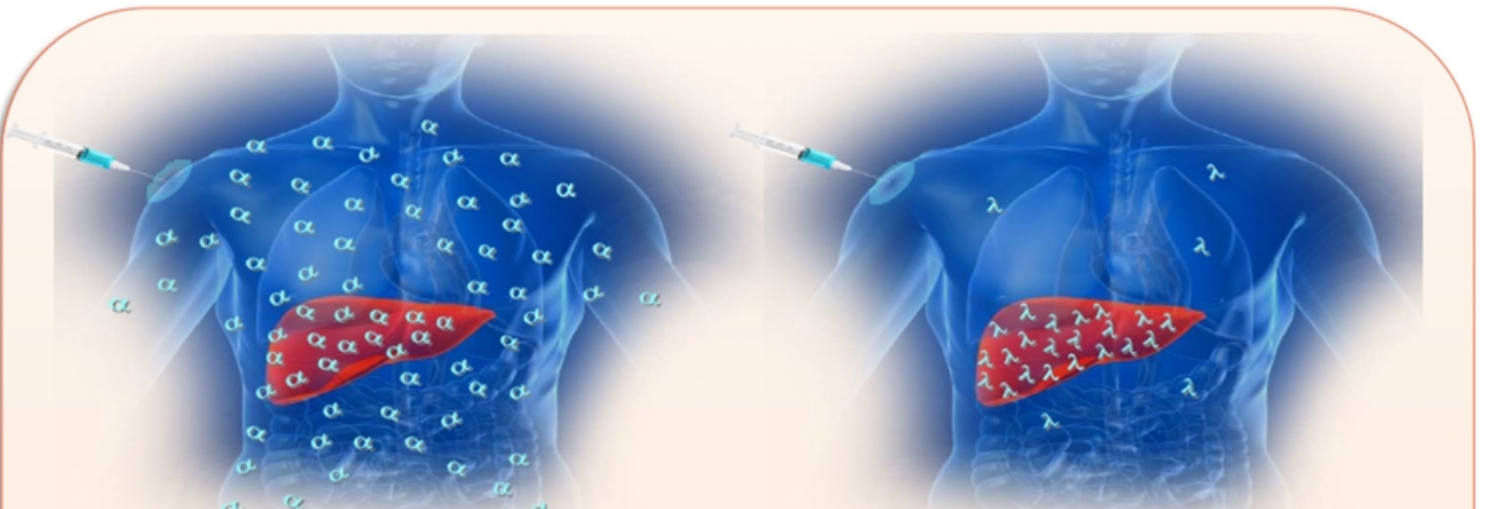
- *A novel, first in class Type III interferon*
 - *Native Lambda is generated by human immune system in viral infections*
- *Binds to a unique receptor versus Type I interferons*
 - *Highly expressed on hepatocytes*
 - *Limited expression on hematopoietic cells and CNS cells*
- *Uses similar downstream signaling pathway as Type I interferons*
- *Anti HCV / Anti HBV activity demonstrated in clinical studies*
- *Antiviral activity with less of the typical IFN α related side effects*
- *Anti HDV activity demonstrated in humanized liver mouse model*

Type I Interferons versus Type III Interferons

alfa, beta, omega versus lambda



Potential Impact of Lambda Receptor Distribution



- IFNα receptors **widely** distributed throughout body
 - Potential for **more** IFN-associated abnormalities:
 - ✓↑Neutropenia
 - ✓↑Thrombocytopenia
 - ✓↑Flu-Like Symptoms
 - ✓↑Musculoskeletal Symptoms
- Lambda receptors **not widely** distributed throughout body
 - Potential for **less** IFN-associated abnormalities:
 - ✓↓Neutropenia
 - ✓↓Thrombocytopenia
 - ✓↓Flu-Like Symptoms
 - ✓↓Musculoskeletal Symptoms

PEG IFN Lambda Safety versus PEG IFN Alfa

Results of Clinical Study in HBV Infected Patients

Type of Event	Event	Lambda 180 mcg (N = 80)	Alfa 180 mcg (N = 83)
		# of patients (%)	
Serious adverse events		7 (8.8)	5 (6.0)
Adverse events leading to discontinuation		6 (7.5)	8 (9.6)
Adverse events (any grade) in >15% in any group	Pyrexia	8 (10.0)	38 (45.8)
	Alopecia	9 (11.3)	25 (30.1)
	Fatigue	26 (32.5)	24 (28.9)
	Headache	11 (13.8)	24 (28.9)
	Neutropenia	0	20 (24.1)
	Myalgia	3 (3.8)	18 (21.7)
	Dizziness	5 (6.3)	13 (15.7)
	Pruritus	7 (8.8)	13 (15.7)
	ALT Increase	15 (18.8)	8 (9.6)
Adverse event categories of special interest	Constitutional	28 (35.0)	26 (31.3)
	Neurological	18 (22.5)	30 (36.1)
	Flu-like	13 (16.3)	45 (54.2)
	Musculoskeletal	5 (6.3)	23 (27.7)
	Psychiatric	11 (13.8)	15 (18.1)

PEG IFN Lambda Safety versus PEG IFN Alfa

Results of Clinical Study in HBV Infected Patients

Type of Event	Event	Lambda 180 mcg (N = 80)	Alfa 180 mcg (N = 83)
		# of patients (%)	
Grade 3-4 laboratory abnormalities	ALT increases (>5 x ULN)	33 (41.3)	19 (23.3)
	AST increases (>5 x ULN)	27 (33.8)	15 (18.3)
	Hyperbilirubinemia (>2.5 x ULN)	3 (3.8)	0
	Neutropenia (<750 cells / mm ³)	2 (2.5)	17 (20.7)
	Thrombocytopenia (<50,000 cells / mm ³)	0	1 (1.2)
	Hemoglobin (<9 g/dL or 4.5 g/dL decrease from baseline)	0	0
ALT flares		13 (16.3)	6 (7.2)
Dose reductions		12 (15.0)	23 (27.7)
Dose interruptions		8 (10.0)	4 (4.8)



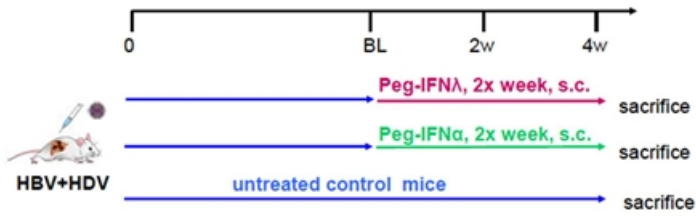
Chan, HLY et al, J Hepatology 2016.



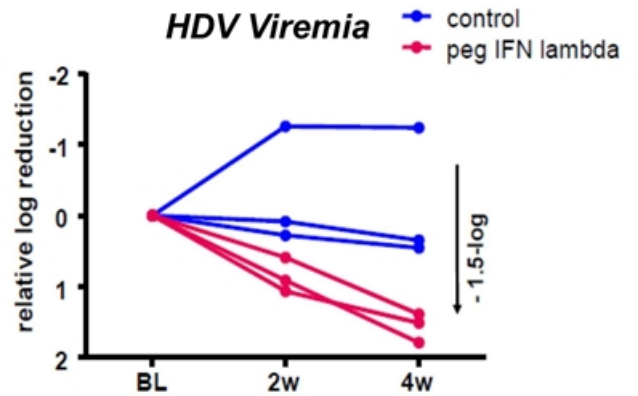
PEG IFN Lambda Suppresses HDV RNA

Strongly Enhanced Innate Immune Response of Human Hepatocytes

Experimental Design



HDV Viremia

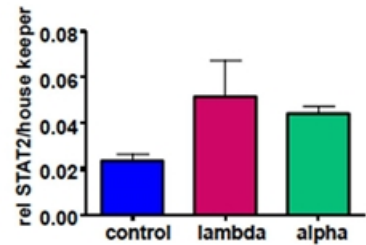
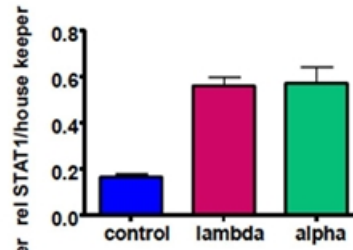
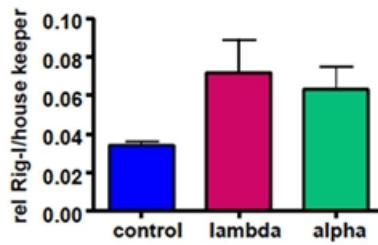
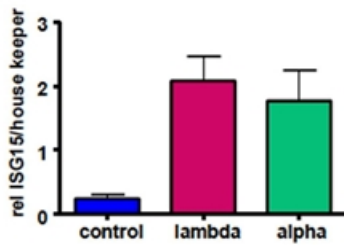


ISG15 = 6.2 Fold

Rig-I = 1.9 Fold











STAT1 = 6.2 Fold

STAT2 = 11.2 Fold



Sarasar[®] (lonafarnib) Phase 2 HDV Program

LOWR 1 and LOWR 2 Include PEG IFN α Combination Dosing

- **Proof of Concept**
 - Monotherapy $N = 14$   Complete
- **LOWR HDV – 1**
 - Combinations **+/- PEG IFN α** $N = 15$   Complete
- **LOWR HDV – 2**
 - Dose Finding **+/- PEG IFN α** $N = 38$   Dosing
- **LOWR HDV – 3**
 - Duration $N = 21$   Dosing
- **LOWR HDV - 4**
 - Titration $N = 15$   Dosing

PEG IFN Lambda

Plans

- *Replace PEG IFN α in next Eiger HDV studies*
- *Efficiently study potential use as:*
 - *An effective monotherapy in HDV*
 - *An effective combination therapy with Lonafarnib in HDV*
- *Identify potential for better tolerability versus PEG IFN α in HDV*
- *Offer a proprietary interferon with more optimal efficacy / tolerability*
- *Apply for Orphan Designation & Fast Track status*
- *Create an HDV franchise opportunity at Eiger*

PEG IFN Lambda

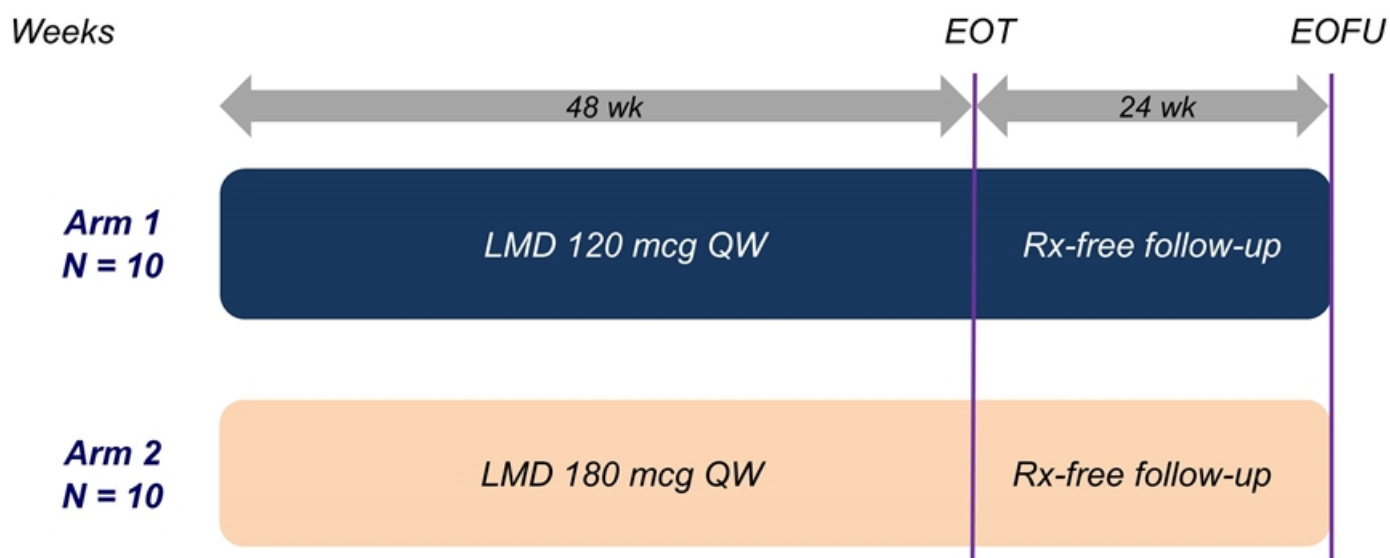
Expected Timelines

- *Drug Product on hand sufficient for Phase 2*
 - *Quantities may supply development through registration*
- *Monotherapy study in HDV to begin in 2H2016*
 - *Lambda alone dose ranging study*
- *Combination study in HDV to begin in 2H2016*
 - *Lonafarnib + Ritonavir + Lambda*
- *Efficient generation of Phase 2 POC data in 4Q2017*
 - *Multiple, international sites*

Monotherapy - Phase 2 POC Study in HDV

LMD 120 mcg QW vs LMD 180 mcg QW

Objective: Safety and Efficacy of LMD 120 mcg vs LMD 180 mcg



New Zealand: Ed Gane (Auckland)



Pakistan: Saeed Hamid (Karachi)





PEG IFN Lambda Monotherapy

Clinical / Regulatory POC Plan



★ Regulatory Filings ✓

Enroll ★

Dosing ★

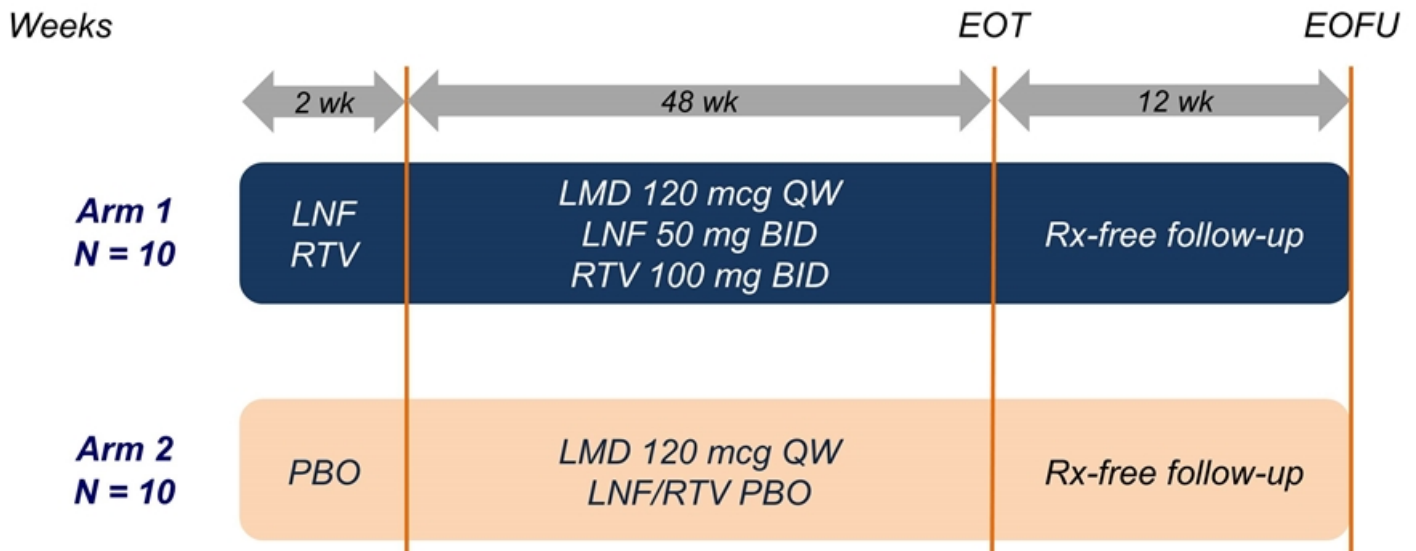
★ EOT Data
AASLD
AMERICAN ASSOCIATION FOR
THE STUDY OF LIVER DISEASES
2017

★ Post TRx Data
EASL
The Home of Hepatology
2018

Combination - Phase 2 POC Study in HDV

LNF 50 mg BID / RTV 100 mg BID + LMD 120 mcg QW

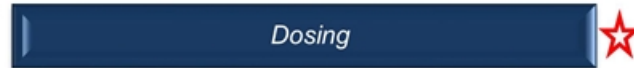
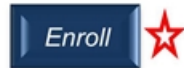
Objective: Safety and Efficacy of LNF + RTV + LMD vs LMD Alone



Planned Sites:

US:  

Turkey:  



Sarasar[®] (lonafarnib) in HDV

Phase 2 Results Expected in 2016 / 2017

2015	2016	2017
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Phase 2 LOWR HDV – 2

N = 38


Interim Data


EASL


THE INTERNATIONAL LIVER CONGRESS™ 2016
APRIL 12-15 BARCELONA, SPAIN


Post TRx Data



AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES


2016



Phase 2 LOWR HDV - 3

N = 21


EOT Data


AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

2016


Post TRx Data


EASL
The Home of Hepatology

2017



Phase 2 LOWR HDV - 4

N = 15


EOT Data


AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

2016


Post TRx Data


EASL
The Home of Hepatology

2017

Potential Registration Pathways

Building an HDV Franchise

<i>HDV Registration Options</i>	<i>Clinical Description</i>	<i>Treatment Option</i> <i>All Oral</i>	<i>Treatment Option</i> <i>Triple Combo</i>	<i>Treatment Option</i> <i>Mono</i>
Cure	HDV RNA Negativity + / - ALT Normalization	LNF / RTV	LNF / RTV + LMD	LMD
Relapse Treatment	HDV RNA Negativity Followed by Relapse Post Treatment	LNF / RTV	LNF / RTV + LMD	LMD
Chronic Treatment	HDV RNA Reduction + / - ALT Normalization	LNF / RTV		



Building a Franchise in HDV

Sarasar[®] (lonafarnib)

Pegylated Interferon Lambda-1a



Eiger BioPharmaceuticals Announces License of Worldwide Rights to Pegylated Interferon Lambda-1a from Bristol-Myers Squibb**Including Rights for All Indications and Associated Patents**

PALO ALTO, CALIF, April 20, 2016 /PRNewswire/ — Eiger BioPharmaceuticals, Inc. (NASDAQ: EIGR) announced today that it has licensed Pegylated Interferon Lambda-1a (“Lambda”), a novel, well-characterized, first in class Type III interferon to be studied as an investigational therapy for hepatitis delta virus (HDV) infection, from Bristol-Myers Squibb. Lambda has been administered in clinical trials involving over 3,000 subjects. It has not been approved for any indication. Eiger plans to evaluate Lambda as a potential monotherapy and combination treatment for chronic HDV infection, the most aggressive and deadly form of human viral hepatitis.

“We are very excited to execute this license with Bristol-Myers Squibb. The addition of Lambda to our pipeline is a significant step toward building a leading HDV franchise,” said David Cory, President and CEO of Eiger. “There is no approved therapy for HDV. Along with Lonafarnib, our Phase 2 candidate for the treatment of HDV, Eiger has established a strategic position with the addition of Lambda. Eiger will leverage existing relationships with clinical investigators and clinical sites for efficient exploration of Lambda alone or in combination with other agents toward an approved therapy for HDV.”

“Most cells in the body express the receptor for interferon alfa, a Type I interferon. However, receptors for Lambda, a Type III interferon, are expressed on liver cells, a desirable location for treating viral hepatitis, but less so on some blood cells and non-liver cells. Lambda represents a promising and potentially better tolerated interferon therapy for HDV,” said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases at Eiger.

The exclusive worldwide license from Bristol-Myers Squibb involved an upfront payment and the issuance of Eiger Common Stock and includes development and regulatory milestones through first commercial sale in the US, EU, and Japan and milestone payments based on commercial sales achievement as well as tiered annual net sales royalties.

About Sarasar™ (lonafarnib)

Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through a process called prenylation. HDV uses this host cell process inside liver cells to complete a key step in its life cycle. Lonafarnib inhibits the prenylation step of HDV replication inside liver cells and blocks the virus life cycle at the stage of assembly. Since prenylation is carried out by a host enzyme, this compound may present a higher barrier to development of viral

resistance mutations to therapy. Lonafarnib has been dosed in over 100 HDV-infected patients across international academic centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and Fast Track Designation by U.S. FDA. Lonafarnib is not approved for any indication, and is licensed from Merck Sharp & Dohme Corp. (known as MSD outside of the United States and Canada).

About Hepatitis Delta Virus (HDV)

Hepatitis Delta (or Hepatitis D) is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. Hepatitis D occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis D leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis D is a disease with a significant impact on global health, which may affect up to approximately 15-20 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 4.3% to 5.7% of chronic Hepatitis B carriers. The prevalence of HDV in patients infected with chronic HBV is even higher in certain regions, including certain parts of Mongolia, China, Russia, Central Asia, Pakistan, Turkey, Africa, and South America, with an HDV prevalence as high as 60% being reported in HBV-infected patients in Mongolia and Pakistan.

About Eiger

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of rare diseases. The company has built a diverse portfolio of well-characterized product candidates with the potential to address diseases for which the unmet medical need is high, the biology for treatment is clear, and for which an effective therapy is urgently needed.

Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives, intentions, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Examples of such statements include, but are not limited to, whether or not pegylated interferon lambda-1a or lonafarnib may be further developed and approved, statements relating to the

availability of cash for Eiger’s future operations, Eiger’s ability to develop its drug candidates for potential commercialization, the timing of the commencement and completion of Phase 2 trials and whether the Lambda product can be successfully developed or commercialized. Eiger may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements and one should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks that Eiger’s planned clinical trials may be prolonged or delayed requiring Eiger to incur additional costs; that Eiger’s planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities; that Eiger’s product candidates may have undesirable side effects which may delay or prevent marketing approval; that, even if approved by the FDA or non-U.S. regulatory authorities, Eiger’s product candidates may not achieve broad market acceptance; and the risks described in the “Risk Factors” sections the Registration Statement on Form S-4 (file no. 333-208521) and of Eiger’s periodic reports filed with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.



SOURCE Eiger Bio, Inc.

Investors: Jim Shaffer, Eiger Bio, Inc., 919-345-4256, jshaffer@eigerbio.com