
**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): July 18, 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))
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Item 8.01 Other events.

On July 18, 2016, the Company issued a press release entitled “Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 LIBERTY Study of Ubenimex in Pulmonary Arterial Hypertension.” A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

On July 20, 2016, the Company issued a press release entitled “Eiger BioPharmaceuticals Announces Completion of Dosing in Phase 2 LOWR HDV – 3 Study at National Institutes of Health (NIH).” A copy of the press release is attached hereto as Exhibit 99.2 and incorporated by reference herein.

On July 25, 2016, the Company issued a press release entitled “Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 ULTRA Study of Ubenimex in Secondary Lymphedema.” A copy of the press release is attached hereto as Exhibit 99.3 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: July 28, 2016

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated July 18, 2016, titled “Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 LIBERTY Study of Ubenimex in Pulmonary Arterial Hypertension.”
99.2	Press release, dated July 20, 2016, titled “Eiger BioPharmaceuticals Announces Completion of Dosing in Phase 2 LOWR HDV – 3 Study at National Institutes of Health (NIH).”
99.3	Press release, dated July 25, 2016, titled “Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 ULTRA Study of Ubenimex in Secondary Lymphedema.”

Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 LIBERTY Study of Ubenimex in Pulmonary Arterial Hypertension**Novel first-in-class inhibitor of LTB₄ targeting disease modification**

PALO ALTO, Calif., July 18, 2016 / PRNewswire / Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today that the first patient was dosed in the Phase 2 LIBERTY study. The LIBERTY study will evaluate the effects of ubenimex added to current standard of care in patients with pulmonary arterial hypertension (PAH). Despite multiple approved vasodilator therapies, PAH remains a progressive, life-threatening cardiovascular disease. Ubenimex is a well-characterized, oral, small-molecule inhibitor of leukotriene A₄ hydrolase, which blocks the production of leukotriene B₄ (LTB₄), an inflammatory mediator implicated in PAH disease.

“The LIBERTY study represents a transformative, clinical translational effort with potential to demonstrate, for the first time, disease modification in PAH,” said Roham Zamanian, MD, Lead Investigator and Director of the Adult Pulmonary Hypertension Program at Stanford University School of Medicine. “While vasoactive agents have utility in the clinical management of the symptoms of PAH, they do not address the underlying inflammation which is an important signature of this cardiovascular disease. We have arrived at a moment of shift of therapeutic paradigm, where we may have a chance to realize a potentially disease modifying approach.”

“The goal of the LIBERTY study is to block LTB₄ with ubenimex as a novel and potentially disease modifying treatment for PAH,” said Joanne Quan, MD, Chief Medical Officer at Eiger BioPharmaceuticals. “Inflammation, now recognized as an important component of PAH, is not addressed by currently available therapies. Recently published preclinical results of studies conducted at Stanford University suggest that elevated LTB₄ levels may play a role in the inflammatory component of PAH, which can lead to obstructed arterioles, vasoconstriction, and worsening cardiac function. Targeted LTB₄ blockade may represent an important new therapeutic approach to this disease.”

About the LIBERTY Phase 2 Study

LIBERTY is a multi-center, randomized, double-blind, placebo-controlled Phase 2 study of ubenimex in patients with pulmonary arterial hypertension. Approximately forty-five patients will be randomized in a 2:1 ratio to receive ubenimex or matching placebo, administered orally for a total of 24 weeks. Patients who complete treatment through Week 24 will be eligible to enroll in an open-label extension study to receive continued treatment. This open-label extension will allow all patients the option to receive ubenimex for at least an additional 24 weeks and provide additional data on safety, tolerability and efficacy.

About LTB₄ and Ubenimex

LTB₄ is a naturally-occurring inflammatory mediator known to be elevated in both animal models of PAH as well as human PAH disease. In animal models, elevated LTB₄ causes inflammation resulting in arteriole occlusion, vasoconstriction and hypertension. Targeted pharmacologic inhibition of LTB₄ reversed PAH disease in treated animals as demonstrated by decreased obstruction of arterioles, improved cardiac function, and improved survival.

Ubenimex is a well-characterized, oral, small-molecule, inhibitor of LTA₄H, the enzyme responsible for the formation of the pro-inflammatory mediator, LTB₄.

Ubenimex is approved in Japan (brand name Bestatin™) as an adjunct to chemotherapy agents to extend survival and to maintain remission after treatment for acute non-lymphocytic leukemia in adults. Ubenimex has been used for over 25 years in Japan and remains commercially available through Nippon Kayaku. Ubenimex has been granted Orphan Drug Designation for treatment of PAH by the US FDA and European Medicines Agency (EMA). Ubenimex is not approved for any indication in the US or Europe.

About PAH

Pulmonary arterial hypertension (PAH) is a type of high blood pressure that affects the arteries in the lungs and the right side of the heart. PAH begins when tiny arteries in the lungs, called pulmonary arterioles, become narrowed, blocked or destroyed. This makes it harder for blood to flow through the lungs, and raises pressure within the lungs' arteries. As the pressure builds, the heart's lower right chamber (right ventricle) must work harder to pump blood through the lungs, eventually causing the heart muscle to weaken and eventually fail. PAH is a progressive, life-threatening illness.

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 or ubenimex or exendin (9-39) 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 number and completion of Phase 2 trials and whether the products can be successfully developed or commercialized. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Eiger makes, including the risks described in the “Risk Factors” sections in the Annual Report on Form 10-K for the period ended December 31, 2015 and 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

Eiger BioPharmaceuticals Announces Completion of Dosing in Phase 2 LOWR HDV – 3 Study at National Institutes of Health (NIH)

PALO ALTO, Calif., July 20, 2016 / PRNewswire / — Eiger BioPharmaceuticals, Inc. today announced the completion of dosing of LOWR HDV – 3 (**L**onafarnib **W**ith **R**itonavir in **H**epatitis **D**elta **V**irus – 3) at the National Institutes of Health (NIH) Clinical Center in Bethesda, Maryland. LOWR HDV – 3 is a double-blinded, randomized, placebo-controlled study designed to evaluate the efficacy and tolerability of three doses of lonafarnib – 50 mg, 75 mg and 100 mg – once daily, each combined with ritonavir 100 mg once daily for 12 or 24 weeks. Twenty-one patients with chronic hepatitis delta were randomized into one of six treatment groups.

“The NIH Clinical Center previously completed the first proof-of-concept Phase 2 study involving lonafarnib in hepatitis delta infected patients, and these results were published in The Lancet Infectious Diseases in 2015,” said Christopher Koh, MD, study lead and staff clinician at the National Institute of Diabetes and Digestive and Kidney Diseases, part of the NIH. “Now that we have completed dosing in a second study with lonafarnib in patients with chronic hepatitis delta, we look forward to reporting results.”

“Hepatitis delta causes the most aggressive form of human viral hepatitis, with fast progression to cirrhosis and other life-threatening complications, and is a major health burden all over the world,” said Eduardo Martins, MD, DPhil, Senior Vice President of Liver and Infectious Diseases Drug Development at Eiger BioPharmaceuticals. “LOWR HDV – 3 is designed to help elucidate the antiviral potential of once daily dosing of lonafarnib in combination with ritonavir in a longer duration study, and we eagerly await results.”

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 during therapy. Lonafarnib has been dosed in over 100 HDV-infected patients across international research centers and is in Phase 2 development for HDV. Lonafarnib has been granted Orphan Drug Designation by the US FDA and European Medicines Agency (EMA), and Fast Track Designation by US 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, and due to migration, may affect up to approximately 15 million people worldwide. The prevalence of HDV varies among different parts of the world. Globally, HDV infection is reported to be present in approximately 5-6% 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.

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Eiger BioPharmaceuticals Announces First Patient Dosed in Phase 2 ULTRA Study of Ubenimex in Secondary Lymphedema**Novel first-in-class inhibitor of LTB₄ production targeting disease modification**

PALO ALTO, Calif., July 25, 2016 / PRNewswire / Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced today that the first patient in the Phase 2 ULTRA study was dosed at Stanford University. The ULTRA study will evaluate the effects of ubenimex in patients with secondary lymphedema of the lower limb(s) who are optimized on physical therapies. Physical therapies, such as compression garments and bandaging, reflect the current standard of care for lymphedema. Ubenimex is a well-characterized, oral, small-molecule, inhibitor of leukotriene A₄ hydrolase (LTA₄H), which blocks the production of leukotriene B₄ (LTB₄), an inflammatory mediator implicated in lymphedema.

“Our research has demonstrated that LTB₄ is elevated in both preclinical models of lymphedema as well as human lymphedema and that elevated LTB₄ is associated with tissue inflammation and impaired lymphatic function,” said Stanley Rockson, MD, Lead Investigator and Professor of Cardiovascular Medicine and Director of the Stanford Center for Lymphatic and Venous Disorders. “Our research suggests that targeted pharmacologic inhibition of LTB₄ promotes physiologic lymphatic repair and reverses lymphedema disease in treated animals. We are excited to investigate a novel therapy with the potential for significant disease modification in the ULTRA clinical trial.”

“Lymphedema can have long-lasting deleterious effects and can significantly impact quality of life. There is no FDA approved pharmacologic treatment. Currently, patients must rely on physical therapies such as manual lymph drainage and compression garments for relief,” said Joanne Quan, MD, Chief Medical Officer at Eiger BioPharmaceuticals. “The ULTRA study is designed to explore a novel approach to the treatment of secondary lymphedema by blocking the production of LTB₄. This approach has the potential to lessen the effects of this serious and debilitating disease and provide an convenient treatment option for patients.”

About the ULTRA Phase 2 Study

ULTRA is a multi-center, randomized, double-blind, placebo-controlled Phase 2 study of ubenimex in patients with secondary lymphedema of the lower limb(s). Approximately forty patients will be randomized in a 1:1 ratio to receive ubenimex or matching placebo, administered orally for a total of 24 weeks. The 24-week study will assess clinical, biomarker, histologic and patient-reported outcomes.

About LTB₄ and Ubenimex

Leukotriene B₄ (LTB₄) is a naturally-occurring inflammatory substance known to be elevated in both preclinical models of secondary lymphedema as well as human lymphedema disease. Elevated LTB₄ causes inflammation resulting in tissue inflammation and impaired lymphatic function. Targeted pharmacologic inhibition of LTB₄ promotes lymphatic repair and reverses lymphedema disease in treated animals.

Ubenimex is a well-characterized, oral, small-molecule, inhibitor of leukotriene A₄ hydrolase (LTA₄H), the enzyme responsible for the formation of the pro-inflammatory mediator, LTB₄.

Ubenimex is approved in Japan (brand name Bestatin™) as an adjunct to chemotherapy agents to extend survival and to maintain remission after treatment for acute non-lymphocytic leukemia in adults. Ubenimex has been used for over 25 years in Japan and remains commercially available through Nippon Kayaku. Ubenimex is not approved for any indication in the US or Europe.

About Lymphedema

Lymphedema can be either primary (hereditary) or secondary (caused by another disease or condition). Primary lymphedema is caused by the absence of certain lymph vessels at birth or abnormalities in the lymphatic vessels and can be divided into three forms, depending on age of onset. Secondary lymphedema usually develops as a result of a lymph vessel blockage or interruption that alters the flow of lymph through the lymphatic system and can develop from an infection, malignancy, surgery, scar tissue formation, trauma, radiation, or other cancer treatment. Primary lymphedema and secondary lymphedema are large unmet medical needs, as both can be debilitating and negatively impact quality of life. There is no approved pharmacologic treatment for lymphedema.

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