



Eiger Announces FDA Fast Track Designation Granted for Pegylated Interferon Lambda in Hepatitis Delta Virus Infection

PALO ALTO, Calif., July 27, 2017 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (Nasdaq: EIGR), focused on the development and commercialization of targeted therapies for rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for pegylated interferon lambda 1a (Lambda) as a potential treatment for chronic hepatitis delta virus (HDV) infection.

"We are very pleased that the FDA has granted Lambda with Fast Track status for the treatment of HDV," said David Cory, President and CEO of Eiger. "Receiving Fast Track status is an important achievement that we hope may facilitate and expedite its development as a treatment for HDV."

The FDA established the Fast Track designation process to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Through the Fast Track program, a product may be eligible for priority review at the time of submission of a New Drug Application (NDA) or Biological License Application (BLA) and may also be eligible to submit completed application sections on a rolling basis. These expedited processes can significantly reduce development and application review time and costs associated with bringing a drug to market.

About Subcutaneous Pegylated Interferon Lambda 1a

Pegylated interferon lambda 1a (Lambda) is a well-characterized, late-stage, first in class, type III interferon (IFN) that stimulates immune responses that are critical for the development of host protection during viral infections. Lambda targets type III IFN receptors which are distinct from the type I IFN receptors targeted by IFN alfa. These type III receptors are highly expressed on hepatocytes with limited expression on hematopoietic and central nervous system cells, which may reduce off-target effects and improve tolerability of Lambda. Although Lambda does not use the IFN alfa receptor, signaling through either the IFN Lambda or IFN alfa receptor complexes results in the activation of the same Jak-STAT signal transduction cascade.

Eiger licensed worldwide rights to Lambda from Bristol-Myers Squibb in April 2016. Lambda has been administered in HBV / HCV clinical trials involving over 3,000 subjects. Lambda has not been approved for any indication.

About Hepatitis Delta Virus (HDV)

Hepatitis Delta is caused by infection with HDV and is considered to be one of the most severe forms of viral hepatitis in humans. Hepatitis delta occurs only as a co-infection in individuals harboring Hepatitis B Virus (HBV). Hepatitis delta leads to more severe liver disease than HBV alone and is associated with accelerated liver fibrosis, liver cancer, and liver failure. Hepatitis delta 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, Middle East 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, lonafarnib, ubenimex or exendin 9-39, including SC formulations, may be further developed and approved, whether additional studies of exendin 9-39 will show safety and activity consistent with early clinical results, statements relating sufficient capital for

Eiger's continued development and 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 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" section in the Quarterly Report on Form 10-Q for the three months ended March 31, 2017 and our periodic reports filed with the Securities and Exchange Commission. Eiger assumes no obligation to update any forward-looking statements, except as required by law.

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