

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.

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.



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