Eiger BioPharmaceuticals Completes Enrollment of Phase 2 ULTRA Study of Ubenimex in Primary and Secondary Lymphedema Patients

- ULTRA Study Data Expected in Second Half 2018

PALO ALTO, Calif., January 4, 2018 -- Eiger BioPharmaceuticals, Inc. (Nasdaq:EIGR), focused on the development and commercialization of targeted therapies for rare diseases, announced completion of enrollment of the Phase 2 ULTRA study. ULTRA is a randomized, placebo-controlled study designed to evaluate the effects of ubenimex in patients with primary and secondary lymphedema of the lower limb(s). There is currently no FDA approved pharmacologic therapy for lymphedema. Compression garments and bandaging are the current standard of care. Ubenimex is a well-characterized, oral, small-molecule inhibitor of leukotriene A4 hydrolase (LTA4H), which blocks production of leukotriene B4 (LTB4), an inflammatory mediator implicated in lymphedema. A total of 54 patients were enrolled across sites in the United States and Australia.

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

“Lymphedema can have long-lasting deleterious effects and significantly worsen 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 primary and secondary lymphedema by blocking the production of LTB4. Ubenimex has the potential to be the first pharmacologic therapy for patients suffering from this serious and debilitating disorder. We look forward to reporting results of the ULTRA study later in 2018.”

About LTB4 and Ubenimex
Leukotriene B4 (LTB4) is a naturally-occurring inflammatory substance shown to be elevated in both preclinical models of secondary lymphedema as well as human lymphedema disease. A recent publication in Science Translational Medicine
demonstrated elevated LTB₄ levels, tissue inflammation and impaired lymphatic function in a mouse model of lymphedema, and targeted pharmacologic inhibition of LTB₄ production promoted lymphatic repair and reversed lymphedema disease.

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 30 years in Japan and is 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 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 focused on the development and commercialization of targeted therapies for orphan diseases. We are committed to translational innovation and developing well-characterized drugs acting on newly identified or novel, validated targets. Our mission is to systematically reduce the time and cost of the drug development process to more rapidly deliver important medicines to patients with orphan diseases. For additional information about Eiger and its clinical programs, please visit www.eigerbio.com.

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 the study results from the Phase 2 ULTRA study will be positive and whether ubenimex may be further developed and approved and whether promising earlier clinical study results will obtain in larger, later clinical studies, 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 most recent Quarterly Report on Form 10-Q for the period ended September 30, 2017 and Eiger’s other periodic reports and filings with the SEC. Eiger does not assume any obligation to update any forward-looking statements, except as required by law.

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