# Eiger BioPharmaceuticals Granted Orphan Medicinal Product Designation for Ubenimex in Pulmonary Arterial Hypertension by European Medicines Agency

PALO ALTO, Calif., March 28, 2016 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. (NASDAQ: EIGR) today announced that the European Medicines Agency (EMA) has granted Orphan Medicinal Product status to ubenimex for the treatment of pulmonary arterial hypertension (PAH).

"We are very pleased with the EMA Committee of Orphan Medicinal Products (COMP) designation of orphan status for ubenimex in PAH," said Joanne Quan, MD, Chief Medical Officer at Eiger. "We will soon begin enrolling the LIBERTY study, a Phase 2, randomized, double-blind, placebo-controlled, multi-center study of ubenimex in PAH patients."

**About Ubenimex**

Ubenimex is a well-characterized, oral, small-molecule, dual-inhibitor of aminopeptidase and leukotriene $A_4$ hydrolase ($LTA_4H$), the enzyme responsible for catalyzing the committed step in the formation of the pro-inflammatory mediator, $LTB_4$. Ubenimex is approved in Japan 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 under the brand name, Bestatin™. Ubenimex is not approved for any indication in the US or Europe. Ubenimex received orphan drug designation for PAH in the US in November 2015.

**About PAH**

Pulmonary Arterial Hypertension 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 Orphan Medicinal Product Designation**

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect no more than 5 in 10,000 people in the European Union. Orphan medicinal product designation qualifies the sponsor of the drug candidate for various development incentives, which may include fee waivers for regulatory procedures or a 10-year market exclusivity period following approval. Orphan medicinal product designation applies specifically to the active moiety and the indication for which it is granted, and is not applicable to other indications for that moiety.

**About Eiger**

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market products for the treatment of rare diseases. The Company has built a diverse, clinical-stage portfolio of product candidates with the potential to address diseases for which the unmet medical need is high, the biology is clear and 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 ubenimex 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. 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.

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

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