Eiger BioPharmaceuticals Granted Orphan Drug Status for Ubenimex in Pulmonary Arterial Hypertension

PALO ALTO, Calif., November 30, 2015 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug status to ubenimex for the treatment of pulmonary arterial hypertension (PAH).

"The FDA Office of Orphan Products Development (OOPD) evaluates scientific and clinical data submissions from sponsors to identify and designate drug candidates that could potentially treat rare diseases to help advance the evaluation and development of such products," said Joanne Quan, MD, Chief Medical Officer at Eiger. "We are pleased with the OOPD's designation of orphan drug status for ubenimex in PAH."

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.

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 and meets criteria for Orphan Designation in the US, EU, and Japan.

About Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition that generally affects fewer than 200,000 individuals in the United States. Orphan drug designation qualifies the sponsor of the drug candidate for various development incentives, which may include tax credits for qualified clinical testing, an exemption from fees under the Prescription Drug User Fee Act (PDUFA), and a seven-year marketing exclusivity period following approval. Orphan Drug status 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 Orphan 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.

Safe Harbor Statements

Additional Information about the Proposed Merger between Celladon Corporation and Eiger BioPharmaceuticals, Inc. and Where to Find It

In connection with the previously disclosed proposed merger between Celladon Corporation and Eiger BioPharmaceuticals, Inc., Celladon and Eiger intend to file relevant materials with the Securities and Exchange Commission, or the SEC, including a registration statement on Form S-4 that will contain a prospectus and a joint proxy statement. Investors and security holders of Celladon and Eiger are urged to read these materials when they become available because they will contain important information about Celladon, Eiger and the proposed merger. Investors and security holders are urged to read the joint proxy statement, prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed merger.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

SOURCE Eiger Bio, Inc.

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