

Eiger BioPharmaceuticals Announces License Agreement with Nippon Kayaku to Develop Bestatin™ (ubenimex) for Inflammatory Diseases Involving LTB₄

First Clinical Target – Pulmonary Arterial Hypertension (PAH)

PALO ALTO, Calif., November 9, 2015 /PRNewswire/ -- Eiger BioPharmaceuticals, Inc. today announced a license agreement with Nippon Kayaku Co., Ltd., Tokyo, Japan, to develop Bestatin™ (ubenimex) for Pulmonary Arterial Hypertension as well as other inflammatory diseases involving leukotriene B₄ (LTB₄). Bestatin is a well-characterized, oral, small molecule inhibitor of leukotriene A₄ hydrolase (LTA₄H), the enzyme responsible for converting LTA₄ to LTB₄, a naturally occurring inflammatory mediator. Bestatin has been marketed in Japan by Nippon Kayaku for over 25 years for a different indication.

Results of a study published in *Science Translational Medicine* by Stanford University researchers demonstrate that both LTB₄ and LTA₄ hydrolase are elevated in animal models of PAH and human PAH disease. Elevated LTB₄ caused inflammation resulting in arteriole occlusion and hypertension in animal models of PAH. Targeted pharmacologic inhibition of LTB₄, including Bestatin, reversed PAH disease in treated animals; obstructed arterioles opened, cardiac function improved, and the animals survived. Bestatin is thus a potential therapeutic candidate for treatment of PAH where pathological inflammation is believed to be important in the etiology of the disease.

“Approved treatments for PAH work primarily by vasodilation of pulmonary arteries. No approved therapy for PAH has been shown to reverse inflammation or modify disease. Recently published results of studies conducted at Stanford University suggest that elevated LTB₄ may play a role in the inflammatory component of PAH disease,” said David Cory, President and CEO of Eiger. “These results suggest a potential for disease modification by targeting inflammation via inhibition of LTB₄ production. Our partnership with Nippon Kayaku and access to Bestatin, a well-characterized, commercially available drug in Japan, allows us to prepare for a clinical study in patients with PAH. The US IND is already approved. Enrollment is scheduled to begin in early 2016.”

“We are pleased to enter into this agreement with Eiger BioPharmaceuticals and establish a path for Bestatin to be studied in PAH,” said Yoshihiro Nambu, MD, PhD, Head of Pharmaceuticals Group, Nippon Kayaku. Bestatin is a well-characterized drug with a long history of use in Japan. PAH is a debilitating, progressive disease and there is no approved disease modifying therapy. It will be exciting to assess the impact of targeted inhibition of LTB₄ production with Bestatin in PAH disease.”

About Bestatin (ubenimex)

Bestatin (ubenimex) is a well-characterized, oral, small-molecule, dual-inhibitor of aminopeptidase and leukotriene A₄ hydrolase (LTA₄H), the enzyme responsible for catalyzing the committed step in the formation of the proinflammatory mediator, LTB₄. Bestatin (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. Bestatin has been used for over 25 years in Japan and remains commercially available through Nippon Kayaku. Bestatin is not approved for any indication in the U.S. or Europe.

About PAH

Pulmonary Arterial Hypertension (PAH) is a type of high blood pressure that affects the arterioles 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 Eiger

Eiger is a clinical-stage biopharmaceutical company committed to bringing to market novel products for the treatment of Orphan diseases. The company has built a diverse, late-stage 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.

About Nippon Kayaku

Head Office: Tokyo, Japan. President: Masanobu Suzuki. Founded in 1916, Nippon Kayaku is a leading Japanese Pharmaceutical, Functional Chemical, Safety System and Agrochemical company with over \$1.34 billion in annual revenues. Since the release of bleomycin in 1969, the Pharmaceutical Group has developed a business with a focus on anti-cancer drugs and related agents. In recent years, Nippon Kayaku has advanced efforts into biosimilars, generic anti-cancer drugs, as well as interventional radiology. Nippon Kayaku continues to provide highly necessary pharmaceuticals and medical devices for patients and exceptionally reliable information to the medical community.



SOURCE Eiger Bio, Inc.

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