



Reata Announces That Kyowa Hakko Kirin Received SAKIGAKE Priority Review Designation for Bardoxolone Methyl in Japan

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IRVING, Texas, March 29, 2018 (GLOBE NEWSWIRE) -- Reata Pharmaceuticals, Inc. (Nasdaq:RETA) (Reata or Company), a clinical-stage biopharmaceutical company, today announced that its licensee, Kyowa Hakko Kirin Co. Ltd. (Kyowa Hakko Kirin), received designation under the Priority Review and Designation System, or SAKIGAKE Designation, by the Japanese Ministry of Health, Labour and Welfare, for bardoxolone methyl (bardoxolone) for the treatment of diabetic kidney disease (DKD).

The Priority Review and Designation System in Japan is designed to accelerate the development of new treatments with the potential to demonstrate significant improvements in efficacy over existing therapies. Designated products are eligible to receive prioritized consultation services and premarket pharmaceutical affairs review by the Japanese regulatory authority.

In December 2009, Reata granted Kyowa Hakko Kirin the exclusive license to develop and commercialize bardoxolone in renal disease and certain other indications in Japan, China, Taiwan, South Korea, and Southeast Asia. Kyowa Hakko Kirin is planning to initiate a Phase 3 clinical study in DKD during 2018 in Japan to validate the efficacy and safety of bardoxolone. Kyowa Hakko Kirin is also currently collaborating with Reata in Japan on the ongoing Phase 3 CARDINAL study for bardoxolone in Alport syndrome, a severe, hereditary form of kidney disease.

About Bardoxolone

Bardoxolone is an experimental, oral, once-daily activator of Nrf2, a transcription factor that activates molecular pathways that promote the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling. The FDA has granted orphan designation to bardoxolone for the treatment of Alport syndrome and pulmonary arterial hypertension. Bardoxolone is currently being studied in CARDINAL, a Phase 3 study for the treatment of Alport syndrome, and CATALYST, a Phase 3 study for the treatment of connective tissue disease associated pulmonary arterial hypertension.

About Reata Pharmaceuticals, Inc.

Reata is a clinical-stage biopharmaceutical company that develops novel therapeutics for patients with serious or life-threatening diseases by targeting molecular pathways involved in the regulation of cellular metabolism and inflammation. Reata's two most advanced clinical candidates, bardoxolone methyl and omaveloxolone, target the important transcription factor Nrf2 that promotes the resolution of inflammation by restoring mitochondrial function, reducing oxidative stress, and inhibiting pro-inflammatory signaling.

About Kyowa Hakko Kirin

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology, and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding the success, cost and timing of our product development activities and clinical trials, our plans to research, develop and commercialize our product candidates, and our ability to obtain and retain regulatory approval of our product candidates. You can identify forward-looking statements because they contain words such as "believes," "will," "may," "aims," "plans," and "expects." Forward-looking statements are based on Reata's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, (i) the timing, costs, conduct, and outcome of our clinical trials and future preclinical studies and clinical trials, including the timing of the initiation and availability of data from such trials; (ii) the timing and likelihood of regulatory filings and approvals for our product candidates; (iii) the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the market opportunities for our product candidates; and (iv) other factors set forth in Reata's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K, under the caption "Risk Factors." The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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