Akebia Therapeutics Announces Submission of Vadadustat New Drug Application in Japan for Anemia Due to Chronic Kidney Disease by Collaboration Partner, MTPC

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JNDA Submission Represents First Regulatory Submission for Marketing Approval of Vadadustat

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 23, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA), today announced that Mitsubishi Tanabe Pharma Corporation (MTPC), its development and commercialization collaboration partner in Japan for vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), has submitted a Japanese New Drug Application (JNDA) to the Ministry of Health, Labor and Welfare in Japan for manufacturing and marketing approval of vadadustat as a treatment for anemia due to chronic kidney disease (CKD).

The JNDA is the first regulatory submission for marketing approval of vadadustat and, if approved, is expected to lead to the first launch of vadadustat worldwide. This submission is supported by positive top-line data from MTPC's two Phase 3, active-controlled, pivotal studies evaluating the efficacy and safety of vadadustat in Japanese subjects with anemia due to CKD and two additional Phase 3 single-arm studies in peritoneal and hemodialysis subjects, which were announced by Akebia and MTPC in March 2019. In Japan, an estimated 13 million people have advanced stages of CKD. Anemia is common in patients with CKD and its prevalence increases as CKD progresses. Injectable erythropoiesis- stimulating agents (ESAs) are currently the standard of care. Vadadustat, if approved for marketing in Japan, would provide patients with a once-daily oral treatment option and has the potential to set a new oral standard of care for the treatment of anemia due to CKD.

"One of our highest priorities is advancing vadadustat in Japan to ensure patient access to this promising treatment option for anemia due to CKD," said Masayuki Mitsuka, President and Representative Director of MTPC. "Akebia is an important partner in fulfilling our strategic objectives and we look to sustain this momentum in the future."

"The prevalence and complexity of anemia due to CKD is a significant global health challenge for people living with the disease and their healthcare providers. We are encouraged by positive data from MTPC's two pivotal Phase 3 studies in Japan that indicate the potential for vadadustat, if approved, to help address the needs of people with anemia due to CKD," stated John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. "This JNDA submission is an important milestone for Akebia and our collaboration partner, MTPC, highlighting our shared commitment to providing an important new treatment option for Japanese patients with anemia due to CKD. We're excited by this progress and congratulate MTPC for their work."

Akebia and MTPC entered into a collaboration agreement in 2015 providing MTPC with exclusive rights to develop and commercialize vadadustat in Japan and certain other Asian countries for the treatment of anemia due to CKD. As a result of the JNDA submission announced today, Akebia will receive a $10 million milestone payment from MTPC, anticipated to be received in the third quarter of 2019. Akebia is eligible to receive up to approximately $205 million in additional milestone payments, based upon achievement of certain regulatory and sales milestones. MTPC is also obligated make tiered double-digit royalty payments to Akebia of up to 20% on sales of vadadustat in Japan and certain other Asian countries, subject to vadadustat's regulatory approval.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease. The company was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with increased production of hypoxia-inducible factor, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat is an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

About Mitsubishi Tanabe Pharma

Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan. For more information, go to https://www.mt-pharma.co.jp/.

Forward-Looking Statements

Statements in this press release regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding the potential launch of vadadustat, the potential benefits of vadadustat, and receipt of milestone and royalty payments. The terms "anticipate," "expect," "potential," "will" and similar references are intended to identify forward-looking statements, although not all forward-looking

statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the timing and content of decisions made by regulatory authorities; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for vadadustat; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019 and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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