August 6, 2014

Akebia Therapeutics Announces Expansion of Management Team

Key additions will help drive strategic growth and advance lead clinical programs

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on harnessing the potential of hypoxia-inducible factor (HIF) biology to develop and commercialize novel therapeutics to treat kidney disease, today announced the expansion of its senior management team with three key additions: Brad Maroni, M.D., as Senior Vice President and Chief Medical Officer, Mark De Rosch, Ph.D., as Vice President of Regulatory Affairs and Tamara Dillon as Vice President of Human Resources.

The new additions to Akebia bring individuals with deep and relevant experience to support the company through its next critical stages, including completion of its Phase 2b study for AKB-6548, initiation and execution of a global Phase 3 program, expanded interactions with regulatory authorities and the early stage development of additional novel products in the company's pipeline.

"Collectively, Brad, Mark and Tamara bring a tremendous breadth and depth of experience to Akebia that will help strengthen our ability to accomplish our goal of delivering innovative products to patients in need," said John P. Butler, President and Chief Executive Officer of Akebia. "We are confident they will make an immediate and important contribution to Akebia as we advance our lead programs, engage in critical regulatory discussions and continue to scale the organization in anticipation of the global Phase 3 clinical development of AKB-6548."

Robert Shalwitz, M.D., co-founder of Akebia and current Chief Medical Officer, will take on the role of Executive Vice President and work closely alongside Dr. Maroni and Dr. De Rosch through the end of this year, at which time he will transition to a multi-year assignment as senior scientific advisor to the company. In this capacity, Dr. Shalwitz will continue to lend his expertise to the clinical and regulatory advancement of AKB-6548, and will also focus on leveraging Akebia's HIF platform and knowledge in a variety of promising future applications.

"Our management team expansion and the evolution of Bob's role will provide Akebia with near-term continuity, while also enabling Bob to focus sufficient attention on the large number of intriguing therapeutic opportunities beyond our initial indication," said Mr. Butler. "Bob's expertise and guidance will be a critical asset as we approach the next phase of the AKB-6548 clinical development program. In the long term, his scientific and strategic insights will be invaluable in guiding the direction of our important early-stage pipeline candidates."

Brad Maroni, M.D., most recently served as Vice President, Medical Research at Biogen Idec. Prior to that role, Dr. Maroni served as Chief Medical Officer of Stromedix, Inc. until the company was acquired by Biogen Idec in 2012. His previous experience also includes serving as Executive Vice President and Chief Medical Officer at RenaMed Biologics, as well as multiple roles at Amgen Inc., including Vice President, Clinical Development and Anemia/Nephrology Therapeutic Area Head. At Amgen, Dr. Maroni led the cross-functional team responsible for the registration program and global regulatory approval of Aranesp®, a novel long-acting recombinant erythropoietic protein, indicated for the treatment of anemia in chronic kidney disease. During his tenure, Amgen also received approval for Sensipar®, a first-in-class small molecule for the treatment of bone disease in dialysis patients. Dr. Maroni trained as a nephrologist at Brigham and Women's Hospital in Boston, Massachusetts, after which he spent 10 years in academia at Emory University.

Mark De Rosch, Ph.D., brings to Akebia over two decades of experience guiding global regulatory strategies for clinical, nonclinical and chemistry, manufacturing and controls (CMC) in multiple therapeutic areas including renal, hemophilia, autoimmune, pulmonary and oncology/hematology, among others. Most recently, Dr. De Rosch served as Vice President, Regulatory Drugs/Biologics & Head, U.S. Operations for Voisin Consulting Life Sciences, where he served as the organization's lead U.S. Food & Drug Administration (FDA) regulatory expert. Previously, Dr. De Rosch served as Vice President, Head of Global Regulatory Affairs for Inspiration Biopharmaceuticals, Inc., leading the development and implementation of global regulatory strategies for the hemophilia-focused company. He also served in multiple key roles at Vertex Pharmaceuticals, Inc., including Senior Director, Global Clinical Regulatory Strategy, where he led the regulatory strategy and submissions process for Kalydeco® in cystic fibrosis leading to approvals in the U.S. and E.U.

Tamara Dillon joins Akebia from Novartis Institutes for BioMedical Research, where she served as Head of Human Resources, Global Discovery Chemistry, responsible for all aspects of human resources across five sites and four countries. Previously, she held several key roles at Genzyme, a Sanofi Company, including Senior Director Human Resources, Global Research and

Development. In this global leadership role, Ms. Dillon oversaw expansive human resources management and coordinated closely with the senior management team to ensure that overall business strategies were translated into effective human resources programs.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on harnessing the potential of hypoxia-inducible factor (HIF) biology to develop and commercialize novel, proprietary therapeutics to treat kidney disease. Akebia's lead clinical program, AKB-6548, is a once-daily, oral therapy currently in Phase 2b clinical development for the treatment of anemia related to chronic kidney disease, a serious medical condition that leads to increased morbidity and mortality if left untreated. For more information on Akebia, please visit www.akebia.com.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of AKB-6548 and the development plan for AKB-6548 and additional product candidates. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions 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 risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of Akebia to successfully complete the clinical development of AKB-6548 or any other product candidate; the ability of Akebia to successfully complete pre-clinical development of additional product candidates; the content and timing of decisions by the FDA and other regulatory authorities; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the content of decisions made by the FDA and other regulatory authorities; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for AKB-6548 or any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Source: Akebia Therapeutics, Inc.

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