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Akebia Prevails in Two Additional European Patent Disputes

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia-inducible factor (HIF), today announced that the Opposition Division (OD) of the European Patent Office has revoked another FibroGen, Inc. HIF-related patent in Europe. In addition, Akebia's challenge to a second HIF-related patent resulted in FibroGen significantly narrowing the claims to cover only an indication for which Akebia is not intending to develop vadadustat. These positive outcomes follow Akebia's success in challenging two other FibroGen European patents (EP 1 463 823 and EP 1 633 333), which were revoked in their entirety by the OD in March and December of 2016, respectively.

"We are pleased with the outcome of this week's proceedings in Europe, which have confirmed, once again, that FibroGen's patents are either invalid or too broad in scope," stated John P. Butler, President and Chief Executive Officer of Akebia. "To date, we have successfully challenged five of FibroGen's HIF-related patents in Europe and Japan, resulting in the patents either being revoked in their entirety or significantly narrowed to a scope that does not impact our commercial plans for vadadustat."

The European Patent Office previously granted EP 2 322 155 (the '155 patent) and EP 2 322 153 (the '153 patent) to FibroGen, Inc. In order to preserve its right to challenge, on May 13, 2015 and July 6, 2015 Akebia filed oppositions to the '155 and the '153 patents requesting that the patents be revoked in their entirety. In oral proceedings held on May 29, 2017, the OD ruled that the '155 patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. Subsequently, in related oral proceedings held on May 31 and June 1, 2017 for the '153 patent, FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed. Written decisions consistent with the oral rulings are expected within a few months.

In other news today, Akebia announced that the Company granted options to purchase 200,000 shares of Akebia's common stock to Rita Jain, M.D., an executive recently hired as Senior Vice President and Chief Medical Officer. In addition, the Company granted four other newly hired employees options to purchase an aggregate of 48,000 shares of the Akebia's common stock. All of these options have a per share exercise price of $13.40, the closing price on the grant date, and will vest as to 25% of the total number of shares subject to the option on the first anniversary of the grant date. The remaining 75% of shares will vest ratably on the first day of each calendar quarter over the next three years. The stock options were inducements material to these new employees entering into employment with the Company, and issued in reliance on NASDAQ Listing Rule 5635(c)(4).

About Vadadustat

Vadadustat is an oral, investigational hypoxia-inducible factor (HIF) stabilizer currently in Phase 3 development for the treatment of anemia related to chronic kidney disease. Vadadustat exploits the same mechanism of action used by the body to adapt naturally to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat has not been approved by the FDA or any other regulatory authority.

About Anemia Associated with CKD

Anemia results from the body's inability to coordinate red blood cell production in response to lower oxygen levels due to the progressive loss of kidney function with inadequate erythropoietin production. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. Anemia is currently treated with injectable recombinant erythropoiesis stimulating agents, which are associated with inconsistent hemoglobin responses and well-documented safety risks. The prevalence of anemia increases with the severity of CKD and is higher in people with CKD who are over age 60.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral, investigational therapy in development for the treatment of anemia related to

chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO$_2$TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and the INNO$_2$VATE studies for dialysis-dependent patients, is currently ongoing. For more information, please visit our website at 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 vadadustat, and the potential commercialization of vadadustat. 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 program for vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the global development program for vadadustat, including the Phase 3 studies, and the availability of financing to cover such costs; the timing of any additional studies initiated by Akebia or its collaborators for vadadustat; the timing and content of decisions made by regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; 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 vadadustat around the world. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Report on Form 10-Q for the quarter ended March 31, 2017, 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.

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