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Akebia Prevails in Additional European Patent Dispute

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 (EPO) has revoked another of FibroGen, Inc.'s HIF-related patents. The patent, EP 1 633 333 (the '333 patent), claimed various compounds that were purported to stabilize HIFα for treating or preventing various conditions, including iron deficiency and specific forms of anemia. This ruling follows Akebia's challenge to FibroGen's earlier European patent, EP 1 463 823, which was revoked in its entirety by the OD earlier this year.

"While we believe that this patent would not have impacted our ability to commercialize in Europe, we are pleased that the EPO has confirmed that another of FibroGen's patents associated with HIF is invalid," stated John P. Butler, President and Chief Executive Officer of Akebia. "Our focus continues to be advancing our Phase 3 program for vadadustat, while progressing our discussions with potential partners regarding a geographic collaboration for vadadustat in regions not currently partnered."

In August 2014, the EPO granted the '333 patent to FibroGen, Inc. In order to preserve the right to challenge this patent, on May 20, 2015, Akebia filed an opposition to the '333 patent requesting that the '333 patent be revoked in its entirety. In an oral proceeding on December 8 and 9, 2016, the OD ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. The written decision consistent with the oral ruling is expected within a couple of months.

In other news today, Akebia provided details related to its December 2, 2016 press release. The company noted that the option to purchase 130,000 shares of Akebia's common stock with a per share exercise price of $8.61, the closing price on the grant date, was granted to Karen Tubridy, an executive recently hired as Senior Vice President and Chief Development Officer. The stock options were inducements material to the new employee entering into employment with the company, and issued in reliance on NASDAQ Listing Rule 5635(c)(4).

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 therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia has commenced its vadadustat Phase 3 Program, 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. 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, development plans for vadadustat, the progress toward securing a geographic collaboration and the timing of the Opposition Division's written decision. 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 vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to prepare for and initiate clinical studies; Akebia's ability to negotiate commercially reasonable terms with a geographic collaboration partner; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the actual time it takes for the Opposition Division to issue its written decision; 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 quarter ended September 30, 2016, 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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