Akebia Therapeutics to Report Second Quarter 2020 Financial Results

August 3, 2020

Company announces database lock and plans to report top-line data from global Phase 3 PRO2TECT program of vadadustat for treatment of anemia due to chronic kidney disease in adult patients not on dialysis

CAMBRIDGE, Mass., Aug. 3, 2020 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced plans to report its financial results for the second quarter ended June 30, 2020 on Monday, August 10, 2020. In lieu of a second quarter financial results and business update call, Akebia management plans to host a conference call and webcast in early September to report top-line data from PRO_2TECT, the second of its two global Phase 3 cardiovascular outcomes programs. The two PRO_2TECT studies, which have progressed through database lock, evaluated the efficacy and safety of vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), versus darbepoetin alfa for the treatment of anemia due to chronic kidney disease (CKD) in 3,513 adult patients not on dialysis.

"The Akebia team, together with all the clinical site staff, did an extraordinary job completing the last patient visits and other work to lock the PRO_2TECT database, despite the logistical challenges of operating under the present COVID-19 environment. Locking the database marks an important step toward the completion of our global Phase 3 program for vadadustat, and we look forward to reporting top-line results from the PRO_2TECT program in early September," said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by 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 (HIF-PH) inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is in global Phase 3 development for the treatment of anemia due to CKD and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

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 plans to report top-line data from PRO_2TECT and the anticipated timing thereof. The terms "believe," "expect" 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 potential direct or indirect impact of the COVID-19 pandemic on our and our partners', collaborators', vendors' and customers' businesses, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; the risk that clinical trials may not be successful; manufacturing risks; risks associated with management and key personnel changes and transitional periods; the timing and content of decisions made by regulatory authorities; 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 and its partners' ability to obtain, maintain and enforce patent and other intellectual property protection. 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, 2020 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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