Akebia to Present Global Phase 3 Vadadustat Data at American Society of Nephrology Kidney Week 2020 Reimagined

October 9, 2020

- Phase 3 data from INNO2VATE program in dialysis and PRO2TECT program in non-dialysis accepted for oral presentation

- Ten additional abstracts accepted

- Company to host investor briefing webcast at 4:10 p.m. ET on October 23, 2020

CAMBRIDGE, Mass., Oct. 9, 2020 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA) today announced that it will present data from its global Phase 3 programs of vadadustat for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis (INNO$_2$VATE) and not on dialysis (PRO$_2$TECT) at American Society of Nephrology Kidney Week 2020 Reimagined (ASN Kidney Week), which is taking place virtually October 22 – 25, 2020. Vadadustat is Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) in development for the treatment of anemia due to CKD.

Accepted vadadustat and other abstracts from Akebia are now available online on the ASN Kidney Week abstract portal: https://www.asn-online.org/education/kidneyweek/2020/program-search-abstract.aspx.

Results from Akebia's global Phase 3 INNO$_2$VATE program will be presented by Kai-Uwe Eckardt, M.D., Professor of Medicine and Head of the Department of Nephrology and Internal Intensive Care Medicine at the Charité in Berlin, Germany, and Co-Chair of the independent Executive Steering Committee for INNO$_2$VATE and PRO$_2$TECT, during the "Breakthroughs in Anemia and Iron Management" session. The presentation, titled "Global Phase 3 Clinical Trials of Vadadustat vs. Darbepoetin Alfa for Treatment of Anemia in Patients with Dialysis-Dependent CKD" (Abstract TH-OR01), is scheduled for Thursday, October 22, at 5:00 p.m. ET. In May, Akebia reported positive top-line results from INNO$_2$VATE demonstrating that vadadustat achieved the program's primary and key secondary efficacy endpoints and also achieved the primary safety endpoint.

Results from Akebia's global Phase 3 PRO$_2$TECT program will be presented by Glenn Chertow, M.D., M.P.H., Professor of Medicine, Chief, Division of Nephrology at Stanford University, and Co-Chair of the independent Executive Steering Committee for PRO$_2$TECT and INNO$_2$VATE, during the "High-Impact Clinical Trials" late-breaker session. The presentation, titled "Global Phase 3 Clinical Trials of Vadadustat vs Darbepoetin Alfa for Treatment of Anemia in Patients with Non–Dialysis-Dependent Chronic Kidney Disease" (Abstract FR-OR54), is scheduled for Friday, October 23 between 10:30 a.m. ET – 12:30 p.m. ET. In September, Akebia reported top-line results from PRO$_2$TECT demonstrating that while vadadustat achieved the program's primary and key secondary efficacy endpoints, it did not meet its primary safety endpoint.

"We have a tremendous set of data to present at the upcoming ASN clinical meeting including, clinical data from our Phase 3 INNO$_2$VATE program, which continues to reinforce our confidence in a straightforward path toward vadadustat's approval in dialysis. We previously announced that this was a positive study and we're excited to present the data at ASN," said John P. Butler, President and CEO of Akebia Therapeutics. "We're also very pleased that our abstract for our Phase 3 PRO$_2$TECT program in non-dialysis was selected as a late-breaking oral presentation."

Several additional abstracts have been accepted for presentation at ASN Kidney Week.

Vadadustat Presentations		
M. Hanudel, S. Wong, G. Jung, B. Qiao, V. Gabayan, T. Ganz	**Amelioration of CKD-Associated Anemia by Vadadustat in Mice is Not Dependent on Erythroferrone**	ePoster #: PO0291
A. Chavan, R. Sawant, L. Burke, S. Paulson	**Pharmacokinetic Evaluation of Drug Interactions between Vadadustat and HMG-CoA Reductase Inhibitors (Statins)**	ePoster #: PO2368
Chronic Kidney Disease Presentations		
E. Michalopoulos, D. Zhao, Y. Farag, M. Sanon, F. Finkelstein	**Association of Anemia with Activities of Daily Living in CKD: The National Health and Nutrition Examination Survey (NHANES), 1999-2016**	ePoster #: PO0277
Y. Farag, B. Langford, N. Yasmeen, L. Sawyer, M. Sanon, X. Wang, L. McCormick, E. Michalopoulos	**Hemoglobin Requirements of Clinical Trials Involving Anemia in Chronic Kidney Disease, and Implications on Future Work: A Systematic Literature Review**	ePoster #: PO0295
O. Darlington, D. Booth, P. Gabb, M. Sanon, E. Michalopoulos, Y. Farag, X. Wang, P. McEwan	**Modelling the Clinical and Economic Burden of Anaemia in Patients with CKD**	ePoster #: PO0275

M. Kabra, T. Hammond, A. Fleetwood, L. Harrison, J. Jackson, S. Clayton	**Physician Attitudes Towards Diagnosis, Treatment Initiation and Unmet Needs in the Management of Anemia Due to Chronic Kidney Disease: Results from a Real-World Survey in Germany, Italy and the United Kingdom**	ePoster #: PO0288
E. Michalopoulos, M. Gauthier-Loiselle, M. Sanon, E. Serra, R. Bungay, D. Clynes, M. Cloutier, E. Kahle, A. Guerin, Y. Farag, J. Wish	**Reported Caregiver Burden in CKD with and without Anemia: A US-Based Survey**	ePoster #: PO0272
Ferric Citrate Presentations		
P. Pergola, D. Belo, P. Crawford, M. Moustafa, W. Luo, A. Goldfarb	**Long-term Use of Ferric Citrate in the Treatment of Iron Deficiency Anemia in Patients with Non-Dialysis-Dependent CKD: The COMPASS Trial**	ePoster #: PO0254
M. Hanudel, S. Wong, K. Chua, G. Jung, B. Qiao, V. Gabayan, T. Ganz	**Renoprotective Effects of Ferric Citrate in a Mouse Model of Chronic Kidney Disease**	Abstract TH-OR07 to be presented on Thursday, October 22, 2020
A. Biruete, N. Chen, C. Metzger, A. Stacy, S. Srinivasan, K. O'Neill, J. Dominguez, K. Avin, M. Allen, S. Moe	**Comparison of the Effects of Ferric Citrate and Intravenous Iron on Markers of Mineral and Bone Disorder and Oxidative Stress in a Rat Model of CKD-MBD**	ePoster #: PO0317

Investor Briefing Webcast
Akebia management will host an investor briefing webcast with Dr. Glenn Chertow on October 23, 2020 at 4:10 p.m. ET to review highlights of the Phase 3 vadadustat data presentations from ASN Kidney Week. To access Akebia's investor briefing webcast and the accompanying slides please log into the Investors section of the Company's website at https://ir.akebia.com and proceed to the events and presentations page at https://ir.akebia.com/events-and-presentations. Please connect to the Company's website at least 10 minutes prior to the online event to ensure adequate time for any software download that may be required to view the webcast. After the webcast concludes, a replay of the event will be available at that same location until October 29, 2020.

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.

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.

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 Akebia's confidence regarding its path toward vadadustat's approval in dialysis. The terms "confidence," "straightforward path toward" 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 advice given and decisions made by health authorities, including marketing approval and labeling decisions; the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; manufacturing and quality risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to continue to commercialize our commercial product, develop and commercialize vadadustat and operate the Company; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; 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 our commercial product, vadadustat and 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 June 30, 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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