Akebia Therapeutics Provides Update on Vadadustat Development Program

February 12, 2018

-- Targets Full Enrollment for INNO2VATE and PRO2TECT by the End of 2018 --

-- Confirms Expectation of Top-Line Results for INNO2VATE and PRO2TECT in 2019, Subject to Accrual of MACE Events --

-- Enhances FO2RWARD and TRILO2GY Study Designs for Commercial Optimization --

-- Confirms No Carcinogenic Effect in Two Non-Clinical Carcinogenicity Studies --

-- Partner Mitsubishi Tanabe Pharma Corporation Initiates Phase 3 NDD-CKD and DD-CKD Program in Japan --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 12, 2018-- 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 provided an update on the global development plan for vadadustat, an oral HIF stabilizer in global Phase 3 development for the treatment of anemia due to chronic kidney disease.

“We continue to execute on our global Phase 3 program for vadadustat. Patient enrollment in $INNO_2VATE$ and PRO_2TECT is advancing, with full enrollment of these studies targeted by the end of 2018,” said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. “We anticipate top-line results for $INNO_2VATE$ and PRO_2TECT in 2019, subject to the accrual of MACE events, with market launch anticipated in 2020.”

“In collaboration with our partner, Otsuka,” added Butler, “we have enhanced the study designs for FO_2RWARD and $TRILO_2GY$. We believe these changes will provide additional characterization and differentiation of vadadustat and further strengthen our commercial position upon the drug’s approval. The investment in these study enhancements reflects our confidence in the program and our desire to position vadadustat for success upon launch.”

Vadadustat Development Program Updates:

$INNO_2VATE$ and PRO_2TECT Phase 3 Programs

- Full enrollment targeted by the end of 2018
- Top-line results expected in 2019, subject to the accrual of MACE events

FO_2RWARD Phase 2 Study

- New study design includes a broader dialysis population in addition to hyporesponders, and a larger sample size; this study will replace the former FO_2RWARD study
- Includes once-daily and three-times-weekly dosing
- Designed to generate data to inform ESA-switching protocols
- Expected to initiate in Q2 2018, with top-line results expected in late 2018 or early 2019

$TRILO_2GY$ Phase 3 Study

- New study design includes once-daily and three-times-weekly dosing and an ESA control, as well as a larger sample size; this study will replace the former $TRILO_2GY$ study
- Designed to generate data to inform switching from Epogen® (epoetin alfa), Aranesp® (darbepoetin alfa) and Mircera® (methoxy PEG-epoetin beta)
- Expected to initiate in late 2018 or early 2019, with top-line results expected in early 2020

Japan Phase 3 Program

- Akebia’s partner, Mitsubishi Tanabe Pharma Corporation, initiated its Phase 3 program to support registration in patient populations with anemia due to non-dialysis-dependent and dialysis-dependent chronic kidney disease
- These studies do not include a MACE endpoint
- Data read-out expected in 2019

Non-Clinical Carcinogenicity Studies

- Akebia completed two carcinogenicity studies, a two-year study in rats and a six-month study in mice, results of which showed no carcinogenic effect of vadadustat

About Vadadustat
Vadadustat is an oral 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 is an investigational therapy

not approved by the U.S. Food and Drug Administration or any regulatory authority.

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. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

Forward-Looking Statements
Statements in this press release regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions or goals are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding the rate and timing of enrollment, including full enrollment, of our clinical trials; the timing, availability and presentation of clinical trial data and results; the benefits, including the potential effect on commercial position, of the designs of our studies; the execution of our global Phase 3 program for vadadustat; the timing of market launch of vadadustat; the potential characterization and differentiation information we believe will result from the designs of our studies; positioning vadadustat for success upon launch; replacing the former FO_2RWARD and the former $TRILO_2$GY with new study designs; the timing of initiation of our clinical trials; and the potential of FO_2RWARD and $TRILO_2$GY to generate data to inform switching. The terms "advance," "anticipate," "believe," "continue," "design," "desire," "enhance," "expect," "expectation," "target," "will," "would" 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 rate of enrollment in clinical studies of vadadustat; the risk that clinical trials may not be successful; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; the actual funding required to develop and commercialize Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; the risk that clinical studies need to be discontinued for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete research and clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the scope, timing, and outcome of any ongoing legal 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 vadadustat and its 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 quarter ended September 30, 2017, 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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