Akebia Therapeutics Announces Third Quarter 2017 Financial Results

November 8, 2017

--Partner Mitsubishi Tanabe Pharma Corporation Initiates Phase 3 Development Program for Vadadustat in Japan--

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 8, 2017-- 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 financial results for the third quarter ended September 30, 2017.

“Akebia continues to execute on our global Phase 3 program for vadadustat in collaboration with our partners,” said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. “In the third quarter, we announced positive Phase 2 top-line results from our vadadustat study in Japanese patients with non-dialysis-dependent chronic kidney disease, and findings from the Phase 2 study in dialysis-dependent patients are expected by year end. In addition, our partner, Mitsubishi Tanabe Pharma Corporation, announced the initiation of Phase 3 clinical studies of vadadustat in Japan. Enrollment continues in the global clinical program with the potential launch of vadadustat in the United States, Europe and Japan anticipated in 2020. In addition, we look forward to initiating our TRILO$_2$GY study later this year or early 2018.”

Third Quarter 2017 and Recent Corporate Highlights

- Announced positive top-line results from a Phase 2 study of vadadustat in Japanese patients with non-dialysis-dependent chronic kidney disease, which confirmed findings from previous studies of vadadustat;
- After a positive consultation with the PMDA, partner Mitsubishi Tanabe Pharma Corporation (MTPC) announced the initiation of a Phase 3 development program of vadadustat in non-dialysis patients and patients receiving peritoneal dialysis in Japan;
- Provided MTPC with an option to access data from Akebia’s global Phase 3 vadadustat program for payments to Akebia of up to $25 million; and
- The Independent Data Monitoring Committee for Akebia’s global Phase 3 PRO $_2$TECT and INNO$_2$VATE programs held another meeting and recommended continuing the studies without modification.

Financial Results

Akebia reported a net loss of ($23.1) million, or ($0.49) per share, for the third quarter of 2017 as compared to a net loss for the third quarter of 2016 of ($36.3) million or ($0.96) per share.

Collaboration revenue was $41.3 million for the third quarter of 2017, which related to the Company’s agreements with Otsuka. Collaboration revenue in connection with Akebia’s agreement with MTPC is expected to commence in the fourth quarter of 2017.

Research and development expenses were $58.7 million for the third quarter of 2017 compared to $31.2 million for the third quarter of 2016. The increase is primarily attributable to external costs related to the global PRO$_2$TECT and INNO$_2$VATE Phase 3 programs, the Phase 2 studies in Japan, and activities related to the FO$_2$RWARD and TRILO$_2$GY programs. Research and development expenses were further increased by headcount and compensation-related costs.

General and administrative expenses were $6.7 million for the third quarter of 2017 compared to $4.9 million for the third quarter of 2016. The increase is primarily attributable to an increase in costs to support the Company’s research and development programs, including headcount and compensation-related costs and associated facility and patent-related costs.

Akebia ended the third quarter of 2017 with cash, cash equivalents and marketable securities of $329.7 million. The Company’s collaborators have committed up to $373.0 million or more in license and cost-share funding, which Akebia continues to receive on a quarterly prepaid basis. Akebia expects existing cash resources to fund the Company’s current operating plan into the second quarter of 2019. Thereafter, committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis.

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. In addition, the Company has initiated the Phase 2 FO$_2$RWARD study of vadadustat in dialysis-dependent chronic kidney disease patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs), and expects to commence the Phase 3 TRILO$_2$GY study to further evaluate a three-times-weekly dosing regimen for vadadustat. 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 regulatory approval of vadadustat, the potential commercialization of vadadustat if approved by regulatory authorities, the potential indications and benefits of vadadustat, the expected timing of clinical studies, anticipated financial contributions from MTPC and Otsuka, and anticipated sufficiency of cash resources. 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 actual funding required to develop 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; early termination of Akebia's agreements with its partners; Akebia's ability to satisfy its obligations under its agreements; the timing and content of decisions made by the regulatory authorities; the timing of any additional studies initiated by Akebia or its partners for vadadustat; the rate of enrollment in clinical studies of 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; 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 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.

Tables Follow

AKEBIA THERAPEUTICS, INC
Consolidated Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2017	**September 30, 2016**	**September 30, 2017**	**September 30, 2016**
Collaboration revenue	$ 41,283	$ —	$ 90,668	$ —
Operating expenses:				
Research and development	58,711	31,238	162,511	82,350
General and administrative	6,748	4,944	19,441	16,066
Total operating expenses	65,459	36,182	181,952	98,416
Operating loss	(24,176)	(36,182)	(91,284)	(98,416)
Other income, net	1,042	(126)	2,090	531
Net loss	$ (23,134)	$ (36,308)	$ (89,194)	$ (97,885)
Net loss per share - basic and diluted	$ (0.49)	$ (0.96)	$ (2.11)	$ (2.61)
Weighted-average number of common shares - basic and diluted	46,938,618	37,897,902	42,202,560	37,528,869

AKEBIA THERAPEUTICS, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2017	**December 31, 2016**
Cash, cash equivalents and available for sale securities	$ 329,705	$ 260,343
Working capital	182,581	182,053
Total assets	338,589	300,216
Total stockholders' equity	99,875	68,120

View source version on businesswire.com: http://www.businesswire.com/news/home/20171108005991/en/

Source: Akebia Therapeutics, Inc.

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