Akebia Secures $100 Million Non-Dilutive Term Loan Financing; Reports Third Quarter 2019 Financial Results

November 12, 2019

- *Funding expected to extend Company's cash runway into 2021, well past its expected topline data readouts for global Phase 3 studies for vadadustat;*
- *MTPC's positive Phase 3 data show vadadustat's effect on hemoglobin was sustained through to 52 weeks;*
- *Auryxia® (ferric citrate) revenue increases to $30.0 million for Q3'FY19, up 13% from Q3'FY18; and,*
- *Company hosts call to discuss financial results and recent business highlights*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 12, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for people living with kidney disease, today reported financial results for the third quarter ended September 30, 2019. The Company will host a conference call today, Tuesday, November 12, 2019, at 9:00 a.m. Eastern Time to discuss its third quarter 2019 financial results and recent business highlights.

Akebia also announced that it has entered into a $100 million non-dilutive, definitive term loan agreement with funds managed by Pharmakon Advisors LP, the investment manager of the BioPharma Credit funds. The loans provide Akebia with up to $100 million of borrowing capacity available in two tranches. Subject to the satisfaction of customary conditions, Akebia expects to draw $80 million at an initial closing later this month, and an additional tranche of $20 million is available for draw at Akebia's option until December 31, 2020. Additional information on the loan agreement will be included in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 that is expected to be filed with the U.S. Securities and Exchange Commission today, November 12, 2019.

"Akebia continues to make great progress advancing our strategy. We achieved a primary objective of the Company by strengthening our balance sheet with $80 to $100 million non-dilutive, tranched term loans, on very competitive terms, to further support our clinical development program for vadadustat, our investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) for the treatment of anemia due to chronic kidney disease (CKD), and other strategic goals. Importantly, we believe these loans, the first tranche of which is expected to close later this month, in combination with our other cash resources, are expected to extend our cash runway into 2021, well past our expected top-line data readouts of our global Phase 3 clinical studies of vadadustat. Auryxia product revenue allows us to service the debt," stated John P. Butler, Chief Executive Officer of Akebia. "As we believe we are now within two quarters of our first readout of our global Phase 3 studies of vadadustat with top-line data of $INNO_2VATE$ on track for Q2'FY20 and PRO $_2$TECT for mid-2020, subject to the accrual of major adverse cardiovascular events (MACE), we're working to sharpen the timelines for completion and keying in on NDA and MAA related activities and commercial plans for vadadustat, upon approval."

Butler continued, "We have a tremendous amount of confidence in the program that we've designed for vadadustat and believe we are positioned well for clinical, regulatory and commercial success. We expect vadadustat to be the first drug of the HIF class to deliver clear data that directly compares its outcomes to the current standard of care in both dialysis and non-dialysis patients for the treatment of anemia due to CKD. We believe these data will be highly informative for physicians, patients and payers as they make important decisions about patient care, and a key consideration when differentiating between HIFs in the class."

Recent Highlights

- Auryxia (ferric citrate) net product revenue increased 13 percent year-over-year to $30.0 million for the third quarter of 2019. Total Auryxia prescriptions increased 15.5 percent year-over-year to 51,700 in the third quarter of 2019.
- In November, Mitsubishi Tanabe Pharma Corporation (MTPC), Akebia's development and commercialization collaboration partner in Japan for vadadustat, presented positive 24-week and 52-week data from two Phase 3 active-controlled pivotal studies evaluating the efficacy and safety of vadadustat in Japanese patients with anemia due to CKD, at the American Society of Nephrology (ASN) Kidney Week 2019. Each study met its primary endpoint based on mean hemoglobin level at week 20 and 24, and showed vadadustat's effect on hemoglobin was sustained through to 52 weeks in each study. (See recent related press release here.) In July, MTPC submitted a Japanese New Drug Application (JNDA) to the Ministry of Health, Labor and Welfare in Japan for marketing approval of vadadustat as a treatment for anemia due to CKD. The JNDA is the first regulatory submission for marketing approval of vadadustat and, if approved, is expected to lead to the first launch of vadadustat worldwide, next year.
- Nine abstracts, including several associated with vadadustat and Auryxia, Akebia's FDA-approved drug, were presented at ASN in November.
- In October, the Independent Data Monitoring Committee reviewed unblinded safety and efficacy data from Akebia's global Phase 3 studies of vadadustat, as planned, and recommended continuation of the studies without modifications.
- In October, Akebia filed a complaint in federal district court against the Centers for Medicare & Medicaid Services (CMS)

and the U.S. Department of Health and Human Services (HHS). The lawsuit challenges a September 2018 decision by CMS that rescinded Medicare Part D coverage of Auryxia, when used for the treatment of iron deficiency anemia (IDA) in adult patients with CKD not on dialysis. The legal action also seeks to reverse a related decision by CMS that imposed a prior authorization requirement for Auryxia when used for the control of serum phosphorus levels in adult patients with CKD on dialysis.

- In April and August, Akebia completed enrollment in its global Phase 3 program, INNO$_2$VATE and PRO$_2$TECT, respectively, evaluating the safety and efficacy of vadadustat in dialysis-dependent and non-dialysis dependent CKD subjects with anemia due to CKD. The Company continues to expect to report top-line data from the INNO$_2$VATE and PRO$_2$TECT studies in Q2'FY20 and mid-2020, respectively, subject to the accrual of MACE.

Financial Results

Total revenue for the third quarter of 2019 was $92.0 million, compared to $53.2 million in the pre-merger third quarter of 2018.

Auryxia net product revenue for the third quarter of 2019 was $30.0 million, compared to $26.6 million, as reported by Keryx Biopharmaceuticals, Inc. (Keryx) prior to its merger with the Company, during the same period in 2018. This represents a 13 percent increase in net product revenue from the third quarter of 2018.

Collaboration and license revenue for the third quarter of 2019 was $62.0 million, compared with $53.2 million in the third quarter of 2018. The increase was primarily due to increased collaboration revenue of $6.8 million from Otsuka Pharmaceutical Co. Ltd (Otsuka). In accordance with the Company's collaboration agreements, Otsuka began funding 80 percent of the development costs for vadadustat in the second quarter of 2019.

Cost of goods sold was $38.3 million for the third quarter of 2019, consisting of $11.2 million of costs associated with the manufacture of Auryxia and non-cash charges of $27.1 million related to the application of purchase accounting as a result of the merger with Keryx. These non-cash, merger-related charges include a $18.0 million inventory step-up charge and $9.1 million of amortization of intangibles.

Research and development expenses were $74.5 million for the third quarter of 2019 compared to $70.6 million for the third quarter of 2018. The increase was primarily attributable to an increase in headcount and other costs to support its research and development programs and clinical and preclinical activities. These increases were partially offset by a decrease in external costs related to PRO$_2$TECT and INNO$_2$VATE Phase 3 studies as they advance toward readout.

Selling, general and administrative expenses were $34.2 million for the third quarter of 2019 compared to $10.4 million for the third quarter of 2018. The increase was primarily attributable to commercialization costs associated with Auryxia, as there were no comparable commercialization costs in the third quarter of 2018.

The Company reported a net loss for the third quarter of 2019 of $54.6 million, or ($0.46) per share, as compared to a net loss of $26.0 million, or ($0.46) per share, for the third quarter of 2018. The Company's net loss for the third quarter of 2019 includes the impact of non-cash charges of $27.1 million related to the application of purchase accounting as a result of the merger with Keryx, offset by an income tax benefit of $1.3 million.

The Company ended the quarter with cash, cash equivalents and available-for-sale securities of $145.6 million. "We are pleased to have further strengthened our balance sheet and extended our operating cash runway with our very recent non-dilutive, tranched term loans for up to $100 million, with the first $80 million tranche expected to close later this month. We expect these loans, coupled with the committed research and development funding from our collaborators and the receipt of a regulatory milestone from MTPC, assuming approval of vadadustat in Japan, to provide us with the cash resources to fund our current operating plan into Q1 of 2021," stated Jason A. Amello, Chief Financial Officer of Akebia.

Conference Call

Akebia will host a conference call today, Tuesday, November 12, 2019, at 9:00 a.m. Eastern Time to discuss its third quarter 2019 financial results and recent business updates. To listen to the conference call, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 9996464. The call will also be webcast LIVE and can be accessed via the Investors section of the Company's website at http://ir.akebia.com.

A replay of the conference call will be available two hours after the completion of the call through November 18, 2019. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 9996464. An online archive of the conference call can be accessed via the Investors section of the Company's website at http://ir.akebia.com.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for people living with 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 currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat is 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 an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

About Auryxia® (ferric citrate) Tablets

Auryxia (ferric citrate) was approved by the FDA on September 5, 2014 for the control of serum phosphorus levels in adult patients with CKD on dialysis and approved by the FDA on November 6, 2017 for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. For more information about Auryxia and the U.S. full prescribing information, please visit www.auryxia.com.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA® (ferric citrate) CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis**: Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please see full Prescribing Information

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 strengthening our balance sheet; the non-dilutive tranched term loan, its terms and their competitiveness, anticipated closing date, use, and means of servicing such debt; the safety and efficacy of vadadustat, the potential launch of vadadustat, the potential indications for and benefits of vadadustat, and market size, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat; the potential for the JNDA filing for vadadustat to form the basis of a launch, if approved; the rate and timing of enrollment of our clinical trials; the potential benefits of the combined company post-merger; the market and growth potential of Auryxia; the anticipated timing of the availability and reporting of clinical trial data and results; potential and anticipated payments from our collaborators, including the timing thereof; continued funding and advancement of development efforts; and expectations regarding financial position, including the cash runway. The terms "anticipate," "believe," "expect," "opportunity," "planned," "potential," "target," "will" 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 risks associated with market acceptance and coverage and reimbursement of Auryxia; the risks associated with potential generic entrants for Auryxia; the rate of major adverse cardiovascular events in our global phase 3 clinical trials for 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; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize Auryxia, vadadustat and other 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 are discontinued or delayed 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 preclinical and clinical studies; the competitive landscape for Auryxia and vadadustat; 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; risks associated with closing the tranched term loan; the risk that we lose, or settle on less favorable terms, other ANDA litigation, or that other ANDA filers enter the market earlier than March 20, 2025, as well as any other potential settlements; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for Auryxia, 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 quarterly period ended June 30, 2019 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.

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

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2019	**September 30, 2018**	**September 30, 2019**	**September 30, 2018**
Revenues:				
Product revenue, net	$ 30,004	$ —	$ 82,204	$ —
License, collaboration and other revenue	61,973	53,169	183,242	147,892
Total revenues	91,977	53,169	265,446	147,892
Cost of goods sold:				
Product	29,162	—	79,888	—
Amortization of intangibles	9,101	—	27,301	—
Total cost of goods sold	38,263		107,189	—
Operating expenses:				
Research and development	74,512	70,634	242,557	203,955
Selling, general and administrative	34,178	10,378	104,537	31,940
License expense	929	—	2,560	—
Total operating expenses	109,619	81,012	349,654	235,895
Operating loss	(55,905)	(27,843)	(191,397)	(88,003)
Other income, net	43	1,796	1,342	4,469
Net loss before income taxes	(55,862)	(26,047)	(190,055)	(83,534)
Benefit from income taxes	(1,277)	—	(4,879)	-
Net loss	$ (54,585)	$ (26,047)	$ (185,176)	$ (83,534)
Net loss per share - basic and diluted	$ (0.46)	$ (0.46)	$ (1.57)	$ (1.54)
Weighted-average number of commons shares - basic and diluted	118,863,063	57,027,598	118,071,674	54,207,973

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

	September 30, 2019	**December 31, 2018**
Cash, cash equivalents and available for sale securities	$ 145,613	$ 321,640
Working capital	75,860	202,582
Total assets	795,220	996,540
Total stockholders' equity	467,562	635,928

View source version on businesswire.com: https://www.businesswire.com/news/home/20191112005619/en/

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