Akebia Reports First Quarter 2021 Financial Results and Highlights Recent Company Milestones

May 10, 2021

- Vadadustat New Drug Application (NDA) submitted to the U.S. Food and Drug Administration (FDA)
- Results of global Phase 3 programs for vadadustat published in New England Journal of Medicine
- Conference call today at 9:00 a.m. ET

CAMBRIDGE, Mass., May 10, 2021 /PRNewswire/ -- Akebia Therapeutics® Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease, today reported financial results for the first quarter ended March 31, 2021 and highlighted recent corporate milestones. The Company will host a conference call today, Monday, May 10, 2021, at 9:00 a.m. Eastern Time.

"Akebia is off to a great start in 2021, building positive momentum with solid execution on strategic priorities that set the stage for an exciting year. Most importantly, we submitted the vadadustat NDA to the FDA, a significant milestone for Akebia and our partner, Otsuka Pharmaceutical Co. Ltd. We are also very proud that the *New England Journal of Medicine* recently published the results from both INNO$_2$VATE and PRO$_2$TECT, the global Phase 3 programs for vadadustat. We believe these publications reinforce the scientific rigor and quality of the vadadustat clinical development program, and we are pleased with early feedback from the medical community," stated John P. Butler, Chief Executive Officer of Akebia. "We believe this progress positions us well to continue advancing vadadustat with the goal of bringing this novel therapeutic to patients as quickly as possible, subject to regulatory approval. We remain confident in the clarity and quality of our data, and we look forward to engaging with the FDA on our NDA. In addition, we are working with Otsuka on the preparation of a Marketing Authorization Application (MAA) for vadadustat for submission to the European Medicines Agency (EMA), expected this year."

Recent Business Highlights:

- In April, the *New England Journal of Medicine* (NEJM) published the results of Akebia's global Phase 3 program for vadadustat, which consisted of two programs that evaluated the efficacy and safety of vadadustat versus darbepoetin alfa for the treatment of anemia due to CKD in adult patients on dialysis (INNO$_2$VATE) and not on dialysis (PRO$_2$TECT).
- In March, Akebia submitted an NDA to the FDA for vadadustat for the treatment of anemia due to CKD in both adult patients on dialysis and adult patients not on dialysis.
- In February, Akebia completed a non-dilutive transaction with an entity managed by HealthCare Royalty Management, LLC (HCR), to monetize the Company's rights to receive royalties and sales milestones on vadadustat net sales under its collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC), with an upfront payment of $45 million.
- In February, Akebia announced that LeAnne M. Zumwalt joined Akebia's Board of Directors. Ms. Zumwalt recently served as Group Vice President, Government Affairs at DaVita Inc.
- In February, Akebia launched its *Medical Engagement Hub*, an online resource dedicated to scientific education and connecting U.S. healthcare professionals with Akebia Medical Affairs.
- In January, the University of Texas Health Science Center at Houston (UTHealth) in Houston, Texas, announced that it had received $5.1 million in government funding for its study evaluating the use of vadadustat as a potential therapy to prevent and lessen the severity of acute respiratory distress syndrome (ARDS), a complication of COVID-19. This investigator-sponsored research study is currently underway and actively enrolling patients.

First Quarter Financial Results

- **Revenues:** Total revenue was $52.3 million for the first quarter of 2021 compared to $88.5 million for the first quarter of 2020. The decrease compared to the same period in 2020 was primarily due to lower collaboration revenue consistent with the Company successfully completing the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs.
  - Collaboration revenue was $21.9 million for the first quarter of 2021 compared to $59.3 million for the first quarter of 2020.
  - Net product revenue was $30.4 million for the first quarter of 2021 compared with $29.2 million for the first quarter of 2020, an increase of 4 percent.
- **COGS:** Cost of goods sold was $34.6 million for the first quarter of 2021 compared to $27.7 million for the first quarter of 2020. The increase was driven by higher non-cash purchase accounting adjustments as a result of the merger with Keryx, and a $5.1 million non-cash charge to inventory reserves related to a previously disclosed manufacturing quality issue related to Auryxia® (ferric citrate), partially offset by an $8.9 million non-cash gain due to a reduction to the liability for

excess purchase commitments primarily as a result of the Company having successfully modified certain supply agreements.

- **R&D Expenses:** Research and development expenses were $40.6 million for the first quarter of 2021 compared to $81.2 million for the first quarter of 2020. The decrease compared to the same period in 2020 was primarily due to the completion of the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs.
- **SG&A Expenses:** Selling, general and administrative expenses were $41.3 million for the first quarter of 2021 compared to $38.0 million for the first quarter of 2020.
- **Net Loss:** Net loss was $69.6 million for the first quarter of 2021 compared to $60.7 million for the first quarter of 2020. The increase in net loss compared to the prior year period was due primarily to lower collaboration revenue and higher cost of goods sold, partially offset by lower operating expenses.
- **Cash Position:** Cash, cash equivalents and available-for-sale securities as of March 31, 2021 were $272.8 million. The Company expects its cash resources to fund its current operating plan beyond the expected U.S. launch of vadadustat, assuming timely regulatory approval and the receipt of associated regulatory milestones.

"Despite the ongoing impact of COVID-19 on dialysis patients, we are encouraged by Auryxia's revenue growth in the first quarter of 2021 when compared to the prior year's period. We believe this performance highlights Auryxia's favorable product profile and the critical nature of this therapy, as well as our team's ability to execute at a high level," stated David A. Spellman, Chief Financial Officer of Akebia. "While we remain cautious due to COVID-19, together with our continued commercial efforts, we believe that Auryxia's positioning will drive product revenue growth for the year."

Conference Call

Akebia will host a conference call at 9:00 a.m. Eastern Time today, Monday, May 10, to discuss its first quarter financial results and recent business highlights. To listen to the conference call, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 6250159. 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 May 16, 2021. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 6250159. 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 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 recently completed its global Phase 3 development program for the treatment of anemia due to CKD. Vadadustat is not approved by the U.S. Food and Drug Administration (FDA) or any other 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 Anemia due to Chronic Kidney Disease (CKD)

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

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: the connection between the publication of results INNO$_2$VATE and PRO$_2$TECT in the New England Journal of Medicine and vadadustat's clinical development program; the commercialization of vadadustat, if approved, and the timing thereof; the timing of submission of an MAA for vadadustat to EMA; the potential impact of COVID-19; the potential for product revenue growth in 2021; and the timing and expectations for the Company's cash runway in relation to the expected timing of the U.S. launch of vadadustat, assuming timely regulatory approval and the receipt of associated regulatory milestones.. The terms "believe," "confident," "expect," "plan," "potential," "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, but not limited to: the timing of regulatory filings and approvals; interactions with the FDA, including reviews and inspections, the timing related thereto and the outcome thereof; the potential therapeutic benefits, safety profile and effectiveness of our product candidates, including vadadustat; the direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which the Company and its partners, collaborators, vendors and customers operate; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the potential indications, demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia and vadadustat, if approved, including estimates regarding the potential market opportunity for the Company's product, vadadustat or any other product candidates and the size of eligible patient populations; enrollment in clinical and preclinical studies; manufacturing, supply and quality risks, and any recalls, write-downs, impairments or other related consequences or potential consequences; risks associated with hiring, training, management and retention and key personnel changes and transitional periods; the actual funding required to continue to commercialize Akebia's commercial product, to develop and commercialize vadadustat, and to operate the Company; the risks associated with potential generic entrants for Akebia's commercial product and vadadustat, if approved; early termination of or changes to the terms of agreements that Akebia has with any of its collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for Akebia's commercial product and vadadustat, if approved; 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 collaborations partners and vendors; expected reliance on third parties, including with respect to the development, manufacturing, supply or commercialization of Akebia's product and product candidates; the Company's expectations, projections and estimates regarding its capital requirements; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for its commercial product, vadadustat and any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the year ended December 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, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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

	Three Months Ended	
	March 31, 2021	March 31, 2020
Revenues:		
Product revenue, net	$ 30,408	$ 29,209
License, collaboration and other revenue	21,896	59,269
Total revenues	52,304	88,478
Cost of goods sold:		
Product	25,595	18,613
Amortization of intangibles	9,011	9,100
Impairment of intangible asset	—	—
Total cost of goods sold	34,606	27,713
Operating expenses:		
Research and development	40,611	81,231
Selling, general and administrative	41,328	37,983

License expense	695	676
Total operating expenses	82,634	119,890
Operating loss	(64,936)	(59,125)
Other expense, net	(4,644)	(1,622)
Net loss	$ (69,580)	$ (60,747)
Net loss per share - basic and diluted	$ (0.45)	$ (0.47)
Weighted-average number of common shares - basic and diluted	153,820,809	128,395,163

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and available for sale securities	$272,764	$268,690
Working capital	192,338	184,291
Total assets	628,703	644,139
Total stockholders' equity	213,891	247,618

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