Akebia Therapeutics Reports First Quarter 2022 Financial Results and Business Update

May 9, 2022

- Net Auryxia® (ferric citrate) product revenue of $41.4M, a 36% increase over Q1 2021
- 2022 Net Auryxia product revenue guidance of $165 - $170M
- Outlines refined strategic focus to deliver shareholder value
- Akebia to host conference call on Monday, May 9 at 4:30 p.m. ET

CAMBRIDGE, Mass., May 9, 2022 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced financial results for the first quarter ended March 31, 2022 and provided business updates.

"While we were surprised and disappointed by the vadadustat Complete Response Letter we received from the FDA in March, our team has responded aggressively by working to strengthen and secure the company financially, with an aim of allowing us to continue to deliver on our purpose to better the lives of people impacted by kidney disease. We plan to focus on Auryxia commercial success while exploring our earlier stage assets and pursuing other value creating business opportunities," said John Butler, Chief Executive Officer of Akebia. "The past six months of Auryxia net sales have been the strongest ever. This is a testament to the strength of our commercial team, which has delivered, even as COVID-19 disproportionately impacted the patients we serve. As we emerge from the pandemic, we believe Auryxia revenue is positioned to continue to grow and provide a solid basis for ongoing financial support for the company."

Akebia has outlined three pillars of its refined strategic focus:

- Drive Auryxia revenue and identify cash management opportunities with the objective to enable Akebia to manage the company with existing cash resources and ongoing cash from operations;
- Support our partners selling and seeking regulatory approval for vadadustat globally, including potential EMA approval and European launch; and evaluate options for potential U.S. approval; and,
- Thoughtfully invest in our pipeline of internal assets and assess other strategic growth opportunities.

Akebia refined its strategic focus following receipt on March 29, 2022 of a Complete Response Letter (CRL) from the U.S. Food & Drug Administration (FDA) for Akebia's New Drug Application for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor for the treatment of anemia due to chronic kidney disease. Akebia plans to request an end of review meeting with the FDA within ninety days of receipt of the CRL. Akebia plans to evaluate and determine potential next steps for vadadustat in the U.S. following the end of review meeting with the FDA. In the meantime, the company is focused on its path forward without a U.S. approval for vadadustat.

Financial Results

- **Revenues:** Total revenue was $61.7 million for the first quarter of 2022 compared to $52.3 million for the first quarter of 2021.
  - Net product revenue was $41.4 million for the first quarter of 2022 compared with $30.4 million for the first quarter of 2021, an increase of 36%.
  - Collaboration revenue was $20.3 million for the first quarter of 2022 compared to $21.9 million for the first quarter of 2021. The decrease in the period compared to the same period in 2021 was primarily due to lower collaboration revenue from Otsuka Pharmaceuticals Co. Ltd (Otsuka) driven by lower development costs incurred subject to cost share provisions under both the Otsuka collaboration agreement for the U.S. and the Otsuka collaboration agreement for certain territories outside the U.S.
  - **Revenue Guidance:** Akebia is providing net product revenue guidance for Auryxia of $165 - $170 million for fiscal year 2022. Guidance assumes, among other things, continued stabilization of the phosphate binder market and continued improvement of net realized price per tablet.
- **COGS:** Cost of goods sold was $31.3 million for the first quarter of 2022 compared to $34.6 million in the first quarter 2021. In 2022, cost of goods sold consisted of costs associated with the manufacturing of Auryxia and supply of Vafseo to MTPC for commercial sale in Japan. Additionally, $5.3 million was related to excess and obsolescence reserves associated with Auryxia partially offset by a $0.8 million reduction to the liability for excess purchase commitments, and $9.0 million related to amortization of intangibles.

- **R&D Expenses:** Research and development expenses were $43.8 million for the first quarter of 2022 compared to $40.6 million for the first quarter of 2021. The increase compared to the prior year period was primarily due to increased headcount compared to the first quarter 2021.

- **SG&A Expenses:** Selling, general and administrative expenses were $44.3 million for the first quarter of 2022 compared to $41.3 million for the first quarter of 2021 due to higher marketing expenses in anticipation of the potential approval of vadadustat.

- **Net Loss:** Net loss was $62.4 million for the first quarter of 2022 compared to $69.6 million for the first quarter of 2021.

- **Cash Position:** Cash and cash equivalents as of March 31, 2022, were $174.6 million. Akebia believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months. Akebia's operating plan includes assumptions pertaining to cost avoidance measures and the reduction of overhead costs resulting from the planned amendment of certain contractual arrangements, including with certain supply and collaboration partners, and the reduction of certain infrastructure costs. The outcome of these measures, such as the potential amendment of certain contractual arrangements with supply and collaboration partners, are outside of Akebia's control.

- **Restructuring:** On April 4, 2022, the Board of Directors of Akebia approved a reduction in workforce of approximately 42% across all areas of Akebia (47% inclusive of the majority of open positions) following the receipt of the CRL. On May 5, 2022, Akebia implemented a further reduction in workforce consisting of several members of management. In connection with the restructuring, the company estimates that it will incur restructuring charges of approximately $16.5 million in the aggregate, primarily related to one-time termination benefits and contractual termination benefits including severance, non-cash stock-based compensation expense, healthcare and related benefits primarily in the second quarter of 2022. Akebia expects that the reduction in force will result in an approximate range of $60-65 million reduction in cash required for operating activities through the end of 2023.

"There has been significant effort made since our CRL in March to streamline our operations with a goal of funding operations from the cash flows of Auryxia as well as funds from our collaboration partners," said David A. Spellman, Chief Financial Officer of Akebia. "There is still work to do, and we are focused on delivering increased revenue and greater cost savings. If we are successful in implementing cost avoidance measures, we believe we will have cash flows to support the business through at least the next twelve months and do not anticipate a near-term requirement to further finance the company to execute our operating plan."

Conference Call
Akebia will host a conference call on Monday, May 9, 2022 at 4:30 p.m. Eastern Time to discuss its first quarter financial results and provide business updates. To listen to the conference call on May 9, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 1273066. 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 15, 2022. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 1273066. An online archive of the conference call can be accessed via the Investors section of Akebia'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 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 an investigational new drug and is not approved by the U.S. Food and Drug Administration (FDA). On March 29, 2022, the FDA issued a complete response letter to Akebia's New Drug Application for vadadustat for the treatment of anemia due to chronic kidney disease (CKD). Vadadustat is currently under review by the European Medicines Agency for the treatment of anemia due to CKD in adults. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

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 Statement

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("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, and include, but are not limited to, statements regarding: Akebia's plans, strategies and prospects for its business, including with respect to Akebia's response to the receipt of the Complete Response Letter (the "CRL") that it received in March 2022; Akebia's future plans with respect to its strategic growth and operating plans, including as it relates to regulatory submissions outside of the U.S.; Akebia's belief that Auryxia revenue will continue to grow and provide a solid basis for ongoing financial support for the company; Akebia's revenue guidance for Auryxia in 2022 and assumptions related thereto; Akebia's plans to request a review meeting with the FDA within 90 days of receipt of the CRL and its plans with respect to vadadustat thereafter; Akebia's expectations related to its April and May 2022 workforce reduction, future charges expected to be incurred in connection therewith and estimated reductions in net cash required for operating activities in connection therewith; and Akebia's goals, objectives and expectations with respect to its operating plan, cash resources and sources of funding for its cash runway, including its ability to deliver greater cost savings, its belief that it will have cash flows to support the business through at least the next twelve months and its belief that it does not anticipate a near-term requirement to further finance the company in order to execute its current anticipated operating plan. The terms "intend," "believe," "plan," "goal," "expect," "potential," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, including potential generic entrants; Akebia's ability to successfully implement its workforce reduction plan and reduce expenses; the impact of the workforce reduction on Akebia's business; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce overhead costs, including its ability to execute amendments to certain contractual arrangements and reduce infrastructure costs; decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings, including the New Drug Application for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. 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, 2021, 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, 2022	March 31, 2021

Revenues:		
Product revenue, net	$ 41,448	$ 30,408
License, collaboration and other revenue	20,251	21,896
Total revenues	61,699	52,304
Cost of goods sold:		
Product	22,333	25,595
Amortization of intangibles	9,011	9,011
Total cost of goods sold	31,344	34,606
Operating expenses:		
Research and development	43,833	40,611
Selling, general and administrative	44,327	41,328
License expense	688	695
Total operating expenses	88,848	82,634
Operating loss	(58,493)	(64,936)
Other expense, net	(3,928)	(4,644)
Net loss	$ (62,421)	$ (69,580)
Net loss per share - basic and diluted	$ (0.35)	$ (0.45)
Weighted-average number of common shares - basic and diluted	179,599,045	153,820,809

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$174,562	$149,800
Working capital	48,773	15,517
Total assets	535,356	525,550
Total stockholders' equity	26,116	76,456

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