Akebia Therapeutics Provides Update on Continued Momentum of Commercial Launch of Vafseo® (vadadustat) Tablets

July 11, 2024

- Akebia regains full rights to sell Vafseo® (vadadustat) Tablets in the U.S. following the execution of a royalty-based termination agreement with CSL Vifor to simplify operational execution and improve economics
- Announced Vafseo WAC pricing of $1,278 for a 30-day supply
- Submitted TDAPA application for Vafseo in June 2024 and expects designation on January 1, 2025

Akebia to host investor conference call at 8:00 a.m. ET on July 11, 2024

CAMBRIDGE, Mass., July 11, 2024 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced key updates pertaining to the commercial launch of Vafseo® (vadadustat) Tablets. Akebia will host an investor conference call at 8:00 a.m. ET on Thursday, July 11, 2024.

"Since Vafseo approval in late March, our team has worked diligently on commercial launch activities to drive prescriber demand with the goal to optimize Vafseo's revenue ramp during the two-year Transitional Drug Add-on Payment Adjustment (TDAPA) period expected to begin in January 2025 and beyond," said John P. Butler, Chief Executive Officer of Akebia. "This is a multi-faceted endeavor, and today I am excited to share progress made on multiple fronts. First, we have established a wholesale acquisition cost (WAC) that reflects the value of Vafseo in both the dialysis and, if approved, non-dialysis populations. Additionally, contracting effectively with dialysis organizations is critical to a successful launch. To help facilitate the contracting process, as well as simplify the operational management of the product, we have agreed with CSL Vifor to terminate the existing license, resulting in Akebia regaining rights to sell Vafseo to Fresenius Kidney Care dialysis centers and specific other third-party dialysis organizations in the U.S. In addition, we have made significant progress in contract discussions with dialysis organizations for both Auryxia and Vafseo. Having now executed this agreement with CSL Vifor, we can accelerate contracting discussions and expect to have contracts in place with dialysis providers treating the vast majority of eligible Vafseo patients before January 2025. I want to thank our colleagues at CSL Vifor for their collaboration over the past years, and I look forward to continuing to work with them under this new relationship."

Vafseo Commercial Launch Updates:

CSL Vifor Agreement: Akebia and CSL Vifor have entered into a termination agreement of the license agreement providing for the payment of royalties by Akebia to CSL Vifor on Vafseo U.S. net product sales. As a result, Akebia regained full rights to sell Vafseo in the U.S. and is able to contract directly with all dialysis organizations effective immediately. Akebia believes its existing and well-established renal sales and medical affairs teams are equipped to drive prescriber demand and enable dialysis organization contracting. Under the terms of the agreement, CSL Vifor is entitled to quarterly tiered royalty payments ranging from a high single-digit percentage on annual net sales up to $450 million to a mid-single digit percentage on annual net sales above $450 million. Akebia has the opportunity to buy down the royalty agreement beginning on July 1, 2027 with a one-time payment to CSL Vifor, which would decrease the royalty payments to a mid-single digit percentage of Akebia's annual net sales of Vafseo up to $450 million and eliminate the royalty payment on annual net sales above $450 million.

TDAPA Submission: In June, Akebia submitted its TDAPA application. Akebia expects to have Healthcare Common Procedure Coding System (HCPCS) codes assigned in October 2024 and full TDAPA designation by January 1, 2025.

Vafseo Pricing: Vafseo WAC has been set at $1,278 for a 30-day supply at the minimum starting dose, or approximately $15,500 per year. The entire dialysis business will be a contracted business, offering an off-invoice discount as well as volume tier discounts off this WAC price. The potential label expansion into non-dialysis patients was an important factor in determining the WAC pricing for Vafseo.

Conference Call Information
Akebia will host a conference call on Thursday, July 11, 2024 at 8:00 a.m. Eastern Time to discuss Vafseo commercial updates. To access the call, please register by clicking on this Registration Link, and you will be provided with dial in details. To avoid delays and ensure timely connection, we encourage dialing into the conference call 15 minutes ahead of the scheduled start time.

A live webcast of the conference call will be available via the "Investors" section of Akebia's website at: https://ir.akebia.com/. An online archive of the webcast can be accessed via the Investors section of Akebia's website at https://ir.akebia.com approximately two hours after the event.

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. Akebia 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.

Forward-Looking Statements

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 updates pertaining to the commercial launch of Vafseo (vadadustat) Tablets, including that commercial launch activities will drive prescriber demand or optimize Vafseo's revenue ramp during the two-year TDAPA period beginning in January 2025 and beyond, and that the WAC price reflects the value of Vafseo in both the dialysis and, if approved, non-dialysis populations; Akebia's significant progress in contract discussions with dialysis organizations for both Auryxia and Vafseo, including Akebia's expectations for timing to have contracts in place with dialysis providers treating the vast majority of eligible [Vafseo] patients; the execution of a royalty-based termination agreement with CSL Vifor to simplify operational execution, improve economics and facilitate the contracting process, including beliefs that Akebia's existing and well-established renal sales and medical affairs teams are equipped to drive prescriber demand and enable dialysis organization contracting; Akebia's expectations for timing to have HCPCS codes and full TDAPA designation; and Akebia's potential label expansion of Vafseo into non-dialysis patients. The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "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 implementation of the provisions of the termination agreement with CSL Vifor, including the ability of Akebia to successfully contract with dialysis organizations; whether Vafseo will be commercially available when expected; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia® and Vafseo, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia and Vafseo, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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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