Akebia Therapeutics Announces Amendment of License Agreement with Vifor Pharma in Preparation for Potential Vadadustat Launch

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Agreement Leverages Vifor Pharma's Exclusive Distribution Arrangement with Certain Dialysis Organizations
Agreement Defines Profit Share Economics of Potential Vadadustat Revenue if Approved
- Vifor Pharma to make equity purchase of $20 million
- $40 million refundable working capital investment to partially fund launch supply
- $25 million upfront payment

CAMBRIDGE, Mass., Feb. 22, 2022 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, and Vifor Pharma Group (Vifor Pharma), today announced that the companies have amended and restated the terms of their license agreement, pursuant to which Akebia Therapeutics, Inc. (Akebia) granted Vifor Pharma an exclusive license to sell vadadustat, Akebia's investigational oral therapeutic for the treatment of anemia due to chronic kidney disease (CKD), to Fresenius Medical Care North America and its affiliates (including Fresenius Kidney Care Group LLC) and other entities in the United States, subject to vadadustat's approval by the U.S. Food and Drug Administration (FDA). Vadadustat's Prescription Drug User Fee Act (PDUFA) date is March 29, 2022.

The new agreement further supports Akebia's commercialization strategy ahead of a potential first-in-class U.S. launch for vadadustat which, as previously noted, provides access to up to 60% of U.S. dialysis patients through existing Vifor Pharma relationships. Previous agreements between the companies granted Vifor Pharma an exclusive license to sell vadadustat, if approved by the FDA, to Fresenius Kidney Care Group for use solely within its dialysis facilities and certain other third-party dialysis facilities in the U.S. The new agreement further expands this license to also include additional independent dialysis organizations.

"Vifor Pharma shares our commitment to bring innovative treatments to people living with kidney disease, which has been a cornerstone of our longstanding relationship," said John P. Butler, Chief Executive Officer of Akebia. "As we approach vadadustat's PDUFA date and potential launch, we are thrilled to clarify the agreement, which we believe will enable our companies to get vadadustat to dialysis patients more quickly."

In consideration for the extension of Vifor Pharma's customer group, Vifor Pharma agreed to an additional equity purchase of $20 million. Further, Vifor Pharma will contribute $40 million for use as working capital to partially fund Akebia's costs of manufacturing vadadustat to support commercialization in the U.S. following FDA approval; such working capital to be refundable over time.

Under the terms of the amended and restated agreement, Vifor Pharma will accelerate payment of the previously agreed upon $25 million milestone to Akebia. Akebia will retain approximately 66% of the profit, net of certain pre-specified costs. Akebia will share the profit with Otsuka pursuant to the License and Collaboration Agreement between Akebia and Otsuka in the U.S.

Akebia has retained all rights to commercialize vadadustat, in collaboration with Otsuka, in the non-dialysis dependent market and to the remaining dialysis organizations representing approximately 40% of the U.S. dialysis market, following FDA approval.

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.

About Vadadustat
Vadadustat is a potential first-in-class 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. The New Drug Application for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) is under review by the U.S. Food and Drug Administration (FDA). Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare. 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.

Forward-Looking Statement
Statements in this presentation 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: vadadustat's potential to be a first-in-class HIF-PH inhibitor for the treatment of anemia due to chronic kidney disease in the U.S. and the anticipated scheduled PDUFA date for vadadustat; the access to dialysis patients and the dialysis market that is provided as a result of Vifor Pharma's relationships; the impact that clarifying the license agreement will have on Akebia's ability to get vadadustat to dialysis patients more quickly; The terms "believe," "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: decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings and approvals, including labeling or other restrictions, for vadadustat and Akebia's outlook related thereto; any delays in the FDA review of, and potential approval related to, Akebia's New Drug Application (NDA) submission for any reason; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the potential indications, demand, potential and acceptance of, and Akebia's estimates regarding the potential market opportunity for Akebia's product candidate, vadadustat, if approved, or any other products or product candidates and the size of eligible patient populations; 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; early termination of any of Akebia's collaborations, including the amended and restated license agreement; and Akebia's and Vifor Pharma's ability to satisfy their obligations under the amended and restated license agreement; the competitive landscape for vadadustat, if approved. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the period ended September 30, 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 presentation, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation.

Akebia Therapeutics
Mercedes Carrasco
Mcarrasco@akebia.com

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