Akebia Therapeutics Enters into License Agreement with Medice Arzneimittel Pütter GmbH&Co.KG for the Commercialization of Vafseo® for the Treatment of Anemia associated with CKD in Europe and Australia

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- Medice brings extensive expertise in nephrology and an established European dialysis business
- Akebia to receive a $10 million upfront payment, potential for up to $100 million in commercial milestone payments, and tiered royalties up to 30% of net sales in dialysis
- Akebia retains majority of economics in non-dialysis indication if approved by EMA and retains rights to all other indications

CAMBRIDGE, Mass., May 25, 2023 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced an agreement with MEDICE Arzneimittel Pütter GmbH&Co.KG (Medice – The Health Family), for Medice to market Vafseo® (vadadustat), an oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor developed by Akebia to treat anemia due to chronic kidney disease (CKD), in Europe. Akebia is retaining the rights to develop and commercialize in Europe for all other indications. The exclusive license agreement grants Medice the rights to market and sell Vafseo in the European Economic Area in addition to the United Kingdom, Switzerland and Australia. Akebia will receive an upfront payment of $10 million, commercial milestone payments up to $100 million, and tiered royalty payments up to 30% of net sales.

"We are thrilled to partner with Medice to bring Vafseo to market in Europe this year," said John P. Butler, Chief Executive Officer of Akebia. "Medice specializes in renal and anemia care and has deep commercial expertise gained by building a successful portfolio in the dialysis space. We believe Vafseo has the potential to be a centerpiece of Medice's portfolio of products for dialysis patients. Our collaboration also provides the flexibility to pursue additional indications to maximize value for Akebia while potentially serving many more patients."

"We're eager to bring Vafseo to market in Europe as we believe dialysis patients with anemia due to CKD could benefit from additional therapeutic options," said Dr. Richard Ammer, Chief Executive Officer of Medice. "We look forward to working closely with Akebia as we prepare for a commercial launch in dialysis this year."

Anemia associated with CKD, common in patients on dialysis, is a debilitating condition which may be associated with many adverse clinical outcomes. Throughout Europe, we estimate that more than 325,000 dialysis patients are currently treated for anemia associated with CKD.

Under the terms of the agreement, in addition to the $10 million upfront payment and commercial milestones of up to $100 million, Akebia will receive tiered royalties from 10% to 30% of net sales. Vafseo is currently approved in Europe and the United Kingdom for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Under the agreement, Akebia has the right to develop Vafseo for use as a treatment of anemia due to CKD in adults not on dialysis. If Akebia exercises this right, Medice will commercialize Vafseo for both indications in the defined territory and Akebia would retain 70% of the net profit margin generated by use in the non-dialysis population, or alternative equivalent financial terms to be negotiated by the parties.

Akebia retains rights to vadadustat for all other indications. If Akebia chooses to develop vadadustat for any other indication and seeks a collaboration partner in the territory, Medice has a right of first offer to collaborate on the development and commercialization of Vafseo in such defined territory.

Vadadustat is approved in 33 countries and regulatory opinions are expected in Switzerland and Australia later this year.

Important Safety Information
For safety information, view the European Summary of Product Characteristics (SPC/SmPC) for Vafseo™ (vadadustat) at https://ec.europa.eu/health/documents/community-register/2023/20230424158854/anx_158854_en.pdf.

The full Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) will be available on the UK MHRA website at https://products.mhra.gov.uk/.

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 not approved by the U.S. Food and Drug Administration. In April 2023 and May 2023 respectively, the European Commission and United Kingdom Medicines and Healthcare products Regulatory Agency granted marketing authorization for vadadustat for the treatment of symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Medice

MEDICE Arzneimittel Pütter GmbH&Co.KG, founded in 1949 and headquartered in Iserlohn (Germany), is a fully integrated pharmaceutical company with own GxP capabilities in development, manufacturing and pan-European and international distribution of pharmaceuticals and medical devices. It is the core of "MEDICE – The Health Family" aiming to improve patient management by offering high quality innovative drugs, non-pharmacological interventions and value adding services. For more information, please visit www.medice.eu, which does not form a part of this release.

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 and expectations with respect to commercializing Vafseo in Europe, including the timing thereof; Akebia's expectations on the timing for certain regulatory decisions for vadadustat by regulatory authorities in Switzerland and Australia; statements regarding the potential market opportunity of vadadustat and beliefs about the benefits that vadadustat could provide to dialysis patients; statements about Akebia's ability to serve more patients while pursuing additional indications for vadadustat and maximizing value; and beliefs about Vafseo becoming the centerpiece of Medice's portfolio of products for dialysis patients. The terms "expect," "intend," "believe," "plan," "goal," "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, vadadustat; decisions made by health authorities, such as the FDA, with respect to regulatory filings; the results of preclinical and clinical research; 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; early termination of any of Akebia's collaborations; and 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 quarter ended March 31, 2023, 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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