Vifor Pharma and Akebia Therapeutics Announce Expansion of License Agreement

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Expanded license creates opportunity for vadadustat to be provided to up to 60% of U.S. dialysis patients, subject to FDA approval

ZURICH & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 9, 2019-- The Vifor Pharma Group (SIX: VIFN) and Akebia Therapeutics, Inc. (Nasdaq: AKBA) today announced that the companies have amended the terms of their license agreement to sell vadadustat to Fresenius Medical Care North America dialysis clinics in the United States, subject to its approval by the U.S. Food and Drug Administration (FDA).

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Under the terms of the agreement signed in May 2017, Akebia granted Vifor Pharma a license to sell vadadustat to Fresenius Medical Care North America for use solely within its dialysis clinics in the U.S., subject to FDA approval. The license has now been amended to allow Vifor Pharma to also sell vadadustat to certain third-party dialysis organizations, for use in the U.S., thereby expanding the potential opportunity for vadadustat under the agreement to up to 60% of U.S. dialysis patients.

The license, which is subject to vadadustat's approval by the FDA and inclusion in the Centres for Medicare & Medicaid (CMS) End Stage Renal Disease Prospective Payment System (ESRD PPS), also referred to as the ESRD bundle, will now also be effective during the Transitional Drug Add-on Payment Adjustment (TDAPA) two-year period that is expected to precede the ESRD bundle period.

Under the terms of the amended agreement, Akebia is eligible to receive an additional $5 million payment, which means Akebia is eligible to receive a total payment of $25 million from Vifor Pharma upon approval of vadadustat by the FDA and the earlier of CMS's determination that vadadustat will be reimbursed under the TDAPA or included in the ESRD bundle.

Vadadustat is an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor currently in Phase III development for the treatment of anemia due to chronic kidney disease (CKD). Vifor Pharma and Akebia believe that vadadustat has the potential to set a new oral standard of care for patients with anemia due to CKD.

Stefan Schulze, President of the Executive Committee and COO at Vifor Pharma said "We are very pleased to have amended our license agreement with Akebia. We believe that vadadustat has the potential to play an important role in the future treatment of anemia due to CKD and we will work closely with our strategic partner Fresenius Medical Care to maximize this opportunity."

"We believe the expansion of this agreement reflects enthusiasm about our development program and the potential for vadadustat to treat anemia due to CKD," stated John P. Butler, President and Chief Executive Officer of Akebia Therapeutics, Inc. "We are excited to be building on our relationship with Vifor Pharma to facilitate access to vadadustat to a larger group of dialysis patients, subject to its approval by the FDA."

The Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for pharmaceuticals and innovative patient-focused solutions. The Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. The Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. The Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit www.viforpharma.com.

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialisation of therapeutics for patients with 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.

Vadadustat is an oral hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitor currently in global Phase III development for the treatment of anemia due to CKD. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilisation and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat is an investigational therapy and is not approved by the FDA or any regulatory authority.

Forward-Looking Statements: This document contains forward-looking statements within the meaning of the federal securities laws. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as "anticipate," "create," "expect," "believe," "may," "will," "should," "plan," "could," "target," "contemplate," "estimate," "position," "predict," "potential," "opportunity," "working to," "look forward" and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including regarding vadadustat's potential to set a new standard of care, vadadustat's therapeutic potential, and vadadustat's market and growth opportunity and potential, are forward-looking statements. Important factors that could cause actual results to differ materially from Akebia's plans, estimates or expectations could include, but are not limited to: the results of Akebia's clinical trials; the timing and content of interactions with and decisions made by regulatory authorities; and success of others in

developing competing products. Other risks and uncertainties include those identified under the heading “Risk Factors” in Akebia’s most recently filed Annual Report on Form 10-K, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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