



## **Vifor Pharma and Akebia Announce Exclusive License Agreement to Provide Vadadustat to Fresenius Medical Care in the U.S. Upon FDA Approval**

- Vifor Pharma Commits to Exclusive Distribution of Vadadustat to Fresenius Medical Care North America for Use in its Dialysis Facilities and Invests \$50 Million in Akebia at a Premium –*
- Additional Funds Support Vadadustat Global Development Program to Data –*

**ZURICH, SWITZERLAND & CAMBRIDGE, MA, USA – 16 May 2017** [Vifor Pharma Group](#) (SIX: VIFN) and [Akebia Therapeutics](#), Inc. (NASDAQ: AKBA) today announced they have entered into an exclusive license agreement to sell vadadustat to Fresenius Medical Care dialysis clinics in the United States upon approval by the U.S. Food and Drug Administration (FDA). Vifor Pharma will also make a \$50 million equity investment in Akebia at \$14 per share. Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer currently in Phase 3 development for the treatment of anemia associated with chronic kidney disease (CKD).

“Vadadustat could represent a significant advancement in the treatment of renal anemia with the potential to establish a new treatment paradigm and overcome the limitations of current therapies for patients with chronic kidney disease. We believe that vadadustat may also be a potential solution for hyporesponder patients who do not respond well to erythropoiesis stimulating agents,” stated Stefan Schulze, President of the Executive Committee and Chief Operating Officer of Vifor Pharma. “This transaction strengthens the nephrology product portfolio of Vifor Pharma and is consistent with our ongoing commitment to deliver innovative products that can improve the lives of patients suffering with chronic kidney disease.”

Under the terms of the agreement, Vifor Pharma will exclusively distribute vadadustat to Fresenius Medical Care North America for use solely within its dialysis facilities in the U.S. to meet their need for an HIF-based treatment for anemia associated with CKD. Fresenius Medical Care is the largest kidney dialysis provider in the U.S. and, in 2016, treated over 185,000 dialysis patients, or nearly 40% of the U.S. dialysis patients. This agreement is structured as a profit-sharing arrangement between Akebia and Vifor Pharma. It is subject to the approval of vadadustat by the FDA and to the inclusion of vadadustat in a bundled reimbursement model, upon which Akebia will receive a \$20 million payment from Vifor Pharma. Akebia’s revenue from the profit share and the milestone payment will be shared with Otsuka Pharmaceutical Co. Ltd., Akebia’s U.S. collaborator. Akebia, in collaboration with Otsuka, plans to commercialize vadadustat in other dialysis organizations and centers and in the non-dialysis market in the U.S.

“This agreement provides the opportunity to build greater commercial momentum for vadadustat in the U.S. rapidly upon launch,” said John P. Butler, President and Chief Executive Officer of Akebia. “We are pleased that Vifor Pharma has selected vadadustat as its exclusive HIF product for distribution to Fresenius Medical Care, one of the largest dialysis providers. We believe that this commitment provides significant further validation of vadadustat’s potential.”

### **About Vadadustat**

Vadadustat is an oral, investigational hypoxia-inducible factor (HIF) stabilizer currently in Phase 3 development for the treatment of anemia related to chronic kidney disease. Vadadustat exploits the same mechanism of action used by the body to adapt naturally to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat has not been approved by the FDA or any other regulatory authority.

### **About Anemia Associated with CKD**

Anemia results from the body's inability to coordinate red blood cell production in response to lower oxygen levels due to the progressive loss of kidney function with inadequate erythropoietin production. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. Anemia is currently treated with injectable recombinant erythropoiesis stimulating agents, which are associated with inconsistent hemoglobin responses and well-documented safety risks. The prevalence of anemia increases with the severity of CKD and is higher in people with CKD who are over age 60.

### **About Vifor Pharma**

Vifor Pharma Group, formerly Galenica Group, is a global specialty 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 specialty pharmaceuticals and innovative patient-focused solutions. 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. 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. Vifor Pharma Group is headquartered in Zurich, Switzerland and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN). For more information, visit [www.viforpharma.com](http://www.viforpharma.com).

### **About Akebia Therapeutics**

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral, investigational therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO<sub>2</sub>TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and the INNO<sub>2</sub>VATE studies for dialysis-dependent patients, is currently ongoing. For more information, please visit our website at [www.akebia.com](http://www.akebia.com).

### **Forward-Looking Statements**

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of vadadustat, the potential commercialization of vadadustat and the anticipated financial contributions and other benefits of the license agreement with Vifor

Pharma. The words “anticipate,” “appear,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of Akebia to successfully complete the clinical development of vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; early termination of the exclusive license agreement by Akebia or Vifor Pharma; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. Other risks and uncertainties include those identified under the heading “Risk Factors” in Akebia's Annual Report on Form 10-Q for the quarter ended March 31, 2017, and other filings that Akebia may make with the 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.

<p><b>Contacts:</b></p> <p><b>Vifor Pharma Media Relations</b>          Beatrix Benz          Head of Global Communications &amp; Public Affairs          Tel.: +41 58 851 80 16  <a href="mailto:media@viforpharma.com">media@viforpharma.com</a></p> <p><b>Vifor Pharma Investor Relations</b>          Julien Vignot          Head of Investor Relations          Tel.: +41 58 851 66 90          E-mail: <a href="mailto:investors@viforpharma.com">investors@viforpharma.com</a></p>	<p><b>Akebia</b>          Theresa McNeely          SVP, Corporate Communications and          Investor Relations          Tel.: +1 617 844 6113  <a href="mailto:tmcneely@akebia.com">tmcneely@akebia.com</a></p>
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