Akebia Therapeutics and Keryx Biopharmaceuticals Complete Merger, Creating Fully Integrated Renal Company

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CAMBRIDGE, Mass. & BOSTON--(BUSINESS WIRE)--Dec. 13, 2018-- Akebia Therapeutics, Inc. (Nasdaq:AKBA) and Keryx Biopharmaceuticals, Inc. today announced the successful completion of their previously announced merger.

"We are very pleased to announce the completion of our merger with Keryx to create a fully integrated renal company that has the potential to set new standards of care for patients with kidney disease," said John P. Butler, President and Chief Executive Officer of Akebia. "With established renal development, manufacturing and commercial capabilities, strong cash position, a flexible balance sheet and experienced management team, our company is uniquely positioned to capitalize on the significant market opportunity by maximizing the growth of Auryxia® (ferric citrate) and build launch momentum for our Phase 3 product candidate, vadadustat, subject to approval by the U.S. Food and Drug Administration (FDA). On behalf of everyone at Akebia, we welcome Keryx and its talented team, and look forward to working together to achieve a seamless transition and to build value for all of our stakeholders."

As previously announced, Keryx shareholders are entitled to receive 0.37433 common shares of Akebia for each common share of Keryx they own.

The combined company will be Akebia Therapeutics, Inc., which will continue to trade on The Nasdaq Global Market under the ticker symbol AKBA. Keryx is no longer listed for trading on The Nasdaq Capital Market.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) currently in global Phase 3 development for the treatment of anemia due to chronic kidney disease. 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 mobilization 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.

About Auryxia (ferric citrate) Tablets

Auryxia (ferric citrate) was approved by the FDA on September 5, 2014, for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis and approved by the FDA on November 6, 2017, for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. Auryxia tablets were designed to contain 210 mg of ferric iron, equivalent to 1 gram of ferric citrate, and offers convenient mealtime dosing. For more information about Auryxia and the U.S. full prescribing information, please visit www.auryxia.com.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA (ferric citrate)

Contraindication: Patients with iron overload syndrome, e.g., hemochromatosis, should not take AURYXIA® (ferric citrate).

Iron Overload: Iron absorption from AURYXIA may lead to increased iron in storage sites. Iron parameters should be monitored prior to and while on AURYXIA. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.

Risk of Overdosage in Children Due to Accidental Ingestion: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep AURYXIA away from children. Call a poison control center or your physician in case of an accidental overdose in a child.

Adverse Events: The most common adverse events occurring in at least 5% of patients treated with AURYXIA were, diarrhea, constipation, nausea, vomiting, cough, abdominal pain, and high levels of potassium in the blood.

AURYXIA contains iron and may cause dark stools, which is considered normal with oral medications containing iron.

Please click here to see full prescribing information for Auryxia.

About Akebia Therapeutics

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

Forward Looking Statements

This document contains forward-looking statements within the meaning of the federal securities law. 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,” “project,” “intend,”

“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 the potential to set a new standard of care, market and growth opportunity and potential, and the potential to realize benefits following the merger, 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 outcome of any legal proceedings related to the merger; Akebia may be adversely affected by various economic, business, and/or competitive factors, including the receipt by Keryx of a notice letters on October 31, 2018, and November 6, 2018, regarding abbreviated new drug applications submitted to the FDA requesting approval to market, sell and use a generic version of the Auryxia; risks that the anticipated benefits of the merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; the impact of legislative, regulatory, competitive and technological changes, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability; expectations for future clinical trials, the timing and potential outcomes of clinical trials and interactions with regulatory authorities. Additional factors that may affect the future results of Akebia are set forth in Akebia’s and Keryx’s respective filings with the U.S. Securities and Exchange Commission (the “SEC”), including each of Akebia’s and Keryx’s most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, the definitive joint proxy statement/prospectus filed by Akebia and Keryx on October 30, 2018, and other filings with the SEC, which are available on the SEC’s website at www.sec.gov. See in particular “Risk Factors” in the definitive joint proxy statement/prospectus, Item 1A of Akebia’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, under the heading “Risk Factors” and Item 1A of Keryx’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, under the heading “Risk Factors.” The risks and uncertainties described above and in the definitive joint proxy statement/prospectus, Akebia’s most recent Quarterly Report on Form 10-Q and Keryx’s most recent Quarterly Report on Form 10-Q are not exclusive and further information concerning Akebia and its business, including factors that potentially could materially affect its business, financial condition or operating results, may emerge from time to time. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that Akebia files from time to time with the SEC. The forward-looking statements in these materials speak only as of the date of these materials. Except as required by law, Akebia assumes no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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