Akebia Announces Approval of Vafseo® (vadadustat) in Australia and Provides Commercial Update

September 26, 2023

CAMBRIDGE, Mass., Sept. 26, 2023 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA) today announced that Australia's Therapeutic Goods Administration (TGA) has granted approval for Vafseo® (vadadustat), an oral hypoxia-inducible factor prolyl hydroxylase inhibitor for the treatment of anemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

The TGA approval for Vafseo is based on data from a comprehensive development program that included over 7,500 patients, including the global Phase 3 clinical program of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis ($INNO_2VATE$).

Vadadustat achieved the primary and key secondary efficacy endpoint in each of the two $INNO_2VATE$ studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin (Hb) between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat also achieved the primary safety endpoint of the $INNO_2VATE$ program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of major adverse cardiovascular events, which is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke across both $INNO_2VATE$ studies.

"The Akebia team continues to execute on our plan to make Vafseo available to patients globally," said John Butler, Chief Executive Officer of Akebia. "With authorization in Australia, the product is now approved in 35 countries. We also expect to resubmit our new drug application for vadadustat in the U.S. by the end of this quarter."

To support the global launch of Vafseo and prepare for a potential launch in the U.S., Akebia also announced an addition to its commercial team. Akebia appointed Graham Ray as Vice President, Key Accounts, reporting to Bennett Smith, Senior Vice President, Commercial, to lead customer engagement. Mr. Ray has a track record of successful product launches, brand growth and sales operations efficiencies, expertise he gained over nearly 20 years at Takeda Pharmaceuticals. Mr. Ray will be responsible for leading the sales efforts to launch vadadustat in the U.S., if approved, as well as work to maximize the value of Auryxia® (ferric citrate).

Akebia slightly lowered Auryxia net product revenue guidance to $170-$175 million for 2023 from $175-$180 million due to an unfavorable impact from market dynamics, volume and payor mix.

Mr. Butler continued, "I'm very pleased to have Graham join the team as he shares our commitment to patients, a core value that is integral to successful customer engagement. I believe Graham can enable the company to maximize the value of Auryxia both in the time before loss of exclusivity and during the expected TDAPA period for phosphate binders. I also look forward to his contributions to the potential launch of vadadustat next year."

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. Vadadustat is approved in Europe for the treatment of symptomatic anemia due to CKD in adult patients 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.

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, https://products.mhra.gov.uk/ and https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/swisspar.html and will be available via the Australian Therapeutic Goods Administration website here.

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

AURYXIA® (ferric citrate) is indicated for:

- The control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis
- The treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis

CONTRAINDICATION

AURYXIA (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. 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 ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis:** Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please see full Prescribing Information

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 expectations and plans with respect to the resubmission of its new drug application ("NDA") for vadadustat, including the timing thereof, plans to make Vafseo available to patients globally, statements about the potential launch of vadadustat in the U.S., and Akebia's revenue guidance for Auryxia in 2023 and assumptions related thereto, including statements about Akebia's ability to maximize the value of Auryxia and expectations about a Transitional Drug Add-on Payment Adjustment ("TDAPA") period for phosphate binders. The terms "intend," "believe," "plan," "goal," "expect," "potential," "anticipate," "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, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings, including the anticipated resubmission of the NDA for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the results of preclinical and clinical research; 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; and early termination of any of Akebia's collaborations. 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 June 30, 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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