Akebia Therapeutics Announces Positive Top-Line Results of Phase 4 IMPACT Study of Auryxia® (ferric citrate) for In-Center and Home Dialysis Patients

June 29, 2023

CAMBRIDGE, Mass., June 29, 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 topline results from IMPACT, a Phase 4 collaborative study investigating the impact of Auryxia® (ferric citrate), when used as the primary phosphate-lowering therapy, on the utilization of erythropoiesis-stimulating agent (ESA) and intravenous (IV) iron as well as on laboratory parameters indicative of phosphate and anemia management compared to the standard of care (SOC) in adult patients with chronic kidney disease (CKD) on dialysis. Auryxia is approved for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis and for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis.

IMPACT, sponsored by U.S. Renal Care Kidney Research in collaboration with Akebia, was a randomized, open-label, active-controlled, multicenter study in adult patients with CKD receiving either in-center hemodialysis or home dialysis. The study enrolled 209 adult patients who were randomized 1:1 to Auryxia (starting dose of 6 tablets per day) or to remain on SOC, defined as non-Auryxia phosphate-lowering agent, for up to 6 months. The two groups had generally similar baseline characteristics with the exception of atherosclerotic cardiovascular disease and congestive heart failure, which were more common in the SOC group.

Co-primary endpoints were the difference in mean change from baseline (month -3 to Day 1) to the efficacy evaluation period (months 4-6) in monthly ESA and IV iron doses between groups. Secondary endpoints were the difference in the proportion of patients with serum phosphate ≤5.5 mg/dL and hemoglobin (Hb) ≥10.0 g/dL, during the efficacy evaluation period (months 4-6). Treatment with Auryxia resulted in a statistically significant difference in mean monthly ESA use (-30.82 mcg/month, *P*=0.02) and a non-significant difference in mean monthly IV iron use (-37.02 mg/month, *P*=0.17). There were similar proportions of patients in each group with Hb ≥10.0 g/dL and serum phosphate ≤5.5 mg/dL.

Three patients stopped Auryxia due to gastrointestinal intolerance (n=2) or adverse events (n=1). Serious adverse events occurred in 39% of patients receiving Auryxia and 59% in those receiving SOC.

"Results from the IMPACT study provide valuable insights into the potential impact of Auryxia in adult patients with hyperphosphatemia on dialysis. These observations are important for nephrologists who are evaluating the appropriateness of Auryxia as a phosphate-lowering agent in this patient population," said Geoffrey Block, MD., Associate Chief Medical Officer and SVP, Clinical Research and Medical Affairs, U.S. Renal Care.

Dr. Block plans to present the full study results at an upcoming scientific meeting.

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. Akebia 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 U.S. Renal Care

U.S. Renal Care partners with nephrologists to care for approximately 27,000 people living with kidney disease nationwide. For over two decades, U.S. Renal Care has been a leader in clinical quality, innovation, and operational excellence – delivering the best experience and outcomes for our patients. U.S. Renal Care operates over 400 in-center and home dialysis programs across 33 states in the U.S. For more information, please visit usrenalcare.com.

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: statements about the potential impact of Auryxia in adult patients with hyperphosphatemia on dialysis. The terms "expect," "anticipate", "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, Akebia's products; 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; decisions made by health authorities, such as the FDA, with respect to regulatory filings; 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; 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.

Akebia Therapeutics Contact
Mercedes Carrasco
Mcarrasco@akebia.com

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