



Akebia Therapeutics Announces Five Poster Presentations at ASN Kidney Week 2023

October 18, 2023

CAMBRIDGE, Mass., Oct. 18, 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 that it will present data at [the American Society of Nephrology Kidney Week 2023](#) (ASN Kidney Week), which will take place at the Pennsylvania Convention Center in Philadelphia from November 2-5, 2023.

Akebia-supported posters will be presented at ASN Kidney Week on November 2, 2023, from 10:00 a.m. – 12:00 p.m. EST. Abstracts are available [here](#). ASN Kidney Week attendees can also visit Akebia at Booth #2515 in the Exhibit Hall.

Notably, Akebia will present a poster with data on alternate dosing for vadadustat, its investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor, for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. Akebia [resubmitted a New Drug Application for vadadustat](#) as a daily treatment to the U.S. Food and Drug Administration in late September and expects a Prescription Drug User Fee Act (PDUFA) date to be assigned before the end of October.

Safety and Efficacy of Vadadustat Thrice Weekly in Patients with Anemia Due to Dialysis-Dependent Chronic Kidney Disease - [Poster Board #: TH-PO983](#)

Randomized Assessment of Auryxia® (ferric citrate) Therapy for In-Center and Home Dialysis Patients - [Poster Board #: TH-PO967](#)

Hospitalizations and RBC Transfusions in Patients with DD-CKD on Auryxia® (ferric citrate) Compared to Other Phosphate Binders - [Poster Board #: TH-PO973](#)

Safety and Tolerability of Auryxia® (ferric citrate) in Children with Hyperphosphatemia Related to Chronic Kidney Disease - [Poster Board #: INFO12-TH](#)

Decision Tree Model Simulating the Burden of Hyperphosphatemia in U.S. Adult Patients with ESKD on Dialysis - [Poster Board #: TH-PO139](#)

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 35 countries, including Europe and Australia, for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis and in Japan as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis-dependent adult patients.

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 six (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 the 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 regarding the acceptance by the FDA and a decision by the FDA on its NDA for vadadustat, including the timing thereof. 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: decisions made by health authorities, such as the FDA, with respect to regulatory filings, including the anticipated FDA decision on the NDA for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; 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; 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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