Akebia Therapeutics Announces Data on Different Dosing Regimens of Ferric Citrate for Iron Deficiency Anemia Presented at 57th ERA-EDTA Virtual Congress

June 10, 2020

CAMBRIDGE, Mass., June 10, 2020 /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 data from an investigational clinical research study on different dose regimens of ferric citrate for the treatment of iron deficiency anemia was presented at the 57th ERA-EDTA Virtual Congress, which took place June 6-9, 2020. For more information about the virtual event, visit: https://www.era-edta.org/en/virtualcongress2020/.

The presentation titled, "Different Ferric Citrate Dose Regimens in the Treatment of Iron Deficiency Anaemia in Patients with Non-Dialysis-Dependent CKD: The COMPASS Trial," (Abstract SO050) was presented virtually online at the ERA-EDTA Virtual Congress. The abstract is now available in *Nephrology Dialysis Transplantation* online here.

The COMPASS trial was designed to investigate the efficacy and safety of dosing ferric citrate twice-daily as compared to the current U.S. Food and Drug Administration (FDA) approved dosing of ferric citrate three times daily in adult patients with chronic kidney disease (CKD) not on dialysis. Adult patients were randomized to receive either one ferric citrate tablet three times daily or two ferric citrate tablets twice daily. The presentation will report data through week 24 of the 48-week study.

Akebia markets ferric citrate in the U.S. as Auryxia® (ferric citrate), which is approved for two indications: the control of serum phosphorus levels in adult patients with CKD on dialysis, and the treatment of iron deficiency anemia in adult patients with CKD not on dialysis.

This study was funded by Akebia.

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.

About Auryxia® (ferric citrate) Tablets
Auryxia (ferric citrate) was approved by FDA on September 5, 2014 for the control of serum phosphorus levels in adult patients with CKD on dialysis and approved by FDA on November 6, 2017 for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. 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
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

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