Akebia Therapeutics Launches AkebiaCares, an Enhanced Patient Access Program for People with Chronic Kidney Disease

June 11, 2019

AkebiaCares connects patients, caregivers and health care providers with resources and important information to support greater access to therapy

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 11, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA) a biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease, today announced the launch of AkebiaCares, its enhanced patient access program. AkebiaCares provides patients, caregivers and health care providers with resources and important information to support greater access to Auryxia® (ferric citrate). Auryxia is the only oral iron tablet approved in the U.S. to treat non-dialysis-dependent-chronic kidney disease (CKD) adult patients for iron deficiency anemia (IDA), and dialysis-dependent CKD adult patients for hyperphosphatemia.

AkebiaCares offers services that include assisting patients and health care providers through the benefits investigation process, prior authorizations, appeals, copay assistance, and a patient assistance program for financially eligible patients. Patients can access these programs at www.akebiacares.com

“Programs like AkebiaCares can provide significant help to patients who need assistance navigating their health insurance benefits and affording out-of-pocket costs. We applaud Akebia’s commitment to helping people with CKD live healthier lives,” said LaVarne Burton, president and CEO of the American Kidney Fund, the national nonprofit fighting kidney disease with comprehensive programs that help patients from prevention through transplant.

“Akebia is committed to advancing care for patients with CKD and helping them better manage their disease,” stated John P. Butler, President and CEO of Akebia. “AkebiaCares was created to support patient needs and ensure continued access to Auryxia when prescribed by their doctor.”

About Akebia Therapeutics

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

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 CKD on dialysis and approved by the 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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Source: Akebia Therapeutics, Inc.

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