Statement from Akebia Therapeutics Regarding Litigation Against Centers for Medicare & Medicaid Services and the U.S. Department of Health and Human Services

October 25, 2021

CAMBRIDGE, Mass., Oct. 25, 2021 /PRNewswire/ -- At Akebia Therapeutics, we are driven by a collective purpose to better the lives of people impacted by kidney disease. As part of our charge to support kidney disease patients, we work to develop and market innovative therapies and ensure that all patients, especially patients disproportionately impacted by chronic kidney disease (CKD), have access to and are reimbursed for these critical therapies.

Akebia has one marketed product, Auryxia® (ferric citrate), which was approved by the FDA for the control of serum phosphorus levels in adult patients with CKD on dialysis, and for the treatment of iron deficiency anemia (IDA) in adult patients with CKD not on dialysis.

In 2018, the Centers for Medicare & Medicaid Services (CMS) made the decision to deny coverage for Auryxia for one of those indications, the treatment of iron deficiency anemia (IDA), under Medicare's outpatient prescription drug program (Medicare Part D). We filed a lawsuit in October 2019 against CMS and the U.S. Department of Health and Human Services (HHS) challenging their decision, hoping to restore coverage for those patients. We also asked the federal district court to issue an injunction to immediately restore coverage for Auryxia when used for IDA while the lawsuit was pending. We filed the lawsuit and the preliminary injunction as we believed that people living with CKD were being deprived of an FDA-approved drug, in an approved indication, because of CMS's withdrawal of full Medicare coverage for the treatment of IDA with Auryxia.

Unfortunately, the federal district court denied our motion for a preliminary injunction and the U.S. Court of Appeals for the First Circuit affirmed the district court's decision. However, the district court recently rejected a motion by CMS to dismiss our lawsuit, concluding that a drug manufacturer such as Akebia has standing and satisfies other jurisdictional requirements necessary to bring a court action directly challenging a CMS coverage decision. This is important as it opens the door for other biopharmaceutical companies to challenge unlawful CMS coverage decisions in the future, rather than requiring patients to do so through a resource-intensive and convoluted appeals process.

Given the importance of reestablishing CMS coverage for Auryxia for the treatment of IDA, many have stood alongside and supported Akebia in its efforts during the past two years. Several organizations filed amicus briefs with the district court expressing their support of our position, including the Medicare Advocacy Project of Greater Boston Legal Services, the Center for Medicare Advocacy, Massachusetts Biotechnology Council, and the Biotechnology Innovation Organization (BIO). Other organizations issued declarations in support of Akebia, including the American Kidney Fund, Dialysis Patient Citizens, and the National Kidney Foundation. In addition, members of Congress and several dozen nephrologists submitted letters in support of Auryxia coverage to CMS. We are grateful to have had such prestigious and engaged individuals and organizations in our corner advocating for kidney disease patients.

We have spent considerable resources and time pursuing this lawsuit during the past two years. We are disappointed by the previous rulings denying our preliminary injunction and discouraged by CMS' continued unwillingness to extend Auryxia coverage for IDA to all kidney disease patients. After carefully considering next steps in this litigation, we have made the difficult decision to dismiss the case against CMS and HHS. Rather, we believe it to be in the best interest of our patients and Akebia to explore alternative approaches to secure coverage. We have had ongoing engagement with U.S. legislators and are pursuing a legislative agenda that could secure Medicare coverage for Auryxia via a recently introduced bill.

All eligible patients deserve access to, and Medicare coverage for, critical, innovative therapies such as Auryxia for chronic kidney disease. We are proud of our efforts to work on behalf of patients toward these goals, which we believe are necessary to advance health equity. Our fight continues, and we remain committed to finding another path forward for those battling IDA and chronic kidney disease.

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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