Akebia Files Lawsuit Against CMS for 2018 Action Rescinding Medicare Part D Coverage of FDA-Approved Auryxia® for its Iron Deficiency Anemia Indication and Imposing a Prior Authorization Requirement for its Hyperphosphatemia Indication

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CMS continues to deny Medicare beneficiaries with chronic kidney disease full access to this innovative therapy

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 15, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a fully integrated biopharmaceutical company focused on bettering the lives of people impacted by kidney disease, today filed a complaint in federal district court against the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (HHS). The lawsuit challenges a September 2018 decision by CMS that rescinded Medicare Part D coverage of Auryxia® (ferric citrate), Akebia's FDA-approved drug, when used for the treatment of iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD) not on dialysis (the IDA Indication). The legal action also seeks to reverse a related decision by CMS that imposed a prior authorization requirement for Auryxia when used for the control of serum phosphorus levels in adult patients with CKD on dialysis (the Hyperphosphatemia Indication).

In the complaint, Akebia asks the court to restore coverage of Auryxia for the IDA Indication and to remove the prior authorization requirement for the Hyperphosphatemia Indication.

Auryxia was approved by the U.S. Food and Drug Administration (FDA) on September 5, 2014 for the Hyperphosphatemia Indication and approved by the FDA on November 6, 2017 for the IDA Indication. Auryxia is the only oral product approved in the U.S. to treat both adult patients with CKD not on dialysis for IDA and adult patients with CKD on dialysis for hyperphosphatemia.

"Together with medical experts and numerous patient advocacy groups, we've been working tirelessly over the past year to urge CMS to restore coverage for Auryxia's IDA indication and remove the prior authorization requirement for the hyperphosphatemia indication. We believe CMS has a legal obligation to restore coverage. Because CMS has failed to act, we find ourselves with no other choice than to pursue litigation seeking to restore access for Medicare patients to this innovative, clinically effective treatment," said John P. Butler, President and Chief Executive Officer of Akebia.

For additional information, a copy of the complaint can be found by visiting HERE.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for people living 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, which does not form a part of this release.

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

Forward-Looking Statements

Statements in this press release regarding 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, including but not limited to statements regarding the CMS determination and resulting denial of Medicare beneficiaries with CKD full access to Auryxia; our choice to pursue litigation seeking to restore access to Auryxia; and statements regarding the benefits of Auryxia, including its innovative, clinically effective and cost-effective nature. The terms "believe," "expect" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the timing and content of decisions made by judicial and/or regulatory authorities; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; the competitive landscape for Auryxia; risks associated with market acceptance and coverage and reimbursement of Auryxia; the risks associated with potential generic entrants for Auryxia; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for Auryxia. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 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 Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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Source: Akebia Therapeutics, Inc.

Kristen K. Sheppard, Esq
VP, Investor Relations
ir@akebia.com