# Akebia Therapeutics Announces Collaboration Partner's Positive Top-line Results of Phase 3 Clinical Study of Riona® (ferric citrate hydrate) in Adult Patients with Iron Deficiency Anemia in Japan

July 10, 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 10, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA), today announced that its collaboration partner, Japan Tobacco, Inc. (JT) and its subsidiary Torii Pharmaceutical Co., Ltd. (Torii), reported positive top-line results from a pivotal Phase 3 comparative study evaluating Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate) for the treatment of iron deficiency anemia (IDA) in adult patients in Japan. JT and Torii hold the exclusive rights to develop and commercialize Riona in Japan. Upon successful completion of its Phase 3 program, JT and Torii stated that they expect to file an application for approval of IDA as an additional indication for Riona in Japan.

Riona was approved in Japan in 2014 as an oral treatment for the improvement of hyperphosphatemia in patients with chronic kidney disease (CKD), including dialysis-dependent and non-dialysis dependent CKD. Ferric citrate is approved and marketed in the United States by Akebia under the trade name Auryxia® (ferric citrate) for the control of serum phosphorus levels in adult patients with CKD on dialysis and for the treatment of IDA in adult patients with CKD not on dialysis.

"We congratulate JT and Torii on this important step toward expanding Riona's indication and look forward to their progress to bring Riona to adult patients for the treatment of IDA in Japan," stated John P. Butler, President and Chief Executive Officer of Akebia.

**About JT and Torii's Phase 3 Study in Iron Deficiency Anemia**
JT and Torii's public announcement highlighted that their study used a double blind, randomized and parallel-group design to evaluate the efficacy and safety of oral Riona in comparison to oral sodium ferrous citrate over seven weeks in adult patients with IDA. The companies have previously disclosed a target sample size of 480 patients. According to their announcement, "The top-line results show that the study met the primary endpoint by establishing non-inferiority of Riona compared with a control drug in the changes in hemoglobin level from baseline at week 7. Riona showed a favorable tolerability profile on safety within the treatment period. Regarding the safety endpoint, the incidence rates of nausea / vomiting (adverse events) were 13.0% / 3.2% (Riona) and 32.7% / 15.2% (control drug), respectively."

Please visit https://www.jt.com/media/news/2019/pdf/20190709_E01.pdf to access the complete public announcement from JT and Torii, which does not form a part of this release.

**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

**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 potential timing and basis of the application for approval of iron deficiency anemia as an additional indication for Riona in Japan and the progress toward expanding Riona's indication. The terms "anticipate," "believe," "expect," "opportunity," "planned," "potential," "target," "will" 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 risks associated with market acceptance and coverage and reimbursement of Riona; the risks associated with potential generic entrants for Riona; manufacturing risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize Akebia's product candidates and operate the company, and the actual expenses associated therewith; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for Riona; the actual time it takes to initiate and complete preclinical and clinical studies; the competitive landscape for Riona; the scope, timing, and outcome of any ongoing legal, regulatory and administrative proceedings; 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 Riona. 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 March 31, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190710005225/en/

Source: Akebia Therapeutics, Inc.

Kristen K. Sheppard, Esq.
ir@akebia.com