Akebia Therapeutics Announces Collaboration Partner's Submission of Supplemental New Drug Application for Use of Riona® (ferric citrate hydrate) to Treat Adult Patients with Iron Deficiency Anemia in Japan

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CAMBRIDGE, Mass., May 18, 2020 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for people living with kidney disease, announced today that its collaboration partner, Japan Tobacco, Inc. (JT), has filed a supplemental New Drug Application (NDA) with the Pharmaceuticals and Medical Devices Agency (PMDA) seeking an additional indication for Riona® Tablets 250mg (generic name in Japan: ferric citrate hydrate) to treat adult patients with iron deficiency anemia (IDA) in Japan. JT and its subsidiary, Torii Pharmaceutical Co., Ltd. (Torii), made a public announcement, which is available here: https://www.torii.co.jp/en/release/2020/20200515_E1.pdf.

The NDA is based on JT and Torii's Phase 3 clinical study and other clinical studies in adult patients with IDA in Japan. To access the complete public announcement on the Phase 3 study from JT and Torii, please visit: https://www.jt.com/media/news/2019/pdf/20190709_E01.pdf.

Riona was approved in Japan in 2014 as an oral treatment for the improvement of hyperphosphatemia in patients with chronic kidney disease (CKD) both on dialysis and not on dialysis. 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.

"IDA can have a significant impact on the health and quality of life of people living with kidney disease. As an oral drug, Auryxia enables CKD patients not on dialysis, a high-risk population, to be treated for IDA while remaining safely at home," said Michel Dahan, Senior Vice President and Chief Operating Officer of Akebia. "We congratulate JT and Torii on their work and are excited by their progress toward expanding Riona's label to treat adult patients with IDA in Japan."

The hyperlinks in this release do 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 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

Contact
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