Akebia Therapeutics Announces Approval for Additional Indication of Riona® (ferric citrate hydrate) for the Treatment of Iron Deficiency Anemia in Adult Patients in Japan

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CAMBRIDGE, Mass., March 24, 2021 /PRNewswire/ -- Akebia Therapeutics, Inc. (Nasdaq: AKBA), today announced that its collaboration partner, Japan Tobacco Inc. (JT), received approval from the Pharmaceuticals and Medical Devices Agency (PMDA) for an additional indication for Riona® Tablets 250mg (Riona) (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.jt.com/media/news/2021/pdf/20210323_E2.pdf.

In 2014, JT obtained manufacturing and marketing approval for Riona, which is currently distributed by Torii as an oral treatment for improvement of hyperphosphatemia in adult patients with chronic kidney disease (CKD) both on dialysis and not on dialysis in Japan. Ferric citrate is also approved and marketed in the United States by Akebia as 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 the expansion of Riona's label and thank them for the work they have done to bring a convenient oral medication to patients with IDA in Japan," said John P. Butler, Chief Executive Officer of Akebia.

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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.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by 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.

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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