Akebia Therapeutics® Announces Settlement of Auryxia® Patent Litigation with Par Pharmaceutical

August 5, 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 5, 2019-- Akebia Therapeutics, Inc. (Nasdaq: AKBA), today announced that its wholly-owned subsidiary, Keryx Biopharmaceuticals, Inc., and its licensor Panion & BF Biotech, Inc., have entered into a Settlement and License Agreement (Agreement) with Par Pharmaceutical, Inc., an Endo International company (Par). This settlement resolves patent litigation brought by Keryx and Panion in response to Par's Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of Auryxia (ferric citrate) tablets prior to the expiration of the applicable patents.

Pursuant to the terms of the Agreement, the companies will grant Par a license to market its generic version of Auryxia in the United States beginning on March 20, 2025 (subject to U.S. FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature. Additionally, in accordance with the Agreement, the parties will terminate all ongoing Hatch-Waxman litigation between Keryx and Panion and Par regarding Auryxia patents pending in the U.S. District Court for the District of Delaware and the U.S. District Court for the Southern District of New York.

The Agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

"We are pleased to have reached this settlement and believe it reinforces the strength of our intellectual property, including the fifteen patents listed in the Orange-Book that cover Auryxia," stated John P. Butler, President and Chief Executive Officer of Akebia.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company focused on the development and commercialization of therapeutics for people 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 chronic kidney disease (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 resolution of patent litigation with Par and all related settlement terms, including the date of generic entry and the potential for earlier generic entry under certain circumstances; the strength of Akebia's intellectual property; the termination of all Par Hatch-Waxman litigation regarding Auryxia; and the submission of the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. The terms "anticipate," "expect," "potential," "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 the timing and content of decisions made by regulatory authorities; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; the risk that we lose, or settle on less favorable terms, other ANDA litigation, or that other ANDA filers enter the market earlier than March 20, 2025, as well as any other potential settlements; 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 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.

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