Keryx Biopharmaceuticals Inc.

Fact Sheet

KERX

LISTED

NASDAQ

KERYX PHARMACEUTICALS

QUICK REFERENCE

Company: **Keryx Pharmaceuticals Inc.**
Ticker Symbol: **KERX**
Shares Outstanding: **105,649,571**
Website: **www.KERYX.com**

BUSINESS SUMMARY

Keryx Biopharmaceuticals is focused on bringing innovative medicines to market for people with renal disease. In December 2014, the company launched its first FDA-approved medicine, Auryxia™ (ferric citrate) in the United States. In January 2014, ferric citrate was approved for use in Japan, where it is being marketed as Riona® by Keryx's Japanese partner, Japan Tobacco Inc. and Torii Pharmaceutical Co. Ltd. In September 2015, the European Commission granted European market authorization for Fexeric® (ferric citrate coordination complex).

AURYXIA

Auryxia™ (ferric citrate) was approved by the U.S. Food and Drug Administration on September 5, 2014 and is indicated in the U.S. for the control of serum phosphorus levels in patients with CKD on dialysis. The U.S. approval of Auryxia was based on data from the company's Phase 3 registration program. In the Phase 3 clinical trials, Auryxia effectively reduced serum phosphorus levels to within the KDOQI guidelines range of 3.5 to 5.5 mg/dL.
Auryxia binds with dietary phosphate in the GI tract and precipitates as ferric phosphate. The unbound portion of Auryxia has been shown to increase serum iron parameters including ferritin and transferrin saturation (TSAT). Iron absorption from Auryxia may lead to excessive elevations in iron stores. Accordingly, physicians should assess and monitor iron parameters before starting and while on Auryxia, and may need to decrease or discontinue IV iron for these patients. The most common adverse events for Auryxia treated patients were gastrointestinal-related, including diarrhea, nausea, vomiting and constipation. For more information about Auryxia and the US full prescribing information, visit www.Auryxia.com.

POTENTIAL LABEL EXPANSION

Pivotal Phase 3 Trial Aimed at Increasing the Number of Adults Eligible for Treatment with Ferric Citrate

In March, the company announced that its 24-week pivotal Phase 3 trial evaluating ferric citrate for the treatment of iron deficiency anemia in adults with stage 3-5 non-dialysis dependent CKD demonstrated statistically significant differences between ferric citrate- and placebo-treated patients for the primary and all pre-specified secondary endpoints. Specifically, 52 percent (61/117) of patients who received ferric citrate achieved the primary endpoint, which was a 1g/dL or greater rise in hemoglobin at any time point during the 16-week randomized efficacy period, compared with 19 percent (22/115) in the placebo group ($p<0.001$). Importantly, the vast majority of patients who achieved the primary endpoint (57/61) had a durable response. In terms of safety, during the randomized efficacy period, the majority of adverse events reported were mild to moderate, with the most common being diarrhea.

The company intends to submit an sNDA for approval to the U.S. FDA in the third quarter of 2016.

Keryx plans to submit detailed Phase 3 results for presentation at the American Society of Nephrology's 2016 Kidney Week taking place November 15 – 20, 2016, and plans to submit data for possible publication in a peer reviewed medical journal.

CONTACT INFORMATION

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Keryx Pharmaceuticals Inc.<> KERX

RECENT PRESS RELEASES (headlines & excerpts)

Keryx Biopharmaceuticals Announces First Quarter 2016 Financial Results

April 28, 2016

- Company reported $6.8 million in first quarter total revenues, including $5.6 million of Auryxia™ (ferric citrate) net U.S. product sales
- 2016 product sales and cash operating expense guidance reiterated
- Company on track to submit supplemental new drug application (sNDA) in the third quarter of 2016 seeking to expand ferric citrate's indication

Conference Call Information

Keryx will host an investor conference call today, Thursday, April 28, 2016, at 8:00 a.m. ET to discuss financial results for the first quarter of 2016. In order to participate in the conference call, please call 1-(888) 396-2320 (U.S.), 1-(774) 264-7560 (outside the U.S.), call-in ID: 90827914. The call will also be webcast with slides, which will be accessible through the Investors section of the company's website at www.keryx.com. The audio replay will be available at **www.keryx.com** for a period of 15 days after the call.

Keryx Biopharmaceuticals Announces Positive Top-line Results from Pivotal Phase 3 Study of Ferric Citrate for the Treatment of Iron Deficiency Anemia in Adults with Non-Dialysis Dependent Chronic Kidney Disease

March 26, 2018

- Registration trial demonstrated statistically significant differences versus placebo for the primary and all pre-specified secondary endpoints
- Majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL increase in hemoglobin vs. 19 percent in the placebo group
- Safety profile consistent with previously reported clinical studies
- Data support Keryx's plan to submit a supplemental new drug application (sNDA) in the third quarter of 2016 seeking to expand ferric citrate's indication

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DEVELOPMENT

Iron Deficiency Anemia Overview

Iron deficiency anemia is the most common type of anemia and among the most common complication of chronic kidney disease. Anemia is a condition where the body does not have enough healthy red blood cells to deliver adequate oxygen throughout the body. This is caused by a lack of iron. When your body does not have enough iron, it will make fewer red blood cells or red blood cells that are too small.

IDA begins to develop in the early stages of chronic kidney disease and tends to worsen as CKD progresses. The majority of symptoms are mild at first and develop slowly. If left untreated, people with IDA will live a poor quality of live and experience symptoms, including headaches, extreme fatigue, loss of appetite, dizziness, concentration and muscle weakness.

It is estimated that approximately 16 million people in the U.S. today have stages 3-5 CKD, with approximately 1.7 million of these people under the care of a nephrologist. Of these patients, approximately 650,000 have received treatment for IDA, with the majority treated with oral iron therapy that is typically not effective due to difficult to tolerate side effects and limited absorption. This results in a need for an improved treatment for IDA.

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Keryx Pharmaceuticals Inc.

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