



Chiesi Group and Apotex Inc. finalize agreement for acquisition of Ferriprox® (deferiprone)

- Chiesi Group expands distribution network via acquisition for worldwide product rights.
- Chiesi Group will establish offices in Toronto, Canada.

PARMA, Italy , Jan. 13, 2020 (GLOBE NEWSWIRE) -- **Chiesi Farmaceutici S.p.A.**, an international research-focused healthcare Group (**Chiesi Group**) and **Apotex, Inc., together with its US subsidiary, ApoPharma USA Inc.**, an innovative drug company, active in the hematology and neurodegeneration therapeutic areas, **today announced** that Chiesi Group has finalized an agreement for the acquisition of the worldwide rights to Ferriprox® (deferiprone). Chiesi Group previously served as a distributor of Ferriprox® in Italy, Brazil, Turkey and certain other countries. Ferriprox® is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. **Thalassemia syndromes** are a group of rare inherited hematological conditions including beta-thalassemia. With the agreement approved by all relevant regulatory authorities, the Ferriprox® franchise will become part of the Chiesi Group's growing portfolio of rare disease products. The team of approximately 50 ApoPharma employees will transition to Chiesi Group, providing a foundation for Chiesi to establish offices in Toronto, Canada.

"Our companies boast more than 20 years of successful collaboration on Ferriprox®" said **Dr. Michael Spino, inaugural president of Chiesi Canada**. "I look forward to this new venture and to exploring how our ApoPharma team can strengthen Chiesi's plan for new drug development in the rare disease space."

"Through this transaction, we will remain dedicated to our mission to provide patients affected by this hematological condition with a proven therapeutic option," said **Ugo Di Francesco, Chiesi Group CEO**. "The addition of Ferriprox® to our portfolio strengthens our offerings to patients and expands our commitment to the rare disease communities around the world. In addition, our presence in Canada represents an entirely new geography for our company and an important milestone in our continued focus on meeting the needs of patients around the world."

"In addition to bringing a trusted therapy to our portfolio, this acquisition is a strong reflection of Chiesi's commitment to be a leader in development and marketing of treatments for rare diseases around the world. We want to improve the lives of people living with rare diseases by providing an integrated set of proven-effective solutions and by partnering with patients, caregivers, patient associations, healthcare practitioners and regulatory authorities. We very much look forward to integrating the ApoPharma team into our organization," said **Giacomo Chiesi, Head of Chiesi Global Rare Diseases**.

Thalassemia syndromes are characterized by impaired hemoglobin production. In certain cases, such as with beta-thalassemia, severe forms of this genetic disorder can lead to life-threatening complications when left untreated or undertreated. Patients affected by this inherited disease require long-term blood transfusions that can put patients at risk of developing very high levels of iron in their blood and vital organs. As the level of labile iron rises, it begins to generate free radicals that can be toxic to proteins and membranes. The liver can tolerate fairly high levels of iron before it exhibits toxicity, but the heart and endocrine glands (pancreas, thyroid, hypothyroid, gonads, etc.) exhibit toxicity at much lower levels. Ferriprox® works by binding to labile iron in the tissues and circulation, thereby inactivating it. Labile iron is then excreted from the body primarily via urine.

Indication

Ferriprox® (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival.

Limitation of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

Important Safety Information

WARNING: AGRANULOCYTOSIS/NEUTROPENIA

- Ferriprox can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis.
- Measure the absolute neutrophil count (ANC) before starting Ferriprox and monitor the ANC weekly on therapy.
- Interrupt Ferriprox if infection develops and monitor ANC more frequently. Advise patients taking Ferriprox to report immediately any symptoms indicative of infection.

Ferriprox is contraindicated in patients with known hypersensitivity to deferiprone or to any of the excipients in the formulation.

Ferriprox can cause fetal harm. Women should be advised of the potential hazard to the fetus and to avoid pregnancy while on this drug.

In clinical studies, 7.5% of 642 subjects treated with Ferriprox developed increased alanine aminotransferase (ALT) values. Four (0.62%) Ferriprox-treated subjects discontinued the drug due to increased serum ALT levels and 1 (0.16%) due to an increase in both ALT and AST. Monitor serum ALT values monthly during therapy with Ferriprox, and consider interruption of therapy if there is a persistent increase in the serum transaminase levels.

Decreased plasma zinc concentrations have been observed on Ferriprox therapy. Monitor plasma zinc, and supplement in the event of a deficiency.

Avoid concomitant use with other drugs known to be associated with neutropenia or agranulocytosis; however, if this is not possible, closely monitor the absolute neutrophil count. Allow at least a 4-hour interval between Ferriprox and mineral supplements or antacids that contain polyvalent cations (e.g., iron, aluminum, or zinc). Avoid use of UGT1A6 inhibitors with Ferriprox.

Advise patients not to breastfeed during treatment with Ferriprox and for 2 weeks after the last dose.

The most common (incidence $\geq 5\%$) adverse reactions are nausea, vomiting and abdominal pain, ALT increased, arthralgia, and neutropenia.

Please see [Full Prescribing Information](#), including **Boxed WARNINGS**, and [Medication Guide](#).

About Chiesi Group

Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused Healthcare Group, with over 80 years of experience in the pharmaceutical industry, and with a global presence in 29 countries. Chiesi researches, develops, and markets innovative drugs in the respiratory therapeutics, specialist medicine, and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and integrated with 4 other key R&D groups in France, the USA, the UK, and Sweden to advance Chiesi's pre-clinical, clinical, and registration programs. Chiesi employs over 5,600 people. Chiesi Group is a certified Benefit corporation. For more information, please visit www.chiesi.com.

About Apotex Inc.

Apotex Inc. is a proudly Canadian, global pharmaceutical company that produces high-quality, affordable medicines for patients around the world. Apotex employs more than 8,000 people worldwide in manufacturing, R&D, and commercial operations. Apotex Inc. exports to more than 100 countries and territories and operates in more than 45 countries, with a significant presence in Canada, the US, Mexico, and India. Through vertical integration, Apotex is comprised of multiple divisions and affiliates including Apotex Inc., focused on generics; Apobiologix, a division of Apotex Inc. focused on biosimilar development; Aveva, an affiliate of Apotex Inc. fully integrated global developer and manufacturer of complete transdermal solutions; Apotex Consumer Products, a division of Apotex Inc. focused on brand name products; and Global Active Pharmaceutical Ingredients (GAPI), a division of Apotex Inc. focused on the manufacturing of active pharmaceutical ingredients (API) for Apotex and third parties. For more information visit: www.apotex.com. ApoPharma Inc. was the Innovative Drug Division of the Apotex family of companies. ApoPharma's research focus is on the use of medicines to treat disorders caused or worsened by excessive iron or faulty processing of iron in cells in the body. This includes generalized iron overload, which affects patients who must undergo repeated blood transfusions.

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