

PRESS RELEASE

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Topic Injectafer[®] (Ferinject[®]): Non Approvable Letter from FDA

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Injectafer[®] (Ferinject[®]): non-approvable letter received from the FDA

The U.S. Food and Drug Administration's (FDA) issued a non-approvable letter for the new intravenous iron replacement therapy, Injectafer[®] (Ferinject[®], ferric carboxymaltose injection), for the treatment of iron deficiency anaemia in postpartum women and women with heavy uterine bleeding. The FDA cited concerns with the benefit/risk ratio in the intended patient population, and the proposed dosing regimen and requested additional safety data from clinical studies.

Galenica was informed yesterday by Luitpold Pharmaceuticals, Inc., the US licensing partner of Vifor Pharma, that they have received a non-approvable letter from the U.S. Food and Drug Administration for Luitpold's New Drug Application for Injectafer[®] (name of Ferinject[®] in the USA, ferric carboxymaltose injection), the new intravenous (IV) iron replacement therapy for the treatment of iron deficiency anaemia in postpartum women and women with heavy uterine bleeding.

Injectafer[®] is a novel and new IV iron therapy, developed by Galenica's subsidiary Vifor Pharma, which provides for the delivery of up to 1000mg of iron in as little as 15 minutes. The innovative injectable iron replacement product was registered under the name Ferrinject[®] by the public health authorities in 18 EU countries in June 2007 and in Switzerland in November 2007. It has been used to treat iron deficiency diseases in Germany since November 2007 and has been on sale in Switzerland from mid-February 2008.

In its letter, the FDA said it needs more information to better characterize the mortality safety signal detected in clinical studies of Injectafer[®]. These concerns were discussed during the FDA's February 1, 2008 Drug Safety and Risk Management Advisory Committee hearing. At the conclusion of the meeting, the Committee voted that the available safety and efficacy data support a favourable risk / benefit profile for Injectafer[®] in the treatment of iron deficiency anaemia in postpartum women or women with heavy uterine bleeding who have had an unsatisfactory response to oral iron or were intolerant of oral iron. This recommendation is in line with the current approvals in Europe.

In its letter, however, the FDA repeated its concerns and requested additional safety data from clinical studies in this patient population.

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“We are disappointed by the FDA’s decision” said Etienne Jornod, Chairman and CEO of the Galenica Group. “We and our US partner Luitpold continue to believe that Injectafer® / Ferinject® is an important new IV iron treatment that can meet the significant unmet medical needs of postpartum women and women with heavy uterine bleeding who experience iron deficiency anaemia. We are committed to working together with Luitpold in furthering ongoing discussions with the Agency to better understand its perspective and to work on defining a regulatory path forward that will lead to NDA approval.”

About iron deficiency anaemia in postpartum women and women with heavy uterine bleeding

Iron deficiency anaemia represents a significant health issue in women. More than half of the 4 million women in the United States who give birth each year develop iron deficiency and approximately 1 million of these women progress to iron deficiency anaemia. In addition, as many as one in five women of reproductive age suffer from heavy uterine bleeding, defined as excessive or prolonged blood loss.

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Galenica is a diversified group active throughout the healthcare market which, among other things, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. The Galenica Group enjoys a leading position in all its business sectors – Pharma, Logistics, HealthCare Information and Retail. A large part of the Group’s income is generated by international operations.

Additional information concerning the Galenica Group can be found on www.galenica.com.