

## PRESS RELEASE

Date December 15<sup>th</sup>, 2011  
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Subject FDA assigns PDUFA Date for Injectafer<sup>®</sup> NDA

*((for public release as from 7.00 a.m. CET on December 15<sup>th</sup>, 2011))*

### FDA assigns PDUFA Date for Injectafer<sup>®</sup> NDA

**Galenica announced in October 2011 that its US partner Luitpold Pharmaceuticals, Inc., had submitted a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for Injectafer<sup>®</sup> (US brand name of Ferinject<sup>®</sup>, ferric carboxymaltose) for the treatment of iron deficiency anaemia. Galenica today announces that the FDA has notified Luitpold Pharmaceuticals, Inc., that it has assigned a Prescription Drug User Fee Act (PDUFA) target action date of 3 August 2012.**

The FDA has assigned 3 August 2012 as the Prescription Drug User Fee Act (PDUFA) target action date to complete its review of the New Drug Application (NDA) for Injectafer<sup>®</sup> for the treatment of iron deficiency anaemia.

The PDUFA action date is a target date for the FDA to complete its review. The FDA could respond sooner or extend the action date as the review and discussions progress.

For more information, please visit:

[http://www.galenica.com/en/medien/medienmitteilungen/2011/20111013\\_626568872\\_meldung.php](http://www.galenica.com/en/medien/medienmitteilungen/2011/20111013_626568872_meldung.php)

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***Galenica** is a diversified group active throughout the healthcare market which, among other things, develops, manufactures, markets and distributes pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. In all of its business sectors – Pharma, Logistics and Retail – the Galenica Group enjoys a leading position. A large part of the Group's income is generated by international operations. Galenica is listed on the Swiss Stock Exchange (SIX Swiss Exchange, GALN, security number 1,553,646).*

*For more information please visit the company's website at [www.galenica.com](http://www.galenica.com).*

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**Iron Deficiency Anemia (IDA)** is a state in which iron stores are inadequate for normal blood formation, as the iron requirements exceed the supply. In severe cases red cells in a patient with IDA are both microcytic (small) and hypochromic (pale), and values for mean corpuscular volume (MCV) and mean corpuscular Hb concentration (MCHC) are characteristically reduced. According to the World Health Organization (WHO) it is estimated that about 700 million people have iron deficiency anaemia (IDA). [Source: World Health Organization. Preventing and controlling Iron Deficiency Anaemia through primary health care. Available at: [http://www.who.int/nutrition/publications/micronutrients/anaemia\\_iron\\_deficiency/ida\\_preventng\\_contr\\_of\\_primary\\_healthcare.pdf](http://www.who.int/nutrition/publications/micronutrients/anaemia_iron_deficiency/ida_preventng_contr_of_primary_healthcare.pdf)]

**Injectafer<sup>®</sup>** is an innovative non-dextran intravenous iron (i.v.) replacement therapy discovered and developed by Vifor Pharma, a company of the Galenica Group. Ferric carboxymaltose is the active pharmaceutical ingredient of Injectafer<sup>®</sup>. To date, **Ferinject<sup>®</sup>** (brand name of Injectafer<sup>®</sup> outside the US) has gained marketing authorisation in 37 countries worldwide for the treatment of iron deficiency where oral iron is ineffective or cannot be used. In many countries, intravenous iron replacement products are primarily used to treat dialysis patients. However, iron deficiency is also a complication of many other illnesses. Vifor Pharma is evaluating new opportunities in the treatment of iron deficiency with Ferinject<sup>®</sup> in different therapeutic areas. Further trials with Ferinject<sup>®</sup> in chronic kidney disease (CKD), oncology (anaemia in cancer patients), cardiology (chronic heart failure), patient blood management and gynaecology are ongoing.