

## **PRESS RELEASE**

Date 11 December 2007  
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Subject Ferinject<sup>®</sup>: registration in Switzerland and first market launch worldwide in Germany

*((for public release on 11 December 2007 from 7.30 a.m. Swiss time))*

### **Further milestones achieved for Ferinject<sup>®</sup>**

**In June, UK medicines agency MHRA became the first authority worldwide to approve the registration of Ferinject<sup>®</sup>. Now the Swiss regulatory agency Swissmedic has also registered the medicine. In November, Ferinject<sup>®</sup> was marketed for the first time in Germany, and the market launch in Switzerland is scheduled for the beginning of 2008. Ferinject<sup>®</sup> is a next-generation intravenous iron replacement product, developed by Vifor (International) for the treatment of iron deficiency and iron deficiency anaemia. The new medicine is characterised by its reliable, simple and thus overall cost-effective use. Ferinject<sup>®</sup> thus not only revolutionises the treatment of iron deficiency in established therapeutic areas, such as nephrology, but also opens up completely new opportunities for further indications.**

#### **Use in various indication areas**

Ferinject<sup>®</sup> is approved in Europe for the treatment of diagnosed iron deficiency and for use in patients with a variety of conditions. The medicine can thus be used not only in traditional therapeutic areas such as nephrology (kidney disease), but also in other areas, such as gastroenterology (diseases of the gastrointestinal tract), oncology, obstetrics and gynaecology.

#### **Germany: the first market launch worldwide**

At the end of June 2007, the UK Medicines and Healthcare products Regulatory Agency (MHRA) became the first authority worldwide to approve the registration of Ferinject<sup>®</sup>. Since the UK is a reference country in the decentralised drug registration process, the new product will be registered in a total of 18 EU countries. In November, Ferinject<sup>®</sup> was launched for the first time in Germany via the Galenica subsidiary Vifor Deutschland. Vifor Deutschland was founded in February 2007 with the aim of also marketing its own products abroad through its subsidiary company. The medicine is produced by Vifor (International) in Switzerland (St. Gallen). The product will be successively rolled out in other European countries following receipt of the registration documents from the 18 EU countries in which Ferinject<sup>®</sup> has been approved. Apart from Germany, five other countries have already issued the required documents.

#### **Swiss market launch set for the beginning of 2008**

In November the Swiss regulatory agency Swissmedic also approved the registration of Ferinject<sup>®</sup>. The decisions regarding reimbursability and pricing are expected by the end of 2007, and the launch on the Swiss market is scheduled for the beginning of 2008.

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### **Registration status in the USA**

The registration dossier for Ferinject<sup>®</sup> for the US market was submitted to the US Food and Drug Administration (FDA) by Luitpold Pharmaceuticals, Inc., the US licence partner of Vifor (International). The FDA announced yesterday that a meeting of the Drug Safety and Risk Management Advisory Committee will be held on 1 February 2008. The FDA requested additional information on efficacy and safety of the product. Luitpold Pharmaceuticals, Inc., has submitted the necessary documentation to the FDA which will be discussed by the Advisory Committee.

The invitation from the FDA is a normal stage in the US New Drug Application (NDA) process. No conclusions can be drawn with regard to the potential approval or non-approval of Ferinject<sup>®</sup> for the US market as a result of the decision to convene a meeting of the Advisory Committee.

The Drug Safety and Risk Management Advisory Committee has no decision-making authority itself, and will make a recommendation to the FDA with regard to the points discussed. This recommendation is not binding on the FDA.

A decision from the FDA on the pending NDA application can be expected by the end of the first quarter of 2008.

### **High demand for intravenously administered iron replacement products.**

According to the WHO, two billion people worldwide suffer from iron deficiency. The global market for iron replacement products has grown sharply in the last six years, with a threefold increase in the demand for intravenously administered medicines alone. With its product Venofer<sup>®</sup>, the Galenica subsidiary Vifor (International) maintains a leadership position worldwide in this sub-market. The company aims to further expand its global leadership with Ferinject<sup>®</sup>. The outstanding properties of Ferinject<sup>®</sup> serve to revolutionise the intravenous treatment of iron deficiency both for patients and for supervisory healthcare professionals, offering impressive development potential for the new product.

### **Effective, simple and well-tolerated form of treatment**

Ferinject<sup>®</sup> (ferric carboxymaltose) is an intravenous iron replacement product from the research & development pipeline of Vifor (International). Ferric carboxymaltose, the active substance of Ferinject<sup>®</sup>, is extremely stable and provides slow, controlled release of iron. As a result, the iron is completely integrated into physiological iron transport routes and can be delivered to specific storage organs and bone marrow for blood formation. Moreover, almost all the iron is assimilated. Compared with conventional products, Ferinject<sup>®</sup> has the major advantage that patients can be supplied with iron in higher doses and more quickly. Thus, with Ferinject<sup>®</sup>, a single dose of 1,000 mg of iron can be administered in a 15-minute intravenous infusion. With other products, either substantially lower doses must be given or - due to potential risks - higher doses can only be administered by infusion over a period of several hours. For patients, this means several visits to the doctor or even admission to a day clinic.

Thanks in particular to optimisation of the time needed for infusion, Ferinject<sup>®</sup> makes it easier to integrate iron replacement therapy into the treatment routine, opening up the possibility of using intravenously administered iron in a wide range of indications. Taking routine processes into account also has economic advantages: Many patients in the future will be able to receive the amount of iron required for their treatment in a single outpatient visit, instead of having to attend several sessions. In addition, consultation time will be considerably reduced. These savings will also benefit the healthcare system overall. Therapy with Ferinject<sup>®</sup> is effective, easy to administer and also well tolerated thanks to its good safety profile.

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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 on the Galenica Group can be found at [www.galenica.com](http://www.galenica.com).

The Galenica subsidiary **Vifor (International)** is mainly active in the research, development and marketing of oral and parenteral iron deficiency treatments (Ferinject<sup>®</sup>, Venofer<sup>®</sup>, Maltofer<sup>®</sup>). As a global market leader in the fight against iron deficiency anaemia, Vifor (International) is expanding its core competencies further into international markets. The company's iron replacement products are sold in over 80 countries. With its over-the-counter products Vifor plays a pioneering role in Switzerland and a select number of export countries.

Additional information on Vifor (International) can be found at [www.vifor.com](http://www.vifor.com).