OTE0002 5 CA 1251 PRN0007 Di, 22.Okt 2019
Gesundheit/Ärzte/Human Interest

- Oral ferric maltol may offer an alternative treatment option to IV iron even in patients who have failed or not tolerated current oral iron treatments[1]

Amsterdam (ots/PRNewswire) - Norgine B.V. highlighted new data from a study supported by its partner company Shield Therapeutics, presented today at the United European Gastroenterology (UEG) Week in Barcelona showing that ferric maltol, a novel oral iron replacement therapy, was found to be non-inferior to intravenous (IV) ferric carboxymaltose (FCM).[1]

Dr. Stefanie Howaldt from the Hamburg Research Institute for IBD, HaFCED e.K., Germany and Principal Investigator of the study presented the new research findings during her oral presentation at UEG Week. Dr. Howaldt said on the importance of the new data for patients: "We know that ferric maltol is effective with an established tolerability profile in patients with IBD based on earlier research but no head-to-head studies between ferric maltol and IV iron have been conducted so far. The results of this head-to-head study may facilitate physicians' treatment decisions enabling them to improve clinical practice and help more patients with IDA and IBD, in some of whom previous oral iron treatments may not have worked. Until recently, these patients may have needed IV administration in hospital but now ferric maltol represents an alternative oral treatment option."

Iron deficiency anaemia can be a serious complication of IBD resulting from inflammation, chronic mucosal blood loss and iron malabsorption. [1] Treatment of IDA involves iron-replacement therapy often with oral ferrous iron supplementation in the first instance.[1] However, use of oral ferrous iron medications may be limited by poor absorption and adverse events [1,2] which can lead to many unwell patients having to receive IV iron in hospital.

The prospective, multicentre, phase 3b, open-label randomised controlled study was designed to compare the efficacy and safety of oral ferric maltol versus IV FCM in the treatment of IDA in adult patients with IBD.[1]

Patients were randomised to 12 weeks of oral ferric maltol 30 mg twice daily or IV FCM administered according to standard prescribing

information. Treatment could continue for up to 52 weeks.[1]

The primary endpoint was Hb responder rate defined as the proportion of patients achieving either a 2 g/dL increase in Hb or normalisation of Hb (women >=12 g/dL; men >=13 g/dL) at week 12, with a non-inferiority limit set to 20%. The primary efficacy analysis was performed for the per protocol (PP) population using observed cases (OC) approach and supportive analysis was performed for the intention-to-treat (ITT) population with missing values imputed using multiple imputation (MI).[1] At 12 weeks, the responder rate of oral ferric maltol was non-inferior to IV FCM (74% vs 83%, respectively; 20% non-inferiority limit in the PP population). [1]

Notes to Editors:

About IDA in IBD

Iron deficiency anaemia (IDA) is frequently seen in inflammatory bowel disease (IBD).

Currently, the only treatment option for IDA patients who cannot tolerate oral iron therapies is IV iron therapy. IV iron therapy, however, can be time and resource consuming to administer.

In the AEGIS-H2H study, ferric maltol demonstrates increases in Hb levels that were comparable to IV FCM and now offers an important alternative option for these patients, maintaining efficacy with good tolerability, without the need for hospital administration.[3]

About the study

The prospective, multicentre, phase 3b, open-label randomised controlled trial was designed to compare the efficacy and safety of oral ferric maltol (FM) and IV ferric carboxymaltose (FCM) in the treatment of IDA in patients with IBD. The results demonstrated increases in the mean Hb levels which were non-inferior to IV FCM.[1]

The study included patients aged over 18 years with confirmed IBD and IDA ([Hb] women 8.0-11.0 g/dL; men 8.0-12.0 g/dL AND either ferritin <30 ng/mL or ferritin <100 ng/mL with transferrin saturation <20%). Patients were randomised to 12 weeks of oral FM 30mg twice daily or IV FCM administered according to standard prescribing information. Treatment could continue for up to 52 weeks. Efficacy was assessed in

all randomised patients (intention-to-treat [ITT] population and in patients without serious protocol deviations (per-protocol population [PP]). The primary endpoint was >=2 g/dL increase in Hb concentration or normalisation of Hb (women >=12 g/dL; men >=13 g/dL) at week 12, with a non-inferiority limit set to 20% in either the ITT or the PP population. The PP population included 178 patients (FM n=86; FCM n=92). At 12 weeks, the PP responder rate was 74% with FM and 83% with FCM in the PP; the difference was therefore well within the 20% non-inferiority limit (p=0.023). No serious adverse events related to the study treatment were reported.[1]

About oral ferric maltol (FERACCRU®)

Ferric maltol is a novel oral ferric iron therapy for the treatment of iron deficiency (ID) in adults. The recommended dose is one capsule (30mg) taken twice a day, morning and evening, on an empty stomach. Treatment duration depends on the severity of the iron deficiency (ID), but generally at least 12 weeks of treatment are required.[4] For further information, please refer to the product Summary of Product Characteristics, available at: https://www.medicines.org.uk/emc/product/2083/smpc.

In the original Phase III AEGIS IBD clinical trial programme, which led to the license being granted, the efficacy and tolerability of ferric maltol was assessed in the treatment of IDA in patients with quiescent or mild-to-moderate IBD versus placebo, who had previously failed to respond, or had been intolerant to previous oral ferrous products (OFP). Ferric maltol was shown to be effective and well-tolerated at both 12 and 64 weeks.[5,6]

About Norgine

Across the globe in 2018, Norgine is proud to have helped 23 million patients and generated EUR395 million in net product sales to reinvest in medicines for the future, a growth of 15% over 2017.

Norgine is a leading European specialist pharmaceutical company that has been bringing transformative medicines to patients for over a century. We understand the complexities of the European healthcare systems and have a direct presence in 14 European countries, as well as Australia and New Zealand. We also have a strong global network of partnerships in non-Norgine markets.

We are a flexible and fully integrated pharmaceutical business, with manufacturing (Hengoed, Wales and Dreux, France), third party supply networks and significant product development capabilities, in addition to our sales and marketing infrastructure. This enables us to acquire, develop and commercialise specialist and innovative products that make a real difference to the lives of patients around the world.

In 2012, Norgine established a complementary business, Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com

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GL/COR/1019/0199 , Date of preparation October 2019

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OTE0002 2019-10-22/09:01

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