



## Shield Therapeutics plc

("Shield" or the "Group")

### **Biomarker data presented at British Society of Gastroenterology demonstrates the potential effect of ferric maltol in patients**

**London, UK, 22 June 2017:** Shield Therapeutics plc (LSE:STX), a specialty pharmaceutical company focused on secondary care, announces that study data via a poster entitled "*Disease activity affects response to Enteral Iron Supplementation; post-hoc analysis of data from the Aegis Study*" will be presented at the British Society of Gastroenterology meeting in Manchester, today, June 22, 2017.

Ferric maltol (Feraccru) is an iron-based therapy for the treatment of iron deficiency anaemia (IDA) and represents the Group's lead asset. Feraccru is a complex of ferric iron (Fe<sup>3+</sup>) and maltol (3-hydroxy-2-methyl-4-pyrone) and is an alternative treatment for patients who are intolerant of oral ferrous therapies.

Elevated levels of hepcidin (the "master regulator" of iron) and other inflammatory markers, such as C-Reactive Protein (CRP) have been associated with poor absorption of oral iron. The aim of the analysis was to investigate the effect of CRP and hepcidin at baseline on the response of Inflammatory Bowel Disease (IBD) patients with IDA to treatment with ferric maltol. This was a post-hoc analysis of results from the pivotal AEGIS study, which investigated the effect of ferric maltol, a novel low dose oral iron formulation<sup>1</sup>, on the treatment of IBD patients with IDA.

There were 64 IBD patients with IDA treated with ferric maltol in the study of which 40 (62.5%) were female. There was no correlation at baseline between C Reactive Protein (CRP) and hepcidin. Baseline hepcidin was not associated with response to iron replacement either at the primary endpoint (week 12) or at one year follow up. However, week 12 ferritin was inversely correlated to baseline CRP (p=0.004), and there was also a trend for an association between transferrin saturation (TSAT) at week 12 and baseline CRP which achieved statistical significance at 12 months (p=0.02).

In this retrospective analysis of factors predicting response to oral ferric maltol in IBD patients with IDA, the master iron regulatory protein, hepcidin, did not appear to be correlated with treatment response, potentially a feature of ferric maltol's mode of absorption. Neither did baseline inflammation as measured by CRP, impact negatively on the haemoglobin response to ferric maltol in this study. This suggests that ferric maltol maintains absorption and efficacy even in patients with active inflammation, however, it seems that patients with elevated CRP at baseline may require a longer course of treatment to replenish iron stores.

**Mark Sampson, Chief Medical Officer of Shield Therapeutics, commented:** "*This study suggests that ferric maltol may be effective in patients with active inflammatory markers. We suggest that the ongoing comparative trial of ferric maltol against iv iron will be useful to challenge the prevalent doctrine prohibiting treatment of patients with active systemic inflammation with oral iron.*"

<sup>1</sup> Gasche C et al. *Inflamm.Bowel.Dis* 2015;21:579-588



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**About Shield Therapeutics plc**

Shield Therapeutics is a specialty pharmaceutical company focused on the commercialisation and development of late-stage, hospital-focused pharmaceuticals which address areas of unmet medical need. Our clear purpose is to help our patients become people again, by enabling them to enjoy the things that make the difference in their everyday lives. The Group has a marketed product, Feraccru<sup>®</sup>, for the treatment of iron deficiency anaemia (IDA) in adult patients with inflammatory bowel disease (IBD) which has exclusive IP rights until the mid-2030's. In addition, the Group is developing PT20, a late-stage pharmaceutical for the treatment of systemic phosphate accumulation (hyperphosphatemia). Shield Therapeutics, headquartered in London, is listed on LSE's AIM under the ticker STX. For more information please visit [www.shieldtx.com](http://www.shieldtx.com)