RNS Number : 8680Y
Shield Therapeutics PLC
18 May 2021

Shield Therapeutics plc
("Shield Therapeutics" or the "Company")

AEGIS-H2H study results published in Inflammatory Bowel Diseases

Study demonstrates long-term effectiveness of ferric maltol compared to intravenous iron

London, UK, 18 May 2021: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru®/Accrufer® (ferric maltol), notes the recent publication in the journal Inflammatory Bowel Diseases of positive long-term results from a study comparing the effectiveness of ferric maltol 30 mg bid with intravenous (IV) iron (ferric carboxymaltose given according to each centre's standard practice) over 52 weeks. The primary endpoint was haemoglobin responder rate (≥2 g/dL increase or normalization) at week 12, with a 20% noninferiority limit in the intent-to-treat and per protocol populations.

The open label Phase 3B study included adults with non-severe active IBD and iron-deficiency anaemia (IDA) and who also had serum ferritin levels below 30 µg/L or ferritin levels below 100 µg/L and transferrin saturation below 20%. The report of this first comparative trial, reflecting real-world conditions in patients with quiescent or mild to moderate IBD and mild to severe IDA, concluded that both oral ferric maltol and standard regimens of IV ferric carboxymaltose achieved clinically meaningful increases in Hb over 12 weeks of treatment, although ferric maltol did not meet the prespecified noninferiority margin vs IV iron. Over the longer term, ferric maltol showed comparable efficacy in maintaining Hb improvements and increasing ferritin up to week 52, consistent with IV iron. The safety profile of each treatment was consistent with previous studies.

The publication can be found at
https://academic.oup.com/ibdjournal/advance-article/doi/10.1093/ibd/izab073/6275616

The lead author, Dr Stephanie Howaldt stated: "*Ferric maltol showed long-term comparable effectiveness in maintaining Hb improvements and increasing ferritin up to week 52, consistent with IV iron. The safety profile of each treatment was consistent with previous studies and mirrors my daily clinical practice. Thus, ferric maltol offers a simple, well tolerated and cost-effective long-term treatment solution of chronic IDA in patients with IBD.*"

For further information, please contact:

Shield Therapeutics plc +44 (0) 191 511 8500

Tim Watts (CEO)
Hans-Peter Rudolf (CFO)

Peel Hunt LLP - **Nominated Adviser & Joint Broker** +44 (0) 20 7148 8900

James Steel / Christopher Golden

finnCap Ltd - Joint Broker +44 (0) 20 7220 0500
Geoff Nash / Alice Lane/George Dollemore

Walbrook PR - Financial PR & IR Adviser +44 (0) 20 7933 8780
Paul McManus / Lianne Cawthorne or shield@walbrookpr.com

About Shield

Shield is a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru ® /Accrufer ® (ferric maltol), a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia.

Shield's lead product, Feraccru®/Accrufer®, has been approved for use in the United States, European Union, UK and Switzerland and has exclusive IP rights until the mid-2030s. The Group plans to launch Accrufer® in the US during 2021 through a highly experienced sales and marketing team. Feraccru® is already being commercialised in the UK and European Union by Norgine B.V., who also have the marketing rights in Australia and New Zealand. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

For more information, please visit www.shieldtherapeutics.com. Follow Shield on Twitter @ShieldTx

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