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Shield Therapeutics PLC
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Shield Therapeutics plc
("Shield" or the "Group")

Shield Presents Positive Results for Feraccru®/Accrufer™ (Ferric Maltol) in AEGIS-H2H phase 3b non-inferiority study at UEG Week 2019

- Feraccru®/Accrufer™ demonstrated as non-inferior to market-leading intravenous (IV) iron therapy in treating iron deficiency anaemia in a phase 3b head-to-head clinical trial

- Feraccru®/Accrufer™ offers a simple, well tolerated and efficacious oral treatment alternative to IV iron therapy, without the need for hospital-based administration

- Maintenance therapy with Feraccru®/Accrufer™ over 52 weeks prevented recurrence of iron deficiency anaemia, whereas 39% (49) of the subjects in the IV treatment group required intervention due to recurrence of iron deficiency anaemia.

London, UK, 22nd October 2019: Shield Therapeutics plc (LSE: STX), a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru®/Accrufer™, announces that results from its multicentre phase 3b, open-label randomised controlled trial will be presented at the 27th United European Gastroenterology Week (UEG). Headline data were previously announced in March 2019.

The data will be presented by Dr Stefanie Howaldt, specialist in internal medicine at the MVZ-Immunology Clinic in Hamburg and principal investigator in the study, on October 22, 10.30-12.00 CET: **Oral Ferric Maltol versus intravenous ferric carboxymaltose for the treatment of iron-deficiency anaemia in patients with inflammatory bowel disease: A multicentre phase 3b, open-label randomised controlled trial.**

The study was conducted unblinded and with a non-inferiority design in which 250 subjects were recruited to compare oral Feraccru®/Accrufer™ 30mg BD for 52 weeks with IV ferric carboxymaltose administered in line with the licensed dosing schedule. The primary endpoint was the response rate (defined as a rise in haemoglobin (Hb) ≥2g/dl or attainment of a normal Hb level) at 12 weeks. The study also allowed evaluation of daily dosing with oral Feraccru®/Accrufer™ in maintaining iron status and preventing recurrence of iron deficiency anaemia.

Key findings:

- Response rate at 12 weeks was 74% for oral Feraccru®/Accrufer™ and 83% for IV ferric carboxymaltose. The 9% difference was well within the pre-specified non-inferiority margin of 20% (p=0.017)

- Recurrence of iron deficiency anaemia occurred at least once in approximately 39% (49) of the subjects in the IV arm of the study following the initial treatment with IV ferric carboxymaltose, requiring a total of 69 additional IV iron infusions to be administered.

- Feraccru®/Accrufer™ was generally well tolerated over 52 weeks of treatment with a side effect profile consistent to that seen in previous placebo-controlled studies

Dr Mark Sampson, Chief Medical Officer of Shield, said: "*This data shows not only that physiological oral iron replacement with Feraccru® can produce a similar response rate to IV iron at 12 weeks, but that Feraccru® is effective and well tolerated over 52 weeks, even in patients who have been unable to tolerate oral iron salts previously*."

Dr Stefanie Howaldt, specialist in internal medicine at the MVZ-Immunology Clinic in Hamburg and principal investigator in the study said "*This data shows that not only is Feraccru® a real oral alternative to IV iron for these patients with iron deficiency anaemia, but that it can also prevent the need for repeated IV infusions."*

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About Shield Therapeutics plc

Shield is a de-risked, commercial stage, specialty pharmaceutical company delivering innovative pharmaceuticals to address patients' unmet medical needs. The Company's clear purpose is to develop products that help patients become people again, enabling them to enjoy the things that make a difference in their everyday lives. The Group's lead product, Feraccru®/ Accrufer™ has exclusive IP rights until the mid-2030s and is approved for the treatment of iron deficiency with or without anaemia in adults in the European Union, the United States and Switzerland. In Europe it is marketed as Feraccru® with commercialisation led by Norgine BV and in the USA the product will be marketed as Accrufer™ with Shield currently in the process of selecting a commercialisation partner. For more information please visit www.shieldtherapeutics.com

About Feraccru®/Accrufer™

Feraccru®/Accrufer™ is a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia that has been shown to be an efficacious and well-tolerated therapy in a range of controlled phase 3 trials, including positive results from the Phase IIIb AEGIS-H2H study in which Feraccru®/Accrufer™ demonstrated it was non-inferior in delivering improvements in haemoglobin levels compared to intravenously-administered (IV) Ferinject®/Injectafer® (ferric carboxymaltose). Feraccru®/Accrufer™ therefore offers a compelling alternative to IV iron for those patients unable to tolerate salt-based oral iron therapies and wish to avoid the complexities of infusion-based iron therapies.

When salt-based oral iron therapies are ingested they can cause a range of mild-to-severe gastrointestinal tract (GI) adverse events, including nausea, bloating and constipation through the release and subsequent reactivity of free iron in the GI tract, leading to poor tolerability, reduced patient compliance and ultimately treatment failure. Feraccru®/Accrufer™ is not an iron salt and, as a result, it does not routinely cause the same treatment-limiting intolerance issues of salt-based iron therapies, whilst the iron from the ferric maltol molecule can be readily absorbed.

Prior to Feraccru®/Accrufer™, IV iron therapies were the only realistic alternative treatment option for iron deficient patients with or without anaemia intolerant of or unwilling to be treated salt-based oral iron therapies. However, use of such an invasive, costly, inconvenient and complex to administer treatment option, which is associated with potentially life-threatening and spontaneous hypersensitivity reactions, means there remains a clear unmet medical need for these patients to have access to an effective therapy that is well tolerated, convenient and does not require hospital-based administration. Feraccru®/Accrufer™ meets those requirements.

About Iron Deficiency

The WHO states that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of women and children in non-industrialized countries, it is the only nutrient deficiency which is also significantly prevalent in virtually all industrialised nations. There are no current global figures for iron deficiency but, using anaemia as an indirect indicator, it can be estimated that most

preschool children and pregnant women in non-industrialised countries, together with at least 30-40% in industrialized countries, are iron deficient.

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