

*The information contained within this announcement is deemed by the Group to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.*

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

## **FDA approves Feraccru® with a broad label of treating iron deficiency in adults**

### ***Feraccru® to be marketed as Accrufer® in the USA***

**London, UK, 26 July 2019:** Shield Therapeutics plc (LSE: STX), a commercial stage, pharmaceutical company with a focus on addressing iron deficiency, announces that the U.S. Food and Drug Administration (FDA) has approved its lead product Feraccru® / Accrufer® for the treatment of iron deficiency in adults.

With this broad label approval Accrufer® (as the product will be marketed in the USA) has taken a big step towards exploiting the very large commercial opportunity in the USA, the world's largest and most attractively reimbursed pharmaceutical market. Market research suggests that the prescription market for iron replacement therapy in the USA is worth over \$1.0bn annually. There are between 8 million and 9 million patients in the USA who suffer from iron deficiency anaemia and management estimate potentially two to three times this number require treatment for iron deficiency.

Accrufer®'s confirmed efficacy, together with its good tolerability and mode of absorption - by which the body absorbs only as much iron from Accrufer® as it needs - means that the product could be the ideal choice for iron deficient patients who cannot tolerate salt-based oral iron alternatives. These features, combined with the non-inferiority results from the AEGIS-H2H study announced in March 2019, mean that treatment with Accrufer® might remove the need for patients to progress to intravenous iron therapy, leading to a change in the current paradigm for the treatment of iron deficiency anaemia.

Together with its advisors, Shield is in discussions with a number of potential commercial partners for the US opportunity for Accrufer® and looks forward to providing updates on these discussions in due course.

Feraccru® is already approved in both the European Union and Switzerland for the treatment of iron deficiency in adults and commercialisation activities in these territories are progressing well via Shield's licensing partners.

**Carl Sterritt, CEO of Shield Therapeutics:** *"We are delighted that the FDA has approved the new drug application for our lead asset. This is a further major milestone for the Company which we have worked tirelessly to achieve, and I am very proud to lead the team within Shield that has made this happen. With this broad approval and IP protection out to 2035, Feraccru®/ Accrufer® has a real and very attractive long-term market opportunity to exploit in the USA. We have been pleased with the levels of interest and engagement shown by 3<sup>rd</sup> parties in commercialising Accrufer® in the USA and we look forward to finalising these discussions and appointing a commercial partner in the world's most attractive pharmaceutical market, so that more patients with iron deficiency can benefit from treatment with Accrufer® at the earliest opportunity."*

**Jackie Mitchell, VP Regulatory Affairs of Shield Therapeutics:** *"The broad label that the FDA has granted provides a very strong signal as to the tolerability and efficacy profile of Feraccru®/ Accrufer® and provides a novel and convenient treatment alternative to the millions of US patients who routinely suffer with iron deficiency. We believe that this broad approval, together with the recent clinical trial data on Feraccru® that showed it to be non-inferior in treatment effect to Ferinject®/ Injectafer®, the leading IV iron therapy, can lead to a change in the current paradigm for the treatment iron deficiency anaemia."*

The person who arranged for the release of this announcement on behalf of Shield Therapeutics plc was Carl Sterritt, Chief Executive Officer.

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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 help its 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> / Accrufer<sup>®</sup>, for the treatment of iron deficiency in adults which has exclusive IP rights until the mid-2030s. Feraccru<sup>®</sup> / Accrufer<sup>®</sup>, is approved by the FDA, EMA and Swiss Medic for the treatment of iron deficiency in adults and is commercialised in the European Union by Norgine BV, with a US commercialisation partner currently being selected. For more information please visit [www.shieldtherapeutics.com](http://www.shieldtherapeutics.com).

**About Feraccru<sup>®</sup> / Accrufer<sup>®</sup>**

Feraccru<sup>®</sup> / Accrufer<sup>®</sup> is a novel, stable, non-salt based oral treatment for adults with iron deficiency with or that has been shown to be an efficacious and well-tolerated therapy in a range of controlled phase 3 trials. Following the recently announced positive results of the Phase IIIb AEGIS-H2H study in which Feraccru<sup>®</sup> demonstrated it was non-inferior to intravenously-administered Ferinject<sup>®</sup> at delivering improvements in haemoglobin levels without requiring hospital-based administration, Feraccru<sup>®</sup> / Accrufer<sup>®</sup> offers a compelling alternative to IV Iron for those patients that cannot tolerate salt-based oral iron therapies and wish to avoid the complexities of infusion-based 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. These lead to poor tolerability, reduced patient compliance and ultimately treatment failure. Feraccru<sup>®</sup> / Accrufer<sup>®</sup> is not an iron salt; iron can be absorbed from the ferric maltol molecule and, as a result, it does not routinely cause the same treatment-limiting intolerance issues.

Prior to Feraccru<sup>®</sup> / Accrufer<sup>®</sup>, IV iron therapies were the only realistic alternative treatment option for patients intolerant of or unwilling to take 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 patients with iron deficiency to have access to an effective therapy like Feraccru<sup>®</sup> / Accrufer<sup>®</sup> that is well tolerated, convenient and does not require hospital-based administration.

**About Iron Deficiency**

The WHO state that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of children and women in non-industrialized countries, it is the only nutrient deficiency which is also significantly prevalent in virtually all industrialized 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-industrialized countries, and at least 30-40% in industrialized countries, are iron deficient.

### **Forward-Looking Statements**

*This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations and include statements related to the commercial strategy for Feraccru. These statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties, many of which are beyond our control, that may cause actual results, performance or achievements to be materially different from management's expectations expressed or implied by the forward-looking statements, including, but not limited to, risks associated with, the Group's business and results of operations, competition and other market factors. The forward-looking statements made in this press release represent management's expectations as of the date of this press release, and except as required by law, the Group disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause our views to change.*