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

Feraccru® granted major extension to approval in Switzerland

Swissmedic approves Feraccru® to treat Iron Deficiency with or without anaemia in adults

London, UK, 24th April 2019: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with or without anaemia via its lead product Feraccru®, announces that the Swiss Agency for Therapeutic Products (Swissmedic) has approved a major extension of the approved indication for Feraccru® to now include treatment of all adults with iron deficiency (ID) with or without anaemia.

This follows an equivalent broadening of the marketing authorisation approval for Feraccru® in the European Union in 2018 and futher increases the commercial opportunity for Feraccru®, which was initially approved in both the EU and Switzerland just for the treatment of iron deficiency anemia (IDA) in adult patients with inflammatory bowel disease (IBD).

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"We are delighted with the positive progress we continue to make with regulatory authorities in relation to maximising the commercial opportunity for Feraccru®. Switzerland represents an attractive market opportunity as it is both well reimbursed and has a much higher level of treatment penetration compared to other markets, particularly for IV iron therapies.*

"Together with the new label, we expect the recent positive result from the AEGIS-H2H phase 3b active comparator study of Feraccru® versus intravenously delivered Ferinject® will have added importance and will provide an enhanced commercial opportunity to Ewo, our Swiss commercial partner. We look forward to working with them to deliver commercial success for Feraccru® in Switzerland at the earliest opportunity."

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About Shield Therapeutics plc

Shield is a de-risked, commercial stage, pharmaceutical company delivering innovative specialty 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®, for the treatment of iron deficiency in adults which has exclusive IP rights until the mid-2030s. Feraccru® is commercialised in the European Union by Norgine BV and the US Food and Drug Administration (FDA) is currently considering a New Drug Application (NDA), with a PDUFA (Prescription Drug User Fee Act) date of 27th July 2019. For more information please visit www.shieldtherapeutics.com.

About Feraccru®

Feraccru® is a novel, stable, non-salt based oral treatment 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. Following the recently announced[1] positive results of the Phase IIIb AEGIS-H2H study in which Feraccru® demonstrated it was non-inferior to intravenously-administered Ferinject® at delivering improvements in haemoglobin levels without requiring hospital-based administration, Feraccru® 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® 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®, 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 with or without anaemia to have access to an effective therapy like Feraccru® that is well tolerated, convenient and does not require hospital-based administration.

Feraccru® is approved and marketed in the European Union for the treatment of iron deficiency with or without anaemia in adults and in Switzerland for the treatment of iron deficiency anaemia in adults with IBD.

About Iron Deficiency

The WHO state that ID 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 ID, 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 timing of future results of Feraccru trials and the timing and success of the Group's regulatory plans and 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 regulatory approval process, 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.

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