Shield Therapeutics plc

("Shield" or the "Group")

Shield Therapeutics announces submission of a New Drug Application (NDA) for Feraccru® for the treatment of iron deficiency with the US Food and Drug Administration (FDA)

London, UK, 1st October 2018: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs, today announces that it has received confirmation from the US FDA of its successful submission of an NDA for Feraccru®, Shield's lead product, which is already approved in the European Union for the treatment of iron deficiency in adults and in Switzerland for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease.

The United States, representing over a third of the global pharmaceutical market, is a very attractive opportunity for Feraccru® and a market which Shield retains full ownership of, as well as complete control of the global intellectual property rights.

Commenting on the announcement, Dr Jackie Mitchell, VP of Regulatory Affairs and Quality at Shield Therapeutics, said: *"This NDA submission is a key regulatory milestone in widening Feraccru's geographical availability for patients suffering from iron deficiency and it builds on the significant broadening of the product's indication from patients with anaemia and inflammatory bowel disease (IBD) to the treatment of all adults with iron deficiency (ID) with or without anaemia approved in the European Union earlier this year."*

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, added: *"Filing of this NDA is a major step towards the potential regulatory approval of Feraccru in the USA. I am delighted with the rapid progress the team has made with this submission and would also like to thank the clinicians and patients who took part in the studies that have formed part of this NDA. Following on from the recently announced licensing agreement with Norgine for the commercialisation of Feraccru in Europe, we are very excited about the future for Feraccru and the value creation opportunities that lie ahead for Shield."*

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About Feraccru®

Feraccru® is a novel, stable, non-salt, oral formulation of ferric iron, which has a differentiated mechanism of action compared to salt-based oral iron therapies. When salt-based oral iron therapies are ingested, the iron must dissociate from the salt in the GI tract to allow the iron to be absorbed and treat the IDA. This free iron readily chelates to form insoluble clumps and produces damaging free radicals that together cause a range of mild-to-severe GI adverse events, including nausea, bloating and constipation, leading to poor tolerability, reduced patient compliance and ultimately treatment failure. In addition, many patients with IDA are concurrently treated with medicines that raise the pH in the gut which further reduces the effect of salt-based oral iron therapies as they require highly acidic conditions to be absorbed. Feraccru® is not an iron salt, and iron can be absorbed from the ferric maltol molecule, and as a result, it does not routinely cause the same treatment-limiting intolerance issues. Feraccru® has been shown in clinical trials to be well-tolerated by patients even when they had previously failed treatment with salt-based oral iron therapies, which should lead to increased patient compliance and better patient outcomes.

Currently, the only treatment option for IDA patients who cannot tolerate salt-based oral iron therapies, is IV iron therapy. IV iron therapies quickly increase iron stores via direct administration of very large doses of iron, causing an increase in Hb levels that is physiologically controlled and occurs over a period of weeks, as is the case with Feraccru®. IV iron therapies, however, are invasive, costly, inconvenient and complex to administer, and also come with potentially life-threatening, spontaneous hypersensitivity reactions.

Feraccru® has been approved by the European Commission for the treatment of iron deficiency in adults, with or without anaemia.

About Shield Therapeutics plc

Shield is a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs. 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®, for the treatment of iron deficiency in adult patients with or without anaemia. Feraccru® has exclusive IP rights until the mid-2030's. For more information please visit www.shieldtherapeutics.com.

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.