Shield Therapeutics plc

("Shield" or the "Group")

Shield Therapeutics announces the New Drug Application for Feraccru® has been accepted for filing and review by the FDA

London, UK, 3rd December 2018: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs, today announces that the US Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for Feraccru®, Shield's lead product. Under the terms of the Prescription Drug User Fee Act (PDUFA), the FDA will shortly confirm to Shield the expected target date in 2019 for completion of the NDA review and Shield will provide a further update at that time.

Feraccru® 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 highly attractive opportunity for Feraccru® and a market which Shield retains full ownership of, as well as complete control of the global intellectual property rights.

In September 2018, Feraccru® was licensed to Norgine B.V. in all European territories not already partnered as well as Australia and New Zealand. In return Norgine B.V. paid a licence fee of £11m, with scope for additional milestones totalling EUR54.5m and royalties on sales ranging from 25% up to 40%.

Commenting on the announcement, Dr Jackie Mitchell, VP of Regulatory Affairs and Quality at Shield Therapeutics, said: *"We are delighted to have achieved this key regulatory milestone in widening Feraccru's geographical availability for patients suffering from iron deficiency. We look forward to interacting positively with the FDA over the coming months and, if approved, Feraccru will provide a novel and much needed treatment option for patients with iron deficiency."*

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, added: *"News that the NDA has been validated and accepted for review by the FDA brings us a major step closer to Feraccru potentially being approved in the USA in 2019. Following the licensing agreement we signed with Norgine in September for the commercialisation of Feraccru in Europe, Australia and New Zealand, we are well-funded and are increasingly excited about Feraccru's future as we continue to enact our plans to realise the value creation opportunities that lie ahead for Shield and its shareholders ."*

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For further information please contact:

Shield Therapeutics plc +44 (0)207 186 8500
Carl Sterritt, Chief Executive Officer
Tim Watts, Interim Chief Financial Officer

Nominated Advisor and Joint Broker +44 (0)203 100 2222
Liberum Capital Limited
Christopher Britton/Steve Pearce

Joint Broker +44 (0)207 418 8900
Peel Hunt LLP
James Steel/ Dr Christopher Golden

Financial PR +44 (0)203 709 5700
Consilium Strategic Communications
Mary-Jane Elliott/Matthew Neal

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.

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.