Shield Therapeutics plc

("Shield" or the "Group")

Shield Therapeutics announces the US New Drug Application PDUFA date for Feraccru®

London, UK, 13 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 confirmed that the target date for completion of the New Drug Application (NDA) review of Feraccru®, under the terms of the Prescription Drug User Fee Act (PDUFA), is 27 July 2019.

The United States, representing over a third of the global pharmaceutical market, is a highly attractive opportunity for Feraccru® and a market for which Shield retains full ownership of, as well as complete control over, the global intellectual property rights. Feraccru® is already approved in the European Union for the treatment of iron deficiency in adults and, following the recent licence agreement for Feraccru® in Europe, Norgine has now commenced its own sales and marketing activities.

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, added: *"Confirmation of the PDUFA date for completion of the review of Feraccru® by the FDA is another important step towards being able to offer Feraccru® to the very large pool of iron deficient patients in the United States who would benefit from this novel new treatment option. We will continue to work closely with the FDA to achieve this goal, whilst also seeking an attractive commercial partner for Feraccru in the USA who can help us realise the full value of the opportunity that would be created by Feraccru's approval."*

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About Feraccru®

Feraccru® is a novel, stable, non-salt, oral formulation of ferric iron, which has a differentiated mechanism of

absorption 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.