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Shield Therapeutics PLC
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Shield Therapeutics plc

("Shield" or the "Group")

Positive results of long-term phase of AEGIS-CKD study further demonstrate the benefits of Feraccru®

- *Haemoglobin levels increased and maintained across 52 weeks of Feraccru® therapy in patients with chronic iron deficiency anaemia (IDA)*
- *Feraccru® efficiently absorbed with good tolerability over extended treatment periods*
- *Subjects switched from placebo to Feraccru® demonstrate similar response as the study's active arm in their first 16 weeks of Feraccru treatment*

London, UK, 29 January 2019: Shield Therapeutics plc (LSE: STX) a commercial stage, pharmaceutical company with an initial focus on addressing iron deficiency, announces positive results from the open-label extension phase of the AEGIS-CKD pivotal study of Feraccru®, a novel oral ferric iron therapy that is approved and marketed in the European Union for the treatment of iron deficiency (ID) in adults and in Switzerland for the treatment of iron deficiency anaemia (IDA) in adults with inflammatory bowel disease (IBD).

The **Feraccru® AEGIS-CKD study** was a pivotal phase III randomized, placebo-controlled, double-blind trial in chronic kidney disease (CKD) patients with IDA, which demonstrated superiority of Feraccru® when the change in haemoglobin (Hb) from baseline after 16 weeks of treatment with oral Feraccru® (30mg twice daily) was compared to placebo. This was followed by a 36-week open-label extension phase during which all subjects were treated with Feraccru®. For those patients initially treated with Feraccru®, Hb levels were maintained over this 36-week follow-up period and the treatment continued to be well tolerated.

In addition, subjects who switched to Feraccru for the open-label phase showed a similar mean rise in Hb over their first 16 weeks of Feraccru® treatment when compared to those initially treated with Feraccru® (0.79g/dl v 0.57g/dl). These data further support the Company's hypotheses that Feraccru® is consistently well absorbed and that chronic treatment with Feraccru® can maintain Hb levels. As previously shown in patients with IDA associated with IBD, this study in CKD

patients demonstrates that Feraccru® is also well tolerated in a group of patients whose IDA is caused by a very different primary disease.

Overall 73.6% of subjects entering the open-label extension period stayed on Feraccru® therapy and successfully completed the 52-week study.

Dr Mark Sampson, Chief Medical Officer of Shield, said *"Iron deficiency is a significant and progressive issue in patients with chronic renal disease which has been challenging to treat due to poor compliance with traditional oral iron salts. These results suggest that Feraccru® offers a well-tolerated and effective treatment option which can benefit patients over the long-term."*

Carl Sterritt, CEO and Founder of Shield, said: *"Such positive long-term treatment data for Feraccru® in complex patients with chronic diseases like CKD provides a very promising signal for the future commercial success of Feraccru®. Having previously seen similar positive long-term effects in IBD patients with IDA this further clinical trial data provides additional evidence that Feraccru is well-tolerated by a majority of treated patients and is effective at correcting IDA. We hope that this positive data provides the necessary evidence to both prescribers and patients with iron deficiency with or without anaemia that Feraccru® offers a simple to administer, well tolerated and efficacious treatment alternative that does not require hospital-based administration."*

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 gastrointestinal tract (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® is approved and marketed in the European Union for the treatment of ID in adults and in Switzerland for the treatment of IDA 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.

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For further information please contact:

Shield Therapeutics plc	www.shieldtherapeutics.com
Carl Sterritt, Chief Executive Officer Tim Watts, Chief Financial Officer	+44 (0)20 7186 8500
Nominated Advisor and Joint Broker **Liberum Capital Limited**	
Christopher Britton/Steve Pearce	+44 (0)20 3100 2222
Joint Broker **Peel Hunt LLP**	
James Steel/Dr Christopher Golden	+44 (0)20 7418 8900
Financial PR & IR Advisor **Walbrook PR**	+44 (0)20 7933 8780 or shield@walbrookpr.com
Paul McManus / Helen Cresswell	+44 (0)7980 541 893 / +44 (0)7841 917 679

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 adults which has exclusive IP rights until the mid-2030's. 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.

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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