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Shield Therapeutics PLC
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This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014

Shield Therapeutics plc

("Shield" or the "Group")

Positive results for Feraccru® in AEGIS-H2H non-inferiority study

- *Feraccru® demonstrated as non-inferior to market-leading intravenous (IV) iron therapy in treating iron deficiency anaemia in a head-to-head clinical trial*
- *Feraccru® again efficiently absorbed and well tolerated over an extended treatment period*
- *Feraccru® offers a simple, well tolerated and efficacious oral treatment alternative to IV iron therapy without the need for hospital-based administration*
- *Under the terms of the September 2018 agreement with Norgine B.V., Shield will now benefit from a €2.5m development milestone payment*

London, UK, 4th March 2019: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company with a focus on addressing iron deficiency with or without anaemia, announces positive results from the AEGIS-H2H clinical trial which compared Feraccru® (ferric maltol), a novel oral iron replacement therapy, to Ferinject® (ferric carboxymaltose (FCM)), the market-leading intravenously delivered iron replacement therapy.

Feraccru® 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). A New Drug Application in the USA is being reviewed by the FDA with a PDUFA date of 27 July 2019.

The **Feraccru® AEGIS-H2H study** was a multi-national Phase IIIb randomised, active-controlled trial in 242 IBD patients with IDA and haemoglobin (Hb) measurements as low as 8.0g/dL. The objective of the study was to assess whether the effect of Feraccru® on Hb response (defined by the protocol as normalisation of Hb or a >2g/dL rise in Hb from baseline) was comparable to the effect seen with FCM treatment at 12 weeks. This was followed by a 40-week extension phase, during which eligible subjects continued treatment with Feraccru® or received FCM in line with clinical need as described in FCM's Summary of Product Characteristics in the EU and its Prescribing Information in the USA.

Primary analysis of the AEGIS-H2H study has shown that response to Feraccru® at 12 weeks was within 9% of the response seen with FCM and within the 20% limit required by the study protocol to confirm non-inferiority (p = 0.022). The increase in Hb levels in the Feraccru® arm was comparable to that seen in the original AEGIS-IBD study.

Secondary endpoints included assessment of Hb response to both therapies and measurement of key iron storage parameters through 52 weeks as well as the usual safety assessments.

More detailed analyses of the data, including the secondary endpoints and safety parameters, will be presented at Shield's upcoming presentation of its preliminary results for 2018, scheduled for early April 2019, whilst the full data will be submitted for peer-review and subsequent presentation by the study's lead investigators at upcoming scientific meetings.

Further to the announcement in September 2018 of an exclusive commercialisation agreement with Norgine B.V. to commercialise Feraccru® in the EU, Australia and New Zealand, the Company will now benefit from a €2.5m milestone payment.

Dr Mark Sampson, Chief Medical Officer of Shield, said: *"In a challenging phase IIIb clinical study, in which Feraccru® has been tested against Ferinject®, the standard of care for patients who cannot tolerate or are unwilling to take salt-based oral iron therapies, orally delivered Feraccru® has demonstrated it is non-inferior to IV iron therapy in treating iron deficiency anaemia. These data enhance the treatment options for such patients as they demonstrate that Feraccru® offers a well-tolerated and effective therapy, which can benefit patients in both the short and long term. I would like to thank the patients, healthcare professionals, our CRO partner Clinipace and Shield's clinical development team both past and present for the dedication, commitment and professionalism shown in completing this complicated and challenging study and achieving this excellent result."*

Carl Sterritt, CEO and Founder of Shield, said: *"We are delighted that Feraccru® has once again performed so well in a phase III clinical trial, this time delivering a major achievement in showing itself to be non-inferior to IV iron therapy, further reinforcing the value of Feraccru®. We are particularly pleased to see such a clinically relevant response to Feraccru® throughout the pre-defined assessment timepoints in this complex study, having previously seen very similar long-term benefits in IBD patients with IDA in the AEGIS-IBD study. These data provide yet further evidence that Feraccru® is well-tolerated by a majority of treated patients and is effective at correcting both their iron deficiency and anaemia.*

"We look forward to presentations of the AEGIS-H2H data at upcoming scientific meetings and working with our commercial partners to ensure prescribers, payors, experts responsible for the publication of treatment guidelines and the many eligible patients are aware that Feraccru® offers a simple to administer, well tolerated and efficacious oral treatment alternative to IV iron therapy, without the need for hospital-based administration."

- Ends -

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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 oral treatment for iron deficiency with or without anaemia which offers a compelling alternative to IV Iron for those patients that cannot tolerate salt-based oral iron 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, leading 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. 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.

Previously, the only treatment option for patients who could not tolerate salt-based oral iron therapies was IV iron therapy, which is invasive, costly, inconvenient and complex to administer as well as being associated with potentially life-threatening and 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.

About Norgine

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. Norgine specialises in gastroenterology, hepatology, cancer and supportive care. In 2017, Norgine's total net product sales were up 17 per cent at €345 million. Norgine employs over 1,000 people across its commercial, development and manufacturing operations and manages all aspects of product development, production, marketing, sale and supply. For more information, please visit www.norgine.com

In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com

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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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