Shield Therapeutics plc

("Shield" or the "Company")

Shield Therapeutics Announces Results of its Pre-Submission Meeting with FDA

Confirms plans to submit a New Drug Application for Feraccru® as soon as possible, provides a strategic review update and announces the appointment of a Non-Executive Director

London, UK, 6 April 2018: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company with an initial focus on addressing iron deficiency with its novel therapy, Feraccru, announces it has received final minutes from the US Food and Drug Administration (FDA) of its recent pre-New Drug Application (NDA) submission meeting. These minutes form the official record of this meeting with the FDA and they have provided Shield with the necessary guidance to progress submission of an NDA for Feraccru without conducting additional pivotal clinical trials. The NDA will be submitted as soon as possible in 2018 and the work will be funded within the Company's current cash resources.

Background

On 16 March 2018 the Company provided an update on the AEGIS-CKD Phase III study following detailed analyses of the data from the double-blind period of this study of Feraccru. At the same time Shield also confirmed it had met with the FDA for a previously scheduled pre-NDA submission meeting. In this meeting Shield shared the data and findings from all available analyses of the AEGIS-CKD Phase III trial, including key safety and efficacy parameters. Based on the minutes of the meeting provided to the Company by FDA and Shield's own review of the data, the Company now intends to finalise and submit an NDA for Feraccru as soon as possible.

Strategic review update

Europe licensing options:

With the recent significant expansion of Feraccru's European marketing authorisation to include all adult patients with iron deficiency, the Company is evaluating ways of more rapidly leveraging the value of Feraccru in Europe and has engaged a third party to facilitate this process. Shield is considering a range of partnering structures that could likely include upfront payments, which would further extend the Company's cash runway, along with sales-based royalties that would provide revenue throughout the life of a partnering agreement.

US market opportunity for Feraccru:

Following feedback from the FDA, Shield is now progressing with the submission of an NDA for Feraccru as soon as possible and the Company will continue to update the market in the normal course of business as the submission progresses. Shield will now also fully re-assess the options for Feraccru's commercialisation in the US.

Appointment of Non-Executive Director

A separate announcement by the Company today confirms the appointment of Rolf Hoffmann, as a Non-Executive Director of the Company. Rolf's extensive experience and knowledge of the pharmaceutical industry and his deep commercial experience will be helpful in assessing the specific decisions the Company is considering in relation to the commercial strategy for Feraccru, as well as part of its ongoing strategy assessment.

Cash runway

There have been no material changes to Shield's cash runway as stated in the business update announcement of 22nd February 2018. The Company will provide a further update in its upcoming preliminary results announcement due on 11th April 2018.

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"As I said at the time, we were surprised and disappointed by the initially reported top-line findings of the AEGIS-CKD study, as Feraccru had previously consistently demonstrated positive efficacy and safety, which facilitated its approval in Europe and where it has continued to gain commercial traction. The discussions with and feedback received from FDA, together with our own review of the AEGIS-CKD data, provides us with the confidence to submit Feraccru's NDA as soon as possible and without conducting additional pivotal trials. If approved, the NDA would permit this novel product to be marketed in the world's most important pharmaceutical market.*

"The US geographic expansion we hope this positive data will facilitate, would hugely increase Feraccru's commercial opportunity, further increasing the attractiveness of an asset that already has broad approval in Europe and gold standard composition of matter protection through 2035 in the two most important pharmaceutical markets in the world. At the same time, we are encouraged by the level of interest shown in the initial stages of our European partnering activities for Feraccru and we will continue to diligently work towards finalising a suitable agreement at the earliest opportunity.

"Finally, on behalf of the Board, I would like to extend a warm welcome to Rolf Hoffmann and I look forward to benefitting from his highly relevant and extensive knowledge of the global pharmaceutical market."

Webcast and conference call for analysts at 1pm BST today

Carl Sterritt, Chief Executive Officer, Dr Karl Keegan, Chief Financial Officer and Dr Mark Sampson, Chief Medical Officer, will host a live conference call and webcast for analysts at 1pm BST today, 6 April 2018, to discuss this announcement.

The presentation and access to the live webcast will be on Shield's website at www.shieldtherapeutics.com.

Dial in details:

Location	Purpose	Phone Number
United Kingdom	Participant	+44 (0)330 336 9105
United States	Participant	+1 646-828-8156

The participation code is: 8668739

To access the audio webcast, please follow this link or alternatively visit Shield's investor relations page.

An audio replay file will be made available shortly afterwards via Shield's website: www.shieldtherapeutics.com.

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This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014. The person who arranged for the release of this announcement on behalf of Shield Therapeutics was Carl Sterritt, Chief Executive Officer.

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 iron deficiency or the anaemia. This free iron readily chelates to form insoluble clumps as well as producing 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 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, 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 patients with iron deficiency with or without anaemia 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, complex to administer and also come with potentially life-threatening, spontaneous hypersensitivity reactions.

About Non-Dialysis Dependent Chronic Kidney Disease and Iron Deficiency Anaemia
The National Institute of Diabetes and Digestive and Kidney Diseases suggests the overall prevalence of CKD in the United States is approximately 14%, and in Europe, the European Renal Association has reported that CKD has a prevalence of 10%.

There are five stages of CKD; in stages 1 and 2 people are typically under the care of a primary care physician and have a mild loss of kidney function. As people progress to stage 3 haemoglobin levels begin to fall, the patient experiences moderate to severe loss of kidney function and is generally referred to a nephrologist. Stage 4 is characterised as advanced disease with multiple complications and by stage 5 a patient is in kidney failure and dialysis would be initiated.

Standard of care currently only consists of measures to help control signs and symptoms and reduce the impact of the many complications, thereby making a patient more comfortable and slowing disease progression.

Anaemia is a major complication of CKD with an average of 15.4% of patients having anaemia, although this prevalence increases with the stage of CKD, rising from around 10% at stage 1 to approximately 55% at stage 5 and is associated with fatigue, lethargy, decreased quality of life and is also believed to be associated with cardiovascular complications, hospitalisations and increased mortality. As with IDA due to other diseases, currently available salt-based oral iron supplements are associated with limited efficacy and dose-limiting tolerability issues.

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 IDA in adult patients with IBD which 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 Company'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 Company'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 Company disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause our views to change.