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

Shield Therapeutics plc

("Shield" or the "Group")

H1 Business Update

- *Feraccru delivered positive results in the pivotal Phase III AEGIS-CKD and AEGIS-Paeds-PK studies*
- *Feraccru sales stable despite reductions in manpower and promotional activity*
- *European Commission endorsed a significantly broader indication for Feraccru*
- *NDA submission for Feraccru remains on course to be filed in 2018*
- *Advanced discussions with a number of parties to out-license Feraccru in Europe*

London, UK, 23rd July 2018: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs, with an initial focus on addressing iron deficiency with its approved product, Feraccru®, today announces a business update following progress made in H1 2018.

Feraccru update

New Drug Application (NDA) submission

Following the Company's detailed analyses of the positive data from the placebo-controlled period of the AEGIS-CKD study, we completed a planned pre-NDA submission meeting with the FDA at which we presented the positive AEGIS-CKD study results together with a broader discussion regarding the Company's intention to file an NDA for Feraccru in 2018. The feedback received meant we have continued preparations for the NDA submission, which remains on course to occur in the second half of the year and is expected to lead to an approval decision being made by the FDA during the second half of 2019.

Broad label in Europe

H1-18 also saw the European Commission (EC) endorse the EMA's recommendation to grant Feraccru a much broader indication and it can now be used across Europe to treat iron deficiency (ID) with or without anaemia in all adults. This is a very significant event for Feraccru as it provides a significantly broader commercial opportunity in Europe, where 40 million[1] people are estimated to be iron deficient as compared to under half a million with iron deficiency anaemia (IDA) associated with inflammatory bowel disease (IBD).

Development progress

AEGIS-CKD study: in March, after a detailed review of all enrolled subjects who completed the initial 16-week pivotal period of the Phase III AEGIS-CKD study, we announced Feraccru had achieved a statistically significant response (p=0.0149) against the primary endpoint - haemoglobin levels after 16 weeks of treatment compared to placebo – as well as for a range of additional iron parameters (TSAT, Ferritin levels, serum iron levels). Since announcing these results we have been finalising and incorporating the Clinical Study Report into the NDA submission. At the same time, we have been continuing to progress the long term 52-week open-

label phase of the study, which will complete active patient involvement in the second half of 2018.

AEGIS H2H study: The first half of 2018 was a period of continued steady recruitment in this non-inferiority study of Feraccru versus Ferinject, the leading intravenous iron therapy. Recruitment is over 90% in this study, whose primary end-point is after 12 weeks of treatment. Data from the study is primarily aimed at supporting pricing strategy in some European markets, and we look forward to reporting full results from this study at the earliest opportunity.

Paediatric PK Study: In June we reported positive data from our first paediatric study of Feraccru, the AEGIS-Paeds PK study. This pharmacokinetics (PK) study of Feraccru was conducted in 36 subjects aged 12-17 years and saw Feraccru achieve all the pre-defined goals of the protocol. Completion of this study signified delivery of the first key milestone in Feraccru's paediatric development plan as agreed with the EMA and allows for dosing schedule optimisation for the Phase III study that will follow subject to funding.

Real World Data: The first half of 2018 also saw two independently published reports of the efficacy and cost-effectiveness of Feraccru in real world settings. These are important as company-sponsored clinical studies can overestimate the effectiveness of new medicines and under-report tolerability issues due to the willingness of subjects to remain in these studies. An issue that has been shown to be common for oral iron preparations, where real life data often demonstrates poorer compliance than that seen in controlled studies.

The FRESH (**F**eraccru® **R**eal World **E**ffectiveness **S**tudy in **H**ospital Practice) study presented at the 2018 meeting of the British Society of Gastroenterology and a health economics analysis reported at the 2018 European Haematology Society meeting by physicians from the London North West University Healthcare NHS Trust provide independent data supporting the clinical and cost effectiveness of Feraccru, all of which add to the increasing body of evidence supporting its growing use. We anticipate that as prescriber experience of Feraccru grows, further positive real world data will be reported at scientific congresses.

Trading update and licensing activities

The Company can report that the number of patients treated with Feraccru in the initial markets of Germany and the UK during the first quarter of 2018 continued to grow positively, continuing the progress seen in the second half of 2017. In the second quarter we saw this higher level of prescribing maintained in both markets which, given the fundamental and rapid reduction in Shield's own headcount and Feraccru promotional activities required from February onwards, is testament to the faith that prescribers who already have experience of Feraccru retain in the product. Revenues for the half year are expected to amount to £0.5m, with £0.4m from sales of Feraccru (H1-17: £0.1m). Commercial experience to date clearly supports the hypothesis that Feraccru is a product that responds well to promotional activity, as well as share of voice and this knowledge has aided our considerations around identifying a suitable licensing partner in Europe.

As announced earlier this year, we have been working to reach agreement with suitable commercial partners for Feraccru across a range of key markets, with an initial focus on finalising an agreement to cover the major markets of Europe. Significant progress has been made and we are now in advanced negotiations with a number of pharmaceutical companies to out-license Feraccru in Europe. The proposals include provisions for a mix of terms such as upfront payments – which could be used to extend the Company's cash runway - development milestone payments, sales milestone payments and sales royalties that would provide revenues throughout the life of the partnering agreement. Progressing these discussions to a successful conclusion is a priority for the Company over the coming months, although there can be no certainty of a license deal being concluded.

Summary and Outlook
Despite the unexpected and impactful issues faced by the Company in February, which led to the Board quickly implementing a number of fundamental decisions about the long-term direction of the Company, real operational progress has continued to be made and both patient and prescriber feedback on Feraccru remains overwhelmingly positive. Highlights such as the successful completion of the AEGIS-CKD study, approval of the broad label in Europe and a positive paediatric study all point to a successful commercial future for Feraccru, if it is given the necessary resources.

As we move into the second half of 2018 our focus is on advancing a number of key value-adding workstreams. Successfully concluding the European partnering discussions for Feraccru is a key priority and the Board expects to be able to update shareholders on progress in the coming months. Alongside this, the completion and filing of a USA NDA for Feraccru is a key deliverable during the second half of 2018 as, should it lead to a positive decision in 2019, Feraccru will be positioned to gain access to the world's most lucrative pharmaceutical market. On costs, since decisive actions were taken in February, the Board has continued to have a focus on conserving cash and believes the Company has sufficient resources to see it towards the end of Q4 2018. Funding beyond this timepoint is expected to be primarily satisfied from a successful conclusion to the ongoing European partnering discussions, although other funding options are being fully considered.

Interim CFO change
We are pleased to announce that Tim Watts will be joining us on an interim basis as CFO, with our current interim CFO, Dr Karl Keegan, leaving the Company shortly. We would like to thank Karl for his service during a time of significant flux for the Company over the last 18 months. Tim has a very significant level of market experience as a CFO in AIM listed businesses, most recently as the CFO of Oxford Biomedica plc and we are very pleased that he has agreed to employ that experience to the benefit of Shield as we proactively move the Company onto a new chapter.

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"The first half of 2018 has clearly been a period of significant change for the Company following the negative impact on the share price of the initial announcement of topline data from the AEGIS-CKD study of Feraccru, despite full analysis of the data subsequently demonstrating a clear and statistically significant result, further reinforcing the efficacy and safety of Feraccru. With such a depressed share price immediate action needed to be taken to conserve the Company's limited cash resources, as the fund raise anticipated on the back of the AEGIS-CKD study result became untenable. Following key decisions taken by our Board in February, we focused on resource conservation, but importantly we have continued to advance value-creating projects including achievement of a significantly broader European label for Feraccru, preparing the submission of an NDA for Feraccru and identifying suitable pharma partners with whom we are negotiating commercial agreements that would see meaningful expansion and acceleration of Feraccru's European commercialisation.*

I would like to sincerely thank all the colleagues who, after these events, are no longer with the Company as well as those that remain for their professionalism, resilience and dedication to Shield Therapeutics, Feraccru and the patients we ultimately serve."

- Ends -

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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 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, 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 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 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.

[1] *Levi, M., Rosselli, M., Simonetti, M., Brignoli, O., Cancian, M., Masotti, A., Pegoraro, V., Cataldo, N., Heiman, F., Chelo, M., Cricelli, I., Cricelli, C. and Lapi, F. (2016), Epidemiology of iron deficiency anaemia in four European countries: a population-based study in primary care. Eur J Haematol, 97: 583-593. doi:10.1111/ejh.12776