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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")

Business and trading update

London, UK, 24 January 2019: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs, today provides a business and unaudited trading update for the year ended 31 December 2018.

Operational highlights

- Norgine commences promotion of Feraccru® in UK and Germany
- Following the positive result from the Feraccru® AEGIS-CKD study, a US NDA was filed and accepted by FDA and the 27 July 2019 has been set as the PDUFA date

Financial highlights in line with market expectations

- Revenues for year ended 31 December 2018 are expected to be c. £11.9 million (2017: £637,000)
- Cash position as at 31 December 2018 was £9.8 million (2017: £13.3 million)

Business update

The Group announced on 19 September 2018 that it had entered into an exclusive licence agreement with Norgine BV for the commercialisation of Feraccru® in Europe, Australia and New Zealand. The financial terms included an £11 million upfront licence payment which was recognised in 2018, up to an additional €54.5 million in development and sales milestones, and royalties on sales which range from 25% to 40%. With a positive working relationship, the transition process progressed smoothly through the last three months of 2018 and Norgine began to promote Feraccru® in both the UK and Germany in December as these are markets where the product was already commercially available and being reimbursed.

Across these two markets Norgine already has approximately 80 sales representatives promoting Feraccru, representing more than four times the number of sales representatives Shield had previously been able to deploy. These

sales representatives are further supported in the field by dedicated pricing and reimbursement-focused staff, and also medical support staff.

Feraccru® will be launched by Norgine in the other major European markets when pricing and reimbursement negotiations are concluded, with these launches not expected before 2020. During 2018 Feraccru® also achieved attractive levels of reimbursement in Sweden and Finland, enabling further commercial rollout by AOP in those markets. 2018 also saw a major broadening of the approved marketing authorisation of Feraccru® in Europe, which significantly expanded the market opportunity from a few hundred thousand patients with IBD-IDA to many millions of patients, as Feraccru® can now be used in all adults to treat iron deficiency with or without anaemia, whatever the patient's primary disease.

The Group also announced on 1 October 2018 that it had submitted a New Drug Application (NDA) for Feraccru® for the treatment of iron deficiency with the US Food and Drug Administration (FDA). Since then the FDA has accepted the filing and confirmed that the target date for completion of the NDA review is 27 July 2019. However, with the prolonged shutdown of federal government operations in the USA, there may be some risk of delay to this review. As previously indicated, as with European commercialisation, the Board is assessing options for the commercialisation of Feraccru® in the USA, including identifying a suitable commercial partner for whom Feraccru® would be an important asset and who would be able to deploy significantly more resources than the Group could in support of the successful commercialisation of Feraccru®.

Discussions are also underway with third parties for the licensing of Feraccru® commercial rights in certain other countries.

Recruitment of patients into the AEGIS-H2H study, comparing Feraccru® with Ferinject (the leading intravenous iron therapy) was completed in September 2018 and the Group expects that results of this study will be available by the end of March 2019. In the event that the study achieves the primary endpoint of non-inferiority a milestone payment would become receivable by the Group under the terms of the Norgine agreement.

The Group has been made aware that a 3rd party has raised objections with the European Patent Office (EPO) to the Group's patents (#2 668 175 and # 3 160 951) which cover "Process for preparing an iron hydroxypyrone" and "Crystalline forms of ferric maltol" respectively. On the basis of specialist advice received and the fact both patents went through an extensive examination process prior to grant, the Group continues to have full confidence in the validity of the patents which expire in 2032 and 2035, and intends to robustly defend its intellectual property, if required. Further information is available on the website of the European Patent Office (EPO) (www.epo.org) and the Group will provide updates in due course.

Financial update

Expected revenues of c. £11.9 million in 2018 are dominated by the £11.0 million upfront received from Norgine on the signing of the licence agreement. The remaining expected c. £0.9m comprised (a) c. £0.6 million Shield sales in the UK and Germany prior to the signing of the licence agreement, (b) c. £0.1 million royalties from Norgine on their sales in the UK and Germany since the September 2018 signing of the licence agreement, and (c) c. £0.2 million sales to AOP Orphan Pharmaceuticals AG and Ewopharma AG, Shield's licence partners for Scandinavia and Switzerland.

Following the receipt of the £11.0 million upfront from Norgine, the Group had a cash balance of £9.8 million as at 31 December 2018. Taking into account expected royalty income from Norgine during 2019, which is anticipated to grow

steadily based on sales in the UK and Germany, but excluding any development or sales milestones which may be received from Norgine, and the planned expenditure on R&D, the Board is confident that the Group's cash runway currently extends into 2020.

Board change

The Group has previously announced that James Karis, a non-executive director since 2016, has been appointed as Chairman of the Board.

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"Shield has entered 2019 in good shape. I have been encouraged by the sales performance of Feraccru® in the UK and Germany, where upward sales momentum has been maintained through the last twelve months despite the lack of active sales promotion since February 2018 and I believe that Norgine, with its much larger field-based sales team and readily available resources, is well placed to build on the positive momentum we saw in 2018 and drive the Feraccru business forwards in Europe. In the USA I am looking forward to the 27 July 2019 PDUFA date for Feraccru® and the opportunity for Feraccru® to be commercialised in the world's largest prescription pharmaceutical market. To enable this we are focused on identifying a suitable US commercial partner at the earliest opportunity, and, based on ongoing discussions I believe we also have the potential to out-license Feraccru® for commercialisation in other parts of the world"*.

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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.

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