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Shield Therapeutics PLC
15 January 2021

Shield Therapeutics plc
("Shield" or the "Group" or the "Company")

Business and trading update

London, UK, 15 January 2021: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru®/Accrufer® (ferric maltol), provides a business and unaudited trading update for the year ended 31 December 2020.

Operational highlights

- Feraccru® 2020 sales volumes in Europe increased by ~70% year-on-year
- China IND application submitted
- First stage of paediatric study plan completed
- Teva challenge to Shield's European patents withdrawn
- Shield continues to evaluate options for launching Accrufer® in the US
- US partnering discussions remain ongoing with a number of parties

Financial highlights

- Trading for the year was in line with market expectations
- Revenues for 2020 expected to be £9.4 million (2019: £0.7 million)
- Cash position as at 31 December 2020 was £2.9 million (2019: £4.1 million)
- Shareholder loan facilities provide means to extend cash runway until late 2021

Business update

US commercialisation

As reported in December 2020, we are currently evaluating both out-licensing and Shield-led alternatives for the launch and commercialisation of Accrufer® in the US. Discussions are ongoing with a number of potential out-licencing partners. Preparation of a Shield-led launch is being led by a US commercial team comprising four managers who have extensive experience of launching and commercialising multiple pharmaceutical products in the US. The work in the US is well advanced and covers preparations for all activities and organisational matters which will be implemented quickly should we decide to launch Accrufer® ourselves including the supply chain, pricing and market access, selling and marketing, and regulatory compliance. Discussions are also taking place with several companies which could co-promote or sub-license Accrufer® in specific therapy areas which could complement a Shield led launch. Launch stocks of Accrufer® have been manufactured in readiness for whichever option we choose. We are also evaluating various alternatives for the financing of the

$30 million - $40 million we estimate the Group needs to reach cash flow break even in the event of the Shield-led launch.

Europe
The number of Feraccru® packs sold in Germany and the UK increased by around 70% in 2020 compared with 2019. Shield's revenue arising from these sales is expected to be £0.7 million (2019: £0.6 million), an increase of 18%. This is less than the stated headline 70% increase in packs sold because 2019 revenue was inflated by the initial sale of Shield's inventory of Feraccru® packs to Norgine when Norgine took over marketing from Shield in early 2019. Sales and marketing activities have inevitably been impacted by the coronavirus pandemic, particularly in the UK, but demand for Feraccru® has increased and there are signs that patients and their doctors are becoming more wary of being treated with intravenous iron which requires hospital visits.

Norgine are using the updated AEGIS H2H detailed study results to reconfirm pricing and reimbursement strategy for Feraccru® in the major European markets of France, Italy and Spain.

China
ASK Pharm, our licence partner in China has submitted the Investigational New Drug (IND) application for Feraccru® to the Chinese regulatory authorities. As we have previously reported, it is probable that the authorities will require only one further study, expected to be a 12-week Phase III study in 120 inflammatory bowel disease patients. Clinical supplies have been manufactured for the study which could get underway in H1 2021. The study is expected to complete during 2022 and marketing approval and product launch could follow in 2023. On approval, Shield is due to receive an $11.4 million milestone payment from ASK Pharm and tiered royalties of 10% or 15% of net sales.

Business development
Although the US has been our commercialisation priority, during 2020 we have continued to have discussions with potential partners in several other countries and are aiming to complete a new licence transaction in 2021.

Paediatric study
The first stage of the paediatric study plan, which was to compare the relative bioavailability of the liquid formulation required for children with the adult capsule, completed during Q4 2020. The study report from this stage will be completed by the end of Q1 2021 and we expect to be able to start the main paediatric study in 120 children around mid-2021. Successful completion of this study could lead to expansion of the available market and potentially further patent protection.

Reanalysis of AEGIS-H2H study
The reanalysis of the H2H (head-to-head) study in which Feraccru®/Accrufer® was compared with intravenous iron demonstrated that Feraccru®/Accrufer® is a credible alternative to IV therapy for iron deficiency anaemia, and maintains haemoglobin levels over the long term. A manuscript covering this study has been submitted to a relevant journal for peer-reviewed publication in due course.

Manufacturing
Towards the end of 2020 we successfully converted Feraccru® capsules from gelatin to HPMC (hydroxypropyl methylcellulose) which provides an improved product with regards to stability and are more suitable for vegetarians and vegans. Also the FDA have approved an immediate extension to the shelf life of Accrufer® packs from 21 months to 24 months and ongoing studies should, in due course, demonstrate stability out to 36 months.

Intellectual property
As we reported in October 2020, following the filing of Shield's defence, Teva Pharmaceuticals has withdrawn both its appeal against the European Patent Office's decision with regard to Shield's patent No.2668175, which covers a "Process for preparing an iron hydroxypyrone" and their opposition with regard to Shield's patent No.3160951 which covers "Crystalline Forms of Ferric Maltol." For the latter patent, this means that the patent will continue to provide protection through to October 2035.

Financial update
Unaudited revenues of £9.4 million for 2020 (2019: £0.7 million), include £8.7 million from the upfront payment received from ASK Pharm on signing of the licence agreement covering China, Taiwan, Hong Kong and Macau. A further £0.7 million came from royalties relating to Norgine's sales of Feraccru® in Europe.

The Group's cash balances at 31 December 2020 amounted to £2.9 million (2019: £4.1 million). As previously reported, loan facilities from two shareholders amounting to approximately £4.4 million would allow the Group to extend the Group's cash runway until late 2021.

Commenting on this update, Tim Watts, CEO of Shield Therapeutics plc, said: *"2020 has been a positive year for Shield on many fronts. European sales volume growth of around 70% despite the COVID pandemic is very encouraging for the long term with launches still to come in France, Italy and Spain and many other European markets, and the withdrawal of Teva's opposition to our European patents has removed a significant uncertainty. Progress by ASK Pharm in defining the necessary development path to product approval suggests that a launch in the huge market of China is possible by 2023. In the US our knowledge of the iron deficiency market and the great opportunity for Accrufer® has developed massively during the year such that we are now evaluating a Shield-led launch in the US as an alternative to out-licensing the product. We aim to give clarity on the US by the end of March and I am sure that 2021 will be a transformational year for Shield."*

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About Shield Therapeutics plc

Shield is a de-risked, specialty pharmaceutical company focused on commercialising its lead product, Feraccru®/Accrufer®, a novel, non-salt based oral therapy for adults with iron deficiency with or without anaemia. Feraccru®/Accrufer® has been approved for use in the United States, European Union, UK and Switzerland and has exclusive IP rights until the mid-2030s. Feraccru® is commercialised in the UK and European Union by Norgine B.V. and the Company is currently in the process of evaluating commercialisation options for the US market, including the potential launch of Accrufer® in the US by Shield. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

For more information, please visit www.shieldtherapeutics.com. Follow Shield on Twitter @ShieldTx

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