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Shield Therapeutics PLC
10 December 2020

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

Update re US partnering discussions
Shield considering launch of Accrufer® in the USA
Loan facilities agreed

London, UK, 10 December 2020: 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 an update on its plans to commercialise Accrufer® in the USA and its cash position.

US commercialisation

Accrufer® was approved in July 2019 by the FDA for the broad indication of treatment of iron deficiency in adults. Since then Shield has conducted an extensive process to identify and appoint a commercialisation partner for the US market and, through this process, the Group and its advisers have engaged with a wide range of interested parties. Since this process began Shield has received numerous indicative proposals from potential commercialisation partners and, whilst some of these reached late stages of negotiation, they did not proceed to completion due to adverse business events specific to the counterparties concerned and unrelated to Accrufer®. The Group remains in discussions with a number of potential commercialisation partners for the US marketing rights to Accrufer® but it is now clear that a transaction will not be completed before the end of 2020.

The length of time that the process has taken and the late-stage setbacks incurred have been frustrating for both the Board and shareholders but Shield's understanding of the US iron therapy market has developed significantly over the last year, and the market itself has also evolved in that time, in large part due to the COVID pandemic. Discussions with potential commercialisation partners have demonstrated to Shield that it is realistic for companies without large sales and marketing infrastructure to launch a product such as Accrufer® in the US. The COVID pandemic has accelerated the trend towards greater reliance on telesales, e-detailing and on-line marketing, reducing the need for very large sales teams. The COVID pandemic has also accentuated some of the advantages that Accrufer®, a well-tolerated and effective oral treatment, offers over intravenous (IV) iron

replacement therapy as it avoids the need for patients, usually with underlying health issues, to visit hospitals or clinics to be infused. Furthermore, Shield believes that the first US launch of an oral HIF inhibitor[(1)] for chronic kidney disease (CKD) patients, anticipated in Q1 2021, is likely to increase the need for effective and well tolerated oral iron replacement therapy.

The Board has therefore concluded that, in order to maximise the Group's options, in parallel with continuing ongoing discussions with potential licence partners it should explore the potential launch of Accrufer® in the US by Shield, possibly including co-promote and/or sub-licence partners in specific therapeutic areas. To this end, work is being carried out with US-based consultants and other advisers to develop a strategy and plans for a Shield-led launch. A key component of this planning is to establish the investment needed for such a launch. Shield estimates that the amount required for the Group to reach the point at which it generates cash, including the US launch costs, the costs of Shield's current non-US operations and the ongoing paediatric study is in the range of $30 million to $40 million. The Company expects that any financing for a Shield led US launch of Accrufer® would include a substantial debt component and Shield is in discussions with several potential lenders and has already received a number of term sheets on acceptable commercial terms.

The Group is continuing to progress both the out-licence and Shield-led launch opportunities and will decide which of the alternatives is likely to deliver greater value to shareholders, taking into consideration the potential financial returns from each alternative, and their respective risks.

The US market opportunity for Accrufer® is substantial and growing:

- Approximately 9-10 million US patients suffer from iron deficiency anaemia , and possibly 2-3 times as many have iron deficiency without anaemia
- Almost 10 million iron replacement prescriptions are written annually in the US, of which a substantial majority are for generic ferrous oral iron salts which are well-known to be poorly tolerated by patients
- In Shield's head-to-head study which compared Accrufer® with IV therapy, Accrufer® was shown to be a credible alternative to IV therapy particularly for maintaining haemoglobin levels over the long term

Shield therefore believes that there is an opportunity for Accrufer® to take significant market share from both the existing oral and IV iron products, and to grow the overall market, potentially leading over time to Accrufer® sales potential of several hundred million dollars per annum.

Cash position and loan facilities

At 30 November 2020 the Group held unaudited cash balances amounting to £3.8 million and, due to prudent cash management, its cash runway now extends into Q2 2021. The Group has received letters of intent from AOP Orphan International AG ("AOP"), a shareholder owning 10.7% of the Company's issued share capital, and Dr Christian Schweiger, a board member and holder of 3.5% of the Company's issued share

capital, confirming that they are prepared to lend the Group up to €4.0 million and CHF1.0 million respectively in order to provide working capital for the Group. In total these amount to approximately £4.4 million which would extend the Group's cash runway until around the end of 2021.

The two loan facilities are unsecured and will be structured identically and provide for 50% of each facility to be drawn down on 1 February 2021 and the remaining 50% to be available for drawdown at Shield's request during the rest of 2021. Interest of 10% pa is payable on the amounts drawn down. The loans will be repayable in cash in the event that Shield receives a licence upfront payment above a certain level, secures a debt facility with another lender, raises new equity or, in any event, by 31 January 2022. However the lenders will have the right, but not the obligation, to convert any outstanding loan balances into ordinary shares in Shield at any time at a 5% discount to the market price at the time or, in the event of a new equity raise, on the same terms as all other investors subscribe. An arrangement fee of 2% is payable to the lenders on signing the formal loan documentation. The letters of intent are binding on both AOP and Dr. Schweiger. Execution of the formal loan documentation will also be subject to Aim Rule 13.

The Company expects to provide a trading update in January 2021.

Commenting on this update, Tim Watts, CEO of Shield Therapeutics plc, said: *"I am very grateful to AOP and Dr Schweiger for making loan facilities available to the Group. These will give us time to secure the best possible outcome for all shareholders. It is clear from our work over the last year, including market research and discussions with potential partners, that there is an exciting opportunity for Accrufer® in the United States. Patients, prescribers and payers express the need for a well-tolerated and effective oral iron therapy as an alternative to IV iron replacement and older oral iron products. Although we continue to have attractive licence discussions, it is prudent that we also assess other options by which we can drive value for our shareholders and a Shield-led launch of Accrufer® is a very credible alternative plan. The Board remains very confident that either way we will secure an outcome which will generate substantial value for shareholders."*

Notes

(1) Hypoxia-inducible factor (HIF) prolyl hydroxylase enzyme inhibitors are a new oral class of agents for the treatment of anemia in CKD. These agents work by stabilizing the HIF complex and stimulating endogenous erythropoietin production even in patients with end-stage kidney disease.

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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, stable, 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 Europe by Norgine B.V. and the Company is currently in the process of selecting a commercialisation partner for the US market. 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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