

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

Business and trading update

Excellent progress during 2019 with the FDA approval of Accrufer® and the results of the AEGIS-H2H study

London, UK, 27 January 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 a business and unaudited trading update for the year ended 31 December 2019.

Operational highlights

- FDA approves Accrufer® with a broad label of treating iron deficiency in adults in the USA
- AEGIS-H2H study positive and results presented at UEG Week, showing non-inferiority to IV iron therapy
- European Feraccru® 2019 sales volumes grew 67% over 2018

Financial highlights broadly in line with market expectations

- Revenues for the year expected to be £2.9 million (2018: £11.9 million)
- Cash position at 31 December was £4.1 million (2018: £9.8 million)

Post-period Highlights

- Feraccru®/Accrufer® licence agreement signed for China with Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm")
- US\$11.4 million upfront received from ASK Pharm in January 2020, extending cash runway into 2021

Business update

USA approval

In July 2019 we announced that the U.S. Food and Drug Administration (FDA) had approved Accrufer® for the treatment of iron deficiency in adults. With this broad label approval Accrufer® has taken a big step towards exploiting the very large commercial opportunity in the USA, the world's largest and most attractively reimbursed pharmaceutical market. Shield is in detailed discussions with potential commercial partners for the US opportunity for Accrufer® and looks forward to providing updates on these discussions in due course.

AEGIS-H2H non-inferiority study results presented at major scientific meeting

In the first half of 2019 we announced the headline results of the AEGIS-H2H study of orally administered Feraccru®/Accrufer® versus Ferinject® which demonstrated that,

after 12 weeks' treatment, the response rate of patients treated with Feraccru®/Accrufer® was non-inferior to the response rate seen in patients treated with Ferinject®, the leading intravenous (IV) iron therapy. In October 2019 detailed results were presented to the 27th United European Gastroenterology Week (UEG) with key findings including:

- a. The patients' response rate at 12 weeks was 74% for oral Feraccru®/Accrufer® and 83% for IV Ferinject®, well within the pre-specified non-inferiority margin of 20% (p=0.017)
- b. Recurrence of iron deficiency anaemia occurred at least once in approximately 39% (49) of the subjects in the Ferinject® arm of the study
- c. Ferinject® patients required a total of 69 additional IV iron infusions to be administered through the study period with the average time to relapse being 85 days
- d. Feraccru®/Accrufer® was generally well tolerated over 52 weeks of treatment with a side effect profile consistent to that seen in previous placebo-controlled studies

This data shows that Feraccru®/Accrufer® is not only a real oral alternative to IV iron for patients with iron deficiency anaemia, but that it can also prevent the need for repeated IV infusions.

European sales

During 2019 Norgine rolled-out its initial commercial activities for Feraccru®/Accrufer®, culminating in a series of major promotional events around presentation of the AEGIS-H2H data at the UEGW Congress in Barcelona in October. Feedback from prescribers and patients continues to be very positive. As previously guided, due to continuing reimbursement constraints related to the originally approved narrow European label for the product - that are expected to be largely addressed through 2020 by the data from the AEGIS-H2H study - during the period Norgine continued to focus its field-based promotional activity of Feraccru®/Accrufer® on the German and English markets. In these limited geographies pack sales continued to climb, being 28% higher in the second six months of 2019 than in the first six months and 67% above those in 2018. Norgine is in the process of submitting pricing and reimbursement (P&R) applications to the P&R authorities in a range of countries in Europe including the major commercial markets of France, Italy and Spain, as well as the other countries in the UK.

Exclusive licence in China

In early January 2020 we announced that the Group had entered into an exclusive licence agreement for Feraccru®/Accrufer® with Beijing Aosaikang Pharmaceutical Co. Ltd ("ASK Pharm") in China, Hong Kong, Macau and Taiwan (the "Territory"). Shield has now received the upfront payment of US\$11.4 million and is eligible to receive a further US\$11.4 million upon regulatory approval of Feraccru®/Accrufer® in China. Shield will also receive tiered ongoing royalties of 10% or 15% of net sales of Feraccru®/Accrufer® and up to US\$40 million in milestone payments upon the achievement of specified cumulative sales targets. ASK Pharm is responsible for all clinical and regulatory costs

and activities as well as all manufacturing and distribution costs for goods sold in the Territory.

Financial update

Expected revenues for 2019 of £2.9 million comprise £2.3 million from milestones received from Norgine and EWO and £0.6 million sales-related revenues from Norgine.

The Group's cash balances at 31 December 2019 amounted to £4.1 million. Following receipt in January of the US\$11.4 million upfront payment from ASK Pharm, the Group's cash runway now extends into 2021.

Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"The Group has made material progress during 2019. Two key successes were the positive results of the AEGIS-H2H study, which demonstrated that Feraccru®/Accrufer® is a credible oral alternative to IV iron therapy; and the FDA's approval of Accrufer which opens up the US market for which we are diligently working towards appointing an appropriate commercial partner. In addition, having worked throughout 2019 to secure a Chinese partner, we were able to announce the agreement with ASK Pharm just after the year end. As well as being delighted to have ASK Pharm as our partner, the US\$11.4 million upfront has further bolstered our balance sheet as we seek to conclude US partnering discussions."*

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About Shield Therapeutics plc

Shield is a de-risked, commercial stage, specialty pharmaceutical company delivering innovative pharmaceuticals to address patients' unmet medical needs. The Company's clear purpose is to develop products that help patients become people again,

enabling them to enjoy the things that make a difference in their everyday lives. The Group's lead product, Feraccru®/Accrufer® has exclusive IP rights until the mid-2030s and is approved for the treatment of iron deficiency with or without anaemia in adults in the European Union, the United States and Switzerland. In Europe it is marketed as Feraccru® with commercialisation led by Norgine BV and in the USA the product will be marketed as Accrufer® with Shield currently in the process of selecting a commercialisation partner. 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

About Feraccru®/Accrufer®

Feraccru®/Accrufer® is a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia that has been shown to be an efficacious and well-tolerated therapy in a range of controlled phase 3 trials, including positive results from the Phase IIIb AEGIS-H2H study in which Feraccru®/Accrufer® demonstrated it was non-inferior in delivering improvements in haemoglobin levels compared to intravenously-administered (IV) Ferinject®/Injectafer® (ferric carboxymaltose). Feraccru®/Accrufer® therefore offers a compelling alternative to IV iron for those patients unable to tolerate salt-based oral iron therapies and wish to avoid the complexities of infusion-based iron therapies.

When salt-based oral iron therapies are ingested they can cause a range of mild-to-severe gastrointestinal tract (GI) adverse events through the release and subsequent reactivity of free iron in the GI tract, leading to poor tolerability, reduced patient compliance and ultimately treatment failure. Feraccru®/Accrufer® is not an iron salt and, as a result, does not routinely cause the same treatment-limiting intolerance issues of salt-based iron therapies, whilst the iron from the ferric maltol molecule can be readily absorbed.

Prior to Feraccru®/Accrufer®, IV iron therapies were the only realistic alternative treatment option for iron deficient patients with or without anaemia intolerant of or unwilling to be treated salt-based oral iron therapies. However, use of such an invasive, costly, inconvenient and complex to administer treatment option, which is associated with potentially life-threatening and spontaneous hypersensitivity reactions, means there remains a clear unmet medical need for these patients to have access to an effective therapy that is well tolerated, convenient and does not require hospital-based administration. Feraccru®/Accrufer® meets those requirements.

About Iron Deficiency

The WHO state that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of children and women in non-industrialized countries, it is the only nutrient deficiency which is also significantly prevalent in virtually all industrialised nations. There are no current global figures for iron deficiency, so using anaemia as an indirect indicator it can be estimated that most preschool children and pregnant women in non-industrialized countries, and at least 30-40% in industrialized countries, are iron deficient.

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