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

Business and trading update

London, UK, 1 May 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), a novel oral iron treatment, provides a business and unaudited trading update.

Coronavirus pandemic
The business has continued to operate effectively since the introduction of the lockdown in the UK. Whilst we have closed both our London and Newcastle offices, all of our employees are able to continue working from home successfully. Generally, we are finding that the businesses with which we have close relationships are also continuing to operate effectively and so we have seen minimal disruption to our commercial progress.

US commercialisation
We are continuing to devote significant effort to secure a commercialisation partner for the USA. There continues to be significant interest from a range of companies in licensing Accrufer® for commercialisation in the USA and we have been able to advance discussions with interested parties in recent weeks. We look forward to providing further updates in due course.

European commercialisation
Norgine, our European commercialisation partner, has continued to see growth in sales of Feraccru® in Germany and the UK during the first quarter of 2020. However, it is too early to say whether, or how, their sales will be impacted by the coronavirus pandemic.

Supply chain
Our contract manufacturing partners continue to manufacture Feraccru® for us without disruption. We rely on a UK company to manufacture ferric maltol, the active pharmaceutical ingredient (API) in Feraccru®, and a French company to convert the API into finished packs. Our UK manufacturer is currently working on a campaign to manufacture around 12.5 metric tonnes of ferric maltol which should be completed by the end of September 2020. This will provide us with sufficient API to last throughout 2021. Our French manufacturer is also continuing to manufacture finished packs for sale by Norgine and AOP in Europe, and we have also placed orders for launch supplies of US packs so that we will be in a position to supply US packs promptly when we have secured a US commercial partner.

China

ASK Pharma, our partner in China, was able to continue working with us during the lockdown in China and we have continued the technical transfer and regulatory support delivering key information which they require to apply for an IND to commence clinical studies in China. We have also been informed by the Chinese Patent Office that our composition of matter patent application has been allowed.

AEGIS-H2H clinical study update

On 17 March 2020 we released an announcement that clarified that the AEGIS-H2H clinical study had not met its primary endpoint which required achievement of non-inferiority at 12 weeks in both the "intention to treat" (ITT) and "per protocol" (PP) populations. Non-inferiority was not demonstrated in the ITT population and hence the overall study failed to meet its primary endpoint. The Board has commissioned a review into the analysis of the study and we will update the market further on this review in due course. As part of this review we are also in discussions with Norgine, our European commercialisation partner, as to how best to use the positive long term data from the H2H study, for example for health economics purposes including pricing and reimbursement negotiations.

Under the 2018 agreement with Norgine a €2.5 million milestone was payable by Norgine to Shield in the event that the H2H study achieved its primary endpoint in the trial protocol. Since it is now clear that the study's primary endpoint was not achieved, we have agreed to repay the milestone to Norgine. However, Norgine remain committed to and enthusiastic about Feraccru® and continue to believe that it is an important advance in the treatment of iron deficiency.

Paediatric Clinical Development Programme

Development of the liquid formulation for the paediatric clinical studies is continuing well and a prototype formulation is undergoing stability studies in readiness for the manufacture of clinical study material. The US FDA has provided guidance on the conduct of clinical studies during the COVID-19 emergency as a result of which we have decided to defer the initiation of the study but we would hope to be able to start the study in the autumn of this year.

European Patent Opposition

We continue to prepare our defence to the challenge to our composition of matter patent (European Patent No. 3160951) which will be heard by the EPO Opposition Division on 23 June 2020.

Financial update

In our 27 January 2020 trading update we stated that expected revenues for 2019 would be £2.9 million. Following the recognition in March 2020 that the AEGIS-H2H study had not in fact met its primary end point and the agreement to repay Norgine the €2.5 million milestone unaudited revenues for 2019 are now expected to be £0.7 million. The Group's unaudited cash balances at 31 March 2020 amounted to £11.3 million and the Group's cash runway extends into the first quarter of 2021.

The Group intends to release the 2019 Annual Report at the same time as the Notice of AGM in late May 2020.

Commenting, Tim Watts, Chief Executive Officer of Shield, said: *"I am reassured that despite the current challenges presented by the global pandemic we continue to operate effectively and there has been little disruption to our commercialisation plans. We are encouraged by the continued interest from potential US partners during uncertain times, confident of the pressing need for our product as an effective alternative treatment for iron deficiency, and remain committed to advancing commercial discussions to secure the best deal for shareholders."*

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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, and 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, including nausea, bloating and constipation 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, it 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 states that iron deficiency is the most common and widespread nutritional disorder in the world. As well as affecting a large number of women and children 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 but, using anaemia as an indirect indicator, it can be estimated that most preschool children and pregnant women in non-industrialised countries, together with at least 30-40% in industrialized countries, are iron deficient.

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