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

US update
Shield confirms it remains on track to launch Accrufer® in the US by end of June 2021

London, UK, 21 May 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 an update on its preparations to launch Accrufer® in the US, confirming the Group remains on track to launch by end of June 2021. Since the fundraise in mid-March 2021, preparatory work has accelerated dramatically. There are five key workstreams underway which are addressed in turn below.

Establishing operational capability

We have established Shield Therapeutics, Inc., a wholly-owned US subsidiary of Shield Therapeutics plc and set up the necessary operating essentials. We are also in the process of setting up the product supply chain and logistics and it is expected that launch stocks will be stored at our US wholesaler by mid-June. Agreements have been signed with providers for product warehousing and distribution.

Marketing

We have carried out market research amongst prescribers which continues to support the Company's belief that Accrufer® has the potential to address a large unmet medical need. From that research we are now developing our strategic approach as we finalise our brand plan. The brand strategy will include a fully integrated marketing plan including both personal and non-personal promotion.

Sales force

Working in conjunction with a well-established contract sales organisation we have designed and contracted a scalable sales team that will be working to build awareness and educate health care providers on the clinical value of Accrufer®. This sales organisation will be 100% dedicated to the promotion of Accrufer®. We are planning to launch initially with 30 sales representatives and we are now in the process of hiring them. The recruitment should be completed by early June and the representatives will then be trained and ready to promote Accrufer® at launch.

Medical Affairs

The purpose of medical affairs is to provide scientific and clinical support about Accrufer® to the medical community. We have developed the necessary materials which will be made available to healthcare professionals online and through a team of medical science liaison (MSL) employees. We plan to run several Advisory Board meetings targeted at relevant specialists and Key Opinion Leaders. The Advisory Board meetings are planned to take place between late May and mid-July.

Market Access

Market access covers price setting and discounting with US payers which include private insurance plans and the Federal Medicare and Medicaid plans. It also includes mechanisms to support patients by reducing patient co-pay requirements. The headline price of a pharmaceutical product in the US is known as the Wholesaler Acquisition Cost (WAC) and for Accrufer® this has been set at $500 per pack (which contains 30 days' supply at two capsules per day) and has now been published by First Data Bank and Red Book.

National Account Managers are already actively engaging payer organisations to provide their patients access to Accrufer®. This process is underway but it will take 12-18 months before we have comprehensive coverage across a large proportion of payers and our sales forecasts in the early months take account of this.

Conclusion

A great deal has been achieved in the last two months since the successful fundraise in March 2021. There are still some critical dependencies on third parties including companies setting up services for us and Government agencies which could potentially disrupt our planning. However we are currently on track for the US launch by the end of June 2021.

Commenting on the progress to date, Tim Watts, CEO of Shield Therapeutics plc, said: *"A huge amount has been achieved in the last two months since the fundraise completed and I am very grateful to all Shield employees, and in particular to Brian Groch and his US team, for the efforts they are making to prepare for launch. This is a very exciting time for Shield and I am looking forward immensely to the Accrufer® launch and the large opportunity available."*

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About Shield

Shield is a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru® /Accrufer® (ferric maltol), a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia.

Shield's lead product, 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. The Group plans to launch Accrufer® in the US during 2021 through a highly experienced sales and marketing team. Feraccru® is already being commercialised in the UK and European Union by Norgine B.V., who also have the marketing rights in Australia and New Zealand. Shield also has an exclusive licence agreement with Jiangsu 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

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 commercial strategy for Feraccru®/ Accrufer® 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 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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