

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

**Provides Full Year Trading Update and  
Reports Progress on the Commercialization of Accrufer®/Feraccru®**

**London, UK, 17 February, 2022:** Shield Therapeutics plc (LSE: STX), a commercial stage specialty pharmaceutical company, is pleased to provide an update on trading for the year ended 31 December 2021, as well as an update on the Company's progress on the commercialization of its lead product Accrufer®/Feraccru® (ferric maltol), an effective, well tolerated, low-dose novel formulation of oral iron replacement therapy with an adverse event profile and discontinuation rate well below the published 40-60% rate for conventional oral iron therapy.

**Unaudited, Revenue and Cash for the year ended 31 December 2021:**

**Total Revenue of £ 1.5 million in line with market expectations** (FY20: £10.4 million) including:

- Net product revenue of £ 0.1 million from U.S. product sales (FY20: nil)
- Royalty revenue of £ 0.9 million from product sales in the EU (FY20: £0.7 million)
- Milestone payments of £ 0.5 million from the upfront payment of Korea Pharma on signing of the license agreement for commercialization in the Republic of Korea (FY20: £9.7 million from ASK Pharma in China)

**Cash** on hand of £ 12.1 million (30 June 2021: £22.6 million; 31 December 2020: £2.9 million)

**U.S. Update:** Shield launched Accrufer® in July, 2021 and reports:

- Payer coverage increased since last update in December, now covering 60 million commercial lives resulting from several additional contracts being executed including Cigna, Humana, and Highmark
- Awareness of Accrufer® among target prescribers doubled since launch to 65%
- Healthcare professionals generated approximately 2500 prescriptions for Accrufer® since launch into our patient assistance and reimbursement hub with significant growth seen from 3<sup>rd</sup> quarter to 4<sup>th</sup> quarter

*"Our priorities for the US launch of Accrufer® were to increase awareness, generate clinical experience, and expand payer coverage, and we have made significant progress across each of these priorities." said Greg Madison, Chief Executive Officer, Shield. "We have been very pleased by the initial feedback and reactions of healthcare providers to Accrufer®, and it is clear there is a need for an effective and well tolerated oral iron therapy for the millions of patients with iron deficiency. We will remain focused on continuing the strong momentum in the US and ensuring the Group has the resources required to deliver on this goal. We believe Accrufer®/Feraccru® has the potential to be the "best in class" oral iron replacement product and our efforts over the last six months have set the Company up to expand access and grow sales in 2022 and beyond."*

**Ex-U.S. Update:** Feraccru® was launched in the European Union and the UK in 2019. Shield reports that:

- Feraccru® volume in Europe increased by 60% (YoY) through the efforts of our partner, Norgine BV, driven in particular by increased demand in Germany
- Out-licensing agreements were signed with two new partners, Korea Pharma Co and KYE Pharmaceuticals, that will bring Accrufer®/Feraccru® to the Republic of Korea and Canada, upon completion of the respective clinical and regulatory processes

**Clinical/Registration Update:** Shield reported that:

- A Phase 3 pediatric study was initiated in the U.S. & UK in Q3 2021
- Norgine BV submitted the reimbursement dossier for Spain in late Q4 2021
- Beijing Aosaikang Pharmaceutical Co., Ltd ("ASK Pharma"), completed a pharmacokinetics study in China, a critical regulatory requirement and are now enrolling patients in the Phase 3 trial

**Greg further commented:** *"We added two new partners, in Korea Pharma Co., Ltd. (Republic of Korea) and Kye Pharmaceuticals Inc (Canada), who are excited and motivated to progress through the regulatory and clinical*

*pathways to approval. The initiation of the Phase 3 study in China is also a major milestone towards potential approval in this territory. I am pleased by the excellent progress that our worldwide strategic partners are making to bring Accrufer®/Feraccru® to more patients worldwide.”*

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**About Accrufer®/Feraccru®**

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt based oral therapy for adults with iron deficiency, with or without anemia. Accrufer®/Feraccru® has a novel mechanism of absorption compared to other oral iron therapies and has been shown to be an efficacious and well-tolerated therapy in a range of clinical trials. More information about Accrufer®/Feraccru®, including the product label, can be found at: [www.accrufer.com](http://www.accrufer.com) and [www.feraccru.com](http://www.feraccru.com)

**About Shield Therapeutics plc**

Shield is a commercial stage specialty pharmaceutical company with a focus on addressing iron deficiency with its lead product Accrufer®/Feraccru® (ferric maltol). The Group has launched Accrufer® in the US and Feraccru® is commercialized 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 license agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialization of Accrufer® / Feraccru® in China, Hong Kong, Macau and Taiwan, with Korea Pharma Co., Ltd. in the Republic of Korea, and with KYE Pharmaceuticals Inc. in Canada.

Accrufer®/Feraccru® has patent coverage until the mid-2030s

Accrufer®/Feraccru® are registered trademarks of the Shield Group

**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 Accrufer®/Feraccru®. 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.