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Shield Therapeutics PLC
09 February 2023

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

Full Year Trading Update
Further Reports of Progress on the Commercialization of Accrufer®/Feraccru®

Accrufer® US Total Prescriptions increased to greater than 25,000 in 2022;
Accrufer® Net Product Revenue increased to US$3.5 million in 2022;
Collaborative Sales Agreement signed with Viatris for Accrufer® in the US;
Completion of US$36.7million in financing (gross); and
Fully funded to support operations through to cash flow break-even by end of 2024.

London, UK, 09 February, 2023: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company focused on the commercialization of Accrufer®/Feraccru® (ferric maltol), a novel oral iron therapy differentiated from other conventional irons by its efficacy, well-tolerated formulation, and broad label, provides the following unaudited trading update for the year ended 31 December 2022, as well as an update on the Company's progress on the implementation of the collaboration with Viatris Inc ('Viatris').

Unaudited Revenue for the year ended 31 December 2022 and Cash position:

Total Revenue of £8.5 million (FY21: £1.5 million) including:
- Net product revenue of £2.8 million from sales of Accrufer® in the US (FY21: £0.1 million)
- Royalty revenue of £1.3 million from product sales in Europe (FY21: £0.9 million)
- Upfront payments of £4.2 million from Viatris and £0.2 million from KYE Pharma on signing of the license agreement for commercialization in Canada (FY21: £0.5 million from Korea Pharma)

Total Financing of c.£30 million (including gross funds received post period):
- US$36.7 million (gross proceeds, comprised of US$21.7 million from placing and open offer, US$5 million upfront payment from Viatris and US$10 million additional borrowings under the amended convertible shareholder loan facility from AOP Health)
- Cash resources sufficient to support operations through to cash flow break-even by end of 2024

US Commercial Update: About 20 million people in the US suffer from anemia including iron deficiency (ID) and iron deficiency with anemia (IDA), reflecting a large, defined yet under-served market. As the first and only FDA approved oral iron to treat iron deficiency with or without anemia, regardless of etiology, Accrufer® has the potential to meet an important unmet medical need for both physicians and patients. Shield has made substantial progress across the following areas:

- **Collaborative Sales Agreement with Viatris** - Shield signed an exclusive, multi-year agreement with Viatris, Inc, a global healthcare company, in December 2022 to co-commercialize Accrufer®. The collaboration expands the commercial footprint and resources for Accrufer®, as the brand aspires to be the oral iron of choice in the US market. The collaboration will result in a 100-person sales team which will promote Accrufer® to over 12,000 Health Care Professionals that write the majority of oral iron prescriptions. Shield received a US$5 million one-time payment and is eligible to receive up to US$30 million in sales milestones. Each company is responsible for its own respective sales force and related selling costs. Shield and Viatris will share revenues and marketing expenses, with Shield retaining a slightly higher percentage of each.
- **Personnel and hiring update** - Shield and Viatris are each hiring a team of dedicated sales professionals as part of the collaboration. Shield's recruitment of the new sales team is well under way with 16 of the targeted 50 representatives already hired and trained and currently promoting Accrufer® in their respective territories. Additionally, approximately 17 sales professionals have either accepted offers or are in process of

offers and acceptances, and those representatives will be trained in late March 2023. Shield is on track for its stated goal to have the field sales team hired and trained by the end of April.

- **US Accrufer® annual sales volume of 25,200 prescriptions** - a nearly 12-fold increase from 2,152 prescriptions in 2021, and an increase of 97% in H2:2022, when compared to H1. Prescription volume in Q4 totalled 9,324; this represents 37% of the annual prescription volume and a quarter-over-quarter increase of 26%. That was achieved with only a limited sales force of c.22 representatives.
- **Continued strong interest from the Women's Health segment**:
  - o Women's health practitioners - account for approximately 50% of Accrufer® prescriptions
  - o General practitioners - account for approximately 43% of Accrufer® prescriptions
- **Broad Reimbursement Coverage** - 100+ million or 40% of eligible lives now have coverage for Accrufer® by US payers across Commercial and Medicaid segments, enabling greater access for patients.
- **New Corporate website** (https://www.shieldtherapeutics.com/) **and branding logo** - launched in September 2022, highlighting Shield's strategic vision and accelerated growth ambitions.

Greg Madison, CEO of Shield Therapeutics, stated: *"We believe Accrufer® has the potential to be the oral iron treatment of choice for patients with ID/IDA. In 2022, we set out to substantially increase product adoption, sales growth, physician awareness and generate positive clinical experience and expand payor coverage. 2022 has been a landmark year for Accrufer®, marked by consistent improvements across all of these key performance indicators, led by a substantial increase in prescriptions and product revenues. I am proud and grateful for the excellent work by our team and our partners.*

"Completion of the Viatris collaborative sales agreement in December 2022 has set Accrufer® up for strong 2023 growth in prescriptions and product sales. We are thrilled to be working with Viatris to bring Accrufer® to more patients suffering from ID/IDA in the US. I am pleased to report that the collaboration is off to a great start and hiring and training is well underway to put the expanded sales team in place. We are pleased to expand our commercial footprint with Viatris' well established prescriber relationships, best in class digital marketing, direct to patient capabilities, and extensive market access experience."

***Ex-US Commercial Update*:**

- **Net sales of Feraccru® in Europe by Norgine increased c.10% in 2022** - Germany now accounts for c.72% of the total net sales of Feraccru® in Europe, followed by the United Kingdom with c.18%. Norgine began expanding its call reach into Women's Health practitioners in Germany at the end of 2022
- **Out-licensing agreement signed with KYE Pharmaceuticals** - to bring Accrufer®/Feraccru® to Canada upon completion of the respective clinical and regulatory processes (expected in H2:2023)

***Clinical/Registration/Product Supply Update*:**

- **FDA Approval of Improved Shelf Life to 48 months** (October 2022) - Improved shelf life from 36 to 48 months provides added flexibility in Accrufer® manufacturing and storage timelines, making the product increasingly accessible and user-friendly
- **Ongoing Phase 3 Paediatric study** - Enrolment in the US/UK study evaluating Accrufer® for children aged one month to 17 years with IDA continues to progress. This is an important study that will expand the label and market opportunity for Accrufer® and completes the fulfilment of all FDA post-marketing commitments
- **Confirmation of Regulatory Path for Korea** - Korea Pharma Co. Ltd reached agreement with the Korean Food and Drug Administration that a single pharmacokinetic study will be required to support a New Drug Application. Korea Pharma recruited the first subject in this study in January 2023. Approval is expected by the end of 2024
- **Ongoing enrolment in Pivotal Trial in China** - Beijing Aosaikang Pharmaceutical Co., Ltd (Aosaikang Pharma) completed a PK study in China in 2021, an essential regulatory requirement, and continue to enrol patients in the Phase 3 registrational trial. Enrolment has been impacted by the COVID-19 pandemic measures in China, and we are working with Aosaikang Pharma to progress enrolment and advance the program
- **KYE submitted the approval dossier to Health Canada** (March 2022) - The submission has been accepted by Health Canada (July 2022), paving the way for a potential H2:2023 approval
- **Presentation at the American College of Gastroenterology Annual Scientific Meeting** (ACG 2022, October 2022) - Presentation of pooled analysis highlighted an early and sustained response in patients with inflammatory bowel disease with IDA who were treated with Accrufer®/Feraccru® ferric maltol, a very under-served group of patients

Change of Auditors

In addition, Shield reports that following the completion of an extensive selection process, its directors have approved the appointment of Mazars LLP ('Mazars') as its new external auditor subject to shareholder confirmation for the year ending 31 December 2022.

Mazars will hold office until the next Annual General Meeting in June 2023 at which time their appointment will be subject to shareholder approval. KPMG LLP has resigned as the Group's auditor and has confirmed to the Group that, in accordance with Section 519 of the Companies Act 2006, there are no circumstances in connection with its resignation which it considers need to be brought to the attention of the Company's shareholders or creditors.

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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 and www.feraccru.com

About Shield Therapeutics plc

Shield is a commercial stage 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 with an exclusive, multi-year collaboration agreement with Viatris, Inc. Feraccru® is commercialized in the UK and European Union by Norgine B.V., that 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. for the Republic of Korea, and with KYE Pharmaceuticals Inc. for 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 and 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 its views to change.

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