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

Shield's Korean Partner files New Drug Application for Accrufer® in the Republic of Korea (South Korea)

Important milestone paves way to increasing global access of Accrufer®

Pending successful review, approval in Korea anticipated in 2025

London, UK, 28 May 2024: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company that delivers Accrufer®/Feraccru® (ferric maltol), an innovative and differentiated specialty pharmaceutical product, to address a significant unmet need for patients suffering from iron deficiency (with or without anaemia), today announces that its Accrufer® partner for Korea, Korea Pharma Co., Ltd (Korea Pharma) has submitted a New Drug Application (NDA) to the Korean Ministry of Food and Drug Safety (MFDS) for the review and approval of Accrufer® to treat patients with iron deficiency anaemia in Korea. Pending a successful review, approval of Accrufer® in Korea is anticipated in 2025.

Korea Pharma's MFDS filing follows the successful completion of a pharmacokinetic (PK) study in Korea. The PK study confirms that the absorption of iron from Accrufer® is comparable between patients in Korea and the patient population enrolled in the key clinical studies supporting Accrufer® effectiveness and safety.

Shield is eligible to receive a development milestone payment of c.$1.9 upon the first sale of Accrufer® in the territory, as well as future commercial sales milestone payments upon the achievement of specified net sales targets. For the duration of the intellectual property, Shield will also receive double-digit royalties on net sales of Accrufer® in Korea. Shield will be responsible for the initial manufacturing and supply to Korea Pharma.

Greg Madison, CEO of Shield, commented: *"Iron deficiency anaemia is a global issue. Shield is committed to working with valued partners, such as Korea Pharma, to enable global access of Accrufer® and advance the care of patients with iron deficiency anaemia around the world. Completion of the MFDS filing by Korea Pharma marks the first filing for Accrufer® in Southeast Asia. We are thrilled to work with our partner to reach this important milestone. We look forward to supporting Korea Pharma as they continue the pathway to making Accrufer® available to patients in Korea."*

Eun-Hee Park, Korea Pharma CEO, commented: *"We are pleased by the positive results for the local PK study. These data enabled us to successfully complete a regulatory filing for Accrufer® with the MFDS. There are an estimated 5.2 million people in the Republic of Korea with iron deficiency and iron deficiency anaemia in need of novel treatment options. Pending approval of the NDA, we look forward to providing Accrufer® to the people of Korea as a potential first choice for the treatment of iron deficiency anaemia."*

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About Iron Deficiency and Accrufer®/Feraccru®
Clinically low iron levels (aka iron deficiency, ID) can cause serious health problems for adults of all ages, across multiple therapeutic areas. Together, ID and ID with anaemia (IDA) affect about 20 million people in the U.S. and represent a $2.3B market opportunity. As the first and only FDA approved oral iron to treat ID/IDA, Accrufer® has the potential to meet an important unmet medical need for both physicians and patients.

Accrufer®/Feraccru® (ferric maltol) is a novel, stable, non-salt-based oral therapy for adults with ID/IDA. 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 specialty pharmaceutical company that delivers Accrufer®/Feraccru® (ferric maltol), an innovative and differentiated pharmaceutical product, to address a significant unmet need for patients suffering from iron deficiency, with or without anaemia. The Company has launched Accrufer® in the U.S. with an exclusive, multi-year commercial agreement with Viatris Inc. (Viatris). Outside of the U.S., the Company has licensed the rights to four specialty pharmaceutical companies. Feraccru® is commercialised in the UK and European Union by Norgine B.V. (Norgine), which also has marketing rights in Australia and New Zealand. Shield also has an exclusive license agreement with Beijing Aosaikang Pharmaceutical Co., Ltd. for the development and commercialisation of Accrufer®/ Feraccru® in China, Hong Kong, Macau and Taiwan; with Korea Pharma Co., Ltd. for the Republic of Korea (Korea Pharma); and with KYE Pharmaceuticals Inc. for Canada. To learn more about Shield Therapeutics, see our website at www.shieldtherapeutics.com or follow us on LinkedIn and X.

Accrufer®/Feraccru® has patent coverage until the mid-2030s.
Accrufer®/Feraccru® are registered trademarks of Shield Therapeutics.

About Korea Pharma Co.,Ltd
Korea Pharma is a prescription pharmaceutical company focusing on CNS (central nervous system) and GI (gastro-intestinal) products. Korea Pharma has previously signed an exclusive distribution agreement with Norgine BV, a global PEG-based bowel cleansing agent development company, for distribution of PLENVU®, the world's first one-litre PEG (polyethylene glycol) bowel preparation drug, and is developing a liquid type PEG laxative.

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 Company'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 Company disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause its views to change.