



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

**Shield announces regulatory pathway and timelines for Accrufer® approval in the Republic of Korea**

**London, UK, 31 October, 2022:** Shield Therapeutics plc (LSE: STX), a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Accrufer®/Feraccru® (ferric maltol), announces that the Korean Food and Drug Administration has agreed that a single pharmacokinetic (PK) study is the only additional study requirement to support a New Drug Application (NDA) submission for Accrufer®. The study is expected to be initiated in Q4 2022 and will be conducted by the Company's partner, Korea Pharma Co. Ltd (Korea Pharma), who have development and commercialisation rights for Accrufer® in the Republic of Korea.

Korea Pharma expects regulatory approval allowing the commercial launch of Accrufer® in the Republic of Korea in late 2023.

**Greg Madison, CEO of Shield Therapeutics, stated:** *"We are delighted that the pathway to regulatory approval for commercialisation of Accrufer® in Korea has been established, and that our partner, Korea Pharma, is now ready to commence the study required to support the NDA submission. There are an estimated 5.2 million people in the Republic of Korea with iron deficiency and iron deficiency anemia, in need of novel treatment options. We look forward to supporting our partner as they continue on the pathway to potentially make Accrufer® available to patients."*

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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 action 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