RNS Number: 6560G Shield Therapeutics PLC 07 November 2025

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

#### ACCRUFeR® receives Marketing Authorisation by Korean Ministry of Food and Drug Safety (MFDS)

**London, UK, 07 November 2025:** Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company focused on addressing iron deficiency, is pleased to announce that the Korean Ministry of Food and Drug Safety (MFDS) has granted regulatory approval for ACCRUFeR® (Ferric Maltol) in the Republic of Korea (South Korea) for the treatment of iron deficiency in adult subjects.

This approval is an important milestone and follows the successful completion of a pharmacokinetic (PK) study which confirmed that the absorption of iron from ACCRUFeR® was comparable between patients in South Korea and the patient population enrolled in the key clinical studies supporting ACCRUFeR® effectiveness and safety and the subsequent submission of a New Drug Application (NDA) by Korea Pharma ("KP") in 2024. This approval marks a significant step forward in expanding access to ACCRUFeR® for patients in South Korea suffering from iron deficiency.

Shield is eligible to receive payments upon the first sale, as well as performance-based sales milestones and royalties on net sales of ACCRUFER® in South Korea.

Anders Lundstrom, Chief Executive Officer, commented: We are delighted with this approval of ACCRUFER® in South Korea and commend Korea Pharma for their dedication and expertise throughout the regulatory process. This achievement reinforces our commitment to making ACCRUFER® available to patients globally and highlights the strength of our international partnerships. Shield looks forward to supporting Korea Pharma in the commercial launch of ACCRUFER® in South Korea and continuing its mission to improve the lives of patients with iron deficiency worldwide."

## For further information please contact:

Shield Therapeutics plc Anders Lundstrom, CEO Santosh Shanbhag, CFO Stephanie Hicks, Investor Relations www.shieldtherapeutics.com

+44 (0) 191 511 8500 Investorrelations@shieldtx.com

# Nominated Adviser and Joint Broker Peel Hunt LLP

laint Proker

Joint Broker Cavendish Ltd

James Steel

Geoff Nash/ Isaac Hooper/Nigel Birks/Harriet Ward

+44 (0)20 7418 8900

+44 (0)20 7220 0500

## 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 anemia (IDA) affect about 20 million people in the US 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 and is now the leading #1 branded prescription oral iron the market today for ID/IDA (data source - IQVIA Xponent PlanTrak). ACCRUFeR®/FeRACCRU® (ferric maltol) is a novel, stable, non-salt-based oral therapy for adults with ID/IDA. The drug 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: <a href="https://www.accrufer.com">www.accrufer.com</a> and <a href="https://www.accrufer.com">www.feraccru.com</a>.

## Korea ID/IDA Market

There are currently 5.2M people in Korea living with ID/IDA as stated in the 'Prevalence and risk factors for iron deficiency anemia in the Korean population: results of the fifth Korea National Health and Nutrition Examination Survey'.

#### 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.

## 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 anemia. The Company has launched ACCRUFeR® in the U.S. with an exclusive, multi-year collaboration agreement with Viatris. Outside of the U.S., the Company has licensed the rights to five exceptions of the U.S., the Company has licensed the rights to five exceptions.

Norgine B.V., 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, with Kye Pharmaceuticals Inc. for Canada, and with VITAL-NET for Japan.

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

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