



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

ACCRUFer® Approved by Health Canada

ACCRUFer® is the only oral iron therapy approved as a prescription drug in Canada

London, UK, 27 August 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 Health Canada has approved ACCRUFer® (ferric maltol) as a prescription drug for the treatment of adults with iron deficiency anemia (IDA). This development allows Shield's partner, Kye Pharmaceuticals Inc. (Kye), to launch ACCRUFer® in Canada. Shield will be responsible for all manufacturing and supply to the Canadian market.

In accordance with the collaborative agreement, Shield is now due to receive a £250,000 milestone payment. For the remaining term of the agreement, Shield will receive additional revenue-based milestone payments along with double-digit royalties on net sales of ACCRUFer®.

Anders Lundstrom, Interim CEO of Shield, commented: *"We are delighted with the progress made in partnership with Kye since the signing of the license agreement in January 2022. Both organisations have demonstrated excellent collaboration and are driven to make ACCRUFer® available to patients in Canada with iron deficiency as quickly as possible. Shield Therapeutics is committed to bringing ACCRUFer®/FeRACCRU® to patients with iron deficiency around the world, and Canada is an important component of that mission."*

John McKendry, President and CEO of Kye, commented: *"ACCRUFer® will be the only prescription oral therapy available in Canada to treat patients who continue to suffer from low iron despite attempts at treatment with other currently available options. Our partnership with Shield and the granting of marketing authorization for ACCRUFer® in Canada grant us the opportunity to bring a novel, high-quality therapeutic option to patients in Canada who are struggling to address mild to moderate iron deficiency or iron deficiency anemia."*

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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.

In Canada, the Canadian Health Measures Survey (CHMS) estimates that 6.1% of the total Canadian population have ID, with females being more disproportionately affected (8.3%) versus males (4%). As the only Health Canada approved prescription 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 KYE Pharmaceuticals Inc.

Kye is a growth-stage Canadian specialty pharmaceutical company committed to bringing value to Canadians by identifying, licensing, and commercializing novel prescription medicines that may not otherwise be available to patients across Canada. With a growing pipeline of novel medicines, Kye's portfolio spans a range of therapeutic areas including cardiology, psychiatry, pediatrics, rare diseases, hematology, and neurology. Kye Pharmaceuticals is a private company headquartered in Toronto focused on bringing medications to the Canadian market which fulfill clinically significant unmet needs. Kye is committed to licensing and launching medicines that matter by delivering better outcomes to our partners, Canadian healthcare professionals, and most importantly, patients across Canada. For more information please visit www.kyepharma.com.

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.