RNS Number: 6440F Shield Therapeutics PLC 22 April 2025

Shield Therapeutics plc

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

Licence Agreement in Japan for ACCRUFeR®

Exclusive Japan licence agreement with VITAL-NET, Inc. Shield to receive an initial payment of ~ 665,000 plus regulatory and sales milestones, and double-digit royalties on net sales

London, UK, 22 April, 2025: Shield Therapeutics plc (LSE: STX), a commercial stage pharmaceutical company specialising in iron deficiency with or without anemia ("ID/IDA") announces that it has entered into an exclusive licence agreement ("the Agreement") for ACCRUFER® with VITAL-NET, Inc. ("VITAL-NET") in Japan. VITAL-NET will undertake and be responsible for all costs, including clinical and regulatory, related to activities required to achieve marketing authorisation and commercialisation of ACCRUFER® in Japan.

Shield will receive an initial payment of circa 665,000 and is eligible to receive additional milestone payments related to the regulatory approval of ACCRUFER® and upon the achievement of specified net sales targets by VITAL-NET. For the term of the agreement, Shield will also receive double-digit royalties on net sales of ACCRUFER®. VITAL-NET to be responsible for, and cover costs of all development and regulatory activity.

Anders Lundstrom, Chief Executive Officer for Shield, commented:"This partnership aligns with our commitment to keep expanding our global footprint for ACCRUFER®. Japan, the third largest pharmaceutical market in the world, is an important market to enter as Iron deficiency is a prevalent health concern in Japan, especially among women, children, and the elderly. ACCRUFER® offers a new option for those who need a more effective treatment to restore their iron levels and improve their overall health. We look forward to working together with VITAL-NET to making ACCRUFER® available to the people of Japan."

Takeshi Ichijo, CEO of VITAL-NET, commented:""We are excited to have entered into the agreement with Shield Therapeutics for the supply, development and marketing of ACCRUFER®. Iron deficiency (ID) patients in pulmonary hypertension (PH) and inflammatory bowel disease (IBD) are our important areas, we believe that our experience will be of great use. We will endeavour to provide the drug to Japanese patients suffering from ID."

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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 anemia (IDA) affect about 20 million people in the US and represent a2.3B 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.

Iron deficiency and iron deficiency anemia (ID/IDA) poses a significant health challenge in Japan, with the country accounting for approximately 39% of ID cases among the seven major markets, which include the USA, EU5 (the UK, Italy, Spain, France, and Germany), and Japan $^{[1]}$. The ID/IDA treatment landscape in Japan primarily consists of oral and intravenous (IV) iron supplements. Oral iron products, including both over-the-counter and prescription formulations, dominate the market in terms of volume $^{[2]}$.

The Japanese iron deficiency therapy market is poised for growth. This growth is attributed to factors such as the introduction of novel therapies, an increasing IDA prevalence, and heightened awareness regarding anemia management^[3]. Japan's ID/IDA market is characterized by a robust demand for both oral and IV iron supplements, influenced by regional demographics and recent pharmaceutical innovations ². The market is expected to expand steadily, driven by ongoing advancements in treatment options and a growing focus on addressing iron deficiency and iron deficiency anemia³.

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: 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 anemia. The Company has launched ACCRUFeR® in the U.S. with an exclusive, multi-year collaboration agreement with Viatris Inc. Outside of the U.S., the Company has licensed the rights to four specialty pharmaceutical companies. FeRACCRU® is commercialized in the UK and European Union by 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 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 Shield Therapeutics.

About VITAL-NET, Inc.

The core business of VITAL-NET is the wholesale of prescription pharmaceuticals and to serve the health of the people and contribute to the fostering of a healthy society. VITAL-NET was founded in 1950 and has supported the lives, health, and well-being of the community up to the present day. Our commitment lies in being "community-oriented." Starting from Miyagi Prefecture as a pharmaceutical wholesaler, we have expanded our sales areas to six prefectures in the Tohoku region, as well as Niigata, Tochigi, and the Tokyo metropolitan area, creating a network of branches as intricate as capillaries. Our deeply rooted business activities and experiences have earned high praise not only from medical institutions but also from local governments, administrative bodies, and industry organizations. We have established agreements for disaster response and collaborations for promoting health in various regions. The speed of changes in the social environment, such as declining birthrates and an aging population, uneven distribution of medical resources, natural disasters, and pandemics, as well as in the business environment, like medical DX, online medical consultations, and the emergence of groundbreaking new drugs, is increasing. However, our role as a social infrastructure to support the provision of safe and secure medical care to patients at any time remains unchanged. To fulfil this responsibility, we pursue new services tailored to regional needs, including stringent quality control of prescription pharmaceuticals, the sale and rental of the latest medical equipment, and life support. We will also challenge new roles as partners in rapidly advancing medical care. VITAL-NET's strength lies in the "human power" of each employee recognising and executing our corporate philosophy of "serving people's medical care and health," as well as in our network with the community.

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^[1] Anemia Market Insight, Epidemiology and Market Forecast

^[2] Clinical management of iron deficiency anemia in Japan: iron prescription patterns, treatment effectiveness, and assessments - PMC

^[3] Iron Deficiency Anemia Therapy Market Size Report, 2030