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Shield Therapeutics PLC
14 November 2025

Shield Therapeutics plc

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

Initiation of a Phase II Clinical Trial for ACCRUFeR® (Ferric Maltol) for the Treatment of Pulmonary Arterial Hypertension (PAH) in Japan.

London, UK, 14 November 2025 Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, today announced that its partner, MEDLEAP Pharma, a subsidiary of Vital KSK Holdings Inc. has initiated a Phase II clinical trial for ACCRUFER® (ferric maltol), a new drug candidate for Pulmonary Arterial Hypertension (PAH), for patients in Japan. This trial is an exploratory study to support a Phase III trial and follows confirmation by the Pharmaceuticals and Medical Devices Agency (PMDA) of the development plan for the drug as a PAH treatment in Japan, based on previous clinical results in Europe, UK and USA.

Subject to the results of this trial, MEDLEAP plans to conduct a Phase III trial (Pivotal Study) and proceed with regulatory submission and launch preparations from 2028 onwards. MEDLEAP positions this drug as a core pipeline in the PAH field.

Trial Details:

Trial Name:	An Exploratory Phase 2 Study to Evaluate the Efficacy and Safety of Ferric Maltol in Patients with Pulmonary Arterial Hypertension (PAH)
Target Disease:	Pulmonary Arterial Hypertension
Trial Design:	Multi-center, randomised, placebo-controlled, double-blind study
Number of Subjects:	Approximately 26 (planned)
Primary Endpoint:	12-week 6-minute walk distance change from baseline
Secondary Endpoints:	Cardiac function-related efficacy parameters, safety, tolerability, etc
Trial Location:	Japan

Dr Jackie Mitchell, VP of Quality, RA and Clinical Development at Shield, commented: *"Shield is delighted with the rapid progress our partner MEDLEAP Pharma has made in agreeing a PAH development plan with PMDA and initiating the Japanese clinical program to develop ACCRUFER for this exciting new indication."*

Professor Masaharu Kataoka, Second Department of Internal Medicine, University of Occupational and Environmental Health, Japan School of Medicine, commented: *"Iron deficiency anemia is highly prevalent in PAH patients and is associated with various clinical manifestations of PAH, including symptoms, exercise tolerance, right heart function, and hemodynamic parameters. Therefore, efficient iron supplementation is recommended. However, existing treatments face challenges in long-term iron supplementation management due to gastrointestinal side effects and low absorption efficiency, creating a need for new therapeutic options. In this context, we look forward to establishing Japan-originated evidence through clinical trials of Ferric Maltol, a completely new compound that overcomes these challenges and enables long-term administration, in PAH patients."*

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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 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** (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: www.accrufer.com and www.feraccru.com.

PAH (Pulmonary Arterial Hypertension) market in 2024 is estimated to be worth over $230M in Japan. Iron supplementation is strongly recommended for PAH patients with iron deficiency anemia according to both European and Japanese guidance (ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension 2022 and Japan Pulmonary Hypertension and Pulmonary Circulation Society Guidance 2024) [Recommendation Class I]. (1) Humbert M, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Respir J. 2023; 61(1):2200879. (2) Japanese Pulmonary Hypertension and Pulmonary Circulation Society. Pulmonary Hypertension Treatment Guidance2024.

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 specialty pharmaceutical companies. FeRACCRU® is commercialised 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 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.

About MEDLEAP PHARMA COMPANY LIMITED
MEDLEAP PHARMA COMPANY LIMITED ("**MEDLEAP**") is a subsidiary of VITAL_NET, INC. which will focus on pharmaceutical research and development. This subsidiary is fully owned by Vital KSK Holdings and will be led by Yuichi Kobayashi, an executive officer of the parent company.

Under its philosophy of "Bringing innovation to Japan's medical future through the creation of original pharmaceuticals," contributes to reducing drug lag in Japan through new drug introduction support business, delivering a healthy future to patients and their families. MEDLEAP promotes competitive new drug creation through collaboration with domestic and international research institutions and companies.

Headquarters:	3-3-1 Yaotome, Izumi-ku, Sendai City, Miyagi Prefecture 981-3112
Representative:	President and CEO Yuichi Kobayashi
Established:	September 2025
Business Activities:	Research, development, manufacturing, and sales of pharmaceuticals

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