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

Positive efficacy and safety results in subjects with Heart Failure (HF) and Iron Deficiency Anemia (IDA) treated with *ACCRUFeR®/FeRACCRU® (ferric maltol)*

Data recently published in the European Journal of Heart Failure

London, UK, August 27, 2025: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, announces positive efficacy and safety results in the ORION-HF study showing improvements in haemoglobin and other iron markers, exercise capacity, and quality of life (QoL) in patients with heart failure (HF) and iron deficiency anemia (IDA), after 16 weeks of treatment with FeRACCRU® (ferric maltol). These results were published in the European Journal of Heart Failure on 21 July 2025.

The ORION-HF study was a multicenter, European, open-label, prospective clinical study, to investigate the impact of orally formulated ferric maltol (30 mg bid) in 50 patients with symptomatic HF and IDA.

Positive and clinically meaningful efficacy and safety results were achieved in the study:

- **Significant increase in haemoglobin (Hb) concentration (Primary endpoint)**: Oral ferric maltol treatment resulted in significantly increased haemoglobin (from 11.4 [10.9-11.9] to 12.8 [11.8-13.8] g/dl) from baseline to week 16 (p<0.001).
- **Statistically significant differences from baseline to week 16 in 6-minute walk test (6MW) (p<0.001) and Quality of Life scores (p=0.004)**
  - Oral ferric maltol treatment resulted in significant increase in distance walked in 6MW test (from 298 [220-405] to 335 [255-430] meters).
  - Oral ferric maltol treatment resulted in a significant increase in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score (from 65 [44-82] to 76 [55-86] score points).
- **Statistically significant differences from baseline to week 16 in Other Iron Markers (ferritin, iron, transferrin saturation) (p<0.001)**
- **Ferric maltol was well-tolerated with no serious related adverse events reported**
  - Adverse event profiles were consistent with previous Phase 3 studies.
  - AEs (N=19) were mainly GI related.

These positive results published in the European Journal of Heart Failure (Oral ferric maltol improves iron deficiency anaemia in patients with chronic heart failure - Kempf - European Journal of Heart Failure - Wiley Online Library,) are consistent with results reported from an earlier study in patients with pulmonary hypertension (PH) and anemia published in the European Respiratory Society (Oral iron supplementation with ferric maltol in patients with pulmonary hypertension | European Respiratory Society).

Shield's licensing partner in Japan (VITAL-NET, Inc. (VITAL-NET)) has recently had an IND approved to further investigate the impact of ferric maltol treatment in Japanese patients with PH and anemia in Japan.

***Professor Johann Bauersachs, Director of the Department of Cardiology and Angiology at Hannover Medical School, and lead author of the HF publication**, said: "We still have a significant clinical unmet need for an effective and well tolerated oral iron therapy for the treatment of heart failure. Ferric maltol could be the practicable oral alternative to intravenous therapy for the treatment of heart failure reducing the challenges of i.v therapy."*

Anders Lundstrom, CEO, Shield Therapeutics commented: *"We are delighted that we once again have clinically and statistically relevant results in new patient populations for ACCRUFeR®/FeRACCRU® and we are excited that our partner, VITAL-NET will further investigate this important new therapeutic area where ferric maltol promises to bring significant clinical benefit."*

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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 a2.2B

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.

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. 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.

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