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

ACCRUFeR® assigned Priority Review in the US by FDA in children with iron deficiency anemia (IDA)

Pending successful review, approval in the US is anticipated in 2026

London, UK, September 4, 2025: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, announces that the US Food and Drug Administration (FDA) has accepted ACCRUFeR®/FeRACCRU® (ferric maltol) as a Clinical Supplement and assigned Priority Review to extend the indication for ACCRUFeR®/FeRACCRU® to include adolescents aged 10 years and above.

Following the positive results from the Phase 3 pediatric clinical trial (FORTIS/ST10-01-305) that confirmed the efficacy, safety, and tolerability of the new oral liquid pediatric formulation in children with (IDA), Shield submitted a clinical supplement application to the FDA in June 2025 for the approval of ACCRUFeR®/FeRACCRU® in the pediatric population. FDA has granted Priority Review for the supplement as it supports the extension of the label to a pediatric population based on a final agreed pediatric study report. Pending successful review, approval is anticipated in 2026.

Shield plans to file for a further extension of the indication to include children 1 month and above in conjunction with the submission of an NDA for a new pediatric formulation (ferric maltol suspension) which was used in the successful FORTIS Phase 3 study in this population. If approved, this formulation may also offer an alternative approach for adults who can't swallow our current capsule formulation.

Shield's licensing partner in the EU, Norgine B.V., also filed a regulatory submission to the EMA in Q2 2025 for the approval of FeRACCRU® (ferric maltol) in the adolescent population. Pending successful review, approval is also anticipated in 2026.

Dr Jackie Mitchell, VP of Quality, RA and Clinical Development at Shield, commented: *"We are delighted to be able to progress a further significant expansion of the patient population to adolescents, who can benefit from a much needed safe and effective oral iron treatment."*

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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.

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.

Details of the FORTIS/ST10-01-305 Phase 3 study

The open label randomized Phase 3 study included children aged 1 month to 17 years with mild to moderate IDA, who also had serum ferritin levels below 30 µg/L or ferritin levels below 50 µg/L and transferrin saturation below 20%. Children aged 2 to 17 years were randomized 1:1 to receive either ferric maltol (N=31) or ferrous sulphate (N = 30). Children 1 months to under 2 years (N=4) were all assigned to receive ferric maltol treatment.
The full data sets, including secondary endpoints and pharmacokinetic (PK) sub-study parameters, will be submitted for peer-review and subsequent presentation/publication. The trial is the final study in the comprehensive pediatric development program that Shield committed to implement with both the European EMA and the US FDA.