RNS Number : 9586G
Shield Therapeutics PLC
11 November 2025

Shield Therapeutics plc

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

ACCRUFeR® Pediatric Pharmacokinetic (PK) Results Will be Presented at the American Society of Hematology (ASH) Conference

Results from PK Sub study of Positive Phase 3 Pediatric Trial (FORTIS) confirmed ferric maltol's suitability for iron replacement in children 1 month and above

London, UK, 11 November 2025 Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, today announced the presentation (Abstract/Video and in person Poster) of a PK study (conducted as a sub-study of the positive FORTIS efficacy, tolerability and palatability pediatric ferric maltol clinical trial) at the American Society of Hematology (ASH) National Conference on 06 December 2025 in Orlando, Florida.

Abstract available online via the **ASH Conference website**: ASH 2025 Annual Meeting - Presentation

Abstract/Poster Details:

Title: Presentation ID 1126: Pharmacokinetics of ferric maltol oral suspension in children and adolescents (1 month to 17 years); A study of iron and maltol metabolism following single and multiple dosing

Presenter: Dr Andrew Freiberg MD (Associate Professor of Pediatrics, Penn State Health, Pennsylvania, United States)

Key Results:

- The PK profile in children and adolescents demonstrated ferric maltol's suitability for iron replacement in all age groups
- Iron was well-absorbed at the age-appropriate doses used in the Phase 3 study
- Maltol was rapidly metabolised and excreted in the urine with no accumulation in any age group
- First data that confirms maltol metabolism and rapid excretion in the urine in infants 1 month to less than 2 years

The FORTIS study, including the PK data, is pivotal in supporting the Clinical Supplement assigned Priority Review by the US FDA to extend the indication for ACCRUFeR® to include adolescents aged 10 years and above.

Dr Jackie Mitchell, VP of Quality, RA and Clinical Development at Shield, commented: *"This first publication of results confirming effective iron absorption and maltol metabolism in children as young as 1 month supports the potential use of ferric maltol as an effective iron-replacement therapy in infants as well as older children, and is an important milestone for Shield in the expansion of ACCRUFeR® to an infant population where there is an unmet need for a safe and effective oral iron treatment."*

For further information please contact:

Shield Therapeutics plc www.shieldtherapeutics.com
Anders Lundstrom, CEO
Santosh Shanbhag, CFO +44 (0) 191 511 8500
Stephanie Hicks, Investor Relations Investorrelations@shieldtx.com

Nominated Adviser and Joint Broker
Peel Hunt LLP
James Steel +44 (0)20 7418 8900

Joint Broker
Cavendish Ltd
Geoff Nash/ Isaac Hooper/Nigel Birks/Harriet Ward +44 (0)20 7220 0500

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.

About the FORTIS/ST10-01-305 Phase 3 study and PK Sub-study

The FORTIS study compared the safety, tolerability and effectiveness of an oral liquid suspension of ferric maltol with oral ferrous sulphate liquid in children with iron deficiency anaemia (IDA) The open-label randomized Phase 3 study

oral ferrous sulphate liquid in children with iron deficiency anaemia (IDA). 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 composite primary endpoints were:

- Frequency of treatment emergent adverse events (TEAEs)/serious adverse events (TESAEs)
- Frequency of discontinuations from the study as a result of TEAEs
- Change in haemoglobin (Hb) concentration from baseline to week 12

Twenty children (2-17 years) participated in the PK study over two assessment days (Day 1 & Day 7-10). On Day 1, after a baseline blood sample, they received a single supervised ferric maltol dose (iron equivalent at 15mg or 30mg doses), followed by PK. Then, twice-daily (BID) dosing of the same dosage continued until Day 7-10, when the morning dose was withheld, and the PK procedure was repeated. Three infants (aged 1 month to < 2 years completed a one-day PK assessment with a single 0.6 mg/kg iron equivalent dose of ferric maltol. Urine samples collected over 12 hours were analyzed for maltol metabolism. If no accumulation of maltol or its metabolites was found, 0.6mg/kg BID dosing continued for 7-10 days. On Day 7-10, after baseline sampling, the same dose was given, followed by PK blood sampling (1-12 hours) and urine collection (0.5-12 hours). PK blood samples were evaluated for plasma maltol and maltol glucuronide levels and serum iron.

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.

END

MSCBBLLFEFLBFBX