

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

ACCRUFer® Phase 3 pediatric trial published in Pediatric Drugs

Clinically relevant positive effectiveness in pediatric trial (FORTIS)
Results confirm safety and effectiveness of ferric maltol treatment in children 2 months and above

London, UK, 28 July 2026, Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, today announced the publication of the positive efficacy, tolerability and palatability results from the ferric maltol pediatric FORTIS clinical trial, comparing the safety and efficacy of ferric maltol and ferrous sulfate for iron deficiency anemia (IDA), in Pediatric Drugs:

Gass, D., Freiberg, A., Auth, M.K.H. and Russell R.K. Safety and Efficacy of Oral Ferric Maltol and Ferrous Sulfate for Iron Deficiency Anemia in Infants, Children and Adolescents: A Multicenter Randomized Trial. *Pediatr Drugs* (2026). <https://doi.org/10.1007/s40272-026-00753-6>

The article concluded: *Ferric maltol significantly improved Hb levels and iron storage within 12 weeks in children aged 1 month and above, offering potentially better tolerability and palatability compared with ferrous sulfate in children and adolescents.*

Key Results (as previously disclosed):

- Clinically and statistically significant Hb improvements vs. baseline were observed across all groups (ferric maltol arms and ferrous sulfate arm (P<0.0001))
- No patient discontinued ferric maltol treatment due to an adverse event compared to one patient who discontinued from the ferrous sulfate arm.
- Treatment related adverse events (AEs) were reported in 6.5% of patients treated with ferric maltol and 13% of patients treated with ferrous sulphate. No treatment related serious AEs (SAEs) were reported in either group.

Professor Richard Russell, corresponding author and Principal Investigator in the study commented: *"This first full publication of results confirming the safety and effectiveness of ferric maltol treatment in children as young as 2 months is an important milestone in expanding therapeutic choices for pediatric patients, who can benefit from a much needed alternative safe and effective oral iron treatment."*

The capsule formulation (30mg) of Ferric Maltol is approved for treatment of adolescents and adults aged 10 years and above (ACCRUFer®) in the USA and 12 years and above (FeRACCRU®) in the EU. Registration of the liquid formulation used in the trial is planned to support the treatment of younger children aged 2 and above.

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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.

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. to include pediatric patients 10 years of age and older with an exclusive, multi-year collaboration agreement with Viartis. 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., to include pediatric patients 12 years of age and older and also have marketing rights in Australia and New Zealand. FeRACCRU® is also commercialised in Canada by Kye Pharmaceuticals Inc. 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, and with Medleap Pharma Company Limited, a subsidiary of VITAL-NET Inc. 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 have been 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.

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