

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

ACCRUFer® Phase 3 pediatric trial presentation at the American Association of Pediatrics (AAP) Conference

Positive efficacy and tolerance in pediatric trial (FORTIS)

London, UK, 01 October 2025 Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, today announced the presentation (virtual and in person) of the positive efficacy, tolerability and palatability results for the ferric maltol pediatric FORTIS clinical trial at the American Association of Pediatrics (AAP) National Conference on 29th September 2025 in Denver, Colorado.

Abstract available online via the **AAP Conference website**: [Browse Poster Hall](#)

The Poster can be viewed via the **Shield website**: [Publications | Shield Therapeutics plc](#)

Poster Presentation Details:

Title: P4.017: "Efficacy And Safety Of A Novel Oral Iron (Ferric Maltol) In Children And Adolescents; A Randomized, Multicenter, Open-Label, Active Comparator Study"
Presenter: Dr David Gass MD MS (Associate professor of pediatrics. Carolinas Medical Centre, Charlotte)

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.

Dr Jackie Mitchell, VP of Quality, RA and Clinical Development at Shield, commented: *"This first publication of results confirming the safety and effectiveness of ferric maltol treatment in children as young as 2 months is an important milestone for Shield to further the expansion of ACCRUFer® in this additional patient population 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 and is now the leading **#1 branded prescription oral iron in 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. 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., 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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