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

Publication of Report in Pediatric Drugs, Reinforcing FDA Approval Milestone

London, UK, 01 April 2026: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, announces that an independent peer-reviewed AdisInsight Report on ACCRUFeR® /FeRACCRU® (ferric maltol) has been published online in *Pediatric Drugs*, a leading international journal for healthcare professionals.

This report, titled Ferric Maltol: Pediatric First Approval, is available via the following link:
https://link.springer.com/article/10.1007/s40272-026-00748-3

The publication reports on the recent US Food and Drug Administration (FDA) approval of the extension of the ferric maltol indication to include pediatric patients aged 10 years and over for the treatment of iron deficiency, which was supported by positive results from the Phase 3 pediatric clinical trial (FORTIS/ST10-01-305) that confirmed the efficacy, safety, and tolerability of a new oral liquid pediatric formulation in children aged 1 month and above with iron deficiency, presenting as iron deficiency anemia (IDA).

Anders Lundstrom, CEO of Shield, commented: "Iron deficiency in children is a serious and often underdiagnosed condition, and today's publication in Pediatric Drugs underscores the clinical importance of having an approved, well-characterised treatment option for pediatric patients. The FDA's decision to extend the ferric maltol indication to patients aged 10 and over is a significant step forward, and we are committed to ensuring that both clinicians and patients can benefit from this approval as quickly as possible."

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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 #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 patients suffering from iron deficiency, with or without anemia.. 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 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., 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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