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Shield Therapeutics PLC
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Shield Therapeutics plc

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

US FDA Grants additional 3 Years Exclusivity for ACCRUFeR®

London, UK, 09 February 2026: Shield Therapeutics plc (LSE: STX), a commercial-stage pharmaceutical company specialising in iron deficiency, announces that the US Food and Drug Administration (FDA) has granted to Shield an additional 3 years of Data Exclusivity for ACCRUFeR® (ferric maltol). This is due to the new clinical investigation conducted by Shield that was essential to the approval of the extension of the indication to include pediatric patients 10 years of age and older. This exclusivity remains in place until 19 December 2028 in addition to the ACCRUFeR®/FeRACCRU® patent coverage valid until the mid-2030s.

The indication expansion was supported by 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 aged 1 month and above with iron deficiency, presenting as iron deficiency anemia (IDA).

Dr Jackie Mitchell, VP of Regulatory, Quality, Clinical and Regulatory Affairs of Shield, commented: "This exclusivity is a significant milestone for Shield and recognises the value of the essential clinical investigation conducted to support the pediatric indication, reflecting the strength of the Phase 3 FORTIS trial. We are well positioned to continue expanding access to ACCRUFeR® and addressing unmet needs in both adult and pediatric populations."

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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 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 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. 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, 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.

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