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

Results from Phase 3 paediatric study

Pivotal Trial of ACCRUFeR®/FeRACCRU® (ferric maltol) in Paediatric Patients with Iron Deficiency Anemia (IDA) proves highly clinically relevant effectiveness

Data will be used to support filing obligations with the US FDA and the European EMA for a paediatric indication in children older than 1 month for ACCRUFeR®/FeRACCRU® in H1 2025

London, UK, 25 September 2024: Shield Therapeutics plc (LSE: STX), the commercial stage pharmaceutical company specialising in iron deficiency, announces results from the Phase 3 paediatric clinical trial (FORTIS/ST10-01-305), confirming the efficacy, safety, and tolerability of the new oral liquid paediatric suspension in children with iron deficiency anaemia (IDA).

This trial is the final study in the comprehensive development program supporting the paediatric investigation plan (PIP/PSP) agreed with the European EMA and the US FDA. The full data set, including pharmacokinetic (PK) sub-study parameters, will be submitted for peer-review and subsequent presentation/publication. The data will be used to support a filing with the US FDA and European EMA for a paediatric indication in children older than 1 month for ACCRUFeR®/FeRACCRU® in H1 2025.

Additionally, Shield is due a total of €1 million as development milestones from its European partner, Norgine BV, upon the compliance notification of the PIP by the Pediatric Committee (PDCO) and the granting of the paediatric indication by EMA.

All primary endpoints were met, and the outcomes were:

- **Change in Hb concentration from baseline to week 12**: Patients in the ferric maltol group demonstrated a highly clinically relevant mean change in Hb concentration at week 12 compared to baseline.
    - The mean change was 1.25 g/dl from baseline to week 12 in the 2 – 17-year-old cohort and was 1.77 g/dl from baseline to week 12 in the infants
    - The mean change was 1.15 g/dl from baseline to week 12 in patients in the ferrous sulphate group.

- **Frequency of discontinuations from the study because of Treatment Emergent Adverse Events (AEs):** No patients in the ferric maltol group discontinued from the study as a result of AEs.
    - In the 2 – 17-year-old cohort, no patient (0/31; 0%) discontinued the ferric maltol treatment due to an AE compared to one patient (1/30; 3.3%) who discontinued from the ferrous sulphate arm.
    - None of the infants discontinued ferric maltol treatment due to an AE.

- **Frequency of AEs/serious adverse events (SAEs):** No patient in the ferric maltol group reported a treatment related SAE and two (2) patients reported treatment related AEs.
    - No treatment related SAEs were reported in either group.
    - In the 2 – 17-year-old cohort, treatment related AEs were reported in 2 out of 31 patients treated with ferric maltol compared to 4 out of 30 patients treated with ferrous sulphate.
    - None of the ferric maltol-treated infants reported treatment related AEs .

Anders Lundstrom, interim CEO commented: *"We are delighted that the results in this important ACCRUFeR®/FeRACCRU® Paediatric Phase 3 study show similar levels of efficacy and safety as in prior trials with adults.*

We will now initiate the work with the regulatory applications to be able to expand the patient population who can benefit from a safe and effective oral iron treatment."

Professor Richard Russell, a FORTIS Principal Investigator, commented: *"These results indicate that the newly developed paediatric liquid formulation will provide a welcome additional well-tolerated and effective therapeutic option for the treatment of IDA in young children and adolescents."*

For further information please contact:

Shield Therapeutics plc	www.shieldtherapeutics.com
Anders Lundstrom, CEO Santosh Shanbhag, CFO	+44 (0) 191 511 8500
Nominated Adviser and Joint Broker **Peel Hunt LLP** James Steel/Patrick Birkholm	+44 (0)20 7418 8900
Joint Broker **Cavendish Ltd** Geoff Nash/ Rory Sale/Nigel Birks/Harriet Ward	+44 (0)20 7220 0500
Financial PR & IR Advisor **Walbrook PR** Charlotte Edgar / Alice Woodings	+44 (0)20 7933 8780 or shield@walbrookpr.com

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.

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 Viatris. Outside of the U.S., the Company has licensed the rights to four specialty pharmaceutical companies. FeRACCRU® is commercialized 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 commercialization of ACCRUFeR®/ FeRACCRU® in China, Hong Kong, Macau and Taiwan, with Korea Pharma Co., Ltd. for the Republic of Korea, and with KYE Pharmaceuticals Inc. for Canada.

ACCRUFeR®/FeRACCRU® has patent coverage until the mid-2030s.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations and include statements related to the commercial strategy for ACCRUFeR®/FeRACCRU®. These statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties, many of which are beyond our control, that may cause actual results and performance or achievements to be materially different from management's expectations expressed or implied by the forward-looking statements, including, but not limited to, risks associated with the Company's business and results of operations, competition and other market factors. The forward-looking statements made in this press release represent management's expectations as of the date of this press release, and except as required by law, the Company disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause its views to change.

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 iron-deficiency anaemia (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 month to under 2 years (N=4, and 3 were treated) were all assigned to receive ferric maltol treatment. The study was not powered to detect a statistical difference in primary endpoints between ferric maltol and the ferrous sulphate comparator group.