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

Business Update

Recruitment completed of the Phase 3 confirmatory Study in China in adult patients with inflammatory bowel disease (IBD) and Iron Deficiency Anemia (IDA)

Progress towards the provision of $10 million of new equity by AOP Health by the end of 2024

Strong sales of ACCRUFeR® in the month of October 2024, guidance reiterated to meet the Group revenue covenant target of $31.5 million for the full year 2024

London, UK, 21 November 2024: Shield Therapeutics plc (LSE: STX), the commercial stage pharmaceutical company specialising in iron deficiency, provides an update covering recent activities.

Clinical Program in China
The Phase 3 confirmatory study in China is jointly sponsored by Shield and its partner Jiangsu Aosaikang Pharmaceutical Co. Ltd. (ASK), the exclusive license holder for the development and commercialisation of ACCRUFeR®/ FeRACCRU® in China, Hong Kong, Macau and Taiwan. This trial is the final study required to support the filing of an NDA in China for the commercialisation of Feraccru®/Accrufer and recruitment has recently been completed of adult patients with IBD and IDA. The Company expects the NDA to be filed with the Chinese National Medical Products Administration (NMPA) in 2025. Further details will be announced in due course.

AOP Health subscription
On 29 October 2024 the Company announced that it had entered into a non-binding term sheet with AOP Health International Management AG ("AOP Health") for the potential provision of $10 million of new equity. The Company is engaged with The Panel on Takeovers and Mergers (the "Takeover Panel") to seek a waiver from the obligation of AOP Health to make an offer under Rule 9 of the Takeover Code and expects to convene a meeting of Shield's shareholders (the "General Meeting") before the end of 2024.

ACCRUFeR® sales performance
Based on strong sales of ACCRUFeR® in October 2024, driven primarily by an increase in Net Selling Price to more than $225 per prescription compared to $167 per prescription in Q3 2024, the Company remains on track to meet the total Group revenue covenant target of $31.5 million for full year 2024 under the debt facility agreement with SWK Funding LLC.

Anders Lundstrom, interim CEO commented: *"We are delighted that our partner, ASK, has completed recruitment into the confirmatory Phase 3 study that will support the filing in China to commericalise ACCRUFeR®/FeRACRRU®*, significantly increasing the global availability of *a welcome additional well-tolerated and effective therapeutic option for the treatment of IDA. In addition, solid growth of ACCRUFeR® revenues in October give us a promising outlook for the rest of the fourth quarter, leaving us on track to meet our 2024 Group revenue covenant target and market expectations for the year."*

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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.

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.
ACCRUFeR®/FeRACCRU® are registered trademarks of Shield Therapeutics.

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 ASKC109-LC-1 Phase 3 study

This study was based on the design of the Phase 3 study that supported the approval of ACCRUFeR®/FeRACCRU® in the EU, USA, and other countries. It is a multicenter, randomized, double-blind and placebo controlled 12 week study confirming the safety and efficacy of ferric maltol capsules (30mg elemental iron) as a twice-daily treatment of IDA in subjects with IBD (Ulcerative Colitis (UC) or Crohn's disease (CD)) where oral ferrous preparations have failed or cannot be used.