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

PT20 paper publication
Demonstrates statistically significant and dose-dependent reduction in serum phosphate concentration

London, UK, 16 July 2020: Shield Therapeutics plc (LSE: STX), a commercial stage, pharmaceutical company with a focus on addressing iron deficiency with its lead product Feraccru®/Accrufer® (ferric maltol), notes the recent publication in Nephrology Dialysis Transplantation of a paper concerning PT20, Shield's iron-based phosphate binder.

PT20 is a novel iron-based phosphate binder that has the potential to treat patients with hyperphosphatemia (when there is too much phosphorus present in the blood) related to dialysis or non-dialysis dependent chronic kidney disease (CKD). The publication Nephrology Dialysis Transplantation has published a paper entitled "**Efficacy and safety of PT20, an iron-based phosphate binder, for the treatment of hyperphosphataemia: a randomized, double blind, placebo-controlled, dose-ranging, Phase IIb study in patients with haemodialysis-dependent chronic kidney disease."** The study, which was funded by Shield, was a pivotal study to support marketing authorisation submissions and was a double-blind, parallel-group, placebo-controlled, dose-ranging study in which the efficacy and safety of 28 days of oral PT20 treatment were evaluated in patients with dialysis-dependent CKD. Participants were randomly assigned to receive PT20 or placebo three times daily. The study demonstrated that PT20 treatment for 28 days resulted in a statistically significant and dose-dependent reduction in serum phosphate concentration and was generally well tolerated.

The paper is available online here:
https://academic.oup.com/ndt/advance-article/doi/10.1093/ndt/gfaa116/5870136?guestAccessKey=88a1458d-6ef5-4e88-adcf-cf016a475be8

Shield has agreed with the US FDA that PT20 requires only one further pivotal Phase III study after which regulatory filings for marketing approval would be expected to follow. Shield will first develop a new formulation of PT20 which will allow the Phase III study to be carried out and which will be suitable for commercial use. It is anticipated that the formulation work could start in the second half of 2020 which would potentially allow the Phase III study to start in 2022, subject to finance being available.

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About Shield Therapeutics plc

Shield is a de-risked, specialty pharmaceutical company focused on commercialising its lead product, Feraccru®/Accrufer®, a novel, stable, non-salt based oral therapy for adults with iron deficiency with or without anaemia. Feraccru®/Accrufer® has been approved for use in the United States, European Union, UK and Switzerland and has exclusive IP rights until the mid-2030s. Feraccru is commercialised in the UK and Europe by Norgine B.V. and the Company is currently in the process of selecting a commercialisation partner for the US market. Shield also has an exclusive licence agreement with Beijing Aosaikang Pharmaceutical Co., Ltd., for the development and commercialisation of Feraccru®/Accrufer® in China, Hong Kong, Macau and Taiwan.

For more information, please visit www.shieldtherapeutics.com. Follow Shield on Twitter @ShieldTx

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