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Shield Therapeutics Announces Successful Placing to Raise £32.5 Million and Proposed Admission to AIM

London, UK, 12 February 2016. Shield Therapeutics plc ("**Shield**" or the "**Company**), a specialty pharmaceutical company focused on the development and commercialisation of secondary carefocused pharmaceuticals, is pleased to announce that it has raised gross proceeds of £32.5 million by way of a placing and subscription of ordinary shares in the capital of the Company ("**Ordinary Shares**") and the issue of warrants to subscribe for Ordinary Shares ("**Warrants**") to a high quality group of institutional, existing and other investors (the "**Placing**") in connection with the admission of its Ordinary Shares and Warrants to trading on the AIM Market of the London Stock Exchange.

The Ordinary Shares and Warrants in Shield are expected to commence trading on AIM by no later than 8:00am GMT on 26 February 2016, under the symbol "STX" and "STXW", respectively. The Company will have a market capitalisation upon Admission of approximately £162 million at the placing price of 150p. Full exercise of the Warrants would generate further gross proceeds to the Company of £17.5m.

Liberum is the Nominated Adviser and Sole Bookrunner to the Company.

Highlights

- Specialty pharmaceutical company with major market opportunities addressing unmet medical needs: Focused on the development and commercialisation of secondary care-focused pharmaceuticals.
- Late-stage company with near-term revenue potential: On 17 December 2015, the Company received a unanimous and positive CHMP recommendation for its marketing authorisation application ("MAA") of Feraccru, a novel and effective oral pharmaceutical product for the treatment of iron deficiency anaemia ("IDA"). Marketing authorisation is expected to be received in the first quarter of 2016 and commercialisation of Feraccru in Europe will commence shortly thereafter.
- Late-stage products that have either been approved or have delivered proof of concept: In addition to the positive opinion received from the EU CHMP for Feraccru's MAA; PT20, a novel phosphate binder that is being developed for the treatment for hyperphosphatemia related to chronic kidney disease ("CKD") has successfully completed a Phase 2b pivotal study.
- **Potential for strong cash generation:** The Directors anticipate near-term revenues with high gross margins following the planned launch of Feraccru in Europe in 2016 with a relatively modest level of future spend on development of existing products to facilitate broader commercial opportunities.
- **Opportunity to create operational leverage and value via own sales infrastructure:** Feraccru and PT20 are intended to be sold directly by the Company using its own commercial team with its own

central and field-based commercial infrastructure in major markets in Europe. The Company will target specialist prescribers based in hospitals and private clinics.

- Strong intellectual property protection: A suite of strong intellectual property, including key patents in major markets, supports each product. With marketing approval in the EU and US, Feraccru will also benefit from data and marketing exclusivity in the EU and data exclusivity in the US.
- **Experienced board and management team:** Extensive expertise in the pharmaceutical and biotechnology industry with successful track records of commercialisation and value creation.

Details of the Placing

The Company has raised £32.5 million through the placing and subscription of 21,666,662 new Ordinary Shares ("**New Shares**") at a price of 150p per Ordinary Share (the "**Placing Price**") to a high quality group of institutional, existing and other investors. In addition, the Company will grant to each participant in the Placing 7 Warrants for every 13 New Shares subscribed for in the Placing, exercisable at the Placing Place until 30 June 2017.

On Admission, Shield will have a market capitalisation of approximately £162 million. Ordinary Shares will trade under the symbol "STX" and will be registered with ISIN GB00BYV81293. The Warrants will trade under the symbol "STXW" and will be registered with ISIN GB00BD97Z526. It is expected that dealings in the Company's Ordinary Shares and Warrants will commence trading on AIM by no later than 8:00am GMT on 26 February 2016.

The Company will shortly publish its Admission Document on its website at <u>www.shieldtherapeutics.com</u>. Capitalised terms used in the Admission Document shall, unless the context provides otherwise, have the same meanings in this Announcement.

Reasons for the Placing and use of proceeds

The Company intends to use its existing cash balances and the net proceeds from the Placing receivable by the Company with the clear primary objective of commercialising and further developing its lead product, Feraccru. The net proceeds from the Placing receivable by the Company are intended to be applied to the following workstreams:

- To prepare for and launch Feraccru into the European markets using its own dedicated central and field based commercial team initially targeted on IDA in inflammatory bowel disease ("IBD");
- To fund expansion of the Group's infrastructure to support the growth of its business;
- To continue to develop Feraccru through conducting further clinical trials to facilitate its commercial plans and to allow further regulatory approvals in other indications and markets including the US;
- To fund regulatory and chemistry, manufacturing and control costs in relation to the launch of Feraccru; and
- To facilitate further development of the Company's additional assets.

In addition to the net proceeds from the Placing, revenues generated from Feraccru will be used to help fund further business development, particularly to expand the approval and commercial uptake

of Feraccru and for the further development of the Company's assets including R&D to continue to drive expansion of Feraccru geographically and by medical indication. In addition, in the event all of the Warrants are exercised, the Directors expect to receive approximately £17.5m of additional funds that, with the monies referred to above, will be used to further finance the Company's business plan as set out in the Admission Document.

The Directors believe that the Placing will raise Shield's profile and enhance its ability to launch and market Feraccru. By raising awareness within the market generally, and with potential marketing and out-licence partners, the Company is expected to be able to attract and retain high quality employees to assist in its development.

Carl Sterritt, CEO of Shield Therapeutics, commented: "This is an important day in the Company's development and in spite of the clearly challenging market conditions I am delighted by the enthusiasm we have received from investors. The funds raised from this IPO will allow Shield to launch Feraccru in key European markets, enabling us to rapidly become a revenue generating specialty pharmaceutical business, as well as enabling expansion of the indications and geographies in which Feraccru can be commercialised. The Company's in-house commercialisation strategy seeks to retain greater value for shareholders and we would like to thank our new and existing investors for their support and look forward to joining AIM for the next stage of Shield's growth."

For further information please contact:

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About Shield Therapeutics

Overview

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Shield Therapeutics is a specialty pharmaceutical company focused on the development and commercialisation of secondary care-focused prescription pharmaceuticals. The Company's lead products are Feraccru and PT20.

Feraccru

Feraccru is a novel and effective oral ferric iron-based pharmaceutical product for which the CHMP has given a unanimous positive opinion that it should be granted a marketing authorisation in all member states of the European Union together with Iceland and Norway. This marketing authorisation is scheduled to be issued in the first quarter of 2016. Initially Feraccru will be licensed to treat iron deficiency anaemia ("**IDA**") in patients with IBD. A phased roll-out of commercialisation of Feraccru is expected to commence within the EU during 2016 targeted to treat IBD patients who have failed treatment on Oral Ferrous Products ("**OFPs**") or for whom such treatment is unsuitable. The Directors believe Feraccru has an achievable global peak annual sales opportunity in excess of £500 million.

Feraccru market opportunity

The Directors believe there is a large and attractive market of patients with IDA whose only current option is either no therapy or intravenous iron therapy, as currently available oral treatments demonstrate limited effectiveness due to negative adverse event profiles leading to low levels of compliance. Intravenous therapies also have limitations as they are expensive to administer, require time-consuming and inconvenient intermittent administration, and due to their potential to cause lifethreatening hypersensitivity reactions are required to be administered in a healthcare facility where cardio-resuscitation facilities are available.

Feraccru addresses a large and structurally growing market, with significant potential in the near-term. GfK UK Limited ("**GfK**"), an established independent market research company, estimate that there are approximately 1.4 to 1.5 million patients in Europe and the US with IBD who have the potential to be treated for IDA¹, of which a significant proportion are currently ineffectively treated. GfK also estimates that there are more than 3.4 million patients in the EU and US with IDA and CKD¹.

In the longer term, the Directors believe that Feraccru has the opportunity to expand into a number of indications and geographies, thus significantly expanding the potential number of patients available for treatment.

In addition, the Directors believe that in the long term there is potential for Feraccru to be established in the primary care setting, where there are a significant number of potential patients, particularly for the treatment of IDA in women's health and treatment of IDA in the elderly population.

Feraccru clinical data

To date, long term clinical studies conducted with Feraccru in IDA patients who have failed treatment on OFPs have demonstrated the potential for it to be an effective daily oral treatment in such patients, therefore providing an alternative therapy to intravenous iron.

The most significant study conducted by the Group was the pivotal Phase 3 Study that completed in 2014, meeting the primary and all secondary endpoints of efficacy and safety. The Group is currently

conducting a randomised Phase 3b study comparing Feraccru with a leading IV iron (Ferinject, ferric carboxymaltose). This study is not required for regulatory approval of Feraccru by the EMA, but is intended to provide further safety data, as well as comparative pharmaco-economic and efficacy data, all of which will further support the commercial positioning and uptake of Feraccru.

Future studies are planned to generate efficacy and safety data in other indications to enable the Company to expand its regulatory approvals initially into the US and then into other geographies and indications.

PT20

PT20 is a novel iron-based phosphate binder being developed for the treatment of hyperphosphatemia related to CKD. The product has completed Phase 2 clinical trials, having recently met all primary and secondary endpoints of a phase 2b pivotal study. It is anticipated that PT20 will be required to undergo one further pivotal study before a marketing authorisation application can be filed in major pharmaceutical markets.

PT20 was invented in the UK by leading Cambridge-based scientists and is exclusively licensed from the Medical Research Council (the "**MRC**"). Patients with late-stage renal disease suffer from hyperphosphatemia, which enhances the risk of vascular calcification, leading to increased morbidity and mortality. Low phosphate diets and regular dialysis sessions are by themselves unable to prevent gradual phosphate accumulation, therefore, oral phosphate binders are routinely used to reduce absorption of phosphate and thereby reduce blood phosphate levels.

The Directors believe there is a large and attractive commercial market for PT20 as current treatments are often limited by at least one of the following problems: limited therapeutic dosing range, low specificity, high pill loading, gastrointestinal side effects, calcium loading or significant toxicity concerns.

PT20 market opportunity

Hyperphosphatemia is a serious and inevitable clinical consequence of the advanced stages of CKD. The hyperphosphatemia market is large and growing and is driven by the rise in CKD in Western populations. GfK estimate there are over 650,000 patients in the EU and US on dialysis, the majority of whom are currently being treated with phosphate binders¹. Current therapies for the treatment of hyperphosphatemia are less than satisfactory and GfK's primary research indicated only a moderate degree of satisfaction with current phosphate binders.

In addition there is a large population of pre-dialysis CKD patients who are much less likely to receive treatment for hyperphosphatemia as the prescribing guidelines vary between Europe and the US for leading phosphate binders. As far as the Directors are aware there are currently no phosphate binders approved for use in pre-dialysis CKD patients in the US. This represents a very large potential market for a novel, safe and effective phosphate binder.

The Directors believe there is a large and attractive market for PT20. Current treatments are often limited by at least one of the following problems: limited therapeutic dosing range, low specificity, high pill burden.

PT20 clinical data

To date, studies conducted by the Company have demonstrated the potential of PT20 to deliver an effective treatment of hyperphosphatemia related to dialysis-dependent CKD.

Whilst the Company has commenced planning for the Phase 3 development of PT20 including manufacturing scale up activity, the Company's near to medium term focus is on evaluating outlicensing deals with potential partners to facilitate the final stage of clinical development prior to launch.

Board of directors

Dr Andrew Heath, Non-Executive Chairman

Dr Andrew Heath is a highly experienced healthcare and biopharmaceutical executive with in-depth knowledge of US and UK capital markets and international experience in marketing, sales, R&D and business development. Dr Heath is currently Deputy Chairman and Senior Independent Director of Oxford BioMedica plc and is a non-executive director of Novacyt SA and Integrated Healing Technologies LLC. He was formerly a director of the BioIndustry Association and he was Chief Executive Officer of Protherics plc from 1999 to 2008, taking the company from 30 to 350 staff and managing its eventual acquisition by BTG plc for £220 million. Prior to this Andrew served as Vice President of Marketing and Sales, for Astra Inc. in the US and held senior positions at Glaxo, Sweden.

Carl Sterritt, Chief Executive Office and co-founder

With around 20 years' of management and executive level experience in pharmaceutical development and commercialisation in both large and small company settings, Carl has led the Group as its CEO since he co-founded the SHG Group in 2008 and PTL in 2011. Previously, Carl held senior management roles at United Therapeutics and Encysive Pharmaceuticals, working on innovative therapies for the treatment of pulmonary arterial hypertension. Carl joined United Therapeutics to establish the company's European operations in preparation for the marketing approval of Remodulin, running the subsidiary for six years. In collaboration with physicians in Germany, he was responsible for and holds patents related to United Therapeutics' decision to develop and commercialise treprostinil; now successfully commercialised in the US as Tyvaso. Carl was instrumental in the successful commercial launch of Thelin and the rapid growth of Encysive's European operations. Carl founded the SHG Group after Encysive was acquired by Pfizer Inc. for more than \$300m.

Richard CM Jones ACA, Chief Financial Officer and Company Secretary

Richard was appointed a Non-Executive Director of SHG in early 2010 and Chief Financial Officer in April 2011. Richard has advised the Group since its inception in his previous role as an investment banker with both Brewin Dolphin Securities and Investec Bank. Richard has a strong track record in advising clients on a wide range of transactions and fundraisings including IPOs, M&A and fundraisings. With more than 10 years' advisory experience in the investment banking industry, his particular focus was in the healthcare sector where he developed extensive experience with a broad range of clients including private companies, private equity and UK and European quoted companies. Richard qualified as a Chartered Accountant with Coopers and Lybrand in 1991.

James Karis, Non-Executive Director

James is a life sciences and healthcare industry executive with over 35 years of experience in the pharmaceutical, healthcare services, technology and medical device industries. A proven entrepreneur he is also an experienced board member for public and private companies with extensive experience in corporate strategy, M&A and all aspects of company financing. He is currently, Chief Executive Officer of privately held Mapi Group, a company focused on conducting late phase studies as well as providing regulatory and reimbursement support to the pharmaceutical and device Industries. James has previously held senior management and executive roles at CollabRx, Entelos, Inc., PAREXEL International, Pharmaco International and Baxter International. He has a B.S. in Management and Economics from Purdue University and a M.A. in Applied Economics from The American University.

Peter Llewellyn-Davies, Non-Executive Director

Peter is a strategic CFO with an over 25 year track record in international M&A deals, company turnarounds, licensing transactions and financing activities with particular experience in chemical and healthcare industries. Peter has been CFO of Medigene AG since 2012 and has supported the turnaround process by outlicensing marketed and legacy products and enhancing shareholder value with a large international investor base. Prior to that he was CFO of Wilex AG, having orchestrated their IPO in 2006 to fund a later stage pipeline and conclude subsequent partnering deals and acquisitions. Peter is a founder of Accellerate Partners, focused on executing change and supporting private and listed companies and advising venture capital and private equity firms. Peter read business management, banking, marketing and controlling in London, St. Gallen and Munich, and has a certificate in business studies from the University of London. Peter was nominated for appointment to the Board pursuant to the Relationship Agreement.

References

¹GfK UK Limited estimates based on market and industry data research undertaken by GfK, which will be set out in the Admission Document in a report prepared by GfK.

Forward-looking statements

This announcement includes statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "expects", "intends", "plans", "may", "will" or "should" or, in each case, their negative or other variations or comparable terminology. All statements other than statements of historical fact included in this announcement are forward-looking statements. They appear in a number of places throughout this announcement and include statements regarding the Directors' or the Group's intentions, beliefs or current expectations concerning, among other things, its operating results, financial condition, prospects, growth, expansion plans, strategies, the industry in which the Group operates and the general economic outlook.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future and therefore are based on current beliefs and expectations about future events. Forward-looking statements are not guarantees of future performance and the Group's actual operating results and financial condition, and the development of the industry in which it operates may differ materially from those made in or suggested by the forward-looking statements contained in this announcement. In addition, even if the

Group's operating results, financial condition and liquidity, and the development of the industry in which the Group operates are consistent with the forward- looking statements contained in this announcement, those results or developments may not be indicative of results or developments in subsequent periods. Accordingly, prospective investors should not rely on these forward-looking statements. Any forward-looking statements that the Group makes in this announcement speak only as of the date of the document, and none of the Company, the Directors, the Selling Shareholders or Liberum undertakes any obligation to update such statements unless required to do so by applicable law. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

Important notice

This announcement does not constitute a prospectus within the meaning of section 85 of Financial Services and Markets Act 2000 ("**FSMA**"), has not been drawn up in accordance with the Prospectus Rules and has not been approved by or filed with the Financial Conduct Authority. This announcement does not constitute an offer of transferable securities to the public within the meaning of FSMA or otherwise.

Important information

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The securities to which this announcement relates have not been, and will not be, registered under the US Securities Act of 1933, as amended (the "**Securities Act**") or with any regulatory authority or under any applicable securities laws of any state or other jurisdiction of the United States, and may not be offered or sold within the United States unless registered under the Securities Act or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in compliance with applicable state laws. There will be no public offer of the securities in the United States.

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The securities to which this announcement relates have not been approved or disapproved by the U.S. Securities and Exchange Commission, any state securities commission in the United States or any United States regulatory authority, nor have any of the foregoing authorities passed upon or endorsed

the merits of the offering of the securities or the accuracy of adequacy of this announcement. Any representation to the contrary is a criminal offence in the United States.

In any EEA Member State that has implemented Directive 2003/71/EC, as amended including by Directive 2010/73/EU (together with any applicable implementing measures in any Member State, the "**Prospectus Directive**"), this announcement is only addressed to and is only directed at qualified investors in that Member State within the meaning of the Prospectus Directive.

This announcement is an advertisement. Investors should not subscribe for or purchase any securities referred to in this announcement except in compliance with applicable securities laws on the basis of information in the Admission Document published by Shield today, 12 February 2016, in connection with the placing of its Ordinary Shares and the proposed admission of its Ordinary Shares to trading on the AIM Market of the London Stock Exchange. Copies of the Admission Document are available, subject to applicable securities laws, from <u>www.shieldtherapeutics.com</u> and at the Company's main office at: Northern Design Centre, Baltic Business Quarter, Gateshead Quays NE8 3DF.

Any purchase of Ordinary Shares in the proposed Placing should be made solely on the basis of the information contained in the Admission Document, which contains detailed information about the Company and its management, as well as financial statements. Before purchasing any Ordinary Shares, persons viewing this announcement should ensure that they fully understand and accept the risks, which are set out in the Admission Document. The information in this announcement is for background purposes only and does not purport to be full or complete. No reliance may be placed for any purpose on the information contained in this announcement or its accuracy or completeness. This announcement does not constitute or form part of any offer or invitation to sell or issue, or any solicitation of any offer to purchase or subscribe for any Ordinary Shares or any other securities nor shall it (or any part of it) or the fact of its distribution, form the basis of, or be relied on in connection with, any contract therefor.

This announcement does not constitute a recommendation concerning the Placing. The price and value of securities and any income from them can go down as well as up. Past performance is not a guide to future performance. Before purchasing any Ordinary Shares, persons viewing this announcement should ensure that they fully understand and accept the risks that are set out in the Admission Document. Information in this announcement or any of the documents relating to the Placing and Admission cannot be relied upon as a guide to future performance. There is no guarantee that Admission will occur and you should not base your financial decisions on Shield's intentions in relation to Admission at this stage. Potential investors should consult a professional advisor as to the suitability of the Placing for the entity concerned.

Liberum, authorised and regulated by the Financial Conduct Authority in the United Kingdom, is acting exclusively for the Company and no one else in connection with the Placing and Admission, will not regard any other person as their respective customer or be responsible to any other person for providing the protections afforded to customers of Liberum, nor for providing advice in relation to the Placing, Admission or any other transaction or arrangement referred to in this announcement. Its responsibilities as the Company's nominated adviser under the AIM Rules for Nominated Advisers are owed solely to the London Stock Exchange and are not, under the AIM Rules for Nominated Advisers, owed to the Company or to any Director or to any other person in respect of his or her decision to acquire Ordinary shares in reliance on any part of the Admission Document. No representation or warranty, express or implied, is made by Liberum as to any of the contents of this announcement (without limiting the statutory rights of any person to whom this announcement is issued). Liberum will not be offering advice and will not otherwise be responsible to anyone other than the Company for providing the protections afforded to customers of Liberum or for providing advice in relation to the Placing, Admission or any other matter. No liability is accepted by Liberum for the accuracy of any information or opinions contained in, or for the omission of any material information from, this announcement, for which the Company and the Directors are solely responsible.

Certain figures contained in this announcement, including financial information, have been subject to rounding adjustments. Accordingly, in certain instances, the sum or percentage change of the numbers contained in this announcement may not conform exactly to the total figure given.