



Improving Lives Together

Investor Presentation
Shares Magazine/AJ Bell webinar

20 January 2021

Disclaimer

These slides have been prepared by Shield Therapeutics plc (the "Company") solely for your information and for use at a presentation for the purpose of providing background information on the Company, its business and the industry in which it operates. For the purposes of this notice, "presentation" means these slides, any oral presentation, any question and answer session and any written or oral material discussed or distributed during the presentation meeting.

This presentation has not been approved by the United Kingdom Listing Authority under the Prospectus Rules (made under Part VI of the Financial Services and Markets Act 2000, as amended) or otherwise, or by the London Stock Exchange plc. This presentation has not been independently verified and no representation or warranty, express or implied, is made or given by or on behalf of the Company or any of its subsidiaries or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, as to, and no reliance may be placed for any purpose whatsoever on the information or opinions contained in this presentation or on the completeness, accuracy or fairness thereof.

This presentation does not constitute or form part of, and should not be construed as, any offer, invitation or recommendation to purchase, sell or subscribe for any securities of the Company in any jurisdiction and neither the issue of this presentation nor anything contained herein shall form the basis of or be relied upon in connection with, or act as an inducement to enter into, any investment activity. This presentation does not purport to contain all of the information that may be required to evaluate any investment in the Company or any of its securities and should not be relied upon to form the basis of, or be relied on in connection with, any contract or commitment or investment decision whatsoever. This presentation is intended to present background information on the Company, its business and the industry in which it operates and is not intended to provide complete disclosure upon which an investment decision could be made. The merit and suitability of an investment in the Company should be independently evaluated and any person considering such an investment in the Company is advised to obtain independent advice as to the legal, tax, accounting, financial, credit and other related advice prior to making an investment.

No undertaking, representation, warranty or other assurance, express or implied, is or will be made or given by or on behalf of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers or any other person as to the accuracy or completeness of the information or opinions contained in this presentation and no responsibility or liability is accepted by any such person for any such information or opinions or for any errors, omissions or misstatements, negligent or otherwise, nor for any other communication written or otherwise. All information in this presentation is subject to verification, correction, completion and change without notice. None of the Company or any of its subsidiary or subsidiary undertakings, or any of such person's respective directors, officers, partners, employees, agents, affiliates or advisers, undertakes any obligation to amend, correct or update this presentation or to provide the recipient with access to any additional information that may arise in connection with it.

The statements contained in this presentation may include "forward-looking statements" that express expectations as to future events or results. Forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "projects", "expects", "intends", "may", "will", "seeks" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by such forward-looking statements. Any of the assumptions underlying forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in forward-looking statements may not actually be achieved. Nothing contained in this presentation should be construed as a profit forecast or profit estimate. Investors and any other recipients of such communications are cautioned not to place reliance on any forward-looking statements. The Company undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.

To the extent available, the data contained in this presentation has come from official or third party sources. Third party industry publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company has not independently verified the data contained therein. In addition, certain of the data contained in this presentation come from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. While the Company believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the data contained in this presentation.

This presentation should not be copied or distributed by recipients and, in particular, should not be distributed by any means, including electronic transmission, to persons with addresses in the United States of America, Canada, Australia, South Africa or Japan, their possessions or territories or to any citizens thereof, or to any corporation, partnership or such entity created or organised under the laws thereof, or any other jurisdiction, where such distribution is unlawful. Any such distribution contrary to the above could result in a violation of the laws of such jurisdictions.

This presentation is confidential and is being supplied to you solely for your information and may not be reproduced, re-distributed or passed on, directly or indirectly, to any other person or published in whole or in part for any purpose. By attending the meeting where this presentation is made or by accepting a copy of this presentation, you agree to be bound by the limitations and restrictions set out above.



SHIELD
THERAPEUTICS PLC

Improving Lives Together

Agenda

Company Overview & Investment Highlights

How is Feraccru[®]/Accrufer[®] distinguished from competitors

US Market Opportunity

Europe/China

Cash

Summary



SHIELD
THERAPEUTICS PLC

Improving Lives Together

Company Overview & Investment Highlights

Introduction to Shield Therapeutics plc

- AIM-listed biotech company (STX.L)
 - Market capitalisation ~£64m (@15Jan2021)
- Primary focus is on developing and commercialising Feraccru[®]/Accrufer[®]
 - A novel oral therapy for treating iron deficiency (ID) in adults, with or without anaemia
 - Approved in the USA and EU
 - Patent protection until 2035
 - Three positive phase III clinical trials have confirmed effectiveness and tolerability
 - Commercialisation out-licensed to
 - Europe, Australia, New Zealand - Norgine in Q4 2018
 - China, Taiwan, Hong Kong, Macau - ASK Pharm in Q1 2020
- Development pipeline
 - Feraccru[®]/Accrufer[®] Phase III paediatric study under way
 - PT20 (a phosphate binder for treatment of hyperphosphatemia), requires one phase III study to submit a MAA in Europe and NDA in the USA
- Semi-virtual UK-based company
 - Out-source clinical trials, manufacturing and Europe/China commercialisation
 - Experienced management team
 - 15 employees

Investment Highlights

1

Current valuation underpinned by commercialisation licence deals in Europe and China

- Europe – commercialisation by Norgine BV, currently marketed in Germany, UK and Scandinavia. Launches in France, Italy and Spain expected in 2021/2022
- China – licensed to Beijing Aosaikang Pharmaceutical Co. Ltd (“ASK Pharm”). One further Phase III study required; approval expected 2023

2

Very substantial valuation upside from US opportunity

- ~10 million ID patients suffering from anaemia
- ~10 million monthly prescriptions per year of oral iron salts; ~2.3 million doses annually of intravenous (IV) iron
- Substantial unmet need because existing 1st line generic oral iron salts are poorly tolerated; 2nd line IV iron is inconvenient for patients and expensive

3

Feraccru®/Accrufer® is a NOVEL ORAL product with broad indication for treatment of ID in adults:

- Three phase III studies confirmed safety, tolerability and effectiveness
- Advantages over both other oral products and intravenous iron therapy
- Patent protection until 2035

4

Accrufer® will be launched in the US

- EITHER via a commercialisation out-licence arrangement
- OR via a Shield-led launch



SHIELD
THERAPEUTICS PLC

Improving Lives Together

How is Feraccru®/Accrufer® distinguished from competitors

Current ID treatment paradigm: significant unmet need

Patient diagnosed with iron deficiency

1st line treatment

- >80% of the Rx iron market volume comes from orals which are primarily generic*
- ~10m-11m TRx annually for oral products*
- Annual net sales ~ \$0.1bn



2nd line treatment

- >90% of the Rx US\$ market value comes from IV iron*
- Annual sales ~\$1.2bn
 - Comprised of primarily branded products:
 - Injectafer®, Feraheme®, Monoferric®, Venofer®,



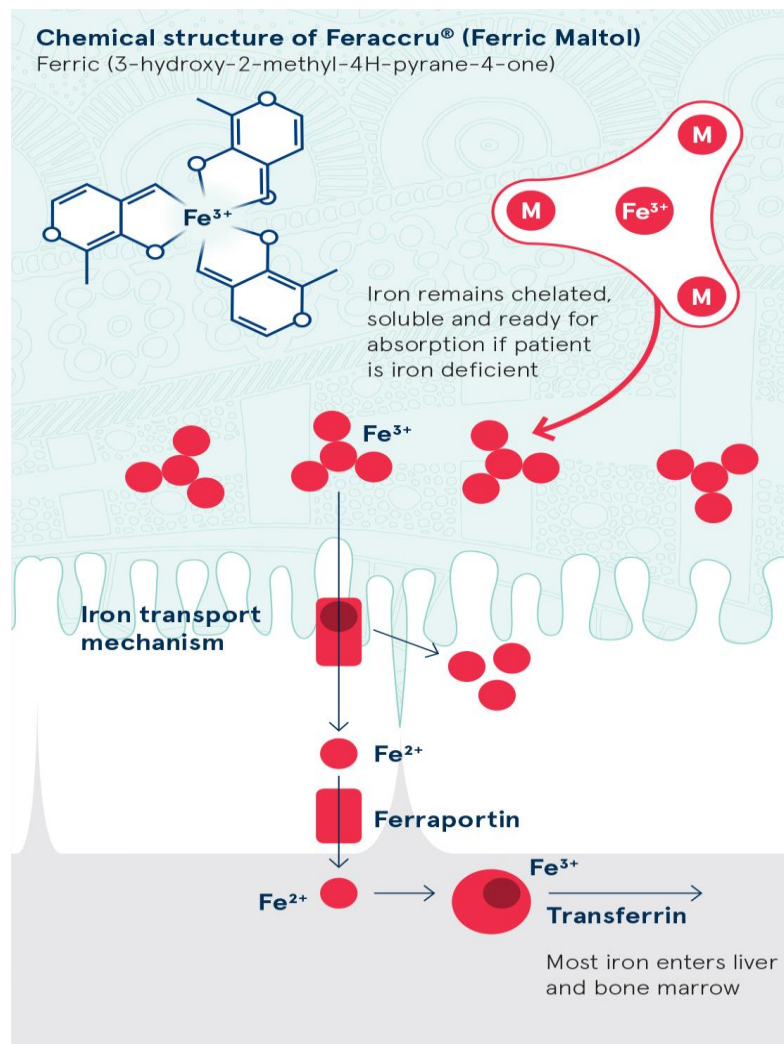
Unmet Need

- **Oral:**
- Mostly salt-based iron compounds
 - + Inexpensive generics
 - + Convenient to take
 - Poor tolerability in the gut
 - Less efficient absorption
 - Slower efficacy
 - Poor compliance
- **Intravenous (IV):**
- Used mainly in patients intolerant of oral therapies
 - + Increases iron levels quickly
 - + Better bioavailability/absorption
 - + No compliance issue
 - Risk of iron overload
 - Risk of allergic reaction
 - Risk of infection
 - Requires hospital administration
 - Inconvenient
 - Expensive

The poor tolerability of salt-based oral iron therapies and the cost/inconvenience of IV iron together create significant unmet need and commercial opportunity for Feraccru® /Accrufer®

Feraccru®/Accrufer® is a novel and different oral formulation

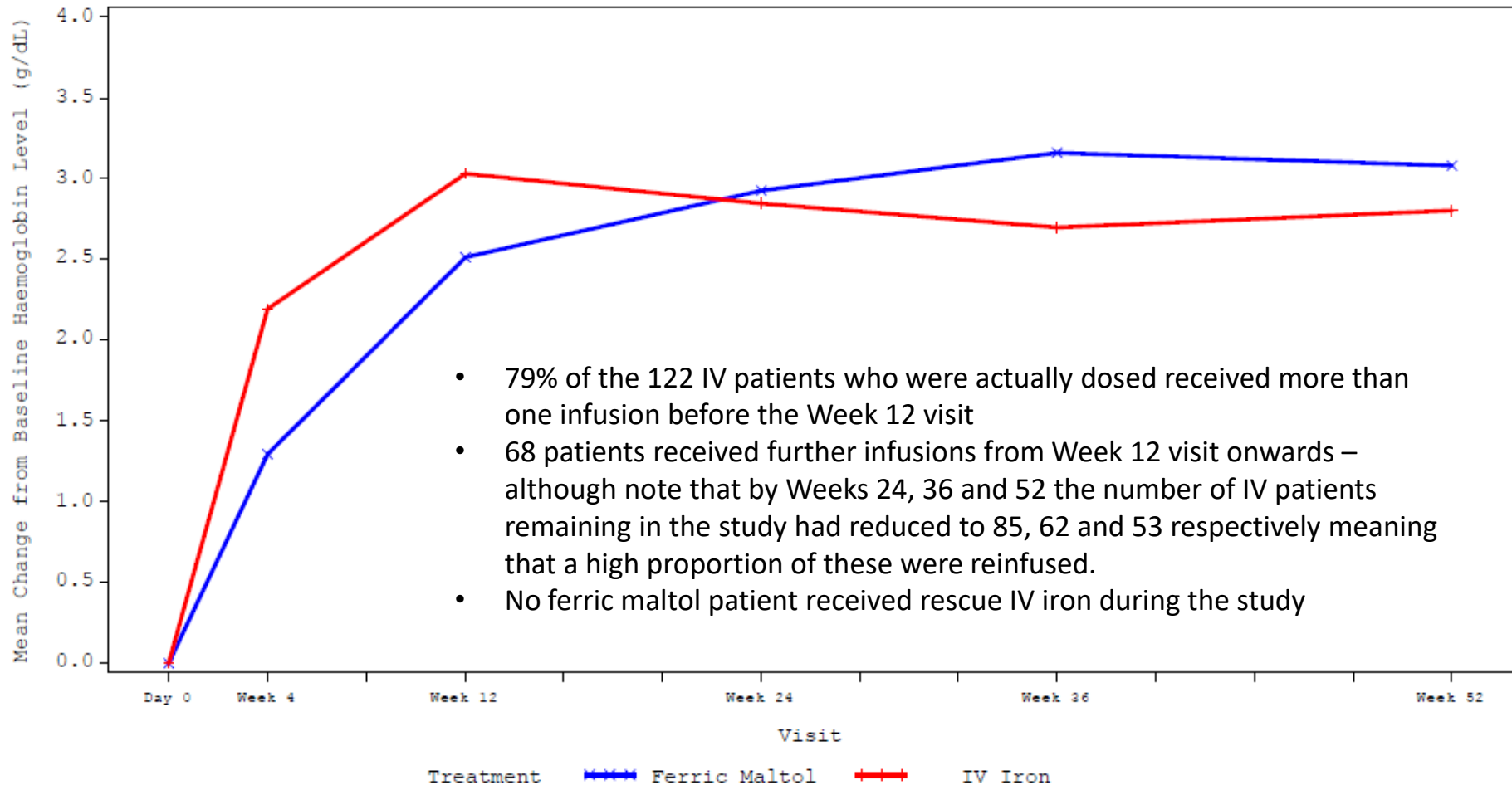
Feraccru® mechanism of action:



- Feraccru® is a low dose oral formulation of a non-salt complex of Fe³⁺, which is stable in the GI tract
 - 30mg capsules, 2x daily
 - Other oral irons are salts and require the Fe to dissociate to be absorbed (e.g. 65mg, 3x daily)
 - This causes formation of insoluble products in the GI tract, causing intolerance in patients
- The Fe³⁺ in Feraccru® remains in complex with maltol until absorbed in the duodenum and the iron is delivered to the bloodstream where it binds to transferrin
 - Maltol gets metabolised and excreted in urine
 - Unabsorbed Feraccru® passes through the digestive system in the benign complex and is excreted in faeces
- Feraccru® is a well tolerated oral iron replacement therapy
 - Potential for use as a first line treatment for patients with iron deficiency or as an alternative to IV iron in patients failing existing oral iron salts

Head-to-head study – comparison with leading IV therapy*

Post-Hoc September 2020 Figure 14.2.1.2.1
Mean Change from Baseline Haemoglobin Concentration (g/dL) by Visit



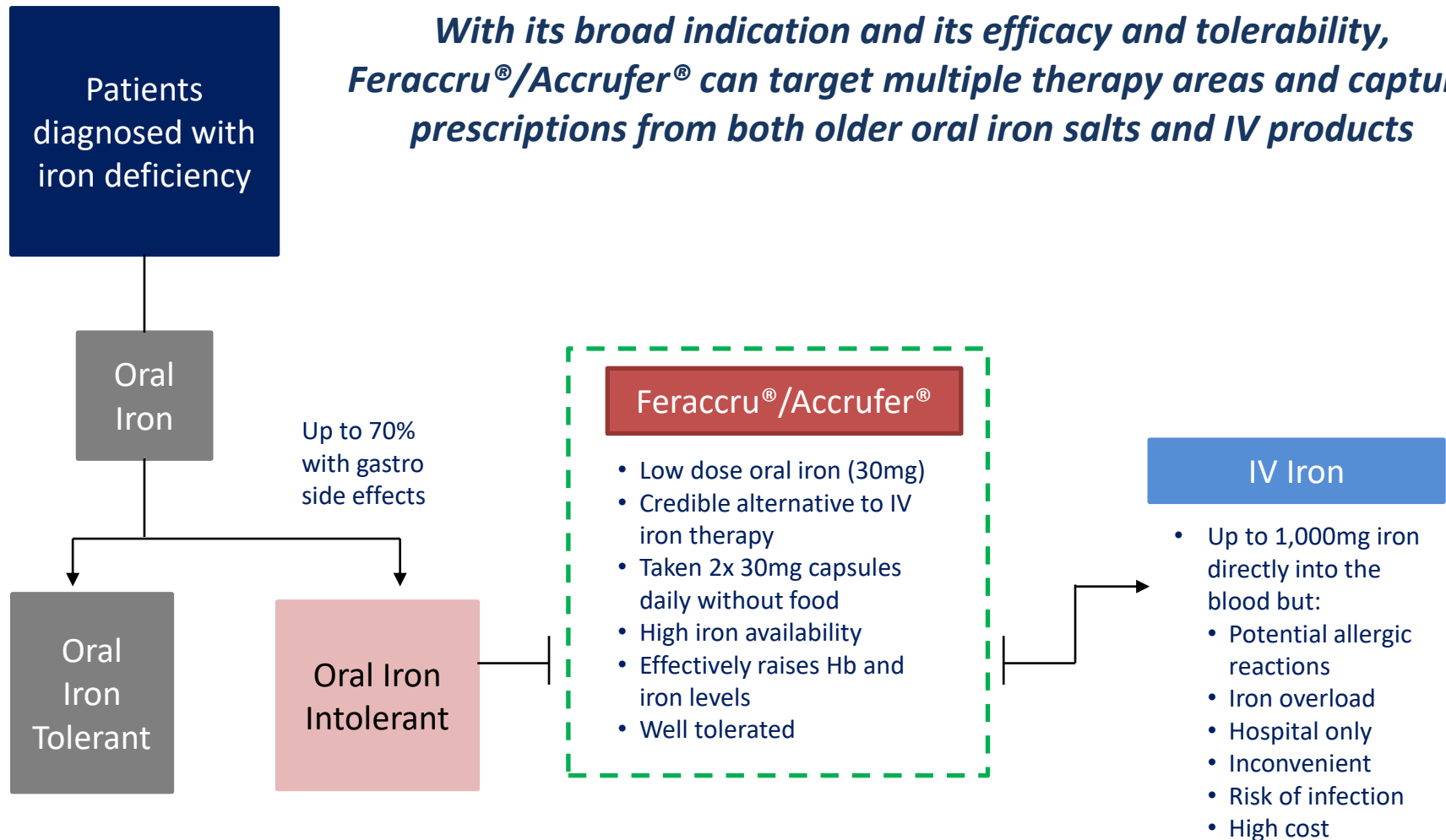
Number of patients (OC):

Ferric Maltol	125	117	106	80	55	50
IV Iron	125	117	115	85	62	53

* Source: AEGIS-H2H clinical study

Feraccru®/Accrufer® positioning to address both oral and IV segments

With its broad indication and its efficacy and tolerability, Feraccru®/Accrufer® can target multiple therapy areas and capture prescriptions from both older oral iron salts and IV products





SHIELD
THERAPEUTICS PLC

Improving Lives Together

US Market Opportunity

~10M Patients suffer from IDA¹ across multiple therapeutic areas in the US

~10-11 million oral Rx annually; ~2.3 million IV doses annually

- **Chronic Kidney Disease (CKD)**

- 37m patients (dialysis & non-dialysis)²
- ~50% of patients at risk³
- ~2.5m patients have Stage 3 or 4 CKD with IDA³

- **Women's Health**

- 1 in 5 women of childbearing age⁴
- Heavy uterine or post partum bleeding

- **Gastrointestinal Disorders**

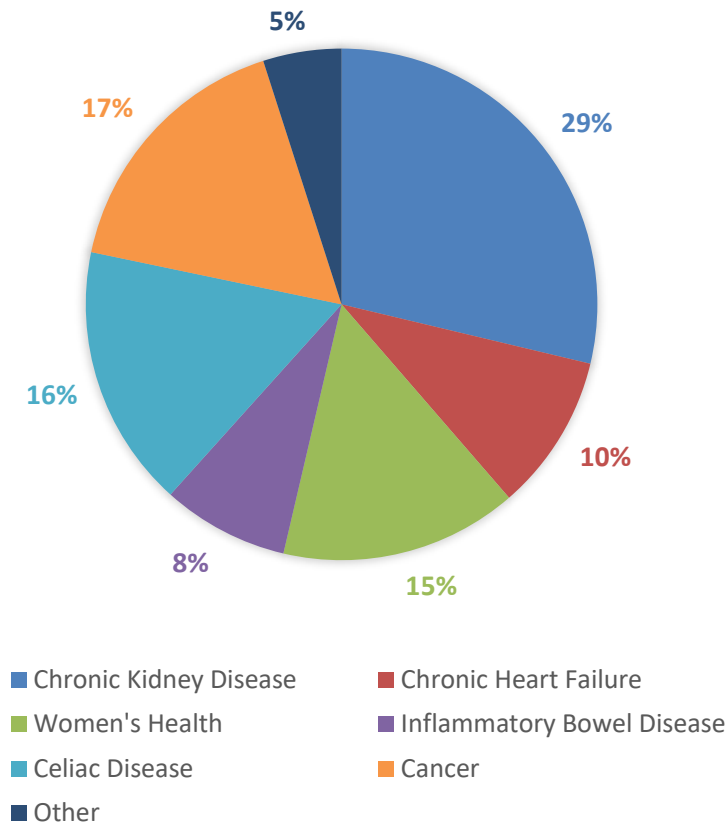
- Inflammatory Bowel Disease (IBD)
 - IDA affects up to 76% of patients⁵
- Celiac Disease
 - 10%-20% of patients at risk⁶

- **Oncology**

- Solid tumors & hematological malignancies
- 32%-60% of cancer patients at risk⁷

- **Cardiology**

- 17% of chronic heart failure patients may be affected⁸



Sources: 1) "Iron Deficiency Anemia" Cold Spring Harb Perspect Med 2013; 3 :a011866 2) Centers for Disease Control and Prevention. Chronic Kidney Disease in the US, 2019. Available at: <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html> 3) Stauffer ME, Fan T (2014) "Prevalence of Anemia in Chronic Kidney Disease in the US" PLoS ONE 9(1); e84843. doi:10.1371/journal.pone.0084943 4) Your Guide to Anemia. National Heart, Lung and Blood Institute website. <https://www.nhlbi.nih.gov/files/docs/public/blood/anemia-ya.pdf>. September, 2011 5) Stein J, Hartmann F, Dignass AU. "Diagnosis and management of iron deficiency anemia in patients with IBD" Nat Rev Gastroenterol Hepatol.2010; 7(11):599-610 6) Daya H, Lebwohl B, Lewis S, and Green P. (2013) "Celiac Disease Patients Presenting with Anemia Have More Severe Disease Than Those Presenting with Diarrhea" Clinical Gastroenterology and Hepatology 2013;11:1472-1477 7) Lima J, Gago P, Rocha M, et al. "Role of intravenous iron in the treatment of anemia in patients with gastrointestinal tract tumors undergoing chemotherapy: a single-center, observational study" Int J Gen Med 2018 Aug 22;11:331-336. doi: 10.2147/IJGM.S165947. collection 2018 8) Klip IT, Comin-Colet J, Voors AA, et al. "Iron deficiency in chronic heart failure; an international pooled analysis" Am Heart J. 2013; 165(4):575-582.e3.

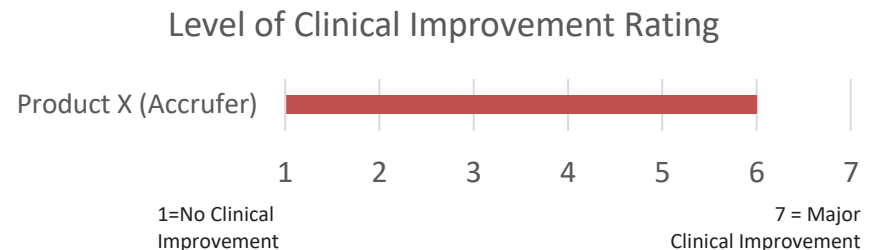
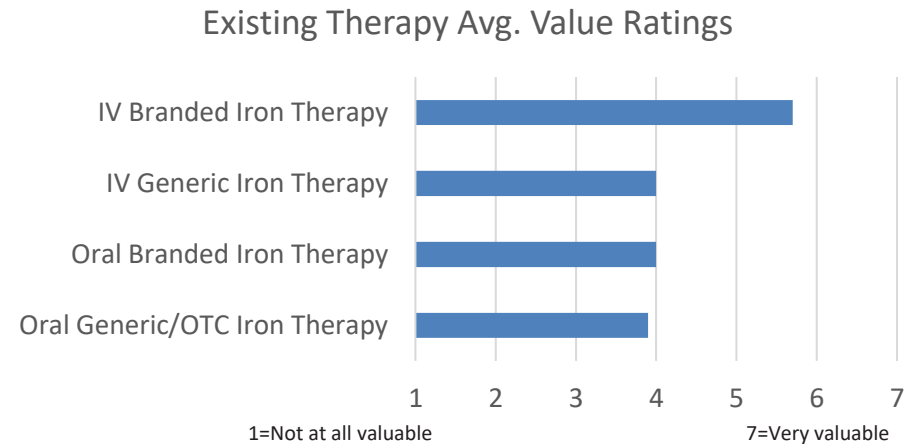
Market research confirms the unmet need*

Physicians believe there is an unmet need in the market.....

- Iron replacement therapy is generally considered an area of unmet need
- Key needs are effectiveness and GI tolerability

....and see Product X (Accrufer®) as delivering a high level of clinical improvement over existing therapies

- Accrufer® was viewed favorably as a significant clinical improvement
 - Good **tolerability** profile and **efficacy** data are key benefits
 - Potential first line use if allowed by insurance plans



Payer research indicates

- Accrufer® would have few restrictions at tested price points ensuring good patient access
- Net sales price \$200-\$250 per pack is achievable (after discounts e.g. patient co-pay, insurance chargebacks, distribution fees, etc)

Other factors supporting use of Accrufer®

COVID-19

Many ID/IDA patients have an underlying condition making them more susceptible to COVID-19 including:

- Chronic kidney disease
- Cancer
- Heart failure
- Those taking immunosuppressant drugs
- The elderly

COVID 19 is changing healthcare delivery and recommendations for the care of at-risk patients

- Taking extra precautions for clinic visits
- Consider providing home treatments
- Switching patients from IV to oral therapies to minimize exposure

Nearly 1 in 3 chronically ill patients report being afraid to leave their home because of COVID-19*

The efficacy, safety, tolerability and convenient dosing of Accrufer® make it the ideal iron replacement therapy for higher risk ID/IDA patients

Launch of HIF inhibitors

A new oral class of agents for the treatment of anaemia in CKD

Stimulate endogenous erythropoietin production, a necessary agent for production of Hb

Iron replacement will still be required in many patients – oral iron therapy likely to be preferable as HIFs are orally administered

Suggests an increasing place for the tolerability and effectiveness of Accrufer®

The 1st HIF inhibitor is expected to launch in the USA in 2021

* Source: InCrowd Novel Coronavirus (COVID-19) Patient Tracking Report, April 2, 2020

US commercialisation options

Out-licence to 3rd party

Financial terms

- Licence upfront – one-off receipt on signing
- Sales royalties based on annual sales - typical royalty rates ranging from 10%-25% depending on sales tiers
- Sales milestones - one-off receipts when annual sales reach specified targets for 1st time

Key issues

- Is the upfront big enough to ensure licensee is committed and has skin in the game?
- Will the licensee commercialise successfully? In particular, will they exploit the full breadth of Accrufer®'s potential
- Will the licensee be committed for the long term – e.g. until 2035 patent expiry

Current activities

- Ongoing early stage discussions with a number of potential licensees

Shield-led launch

Summary

- Shield retains full control over Accrufer® in US
- Also retains full ownership of Accrufer® profits
- Potential to sub-licence to 1-2 companies for broadening reach into specific therapy areas
- Shield clearly 100% committed

Key issues

- Overcome doubts that Shield can execute commercialisation as well as a potential licensee
- Finance required – estimated \$30m-\$40m to reach Group cash breakeven, expected during 2022

Current activities

- Detailed planning underway (see later slide)

Planning for successful Shield US launch

- Shield has recruited 4 experienced US commercial executives to plan and lead US launch
 - Currently on fixed term consultancy contracts pending firm decision for Shield to launch in US, at which point the intention is that they will become Shield US employees
 - Specific areas of expertise cover market access, marketing, medical affairs and operations/supply chain logistics
 - Each has 20+ years pharmaceutical experience
 - Extensive knowledge of Accrufer® built while working for a company which was seeking to licence Accrufer®
- Detailed planning underway for Q2 2021 launch covering:
 - Supply chain and operations e.g.
 - Planning supply of packs from Europe to pharmacies throughout USA, identifying warehousing and wholesalers, logistics providers
 - Market research and marketing e.g.
 - Brand planning, assessing agencies, developing further market research requirements
 - Sales force recruitment and training
 - Planning to target the top 30% of iron prescribers – about 15,000 physicians who in aggregate write at least 70% of all iron prescriptions*
 - Likely to need 30-60 sales reps to reach these prescribers, utilising both face-to-face and on-line meetings
 - Assessing whether to recruit in-house or outsource
 - Developing training materials
 - Market access e.g.
 - US Government pricing & managed services, insurance pricing and contract strategy, co-pay/patient assistance strategy,
 - Medical affairs e.g.
 - KOL Advisory Boards, scientific message platform, pharmacovigilance
 - Exploring potential to sub-licence to, or co-promote with, one or two therapy area specialists

** Source: IQVIA National Prescription Audit accessed November 2020*

Accrufer® US sales and profit potential

- On average, patients assumed to take 4-5 months' Accrufer® to allow time for restoration and maintenance of normal Hb levels
- At \$200-\$250 net sales price per pack => \$1,000 per patient per year

Potential Year 5 sales

- Sales of \$200m pa therefore require 200,000 patients treated annually
 - only 2% of 10 million IDA patients*
 - ~10% of current total oral prescriptions without any expansion of the market
 - <10% of the 2.3 million IV doses*
 - <20% of current \$1.2bn market* size BUT market likely to grow significantly

Shield launch scenario – potential profit/cash flow by Year 5

- 90% gross margin, after manufacturing costs and Vitra 5% royalty
⇒ \$180m gross margin
- US SG&A costs 2021 forecast to be ~\$25m-\$30m, rising to ~\$40m-\$45m by Year 5
⇒ **Year 5 US profit and cash generation ~ \$130m**

Licence scenario (Year 5) – royalty flow

- Assume average royalty of 20% => \$40m royalty
- Less 5% net sales (\$10m) payable to Vitra => **net income to Shield \$30m**



SHIELD
THERAPEUTICS PLC

Improving Lives Together

Europe/China

Feraccru® in Europe & China

Europe

Licensed to Norgine

- Sales royalties 25%-40% (Shield pays cost of goods)
- Sales milestones – up to €50m
- On market in Germany, England & Scandinavia
- 2020 sales volumes in Germany/UK up 70% vs 2019 - £0.7m royalties
- Pricing & reimbursement negotiations in France, Italy, Spain expected in 2021

China

Licensed to ASK Pharm

- IND application submitted - likely to require only one Phase III 12-week study in 120 IBD patients
- Potential approval & launch in 2023
- \$11.4m milestone due on approval
- Sales royalties 10%-15% (ASK pays cost of goods)
- Sales milestones – up to \$40m

On assumption that aggregate net sales in Europe + China rise to \$150m- \$200m by 2030, Shield's current market valuation is supported entirely by Europe and China licence deals



SHIELD
THERAPEUTICS PLC

Improving Lives Together

Cash position & Summary

Cash position

- Cash at 31 December 2020 - £2.9m
- Convertible loan facilities agreed with shareholders AOP (10.7%) and Dr Christian Schweiger (3.5%, also a board member)
 - ~£4.4m in total
 - 1st 50% tranche available 1 February 2021, 2nd 50% tranche available if needed during rest of 2021
 - Interest of 10% payable on tranches drawn down
 - Arrangement fee of 2%
- Loans extend cash runway (excluding substantial US spend) until end 2021
 - Protects the company if no licence deal or other fundraise in short/medium term
 - Shows commitment of significant shareholders

Summary

- Feraccru[®]/Accrufer[®] has unique attributes of efficacy, tolerability and breadth of application in ID
- ID is a large global market, including in the USA
- We are evaluating both out-licence and Shield-led launch alternatives
- To prepare for a Shield launch scenario, we have recruited 4 experienced US commercial managers who are planning the proposed launch in detail
- Clarity as to course of action likely during Q1 2021
- Today's market capitalisation does not reflect any value for US commercialisation
- Announcement of either a US licence deal or Shield-led launch is likely to lead to a rapid re-rating



Improving Lives Together

To be kept up to date with Shield Therapeutics plc news and to receive relevant investor communications on the Company going forward, please email Walbrook PR at shield@walbrookpr.com to subscribe