SHIELD THERAPEUTICS PLC

Improving Lives Together

Investor Presentation

16 December 2020

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SHIELD THERAPEUTICS PLC

Improving Lives Together

Agenda

Company Overview & Investment Highlights

How is Feraccru®/Accrufer® distinguished from competitors

US commercialisation - Summary of last 18 months

US Market Opportunity

Europe/China

Cash

Summary

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Company Overview & Investment Highlights

Introduction to Shield Therapeutics plc

- AIM-listed biotech company (STX.L)
  - Market capitalisation ~£71m (@15Dec2020)

- Primary focus is on developing and commercialising Feraccru®/Accrufer®
  - A novel oral therapy for treating iron deficiency (ID) in adults
  - Approved in the USA and EU
  - Patent protection until 2035
  - Three positive phase 3 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
  - PT20 (a phosphate binder for treatment of hyperphosphatemia), requires one phase 3 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 £71m 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 IV Iron
- Existing 1st line generic oral iron salts are poorly tolerated; 2nd line IV iron is inconvenient for patients and expensive
- Substantial unmet need

3

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

- Phase III studies in inflammatory bowel disease (IBD) and chronic kidney disease (CKD)
- Further application in e.g. chronic heart failure, women's health, oncology, and care of elderly
- Patent protection until 2035

4

Feraccru®/Accrufer® is effective and well tolerated:

- Three phase 3 clinical trials have confirmed safety and effectiveness
- In head-to-head Phase 3 study against Ferinject/Injectafer (market leading IV treatment) Accrufer® demonstrated comparable effectiveness over 52 weeks and could be a more cost-effective alternative to IV iron

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How is Feraccru®/Accrufer® distinguished from competitors

Iron deficiency (ID)

- Iron is a key component of haemoglobin (Hb)
  - ID is the most common cause of anaemia (iron deficiency anaemia or “IDA”)

- ID is caused by malnutrition or bleeding and is associated with many diseases, in particular:
  - Inflammatory bowel disease (IBD), Chronic kidney disease (CKD), Womens’ health, Congestive heart failure (CHF), oncology, ageing

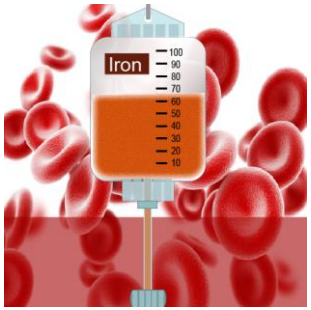
Iron replacement therapy

Typically initiated with oral, followed by IV therapy if needed

Patient diagnosed with iron deficiency

1st line treatment

2nd line treatment



Oral

- Iron salts
- Inexpensive and convenient to take but…
- Not well tolerated = poor compliance = unable to restore iron levels
- Poor absorption = slower to restore iron levels and…

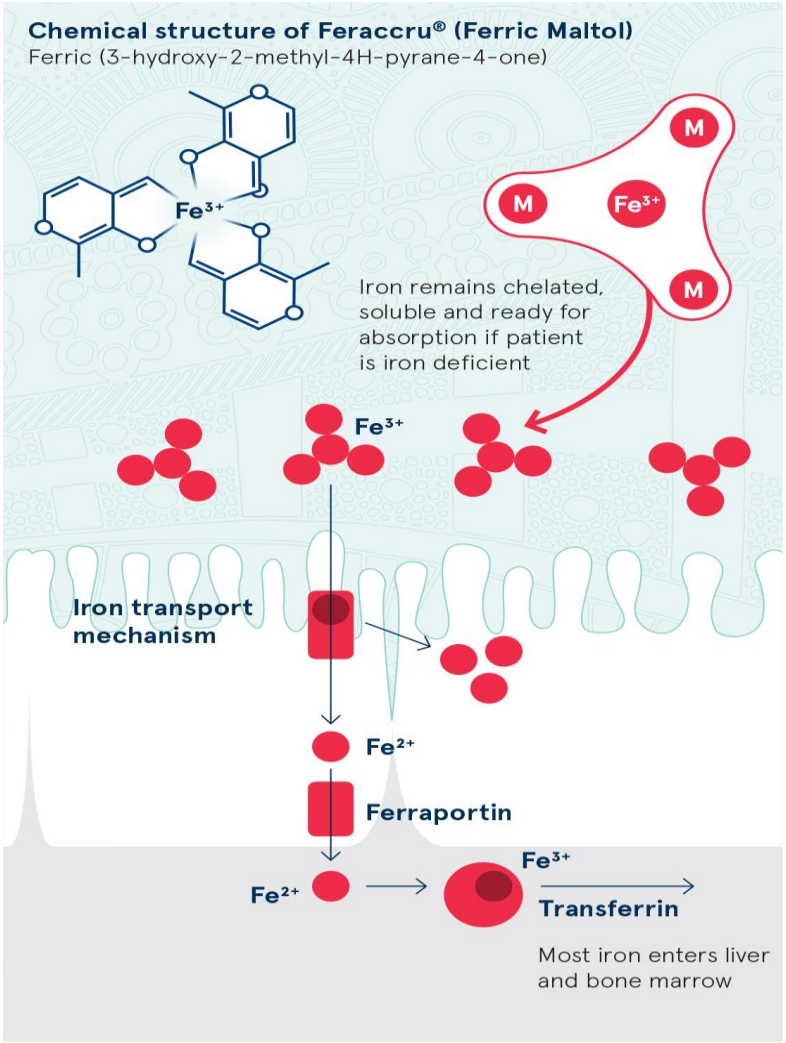
Intravenous (IV)

- Used mainly in patients intolerant of oral therapies
- Up to 1,000mg iron infused into blood stream
- Requires hospital administration due to safety risk
- Resource heavy, inconvenient & costly

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:



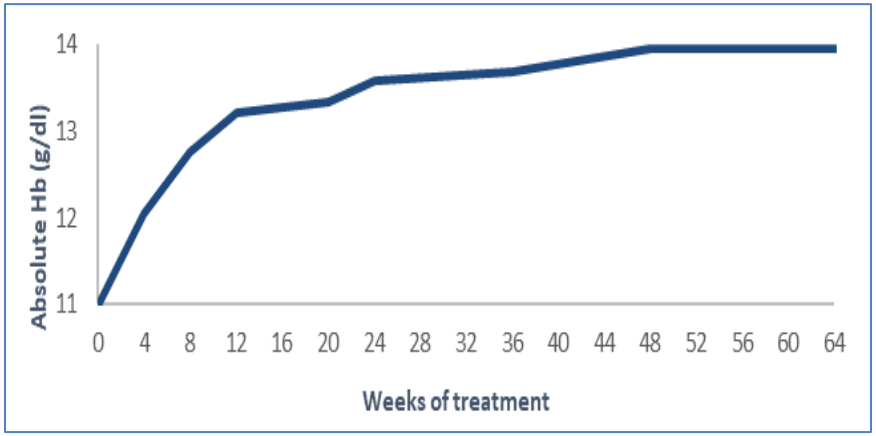
- Feraccru® is a low dose oral formulation of a non-salt complex of Fe^{3+}, which is stable in the GI tract
  - 30mg capsules, 2x daily
  - Other oral irons are salts and require the Fe to dissociate to be absorbed (e.g. 65mg, 3x daily)
  - This causes formation of insoluble products in the GI tract, causing intolerance in patients
- The Fe^{3+} 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

Source: Shield Therapeutics Investor Materials, 2017; MedScape; EMA; Stallmach *et al.* 2015; Abbaspour *et al.* 2014; L.E.K. research

Regulatory clinical studies used for approval of Feraccru®/Accrufer® in Europe and USA

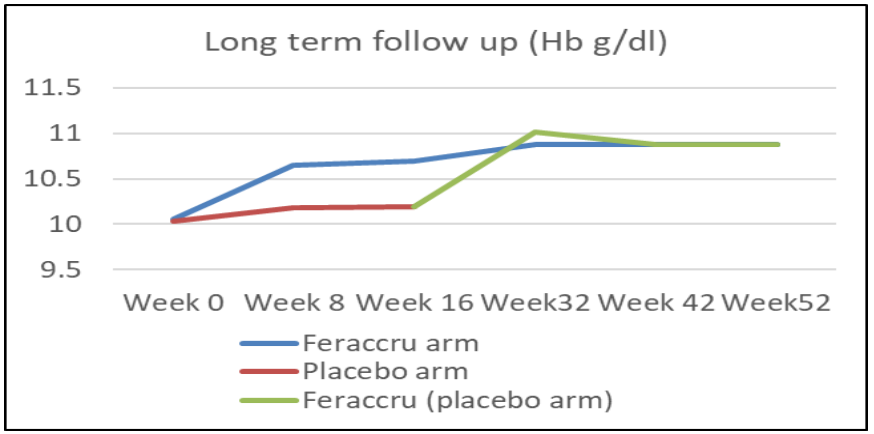
AEGIS-IBD (Inflammatory Bowel Disease)

- Feraccru provides rapid results – met primary end-point (change in Hb from baseline) at 12 weeks
- delivered 2.3g/dL rise in 12 weeks with 1g/dL in only 4 weeks
- Works over long term
- Well tolerated



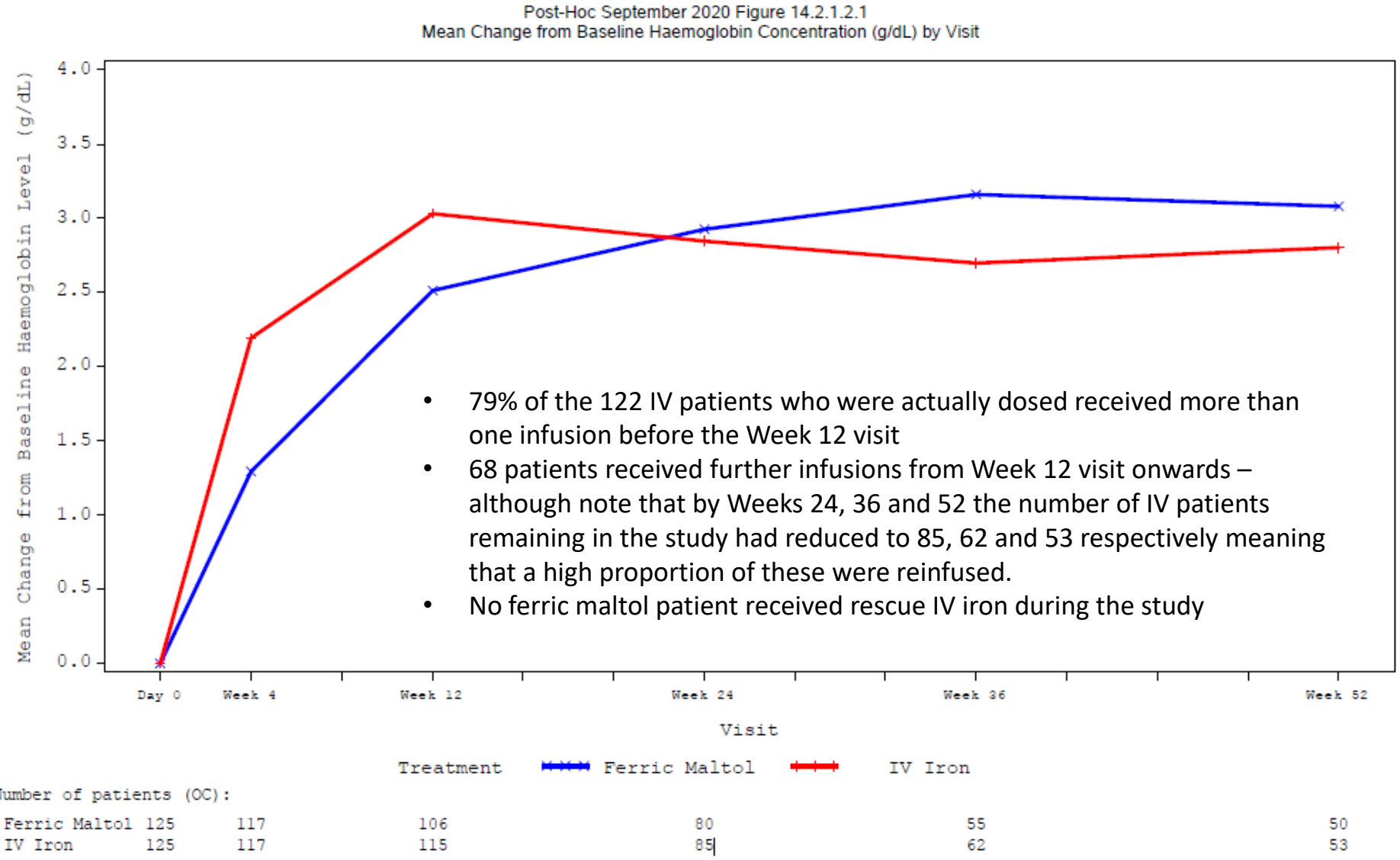
AEGIS-CKD (Chronic Kidney Disease)

- met primary endpoint (change in Hb from baseline) at 16 weeks
- Hb levels increased and maintained over 52 weeks
- Well tolerated
- NB – protocol barred ESAs* so Hb increase limited by patients' endogenous erythropoietin. Iron not used for Hb production was stored



* Erythropoietin stimulating agents

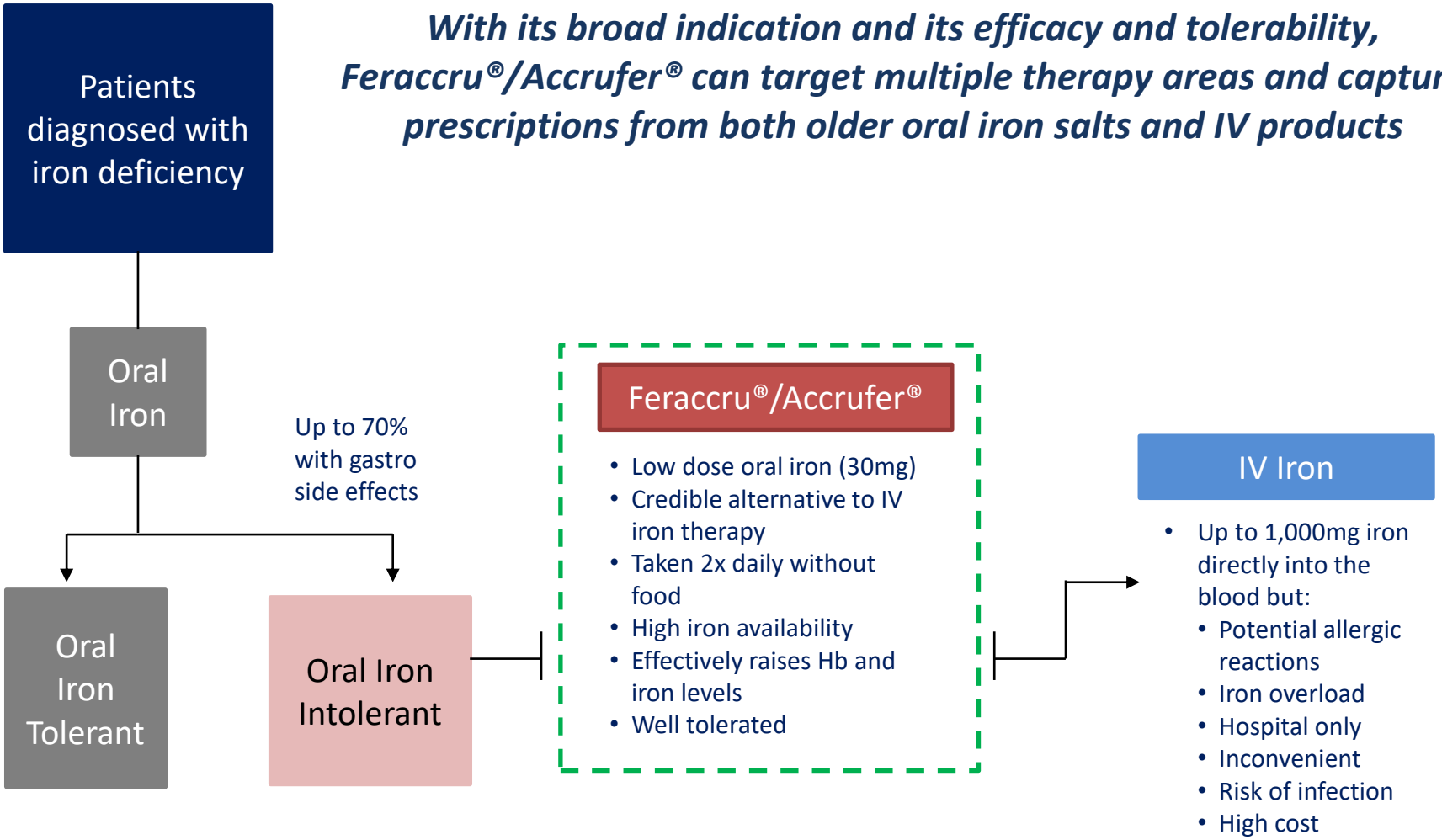
Head-to-head study – comparison with leading IV therapy



- 79% of the 122 IV patients who were actually dosed received more than one infusion before the Week 12 visit
- 68 patients received further infusions from Week 12 visit onwards – although note that by Weeks 24, 36 and 52 the number of IV patients remaining in the study had reduced to 85, 62 and 53 respectively meaning that a high proportion of these were reinfused.
- No ferric maltol patient received rescue IV iron during the 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



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US commercialisation
Summary of last 18 months

Summary of last 18 months' outlicence activities

- FDA approval – July 2019
- Intent to out-licence US commercialisation – contacted >100 companies
- Strong interest in Accrufer® from many companies
  - Particularly from smaller/mid-size companies focused on one therapy area, typically seeking to licence Accrufer® to build out their own sales and marketing presence
  - Minimal interest from "Big Pharma" companies which are focused on products to address underlying disease rather than associated iron deficiency
- Multiple term sheets discussed in depth but ultimately not pursued
  - Financial terms not sufficiently attractive – especially smaller companies unable to offer large enough upfront payment to create "skin in the game" and justify taking control of Accrufer®
  - Concerns that counter-parties would not deliver Accrufer® sales across the broad range of therapy areas where iron deficiency is common
- Two potential transactions reached very late stage (full legal documentation almost completed) but failed due to issues arising in counter-parties' businesses
  - Company A's own product was under-performing so they changed strategy in a way that undermined their economic analysis of the Accrufer® licence opportunity
  - Company B was seeking to licence Accrufer® to build its own US commercial presence ahead of bringing its own Phase III product to market. When their Phase III product failed, it proved impossible to complete the transaction.
- A number of credible potential licensees currently engaged but at early stages

Learnings and opportunities arising over last 18 months

- Detailed discussions with many potential out-licence counterparties provided us with a wide variety of information about the US market and how counterparties proposed to launch and promote Accrufer® - e.g.
  - Pricing and interactions with insurance company payers
  - Physician/prescriber and payer market research
  - Sales force sizing
  - Prescriber targeting
  - Competitive landscape

- A number of potential counterparties were proposing to use Accrufer® as their first product, to build a commercial presence ahead of either bringing their own Phase III product to market or licensing in further products

- Helped us to understand that there is no reason in principle why Shield should not also contemplate launching Accrufer®

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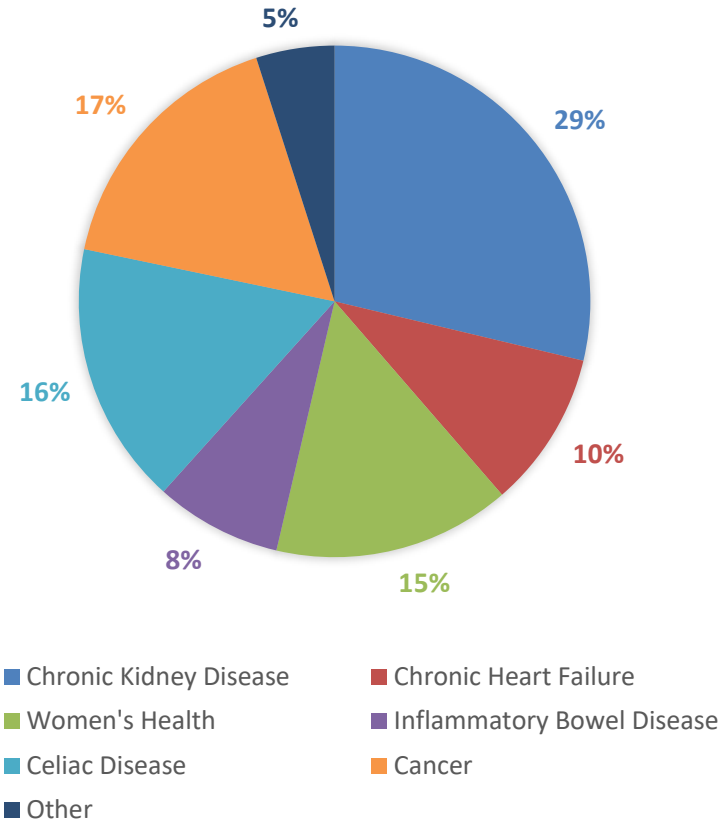
US Market Opportunity

~10M Patients suffer from iron deficiency anaemia[1] across multiple therapeutic areas in the US

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

- **Chronic Kidney Disease (CKD)**
  - 37m patients (dialysis & non-dialysis)[2]
  - ~50% of patients at risk[3]
  - ~2.5m patients have Stage 3 or 4 CKD with IDA[3]
- **Women's Health**
  - 1 in 5 women of childbearing age[4]
  - Heavy uterine or post partum bleeding
- **Gastrointestinal Disorders**
  - Inflammatory Bowel Disease (IBD)
    - Affects up to 36%-76% of patients[5]
  - Celiac Disease
    - 10%-20% of patients at risk[6]
- **Oncology**
  - Solid tumors & hematological malignancies
  - 32%-60% of cancer patients at risk[7]
- **Cardiology**
  - 17% of chronic heart failure patients maybe affected[8]



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.*

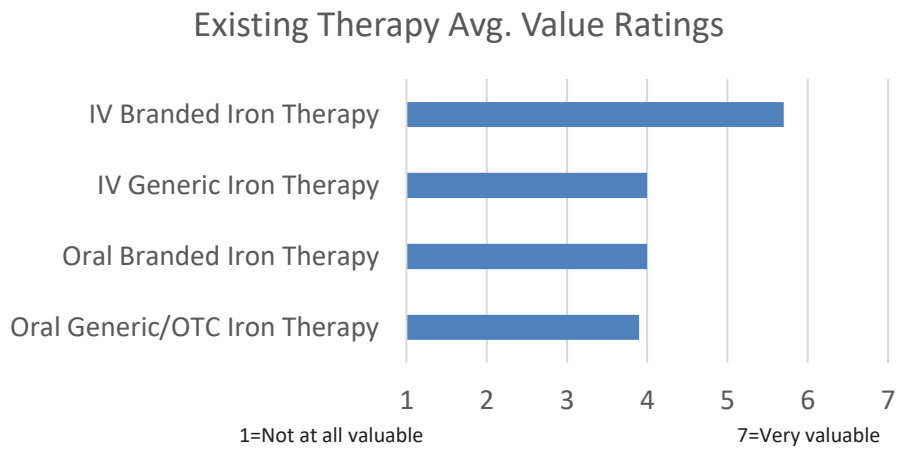
Market research confirms the unmet need

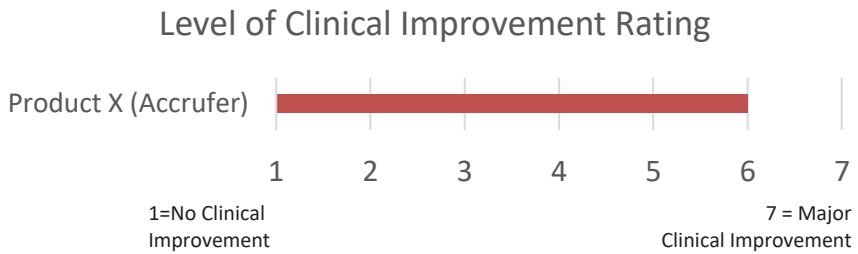
Physicians believe there is an unmet need in the market…..

- 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

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
- Although 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)

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 US IDA patients
  - ~10% of current total oral prescriptions without any expansion of the market
  - <10% of the 2.3 million IV infusions

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

- 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**

<u>Licence scenario (Year 5) – royalty flow</u>

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

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

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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
- Pricing & reimbursement negotiations in France, Italy, Spain expected in 2021

China

Licensed to ASK Pharm

- Likely to require only one Phase III study in IBD
- 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

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Cash position
&
Summary

Cash position

- Cash at 30 November - £3.8m
  - Cash runway extends into Q2 2021 (assuming minimal US expenditure)

- 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
- These positive attributes, perversely, have contributed to the reasons why it has proved difficult to secure an out-licence transaction
- Evidence gained throughout the US process, supported by consequences caused by the pandemic, has given Shield the confidence to consider launching Accrufer® in the US
- Although we continue to have out-licence discussions with 3rd parties
- To help prepare for a Shield launch scenario, we have been able to recruit 4 experienced US commercial managers who are planning the proposed launch in detail
- Clarity as to course of action likely during Q1 2021
- The shareholder loan facilities extend our cash runway (excluding substantial US spend) until end 2021

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