SHIELD THERAPEUTICS PLC

Improving Lives Together

Corporate Presentation

Growth & Innovation Forum

11 February 2020

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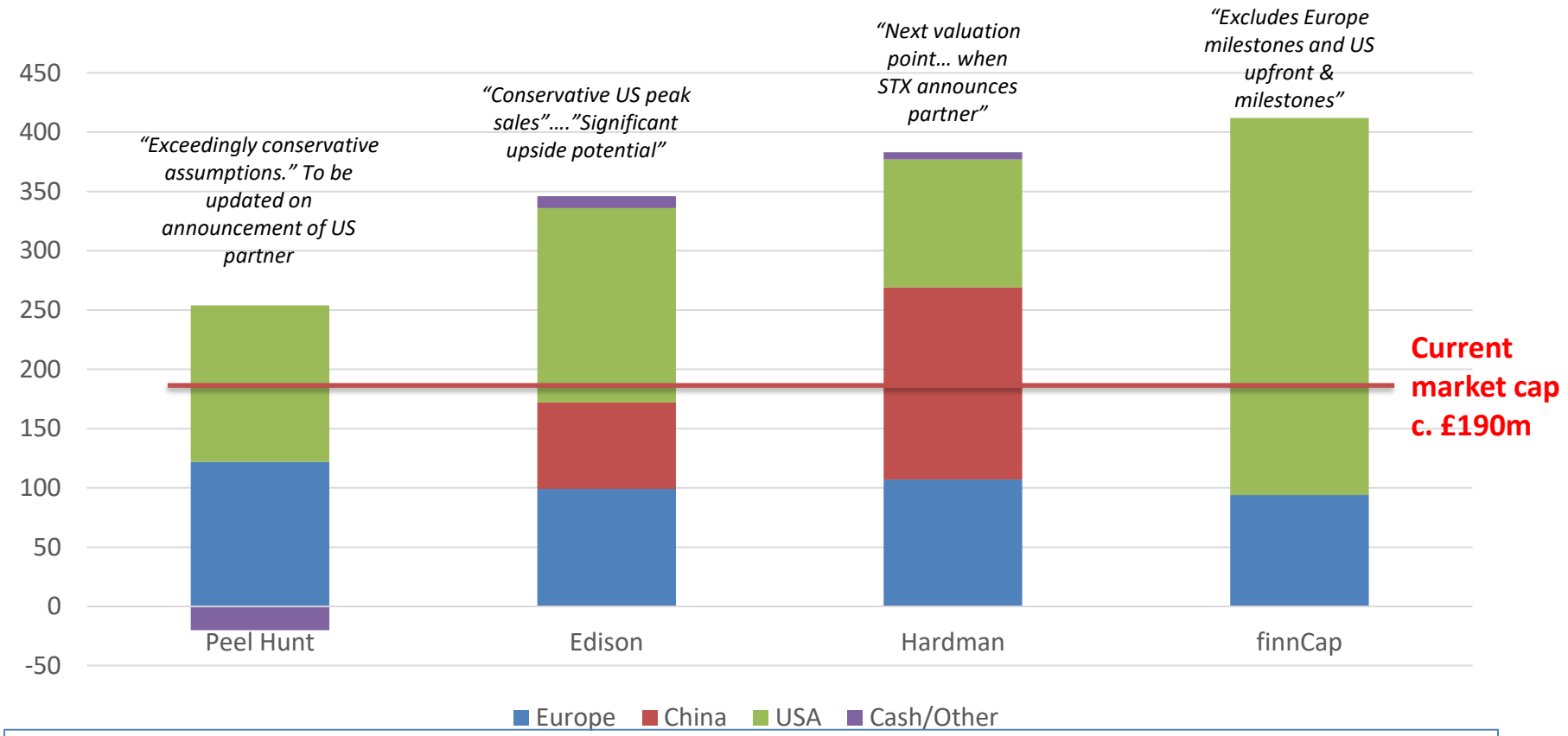
Introduction to Shield Therapeutics

- AIM-listed biopharma company (STX.L)
  - Market capitalisation ~£190m (@31Jan2020) supported by Europe and China transactions
  - Substantial upside from potential US transaction
- Primary focus is on developing and commercialising Feraccru®/Accrufer®
  - A novel oral treatment for treatment of iron deficiency in adults (with or without anaemia)
  - Approved in Europe and the USA (July 2019)
  - Three positive phase 3 clinical trials have confirmed effectiveness, tolerability and non-inferiority to intravenous (IV) iron therapy
  - Feraccru® is out-licensed
    - to Norgine in EU, Australia, New Zealand
    - to ASK Pharm in China
  - Additional late stage asset, PT20 (a phosphate binder for treatment of hyperphosphatemia), requires one phase 3 study to submit a MAA in Europe and NDA in the USA (further information in Back Up)
- Semi-virtual UK-based company – conduct of clinical trials as well as manufacturing and sales & marketing are out-sourced
  - Highly experienced management team
  - Approx. 20 staff
- Cash runway extends into 2021 following receipt of China licence fee from ASK Pharm

Analyst research – valuation £m



Notes

1) All analysts value STX >> current market capitalisation
2) All analysts see significant further upside in their valuations
3) Peel Hunt and finnCap have not yet included any value for China transaction
4) Edison/Hardman - current market capitalisation covered by Europe + China (excl USA)

US licence scenario analysis *(Peel Hunt Oct-19)*

Table 1: Scenario analysis for potential NPV of Accrufer in the US
Source: Peel Hunt

Patient penetration (%)	Absolute # of pts treated at peak (m)	In-market US sales (£m) at peak	NPV (p)
0.5%	0.13	122	82
1.0%	0.26	244	164
1.5%	0.40	366	246
2.0%	**0.53**	**488**	**330**
5.0%	1.32	1,221	821
10.0%	2.64	2,442	1,643
20.0%	5.29	4,884	3,286

Key assumptions

- Total addressable patients for IRON DEFICIENCY in the US in 2019 was c.25m
  - Going forward, assumed population growth rate of 0.7% pa
- Annual net US price of treatment conservatively assumed as $1,200
  - Model assumes 2% inflation pa going forward
- Q4-20 as time of launch and then conservatively 7 years to reach peak sales
- Royalty rate of 25% to 40% (mirrors Norgine terms in absence of any other benchmark)
- No milestones assumed and a tax rate of 25% (conservative given the patent box qualification of Feraccru)

Iron deficiency and Feraccru®/Accrufer®

Iron deficiency (ID)

- Iron is required for multiple vital functions:
  - Key component of haemoglobin, carrying oxygen from lungs to tissue
  - Transport mechanism for electrons within cells
  - Facilitating oxygen enzyme reactions
- Iron deficiency occurs when a body either:
  - Does not absorb enough iron to supply its needs or,
  - Loses iron through blood loss
- Iron deficiency can be caused by malnutrition, bleeding and a number of chronic diseases, in particular:
  - Inflammatory bowel disease (IBD)
  - Chronic kidney disease (CKD)
  - Womens' health
  - Congestive heart failure (CHF)
- Iron deficiency is the most common cause of anaemia (iron deficiency anaemia or "IDA")
- ID/IDA can be treated with oral or IV iron replacement therapy

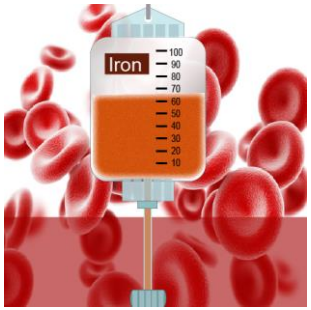
Iron replacement therapy

Typically initiated with oral, followed by IV therapy <u>if needed</u>

Patient diagnosed with iron deficiency

1st line treatment

2nd line treatment



<u>Oral</u>

- Mostly salt-based iron compounds
- Inexpensive and convenient to take but…
- Poor absorption = slower to restore iron levels and…
- Not well tolerated = poor compliance = unable to restore iron levels

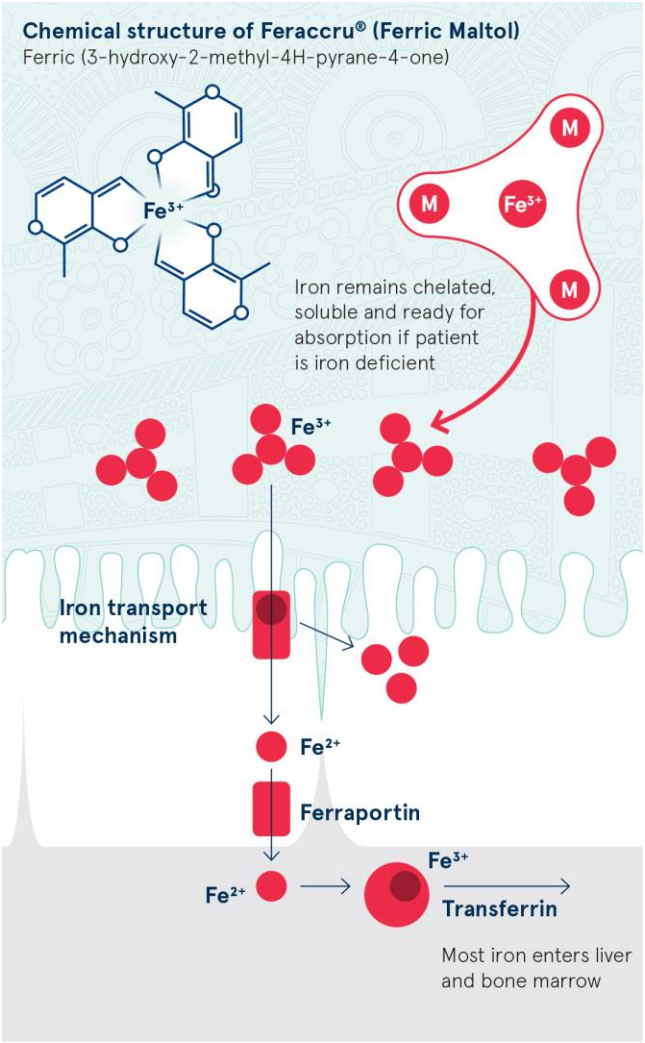
<u>Intravenous (IV)</u>

- Used mainly in patients intolerant of oral therapies
- Requires hospital administration due to safety risk
- Resource heavy, inconvenient & costly

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

Feraccru®/Accrufer® is a novel 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
  - Other oral irons are salts and require the Fe to dissociate to be absorbed
  - 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 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

Feraccru®/Accrufer® in the treatment algorithm

Patient diagnosed with iron deficiency

- ID/IDA arises in multiple primary diseases
- Failure to treat leads to lethargy as well as much more serious consequences (e.g. immune & heart complications)

Oral Iron

Up to 70% with gastro side effects

Oral Iron Intolerant

Oral Iron Tolerant

Fe^{2+} Fe^{2+} → Insoluble complexes + Radicals → Gut damage side effects

Key features of Feraccru®/Accrufer®:

- ✓ Low dose oral iron
- ✓ Non-inferior to IV iron
- ✓ Taken twice-daily without food
- ✓ High iron availability
- ✓ Effectively raises Hb and iron levels
- ✓ Well tolerated
- ✓ No patients in Feraccru long term studies required interventional IV Iron

Feraccru®/ Accrufer®

- Patent-protected until 2035
- Approved in USA and Europe for the treatment of iron deficiency in adults

Intravenous (IV) Iron

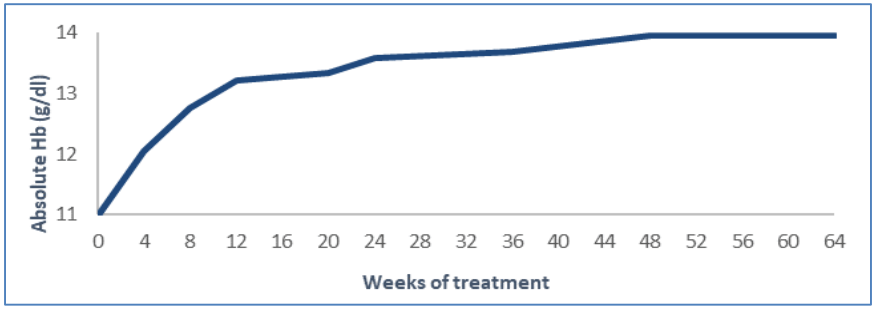
- Iron directly into the blood
- But:
  - Potential allergic reactions
  - Iron overload
  - Hospital only
  - Resuscitation team required
  - Inconvenience and high overall cost

Feraccru®/Accrufer® clinical studies

Clinical study summary – completed studies (see Back Up for further detail)

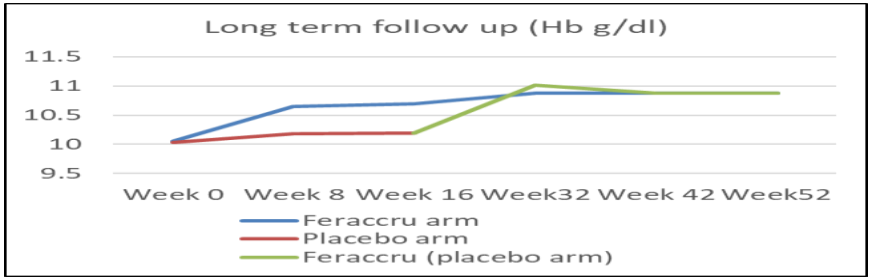
AEGIS-IBD (Inflammatory Bowel Disease)

- Feraccru provides rapid results – met primary end-point (change in Hb from baseline) at 12 weeks
- Works over long term
- Well tolerated



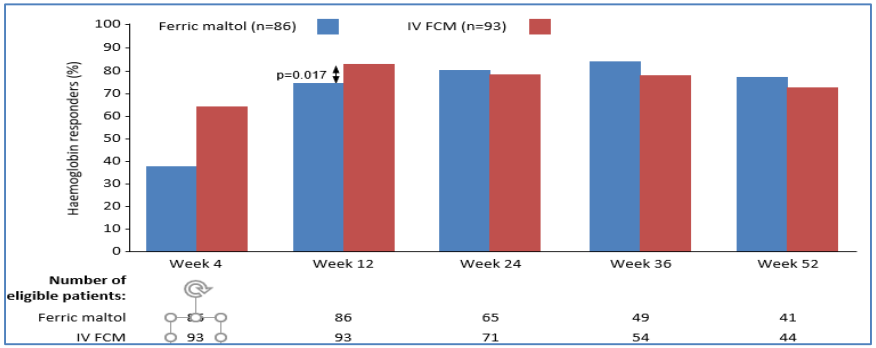
AEGIS-CKD (Chronic Kidney Disease)

- met primary endpoint (change in Hb from baseline) at 16 weeks
- Hb levels increased and maintained over 52 weeks
- Well tolerated



AEGIS-H2H (Head-to-Head)

- Feraccru® shown to be non-inferior in responder rate to Ferinject®, the market-leading IV iron therapy for IDA
- Well tolerated



Clinical study summary – planned paediatric study

- Protocol designed to meet requirements of both EMA and FDA
- Liquid formulation in final stages of development
- “Crossover” study required to confirm equivalence of liquid formulation to capsules – expected to be completed by end Q3 2020
- Patient recruitment to main study likely to start Q4 2020
- Estimated cost - ~£5-6m over next 3 years

Commercial opportunity

Iron replacement therapy can be oral or intravenous (IV)

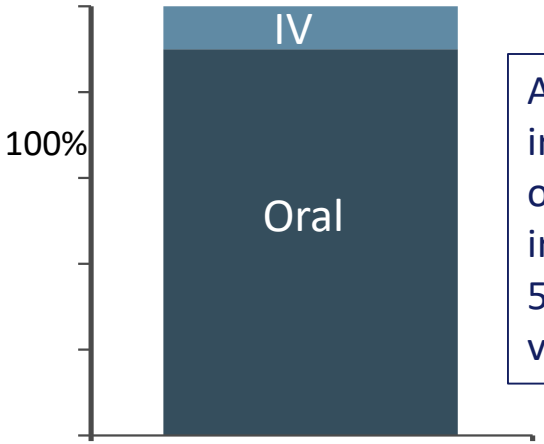
Oral

- Mostly salt-based iron compounds
- Inexpensive and convenient but…
- Poor absorption = slower to restore iron-levels and…
- Not well tolerated = poor compliance

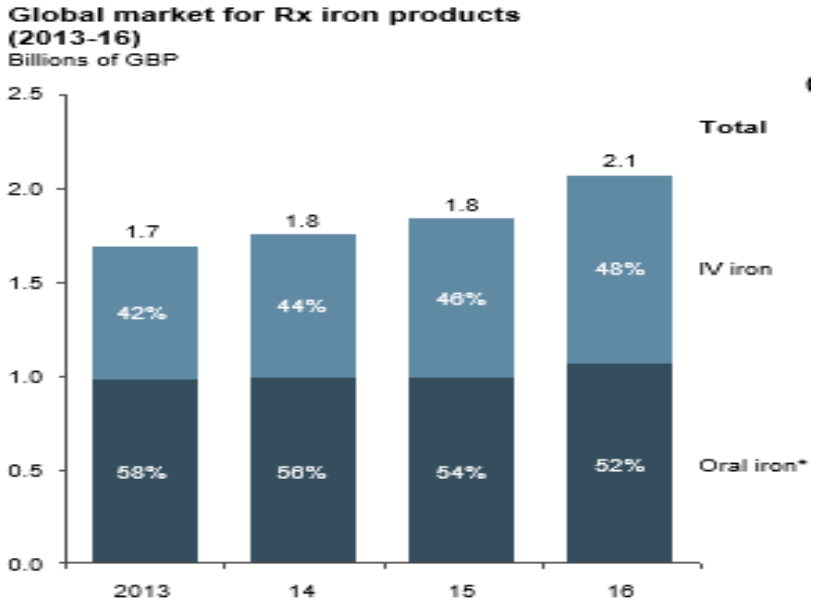
Intravenous

- Used mainly in patients intolerant of oral therapies
- Requires hospital administration due to safety risk
- Resource heavy, inconvenient & costly

***Iron market by volume & value*:**

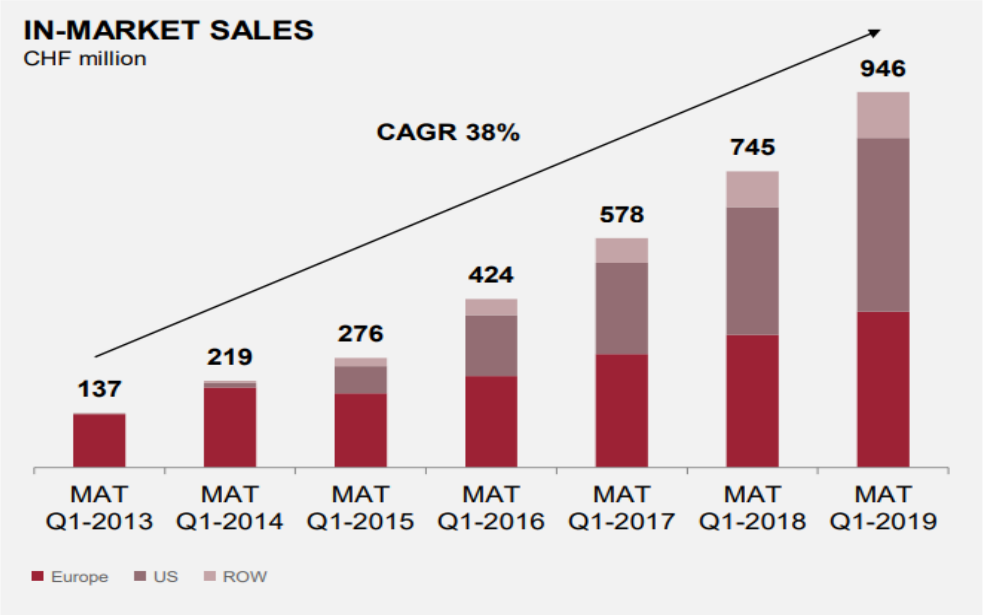


Although oral iron has majority of volume, IV iron has close to 50% of market by value



The tolerability of salt-based oral iron therapies and the cost and inconvenience of IV iron together create a major unmet need and commercial opportunity

The clear opportunity created by Ferinject®…



MAT[1] DATA FROM MARCH 2019[2]

- Global i.v. iron market size of CHF 1,917 million, +18% versus prior year period
- Ferinject® in-market sales increase of 27% to CHF 946 million
- Market share of Ferinject® in value of 49% worldwide (55% in the top 10 markets)
- In-market sales of Injectafer® in the US now higher than Ferinject® in-market sales in Europe

[1] Moving Annual Total

[2] Based on quarterly IQVIA™ MIDAS® panel, Farma&Cia, GERS, DLI at wholesale acquisition costs. Average 2018 exchange rates have been applied.

Which can now be directly targeted by Feraccru®/Accrufer®:

Results from the recently reported AEGIS-H2H phase 3b study in ~250 IDA patients showed that:

- *Feraccru®/Accrufer® was non-inferior in responder rate to Ferinject® in treating iron deficiency anaemia*
- *Feraccru®/Accrufer® again showed it was efficiently absorbed & well tolerated over 52 weeks*
- *Feraccru®/Accrufer® offers a simple, well tolerated and effective oral treatment alternative to IV iron therapy without the need for hospital-based administration*

Source: Vifor

Feraccru®/Accrufer® commercialisation

European commercialisation activity

Feraccru® licensed to Norgine in Europe (and Australia/New Zealand)

- See Back Up for more detail

Germany - Norgine launched Q1-19

- Initially targeting office-based gastroenterologists/IBD
- Reimbursed throughout Germany

UK - Norgine launched Q1-19

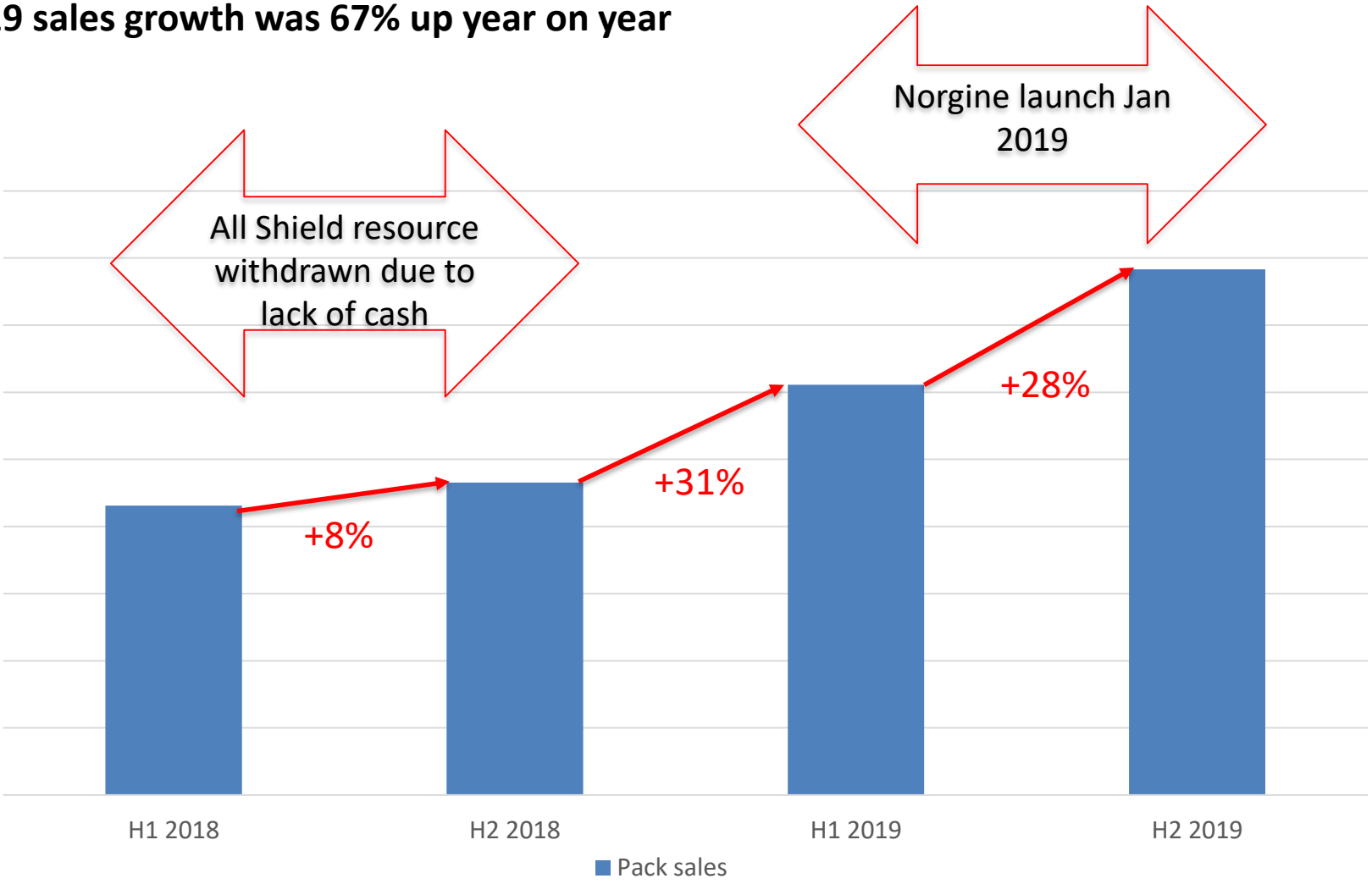
- Initially targeting gastroenterologists/IBD
- Reimbursement
  - England – Feraccru® on approximately one-third of formularies
  - Scotland, Wales, Northern Ireland – not yet on formulary
- AEGIS-H2H study results support ongoing formulary applications

Other markets

- In particular, France, Italy, Spain pricing & reimbursement (P&R) submissions begin Q1-20
- AEGIS-H2H study results support ongoing P&R applications
- Subsequent launches targeted from Q1 2021

Germany & UK pack sales (ex-wholesaler)

2019 sales growth was 67% up year on year



China commercialisation – ASK Pharm* licence headlines

- Exclusive licence to develop and commercialise Feraccru® in China (announced 8 January 2020)
  - $11.4 million upfront licence payment
  - $11.4 million development milestone on regulatory approval
  - Up to $40million in sales milestones
  - Tiered royalties of 10% or 15% as sales increase
- ASK Pharm responsible for:
  - Clinical and regulatory activities, and associated costs, in China
  - Costs of manufacturing and distribution
- *Why ASK Pharm?*
  - founded in 2003 and listed on Shenzhen stock exchange (XSEC:002755) with a market capitalisation of approximately CNY15 billion (US$2.2 billion)
  - an integrated pharmaceutical business focusing on the GI and oncology therapeutic areas
  - one of China's leading manufacturers of proton pump inhibitor and oncology medications
  - 2018 sales revenues in China equivalent to more than US$560 million
  - over 1,000 sales representatives
- Local Phase III clinical study and regulatory approval likely to take 2-3 years

* Beijing Aosaikang Pharmaceutical Co. Ltd

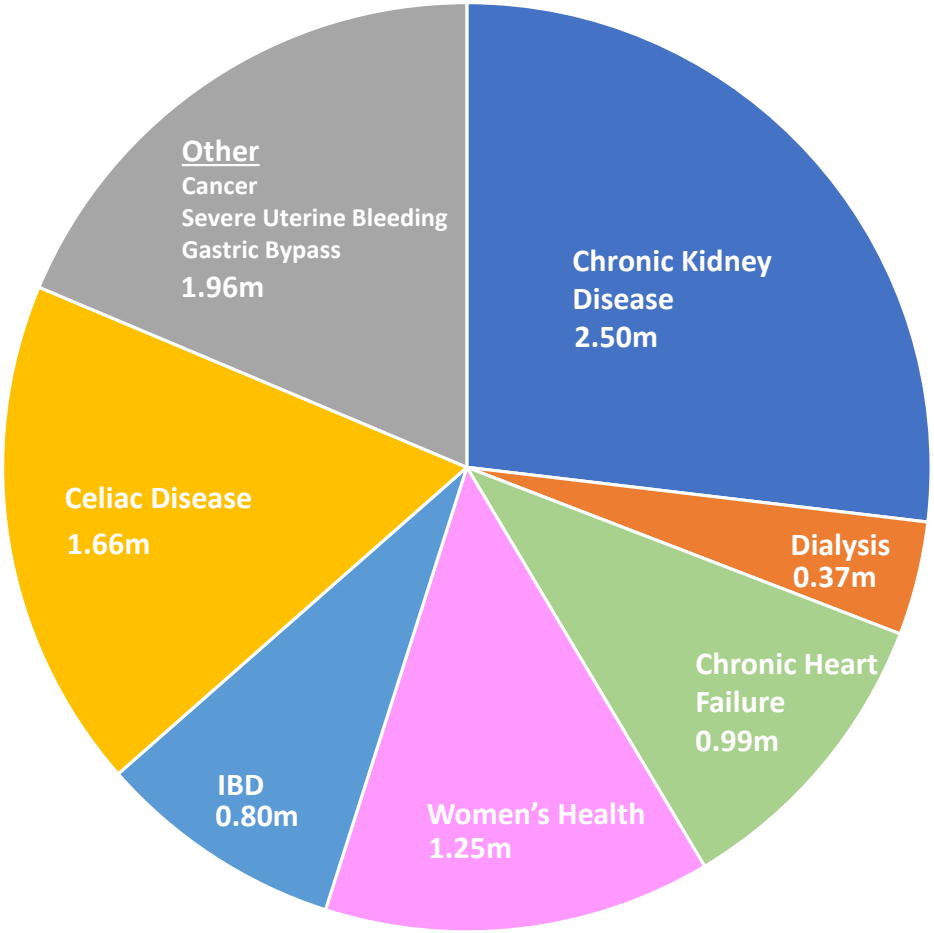
Accrufer® USA

Accrufer®

- FDA approval for broad indication - treatment of iron deficiency in adults
- Post-approval commitments
  - Paediatric study – our planned paediatric study meets the FDA requirements
  - Food effect study
  - Drug interaction study
- Major market opportunity
  - Estimated 8-9 million US patients with iron deficiency anaemia
  - Current US IV iron market worth around $1bn but only ~10% of iron therapy prescriptions
  - Potentially 2-3 times more with iron deficiency, many of whom should be treated to prevent onset of anaemia
  - Accrufer® initial positioning as a non-inferior oral alternative IV iron and, in due course, as an alternative to existing oral iron salts
  - Accrufer® annualised pricing expected to be similar to a single course of IV iron therapy, offering savings on repeat IV dosing and hospital administration costs
  - Launch likely to be focused on specialists initially, before broadening out to primary care

US Iron Deficiency Anaemia (IDA) market

Iron Deficiency Anaemia (IDA) – 9.5m patient addressable market



- Potentially a further 2-3 times this number suffering from iron deficiency without anaemia
- IDA patients could be considered as ID treatment failures in many cases

Sources: Global Data, European Medical Journal, Daiichi Sankyo annual report, LEK Consulting, CDC, EVOLUTION research and assumptions

US out-licensing process

- Working with a sector-specific US adviser
- Outreach process to potential licensees considered to have
  - strategic interest in Accrufer® and
  - capabilities required to commercialise successfully
- Discussions with multiple interested parties ongoing
- Working to close a transaction at the earliest opportunity

January 2020 trading update

2019 trading update (27 January 2020)

- 2019 revenues of £2.9 million
  - £2.2m H2H milestone
  - £0.1m Swiss label extension milestone
  - £0.6m European sales-related income
- Cash balance at 31 December 2019 - £4.1 million
- $11.4m upfront received from ASK Pharm in January 2020
- Cash runway extends into 2021

Newsflow and summary

Anticipated newsflow

Indicative timing	Event
Q2 2020	Start of paediatric crossover study
H1 2020	Potential out-licensing agreement for Accrufer® in USA
H2 2020	Further formulary approvals in UK
H2 2020	Potential identification of optimal formulation for PT20
Q4 2020	Initial pricing & reimbursement approvals in Europe
Q4 2020	Start of paediatric main study
Q1 2021	Further pricing & reimbursement approvals in Europe

Summary

- Valuation upside potential
  - Current market capitalisation supported by Europe and China transactions
  - Substantial upside from potential US transaction

- Feraccru®/ Accrufer®
  - Approved in Europe and USA with broad “iron deficiency” label
  - H2H results - a real oral alternative to IV iron
  - Out-licensed in Europe, China, Australia, New Zealand
  - Marketed in Europe (currently Germany and England)
  - Accrufer® approved in USA (July 2019)

- Broad iron deficiency label and H2H non-inferiority opens up very substantial market opportunities

- 67% Feraccru® sales volume growth (2019 cf 2018) in Germany and England

- Cash runway extends to 2021 (excluding upfront from potential US transaction)

SHIELD
THERAPEUTICS PLC
Improving Lives Together

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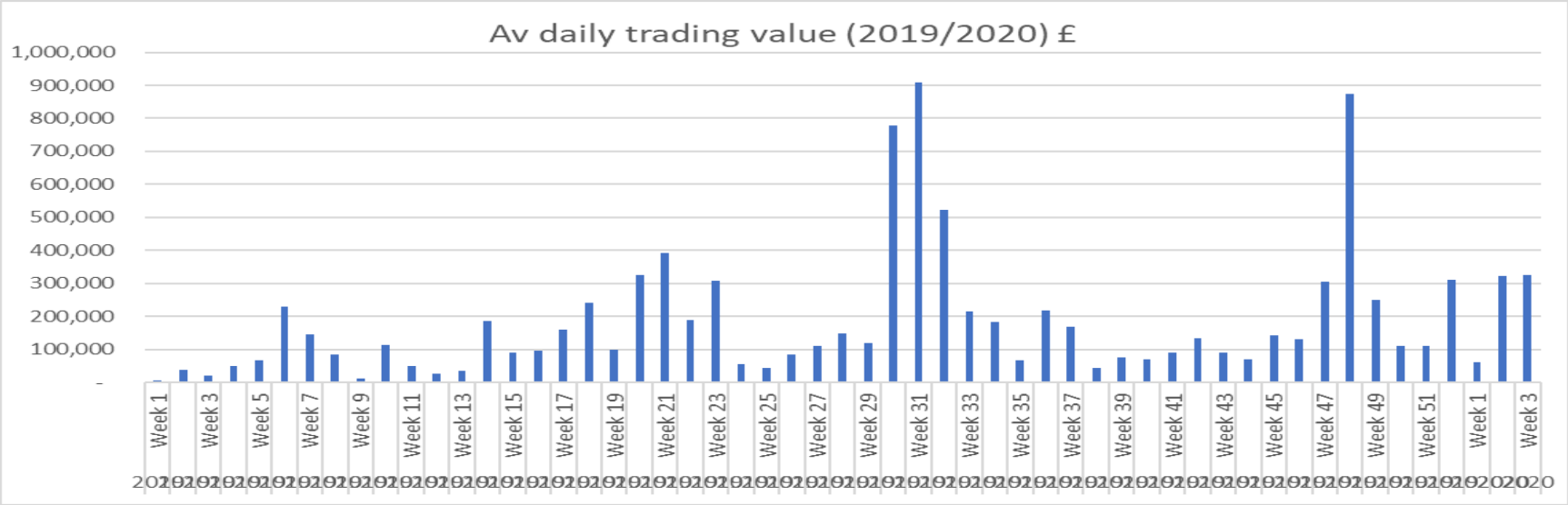
Management team

Name	Role	Biography
Carl Sterritt	CEO & Founder	Started Shield Therapeutics in 2008 and identified the Feraccru opportunity in 2010. Previously held senior management roles at United Therapeutics and Encysive Pharmaceuticals, working on innovative therapies for the treatment of pulmonary arterial hypertension; founding the Group after Encysive was acquired by Pfizer Inc
Tim Watts	Chief Financial Officer	Tim joined the company as Interim Chief Financial Officer in August 2018 and has over 25 years' experience in the pharmaceutical and biotech sectors. A chartered accountant, he was Group Financial Controller of AstraZeneca plc (2002-2006), CFO of Archimedes Pharma (2007-2011) and CFO of Oxford Biomedica plc (2012-2017)
Mark Sampson	Chief Medical Officer	Having joined in 2015, Mark has more than 25 years of pharmaceutical development and commercialisation experience at companies such as SmithKline Beecham, Amgen and Gilead. Before entering into the pharmaceutical industry Mark qualified and practised in the NHS for 5 years
Jackie Mitchell	VP, Regulatory Affairs and Quality	With over 20 years' experience in regulatory affairs Jackie has led the group's regulatory activities since 2012. She has led several major regulatory projects, including successful MAA and NDA submissions, including MAAs for the Feraccru, Kaletra and Humira.
David Childs	Director, Product Supply & Commercial Alliances	David joined in 2011 as Director of Manufacturing. During his tenure at GSK, David gained over 18 years' of experience in chemical and pharmaceutical development and worked closely with several outsourcing partners.
Lucy Bailey	General Counsel & Company Secretary	Lucy has worked with Shield since 2015 and was a key member of the team working on the admission of Shield Therapeutics to the AIM market in 2016. She is admitted as a Solicitor of the Senior Courts of England and Wales and has worked previously at both a boutique and an international US law firm based in Singapore

Share register and average daily trading

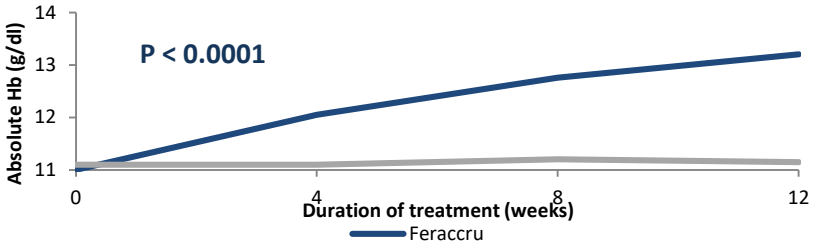
W Health/Inventages	48%
MaRu AG	11%
Carl Sterritt	9%
Richard Griffiths	5%
Christian Schweiger	4%
Universities Superannuation Scheme	4%
Others less than 3%	19%



Feraccru®/Accrufer® clinical studies

Feraccru's efficacy and safety are key differentiators: AEGIS-IBD

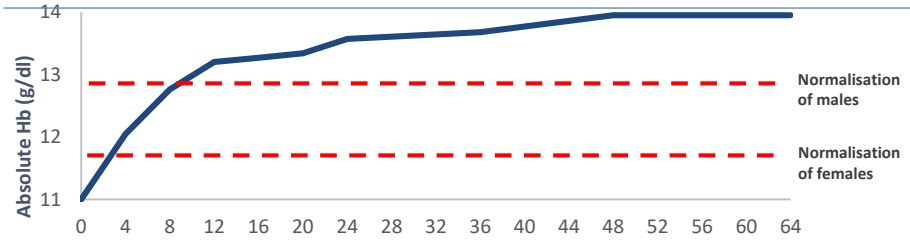
Feraccru provides rapid and effective results...



Source: Marketing Authorisation Application (MAA)

- Study of 128 IBD patients with IDA
- Patients were intolerant of or unwilling to take oral iron salts
- A clinically relevant haemoglobin (Hb) increase is considered to be 1g/dL
- Feraccru® delivered highly relevant and rapid 2.3g/dL rise inside 12 weeks with 1g/dL in only 4 weeks

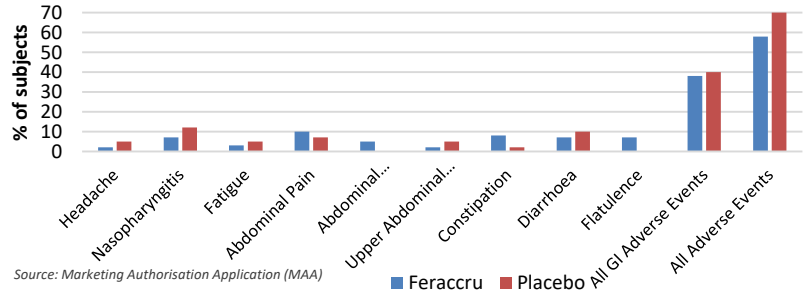
...works over the long term



Source: Marketing Authorisation Application (MAA)

- Normalised mean Hb by week 12
- Long term compliance levels of 97%
- With chronic therapy patients' anaemia did not recur and iron indices continued to improve
- Ongoing Feraccru® therapy may prevent need for IV iron

...and is well-tolerated

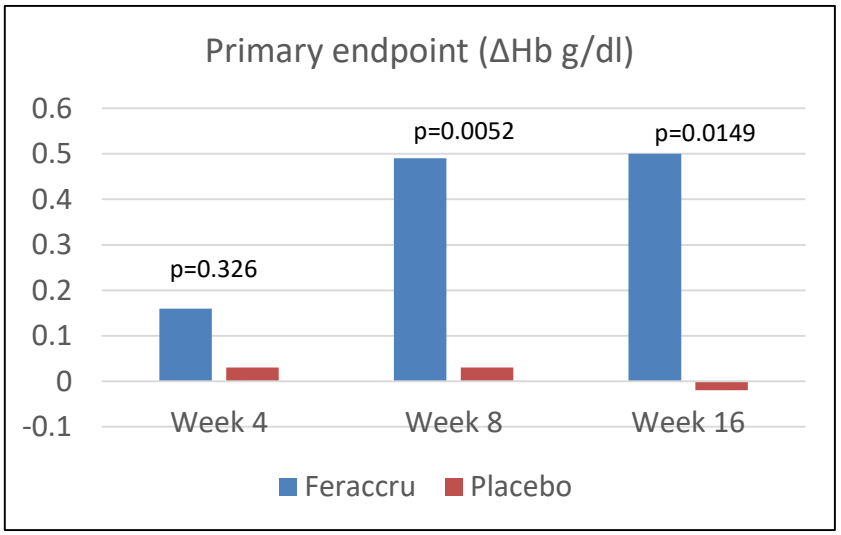


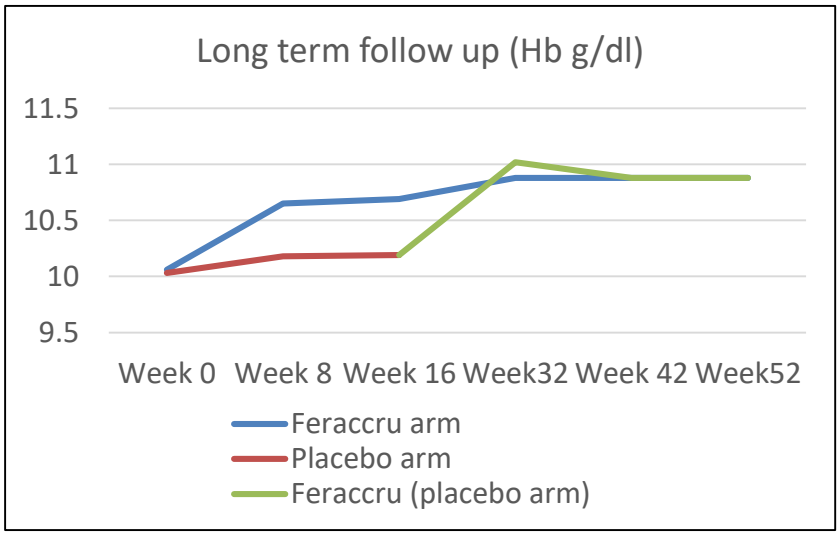
Source: Marketing Authorisation Application (MAA)

- Majority of adverse events were related to IBD status
- Low incidence of other adverse events
- Neither short or long-term Feraccru® therapy led to iron overload

AEGIS-CKD Study Analysis (1) (2)

- Study met primary endpoint of change in Hb from baseline at 16 wks (p = 0.0149)
- Statistically significant change in Hb is observed across all analyses (ITT, mITT and PP) and in all sensitivity analyses at both wk 8 and 16
- Change in ferritin, TSAT and serum iron from baseline statistically significant at weeks 4, 8 and 16 demonstrating early effect
- Hb levels increased and maintained over 52 weeks



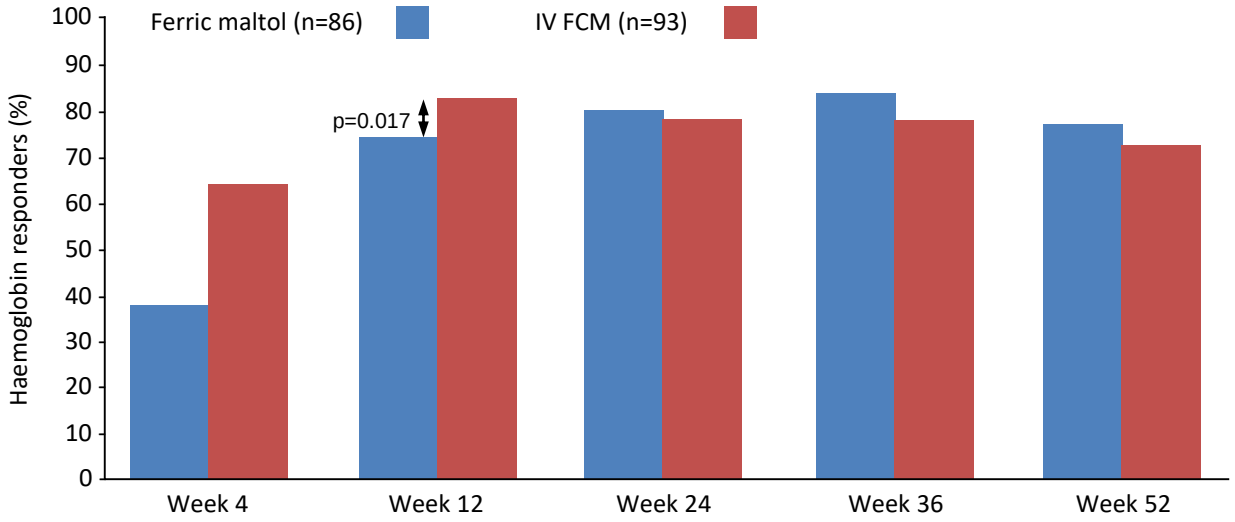


ITT: intention-to-treat; MI: multiple imputations

(1) SAP v1.1 (2) 169 patients

AEGIS-H2H study

- Feraccru® shown to be non-inferior[1] in responder rate to Ferinject®, the market-leading IV iron therapy for IDA
  - **Results showed that the response rate[2] to treatment with Feraccru® at 12 weeks was non-inferior to the response rate seen with Ferinject®**
- Both 12-week and 52-week data is being used to support pricing and reimbursement negotiations in Europe and beyond



Number of eligible patients:					
Ferric maltol	86	86	65	49	41
IV FCM	93	93	71	54	44

- 49 subjects treated with IV FCM required 69 additional IV infusions during the study
- One subject in the ferric maltol arm required IV iron as they had a flare in IBD at week 48

[1] Stefanie Howaldt, UEGW 2019
[2] Response defined as Hb normalisation or a rise of 2g/dl rise from base line

Feraccru®/Accrufer® commercialisation

Europe commercialisation - Norgine licence headlines

- Exclusive licence to commercialise Feraccru® in the EU, Australia and New Zealand (announced September 2018)
  - £11 million upfront licence payment
  - Up to €54.5million in development and sales milestones with €2.5million development milestone already triggered by AEGIS-H2H results
  - Royalties ranging from 25% to 40% as sales increase

- *Why Norgine?* A well-resourced, European-focused specialty pharma business with a proven commercial record for whom Feraccru® is a key growth product

- Shield retained responsibility for:
  - Manufacture and supply of Feraccru®
  - All aspects of current and future development
  - All aspects of intellectual property

- Shield also retained full commercial rights to Feraccru® in all unlicensed countries including the USA

PT20

PT20 – a treatment for hyperphosphatemia

- Elevated phosphate levels in the blood is a ubiquitous complication of moderately and severely reduced kidney function
- Standard of care for phosphate control remains the prescription of phosphate binders. Older phosphate binders suffer from side effects, poor tolerance and lack of effectiveness.
- Latest generation are iron-based (Velphoro and Auryxia) and are both approaching $100m pa sales in USA
- The overall market size in USA is ~$1bn pa
- PT20 is a novel formulation iron-based phosphate binder which enhances phosphate binding and reduces side effects compared with Velphoro and Auryxia
- PT20 has completed one Phase II pivotal study and now requires one further Phase III pivotal study to allow a NDA to be filed
- Work has started to develop a commercially-suitable formulation of PT20 which will be used in the Phase III study
- Phase III study estimated to cost ~£20m over 2-3 years