



SHIELD
THERAPEUTICS

Improving Lives Together

Investor Presentation

Mello London

27 November 2018

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Introduction to Shield Therapeutics

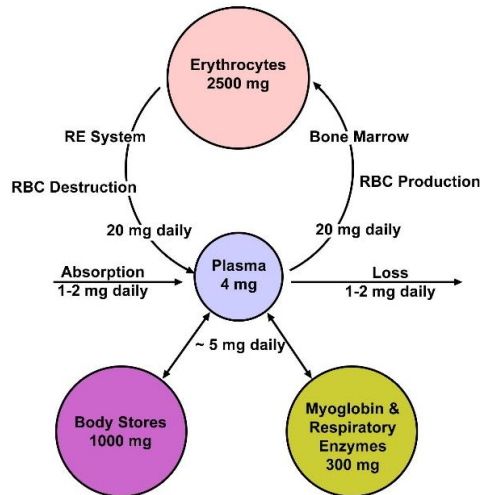
- AIM-listed biotech company (L.STX)
 - Market capitalisation £39m
- Focused on developing and commercialising Feraccru[®]
 - a novel treatment for iron deficiency
 - Out-licensed to Norgine in Europe, Australia, New Zealand
 - US NDA submitted September 2018
- Semi-virtual company – clinical trials, manufacture and commercialisation are out-sourced
 - Experienced management team
 - 15 employees
 - Small offices in London and Newcastle
- Recent £11m up-front receipt means company is funded for at least 12 months



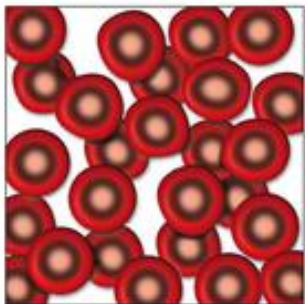
Iron deficiency and Feraccru[®]

Iron deficiency is caused by depletion of iron stores in the liver resulting in insufficient iron to fuel RBC production

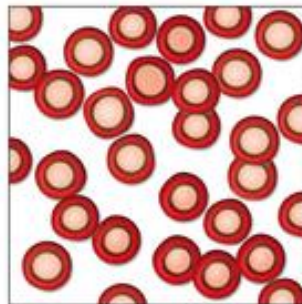
Iron recycling in the body



Iron deficiency



Normal erythrocytes

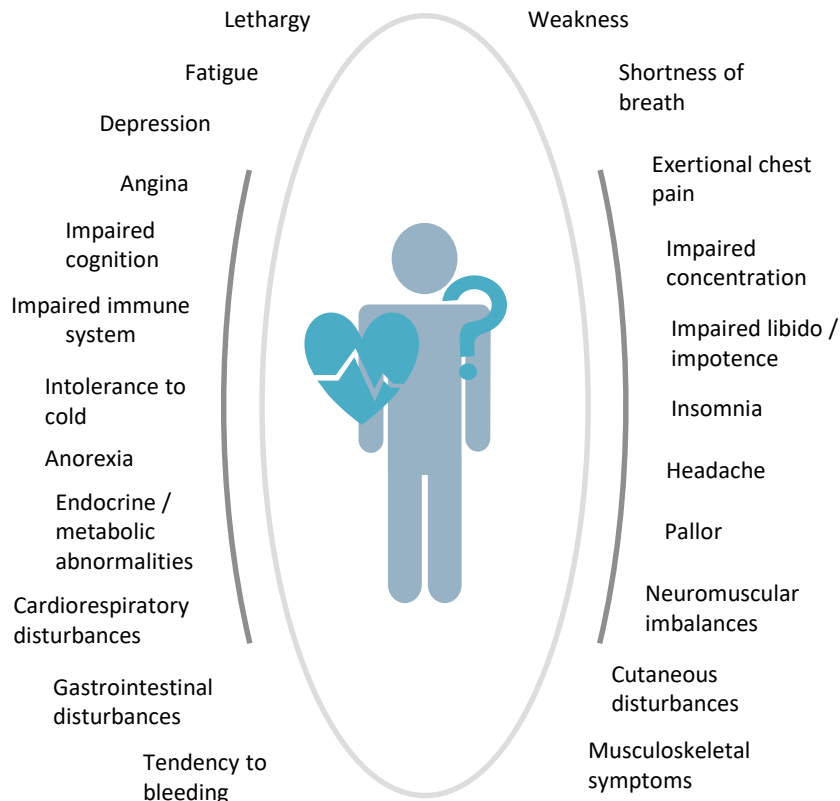


Hypochromic erythrocytes containing less haemoglobin

- The body requires iron for the production of haem groups, used in oxygen carrying proteins such as haemoglobin (Hb) and myoglobin, as well as other enzymes involved in metabolism
- Iron is typically absorbed from food, either as haem-iron from meat (more easily absorbed) or non-haem iron from plant material (less easily absorbed)
- After absorption in the GI tract, iron is released to the blood stream where it binds an iron transporter (transferrin), which delivers the iron to the body's stores in the liver and bone marrow
 - iron is released as required to fuel production of red blood cells (RBCs) in the bone marrow
 - iron is also recycled from dead RBCs by the spleen
- Iron deficiency occurs where iron requirements exceed iron intake leading to depletion of iron stores, which can ultimately impact the body's ability to synthesise RBCs
- Can be caused by bleeding, malnutrition and a number of disease areas including **Irritable Bowel Disease (IBD)** and **Chronic Kidney Disease (CKD)**

Iron Deficiency Anaemia (IDA) - broad range of symptoms, but many of these also occur in other conditions leading to potential misdiagnosis or underdiagnosis

Symptoms of anaemia



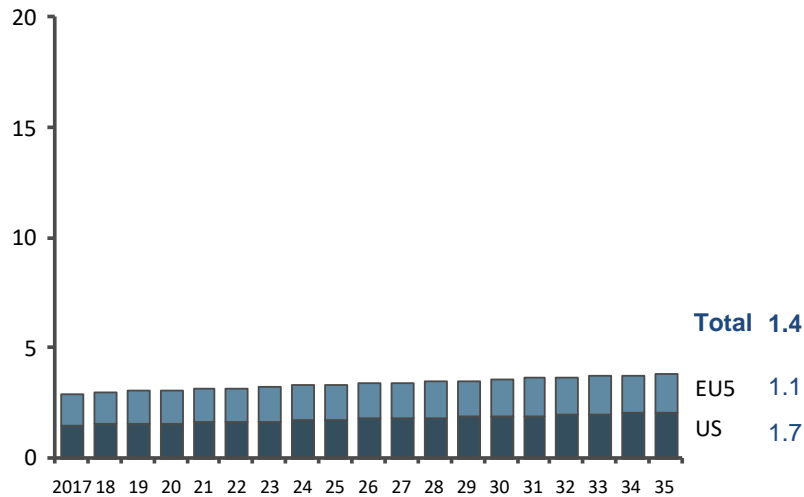
- Early symptoms of anaemia are vague and may go unnoticed
 - patients that develop symptoms slowly may not recognise them or may attribute them to other causes
 - often patients only appreciate the impact of their symptoms once the anaemia has been treated and resolved and function returns to normal
- As the symptoms of anaemia are not specific to its underlying cause they do not help differentiate between types of anaemia, which include:
 - anaemia of chronic disease
 - iron deficiency anaemia
 - vitamin deficiencies

c.15 million patients are estimated to have diagnosed IBD or CKD in 2017. This is expected to grow to c.19 million by 2035

IBD diagnosed prevalence in US, EU5 (2017-35F)

Millions of patients

CAGR %
(2017-35F)



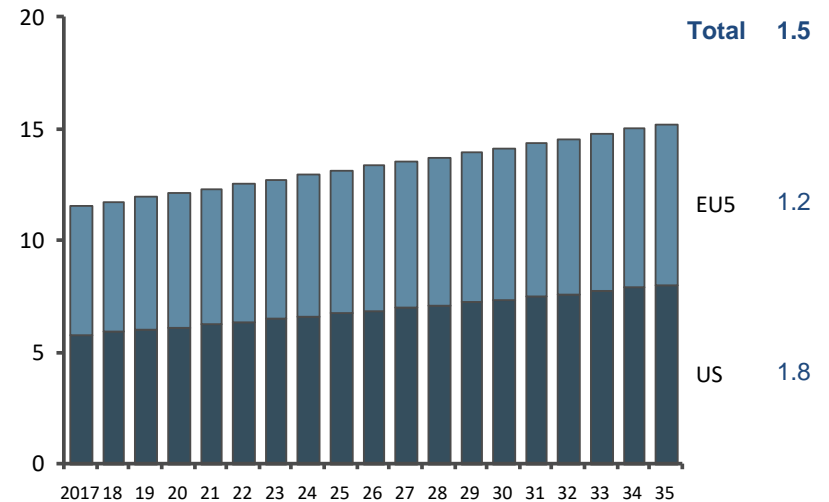
Key assumptions

- IBD diagnosed prevalence was identified from systematic reviews and country specific surveys with country specific assumptions being used where available – see appendix for further detail
- Growth in IBD prevalence driven by population growth and in underlying proportion of people developing IBD
 - IBD rate estimated to be growing at c.1% p.a. in developed nations driven by improved awareness amongst other factors
 - population growth estimated at c.0.7% and c.0.1% p.a. in the US and EU5

CKD diagnosed prevalence in US, EU5 (2017-35F)

Millions of patients

CAGR %
(2017-35F)



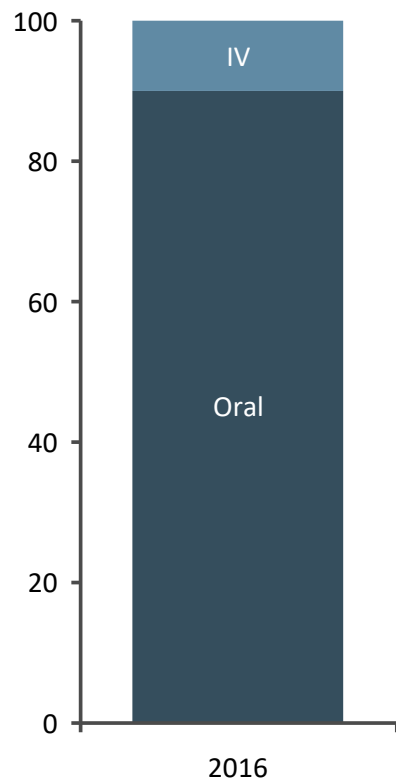
Key assumptions

- CKD prevalence identified from NHANES studies to be c.15% in 2016
- Growth in CKD prevalence is driven by population growth in population over 50 years old as kidney function declines with age
 - CKD rate estimated to be growing at c.1.1% p.a. in developed nations based on subsequent NHANES studies
- The diagnosis rate of CKD is not expected by physicians to change over the forecast period and has been stable since 2000

Iron deficiency (ID) is treated with iron replacement therapy which can be delivered orally or intravenously

INDICATIVE

Iron market by volume
Percent



IV iron

Key characteristics

- Rapid increase in iron
- Risk of iron overload / anaphylaxis
- Inconvenient route of administration – infusion at hospital / clinic
- Expensive
- Use more restricted to severe / urgent / refractory patients

Examples

- Venofer (Vifor)
- Injectafer / Ferinject (Vifor)
- Feraheme (AMAG)
- Ferrlecit / Ferrlexit (Sanofi)
- Monofer (Pharmacosmos)

Oral iron / Oral Ferrous Products (OFPs)

Key characteristics

- Chronic treatment
- Poor tolerability
- Slower restoration of iron levels
- Convenient / self-dosed
- Cheap / genericised
- Typically 1st line usage

Examples

- Ferrous sulphate
- Ferrous gluconate
- Ferrous fumarate

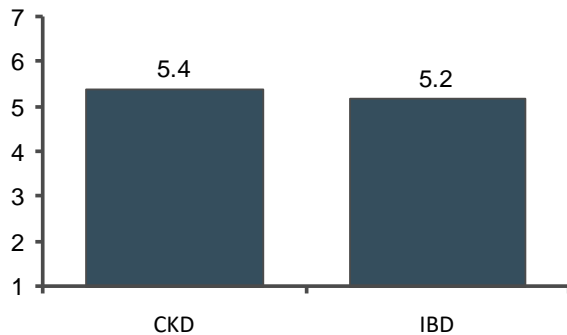
- Physicians try to treat the underlying condition causing ID, but will often need to also treat the ID
- Iron replacement therapy is used to deliver additional iron to deficient patients to refuel their bodily stores
- Iron products can either be delivered orally (e.g., tablets / capsules) or intravenously (IV)
 - route of administration is the major differentiator between different iron products

The tolerability of oral therapies is a major unmet need

Degree of unmet need in oral iron therapy

(Physician interviews, N=9 (CKD), N=10 (IBD))

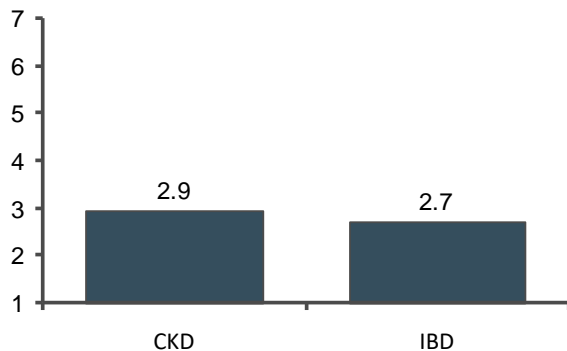
Score 1-7*



Degree of unmet need in IV iron therapy

(Physician interviews, N=9 (CKD), N=10 (IBD))

Score 1-7*



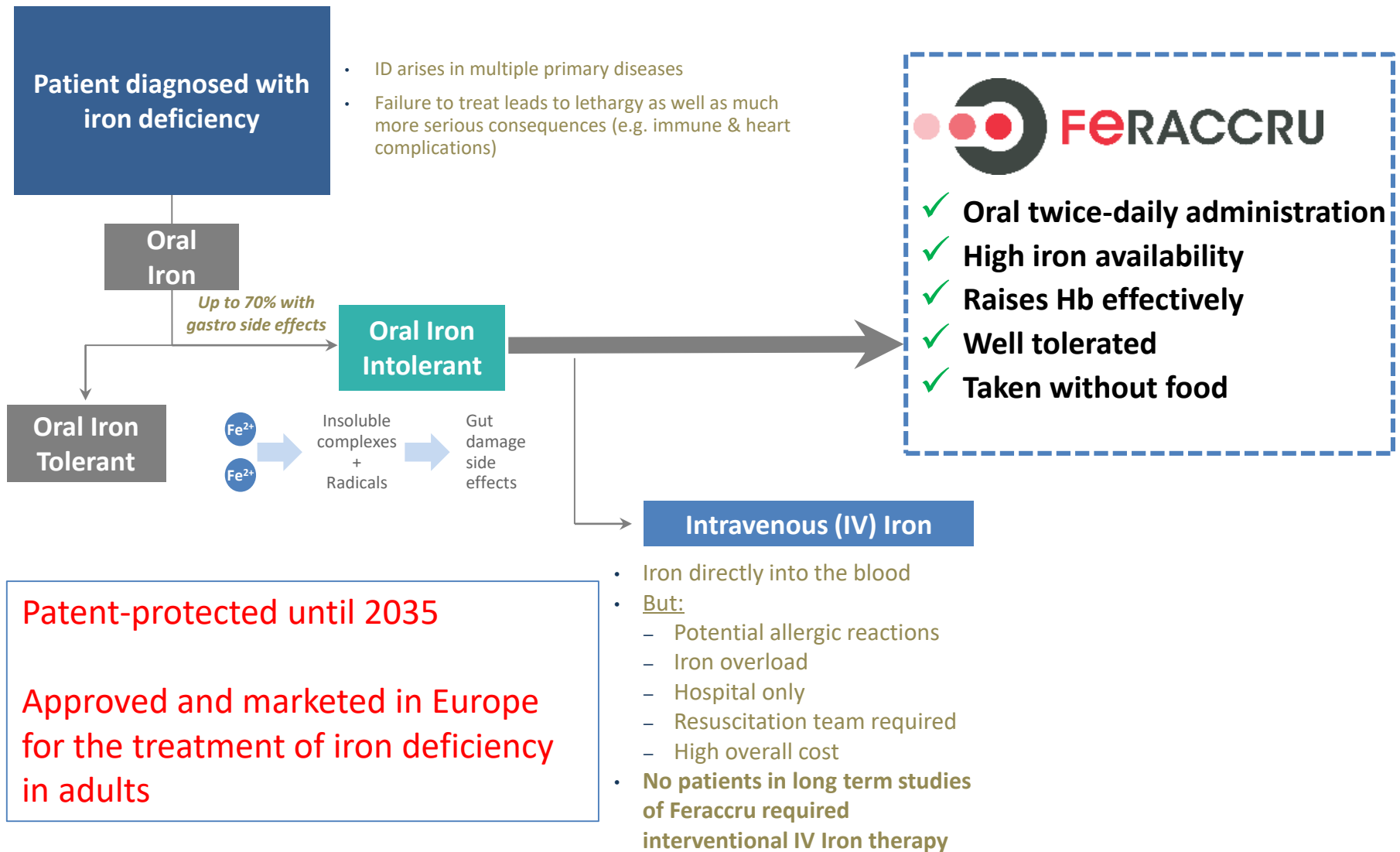
Oral iron therapy

- Oral iron is considered to be relatively efficacious, however physicians perceive the slow improvement in iron levels to lead to slow improvements in haemoglobin levels
- The key unmet need in oral therapy is tolerability, with 60-70% of patients unable to tolerate a course of treatment at full dosage
- Nephrologists indicated that oral iron is preferred because hospital visits are not required (they can be costly and time consuming for patients)
- Gastroenterologists highlighted absorption of iron as being more of an issue in IBD than CKD due to the higher level of GI inflammation

IV iron therapy

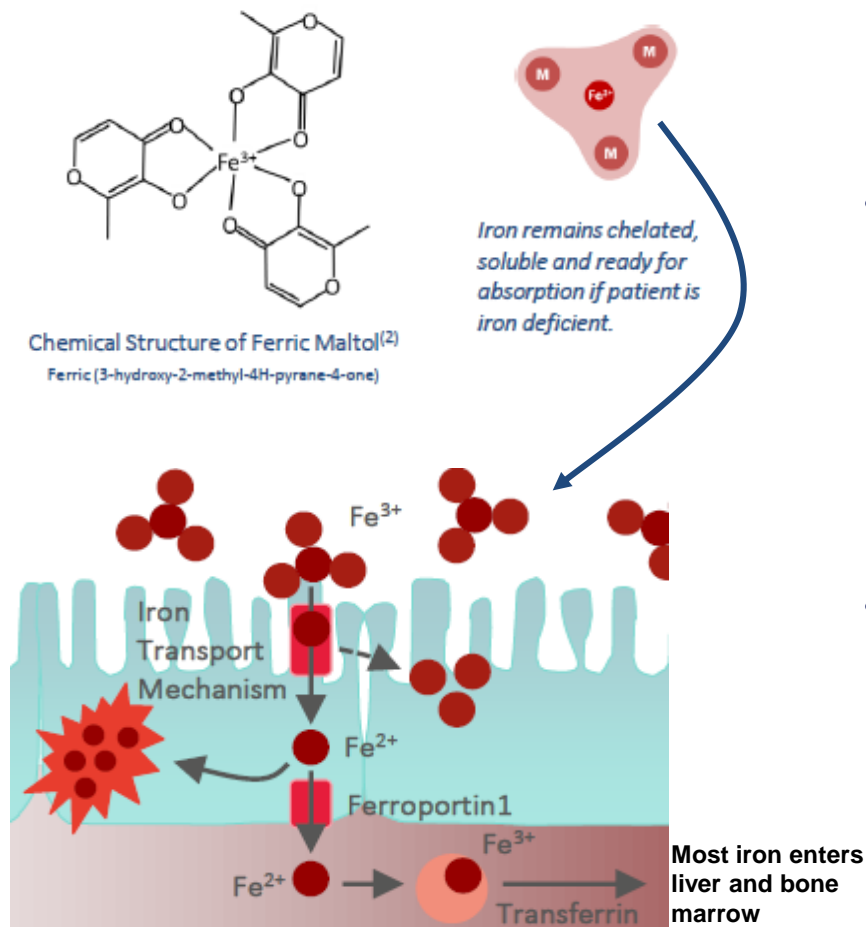
- Efficacy of IV iron treatments is typically good and it is considered to be faster acting than oral irons
- While there have been concerns around the safety of IV irons in the past, physicians believe that newer formulations have addressed this problem
- Physicians view the route of administration of IV iron as its most significant issue, raising concerns over vascular preservation, and the costly and time consuming nature of hospital visits

Feraccru overview: A novel oral ferric iron therapy



Feraccru delivers iron to the blood stream with minimal formation of insoluble complexes in the gut

Feraccru mechanism of action



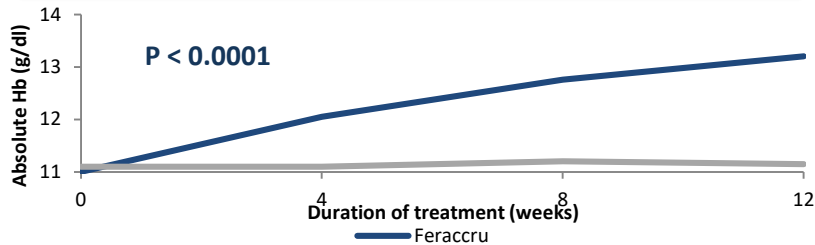
- Feraccru is an oral formulation of a complex of Fe³⁺ (ferric maltol), which is stable in the gastrointestinal tract
 - existing oral ferrous products (OFPs) deliver iron as Fe²⁺, which can form insoluble products in the GI tract, causing intolerance in patients
- The Fe³⁺ in Feraccru remains in complex with maltol until absorbed by the enterocyte, which then delivers the iron as Fe²⁺ to the bloodstream where it binds transferrin
 - maltol is absorbed separately and is glucuronidated and excreted in urine
 - unabsorbed Feraccru passes through the digestive system in 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 OFPs



Feraccru[®] clinical studies

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

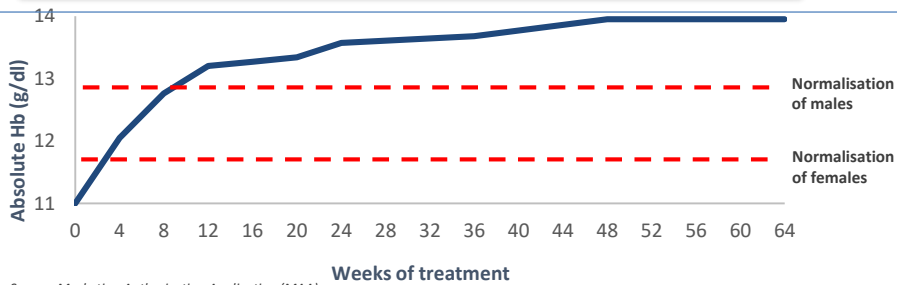
Feraccru provides rapid and effective results...



Source: Marketing Authorisation Application (MAA)

- 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

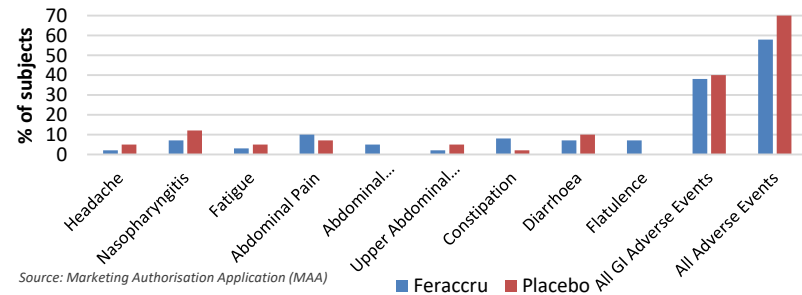
...works over the long term



Source: Marketing Authorisation Application (MAA)

- By week 12 mean Hb of the treated group had normalised
- 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

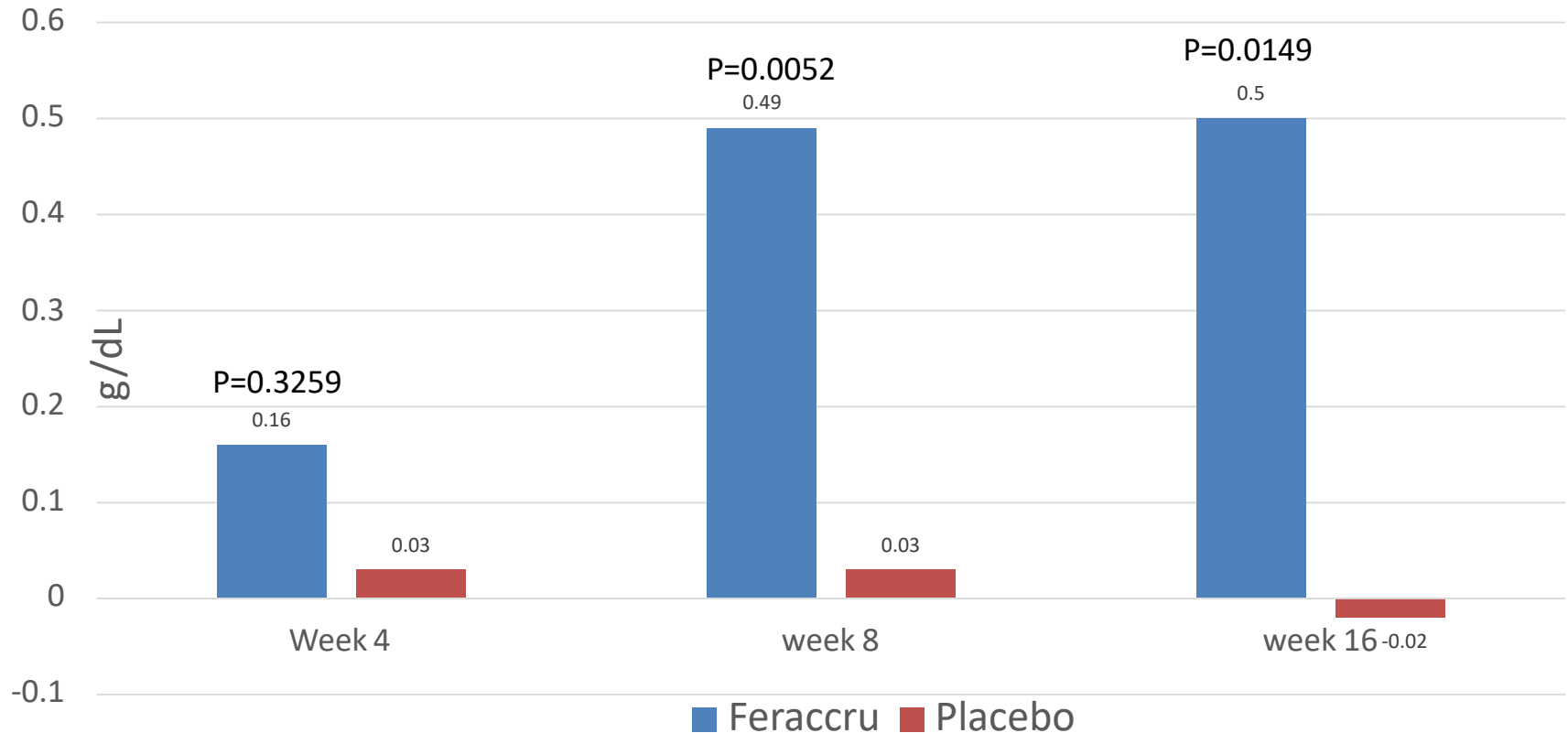


Source: Marketing Authorisation Application (MAA)

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

AEGIS-CKD Study Analysis (1) (2)

- Study met primary endpoint (change in Hb from baseline at 16 wks)
- Statistically significant change in Hb is observed across all analyses (ITT, mITT and PP) and in all sensitivity analysis 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



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

Other Feraccru[®] studies

AEGIS-PAED PK Phase I Pharmacokinetics study

- Top-line data reported June 2018
- 36 subjects aged 12-17 years
- Feraccru[®] achieved all pre-defined goals including positive effects on serum parameters and good tolerance at all dosing levels

AEGIS-H2H (Head-to-Head) study (242 patients)

- Phase IIIb non-inferiority study
- Comparing efficacy and safety of Feraccru[®] to IV iron
- Data will support pricing and reimbursement negotiations
- Recruitment completed September 2018
- Preliminary results anticipated Q1 2019

Planned Phase III paediatric study

- Expected to start recruitment H2 2019



Europe commercialisation Norgine licence headlines

Norgine licence headlines

- Exclusive licence to commercialise Feraccru[®] in Europe*, Australia and New Zealand
- £11 million upfront licence payment
- Up to €54.5million in development and sales milestones
- Royalties ranging from 25% to 40% as sales increase
- Norgine is a well-resourced, European-focused specialty pharma business with a proven commercial track record for whom Feraccru will be a central product in its future growth
- Shield globally responsible for
 - Manufacture and supply of Feraccru[®]
 - All aspects of current and future development
 - All aspects of intellectual property
- Shield also retains full commercial rights to Feraccru[®] in all unlicensed countries including the USA



USA

USA

- NDA submitted September 2018, filed November 2018
- Potential US approval H2 2019
- Board currently assessing commercial options
 - Out-license
 - JV
 - Self-commercialise



Financial headlines & Management Team

Financial position

- Cash balance at 30 June 2018 - £3.5m
- £11m upfront received September 2018 from Norgine transaction
- Cash runway – “funded for at least 12 months” (September RNS announcing Norgine transaction)

Management team

Name	Role	Biography
Carl Sterritt	CEO/co-founder	Co-founded the Group in 2008. Previously Carl held senior management roles at United Therapeutics and Encysive Pharmaceuticals, working on innovative therapies for the treatment of pulmonary arterial hypertension. Carl founded the Group after Encysive was acquired by Pfizer Inc.
Mark Sampson	Chief Medical Officer	Appointed as VP, Medical Affairs at Shield in 2015, transitioned into the role of CMO in 2017. Mark has more than 25 years of medical practice, pharmaceutical development and commercialisation experience at companies such as SmithKline Beecham, Amgen and Gilead.
Jackie Mitchell	VP, Regulatory Affairs and Quality	Jackie has run the group's regulatory activities since 2012 and has over 20 years' experience in regulatory affairs working for several pharmaceutical companies, including Boehringer Ingelheim, Abbott and Archimedes. She has led several major regulatory projects, including successful MAA and NDA submissions, including MAAs for the NCEs Kaletra and Humira.
David Childs	Director of 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 been with the Group since August 2015 and was a key member of the team working on the admission of Shield Therapeutics to the AIM market in 2016. Lucy is admitted as a Solicitor of the Senior Courts of England and Wales and has worked previously at a boutique corporate law firm and an international US law firm in Singapore.
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 from 2002-2006. From 2007-2011 Tim was CFO of Archimedes Pharma and then CFO of Oxford Biomedica plc from 2012-2017.



Newsflow and investment highlights

Anticipated newsflow

Indicative timing	Event
Nov/ Dec 2018	FDA acceptance of NDA submission
Q1 2019	AEGIS –H2H study results
Q3 2019	Potential PDUFA date for US approval
H2 2019	Start of Paediatric Phase III study
Ongoing/ad hoc	Further out-licensing agreements in other territories

Key messages and investment highlights

- Iron deficiency is a major market with significant unmet needs
- Ferracru
 - novel oral ferric iron with broad approval in Europe
 - Norgine commercialisation agreement for Europe
 - US NDA submission completed for Ferracru with potential approval in the world's largest and most attractive pharma market during H2-19
 - Further licensing opportunities being actively pursued for Ferracru in geographies inc. USA, China etc...
- Cash runway extending at least 12 months
- Valuation upside
 - Current market capitalisation - £39m (34p)
 - Consensus analyst valuation* - £80m - £90m (70p-80p)
 - USA approval



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