



SHIELD
THERAPEUTICS

Improving Lives Together

Investor Presentation

January 2019

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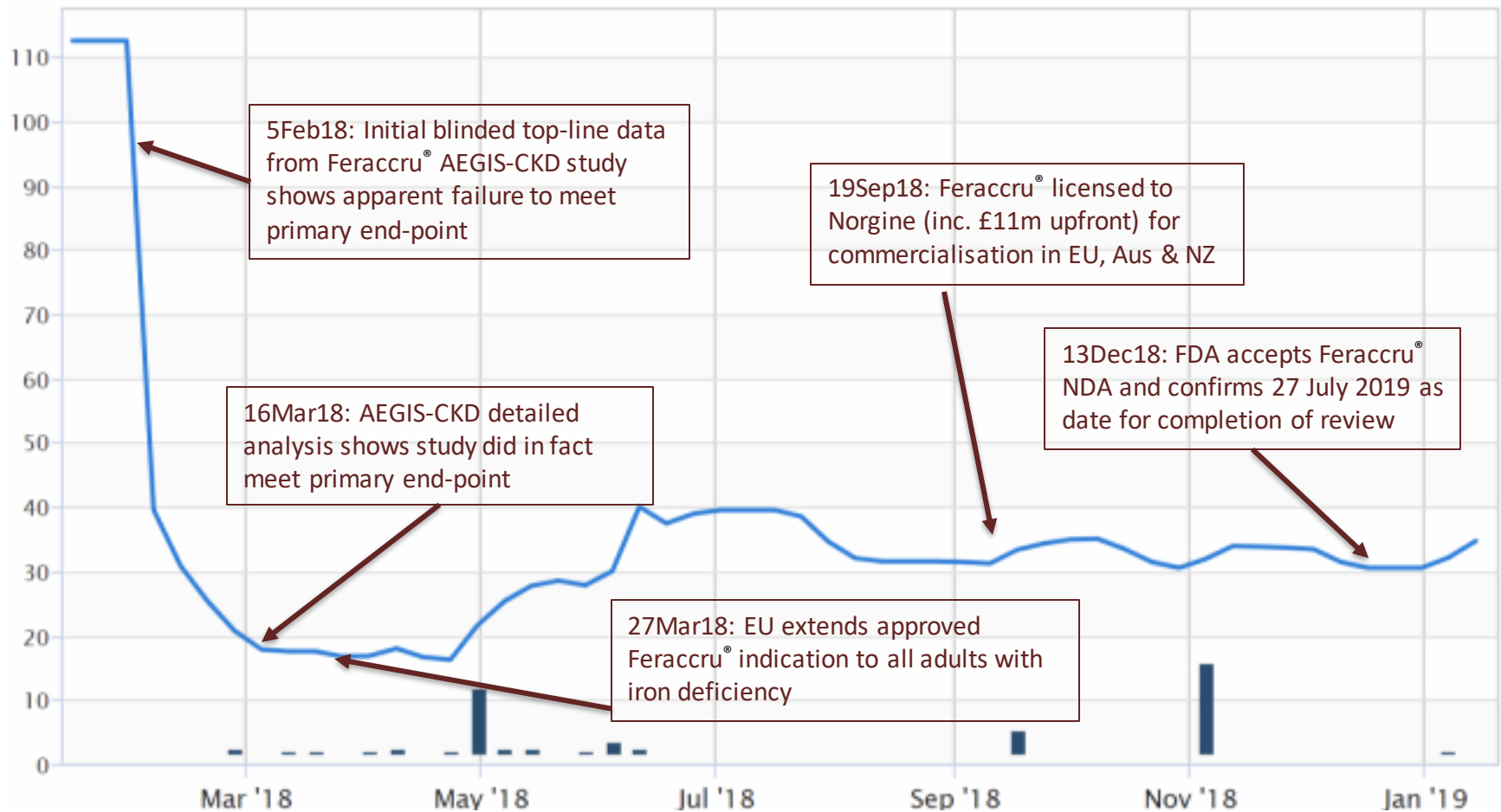
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Introduction to Shield Therapeutics

- AIM-listed biotech company (L.STX)
 - Market capitalisation £43m
- Primary focus is on developing and commercialising Feraccru[®]
 - A novel oral treatment for iron deficiency
 - Out-licensed to Norgine in EU, Australia, New Zealand
 - US NDA submitted September 2018
 - Additional late stage asset, PT20, requires one further phase 3 study prior to submission for marketing authorisation in Europe and the USA
- Semi-virtual UK-based company – clinical trials, manufacture and commercialisation are out-sourced
 - Highly experienced management team
 - 15 employees
- £11m up-front licence payment for EU territory from Norgine in September 2018 means company is comfortably funded into 2020

A brief history of last 12 months...



Investment proposition – the recovery of the business from the consequences of the initial and ultimately incorrect AEGIS-CKD study results have not yet been reflected in the share price



Iron deficiency and Feraccru[®]

Iron deficiency (ID)

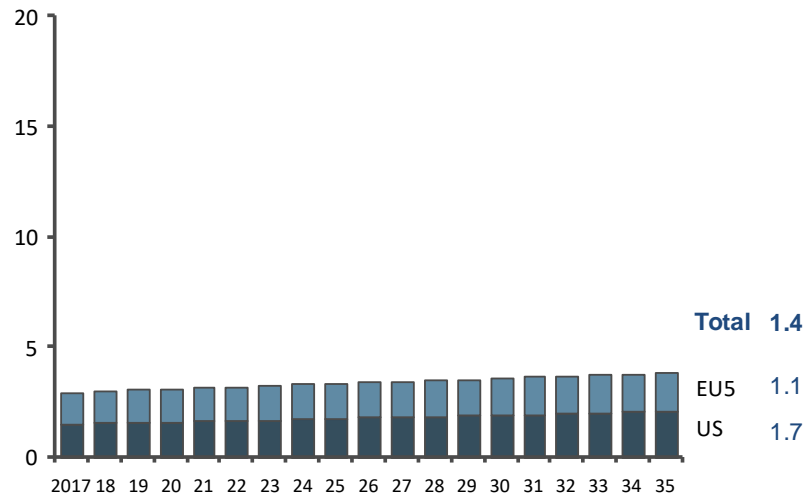
- Iron deficiency is the most common form of anaemia
- Iron required for multiple vital functions
 - Key component of haemoglobin, carrying oxygen from lungs to tissue
 - Transport mechanism for electrons within cells
 - Facilitating oxygen enzyme reactions
- Iron deficiency occurs when a body either: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

IBD and CKD are prevalent diseases

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

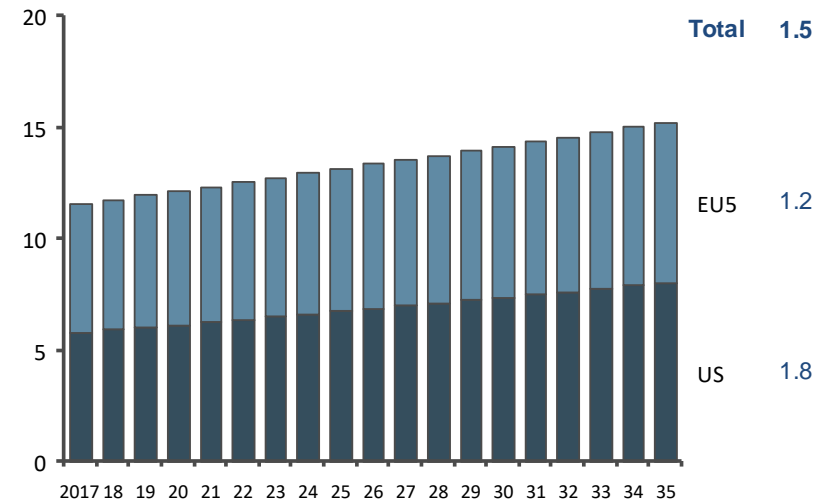
IBD diagnosed prevalence in US, EU5 (2017-35F) Millions of patients

CAGR % (2017-35F)



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

CAGR % (2017-35F)



- 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

- Growth in CKD prevalence driven by higher levels of obesity leading to diabetes and 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

Anaemia and IDA

- Anaemia is a condition characterised by abnormally low levels of red blood cells or low levels of haemoglobin within red blood cells
- Symptoms of anaemia are multiple including
 - Lethargy, fatigue, weakness, depression, impaired immune system, gastrointestinal disturbances, neuromuscular imbalances
- WHO stages of anaemia

Anaemia stage	Haemoglobin concentration		Management
	Men	Women	
Mild	11-13 g/dL	11-12 g/dL	<ul style="list-style-type: none">● Often asymptomatic● May escape detection
Moderate	8 -11 g/dL	8-11 g/dL	<ul style="list-style-type: none">● May present with symptoms● Warrants timely management to prevent long-term complications
Severe	< 8 g/dL	< 8 g/dL	<ul style="list-style-type: none">● Warrants investigation and prompt management

- IDA is treated with iron replacement therapy

Iron replacement therapy can be oral or intravenous (IV)

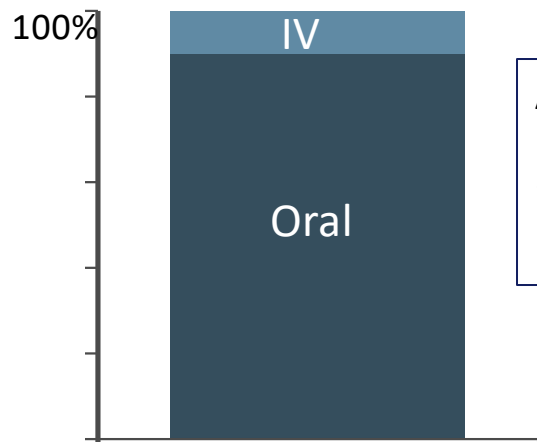
Oral

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

Intravenous

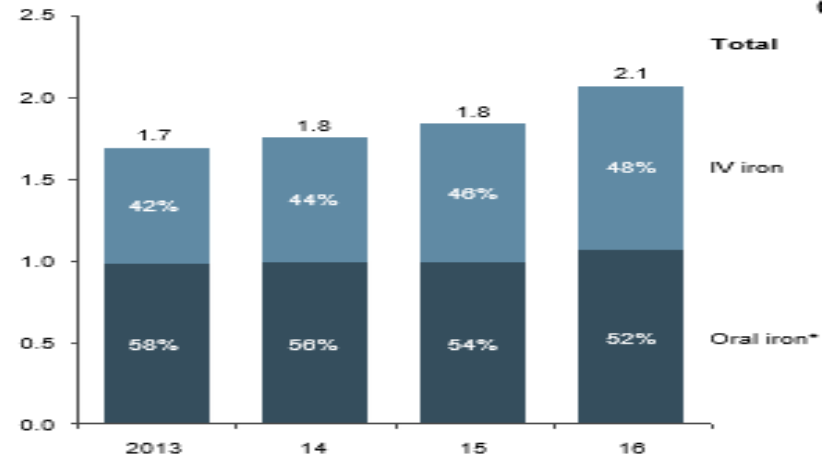
- Used in more severe patients or patients intolerant of oral therapies
- Requires intravenous infusion in hospital or clinic setting due to safety risk
- Resource heavy, inconvenient and expensive

Iron market by volume:



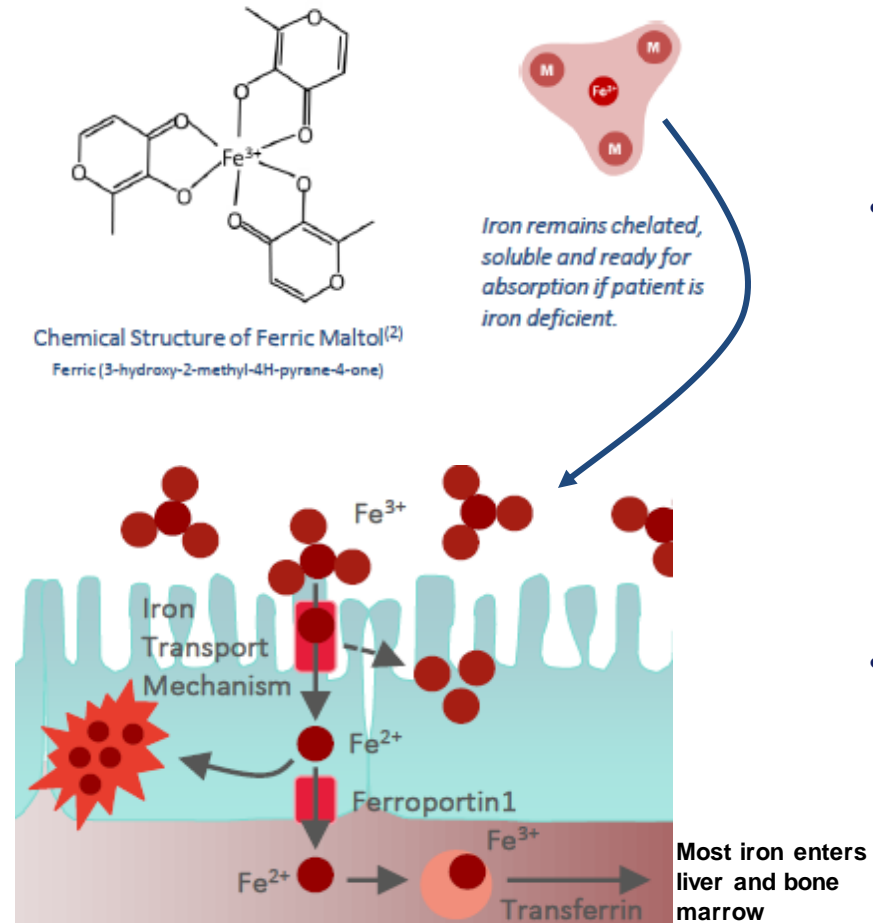
Although oral iron has majority of volume, IV iron has close to 50% of market by value

Global market for Rx iron products (2013-16)
Billions of GBP



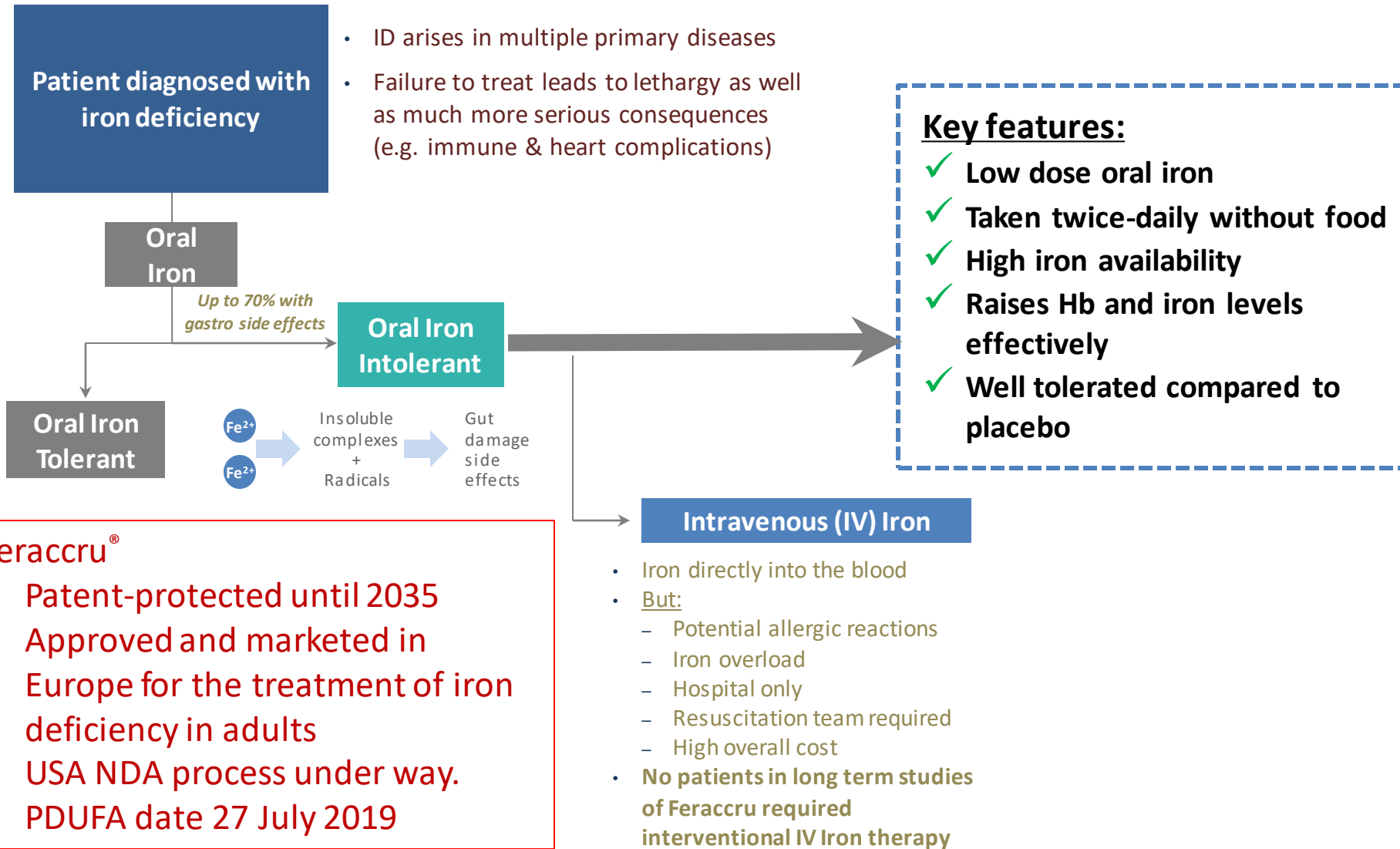
Feraccru is a novel oral formulation

Feraccru[®] mechanism of action:



- Feraccru[®] is a low dose oral formulation of a complex of Fe³⁺ (ferric maltol), which is stable in the gastrointestinal tract
 - Existing iron salts deliver iron as Fe²⁺, which form insoluble products in the GI tract, causing intolerance in patients
- The Fe³⁺ 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 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

Feraccru[®] opportunity



Feraccru[®]

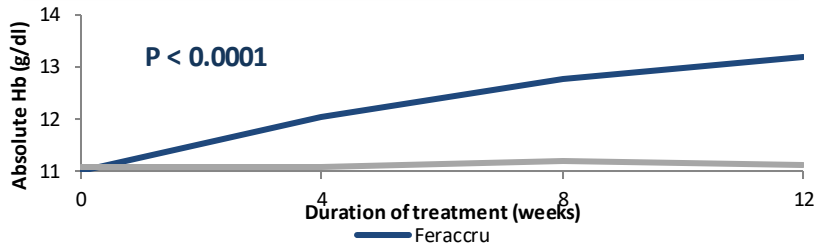
- Patent-protected until 2035
- Approved and marketed in Europe for the treatment of iron deficiency in adults
- USA NDA process under way. PDUFA date 27 July 2019



Feraccru[®] clinical studies

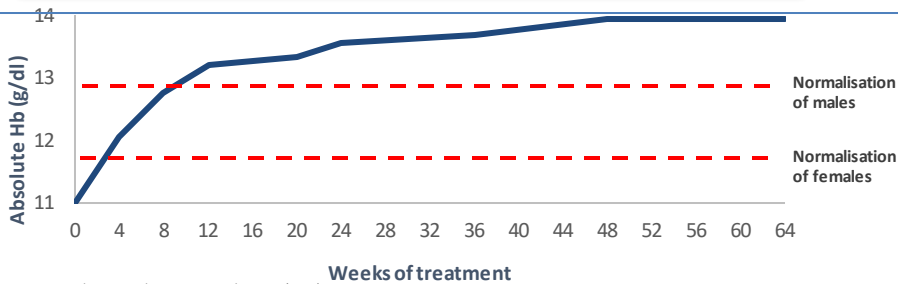
Feraccru's efficacy and safety are key differentiators: AEGIS-IBD

Feraccru provides rapid and effective results...



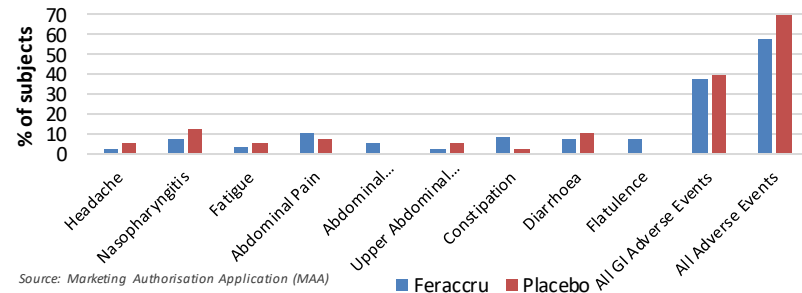
Source: Marketing Authorisation Application (MAA)

...works over the long term



Source: Marketing Authorisation Application (MAA)

...and is well-tolerated



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

- 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

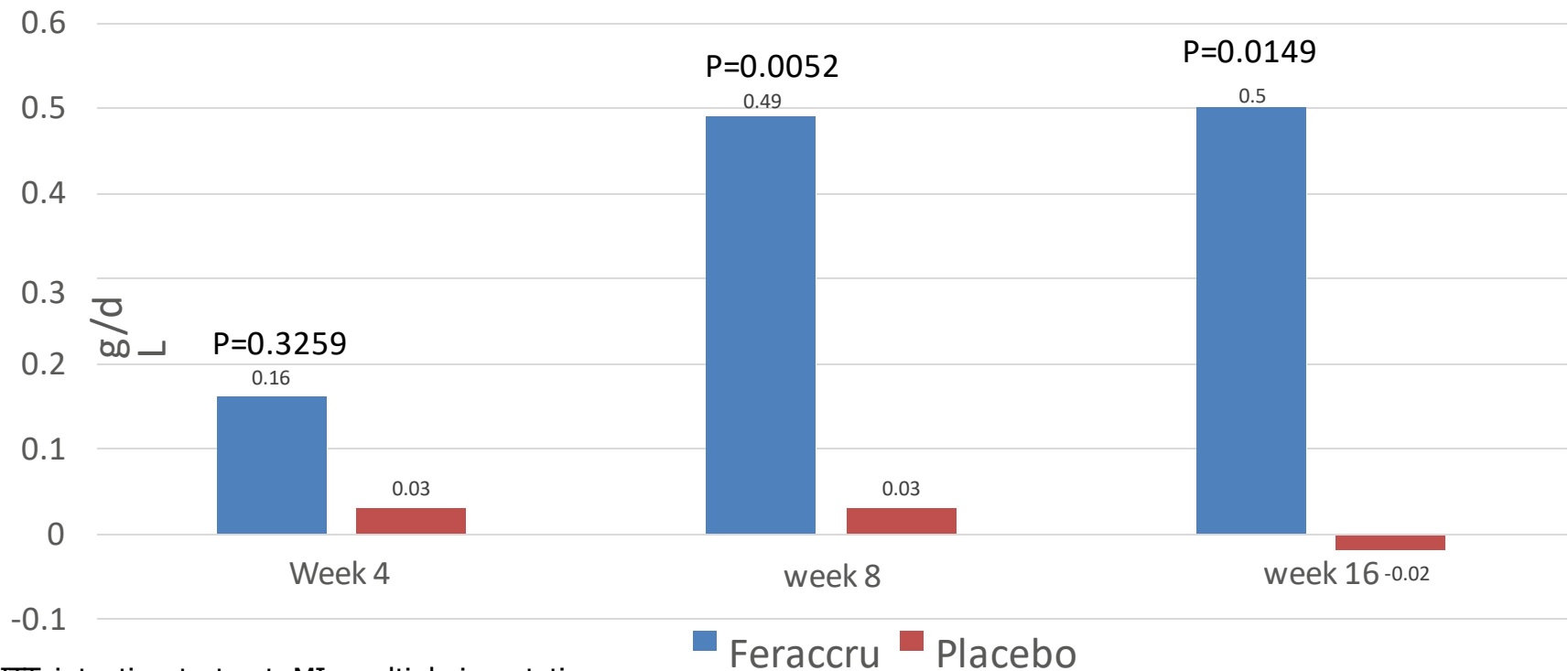
- Majority of adverse events were related to IBD status
- Low incidence of other adverse events
- Neither short or long-term Feraccru® therapy led to iron overload

AEGIS-CKD Study: the story

- A pivotal Phase III study with primary endpoint evaluating haemoglobin response to Feraccru[®] after 16 weeks compared with placebo, in patients with pre-dialysis chronic kidney disease (CKD)
- Initial blinded top-line data suggested that Feraccru[®] had failed to meet primary endpoint
- Detailed investigation identified a number of patients who experienced pre-defined events that led to withdrawal but, as permitted in the study protocol, week 16 endpoint data was collected which confounded the blinded analysis
- Full analyses using the pre-specified statistical analysis plan, using a last observation carried forward methodology, was agreed with regulators, corrected for this confounding data
- Study showed that patients treated with Feraccru[®] demonstrated a highly statistically significant response ($p=0.0149$) in haemoglobin levels after 16 weeks of treatment compared to placebo
- Secondly, a highly statistically significant response ($p=0.0052$) in haemoglobin levels compared to placebo was already seen after just 8 weeks of treatment
- Furthermore, ferritin levels (key marker of iron absorption) increased significantly compared to placebo at 4, 8 and 16 weeks ($p=0.0004$)

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 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



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:

- Phase IIIb non-inferiority study in 242 subjects
- Comparing efficacy and safety of Feraccru[®] to IV iron (Ferinject[®])
- Data will support pricing and reimbursement negotiations
- Recruitment completed September 2018
- Preliminary results anticipated Q1 2019

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 (announced September 2018)
 - £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
 - Commercial operations now active in the UK and Germany, with >80 field-based staff promoting and supporting Feraccru[®]
- 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

- September 2018 - NDA for Feraccru[®] submitted
- December 2018 - FDA accepted Feraccru[®] NDA for review
- December 2018 – PDUFA date (completion of review) confirmed as 27 July 2017
- Shield now considering commercialisation options for Feraccru[®] in the USA, most likely to out-license



Financial headlines & Management Team

Financial position

- Revenues of £11.9m* in 2018
 - £11m upfront payment from Norgine to licence Feraccru® in the EU
 - £0.9m of Feraccru® sales despite the product being commercially unsupported since February 2018
 - Feraccru® demonstrated quarter on quarter growth of ‘in market’ sales through 2018
- Cash balance of £9.8m* at year end
- Cash runway – “funded for at least 12 months” (September RNS announcing Norgine transaction)

* Unaudited results

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 as a surgeon in the NHS
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



Newsflow and investment highlights

Anticipated 2019 newsflow

Indicative timing	Event
Q1 2019	AEGIS-H2H study results
27 July 2019	PDUFA date for US approval of Feraccru [®]
H1 2019	Long term data from AEGIS-CKD study
H2 2019	Start of Paediatric Phase III study
Ongoing/ad hoc	Potential further out-licensing agreements for Feraccru [®] in USA and other territories

Key messages and investment highlights

- Iron deficiency is a major market with significant unmet needs and an attractive commercial opportunity
- Feraccru®
 - Novel oral ferric iron therapy with broad approval in Europe
 - Commercialisation agreement for Europe signed with Norgine who now already have >80 field-based staff promoting and supporting Feraccru® in UK and Germany
 - US Feraccru® NDA review completion by 27 July 2019 with potential approval in the world's largest and most attractive pharma market
 - Further licensing opportunities being actively pursued for Feraccru® in geographies inc. USA, China etc...
- Cash runway extending into 2020
- Valuation upside
 - Investment proposition – the underlying recovery from the consequences of the initial AEGIS-CKD study results have not yet been reflected in the share price
 - Current market capitalisation - £43m (@36p as of 17Jan19)
 - Consensus analyst valuation¹ - £80m - £90m (70p-80p)
 - US NDA approval for Feraccru®, positive H2H study data, additional out-licensing agreements

¹ Peel Hunt & Liberum; based on European commercialisation only, conservative sales forecasts



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