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Pharma & Biotech

52-WEEK HIGH	100.00p
52-WEEK LOW	23.00p
PRICE	94.40p
MARKET CAP MLN	£110.94

Share Price

Major Shareholders

W. Health L.P. 48.1%
MaRu AG 10.8%
Carl A Sterritt 8.7%

Shares in issue	117,088,657
Avg Three-month trading volume	194,719
Primary Index	AIM
Next Key Announcement	27th July 2019

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Shield Therapeutics PLC Heading for a US approval decision

Further progress with Feraccru

Shield Therapeutics (LON:STX) is making excellent progress having reported two sets of new supportive clinical data on its lead product Feraccru, a low dose oral iron capsule. Feraccru is being positioned as an alternative therapy for patients with iron deficiency (ID) and iron deficiency anaemia (IDA) unable to tolerate or unresponsive to first-line oral iron tablets and as an alternative to second line invasive intravenous (IV) iron.

Headline conclusions

- New data from AEGIS H2H multi-national phase IIIb randomised, active-controlled trial, announced in March, showed non-inferiority to a market leader Ferinject. The latest head-to-head data is compelling and presents a clear commercial challenge to market incumbents.
- The value of the iron replacement market is approaching $3bn, while Ferinject achieved FY18 in-market sales of CHF 900m in a global IV iron market worth $1.8bn, according to IQVIA. Sales in some geographies are growing at a double-digit rate. Feraccru's convenience could lead to better compliance and improved penetration – growing the overall market size.
- The positive outcomes triggered a €2.5m development milestone receivable from European/Australasia license partner Norgine out of total potential development and sales milestones of up to €54.5m over the life of the deal.
- Phase III AEGIS CKD (chronic kidney disease) long-term follow-up study results announced in January showed that Feraccru's long-term efficacy and tolerability was maintained at 52 weeks, having met the original primary endpoint at 16 weeks (announced in 2018). The study provided additional evidence of the maintained benefit with continued Feraccru therapy, a lack of relapse and therefore no requirement for IV iron.
- We contend that Feraccru can command a high market share as well as premium pricing because of its convenience and supported by further evidence emerging from clinical studies that it provides a long-term treatment for maintaining the body's iron stores, thereby preventing recurrence of IDA.
- If the US approval decision is positive, Feraccru has a strong data package to support partnering discussions and facilitate commercial success. A late-stage asset such as Feraccru would likely command attractive royalties as well as upfront and commercial milestone payments.
- Shield has a cash reach into Q320 on its end-December 2018 net cash position of £9.8m.

Carl Sterritt has led the company as its CEO since co-founding the group in 2008 with Dr.Christian Schweiger.

Tim Watts joined the company as interim CFO in August 2018 and brings with him more than 25 years' experience in the pharmaceutical and biotech sectors.

Shield Therapeutics: a late-stage specialty pharma company

Shield Therapeutics is a specialty pharmaceutical company focused on the development and commercialisation of late-stage pharmaceuticals. The company's lead asset, Feraccru, is an oral treatment for iron deficiency with or without anaemia. Feraccru is approved and marketed in Europe, with US approval decision pending for July 27, 2019. It also has a pipeline of prescription pharmaceutical assets. The most advanced is PT20, a phase III-ready treatment for the electrolyte disorder, hypophosphatemia, which is extremely common in patients with chronic kidney disease.

Further progress with Feraccru

Shield Therapeutics (STX) is making excellent progress having reported two sets of new supportive clinical data on its lead product Feraccru, a low dose oral iron capsule. Feraccru is being positioned as an alternative therapy for patients with iron deficiency (ID) and iron deficiency anaemia (IDA) unable to tolerate or unresponsive to first line oral iron tablets and as an alternative to second-line invasive intravenous (IV) iron. Feraccru has a range of features that help differentiate it from the more established iron treatments including:

- Twice-daily dosing without food providing high iron availability
- Raises haemoglobin and iron levels effectively
- Prolonged therapy maintains Hb levels
- Well tolerated
- Non-inferior to IV iron
- Feraccru is a stable, non-salt, oral formulation of ferric iron, which has a novel mechanism of action compared to salt-based oral iron therapies

Unmet need in ID and IDA

IDA is a common disorder: anaemia affects around 33% of the world's population, and about half the cases are due to iron deficiency

Iron deficiency (ID) and iron deficiency anaemia (IDA) are caused by low levels of iron in the body. IDA is a common disorder. Anaemia affects around 33% of the world's population, and about half the cases are due to iron deficiency. Children and non-pregnant women are among the groups most affected. Commonly ID is the precursor to IDA so that treatment of the first signs of ID can prevent progression.

Moderate to severe IDA may cause fatigue or tiredness, breathing problems or chest pain. The most common reasons for ID are insufficient iron intake in the diet, an inability to absorb iron well in the body and/or loss of iron of blood through bleeding. Treating ID and IDA - which are common and often serious complications in people suffering chronic heart or kidney disease, cancers or gastrointestinal diseases - can help improve patients' symptoms and quality of life.

Feraccru receives expanded approval in Switzerland also, widening the patient pool from IBD patients with IDA to a broad approval

Feraccru is approved and marketed in the EU and with an extended label, which covers the treatment of adults with iron deficiency with or without anaemia. In April, Feraccru received expanded approval in Switzerland also, widening the patient pool from IBD patients with IDA to a broad approval. This was supported by positive CKD trial results - a very hard-to-treat patient pool - announced in 2018. ID affects up to five-times as many people than IDA.

Key takeaways from the latest clinical data

Feraccru stands to challenge current Standard of Care

STX recently reported additional data supporting the existing dataset, providing current and potential partners with additional material to support commercialisation and reimbursement efforts including from:

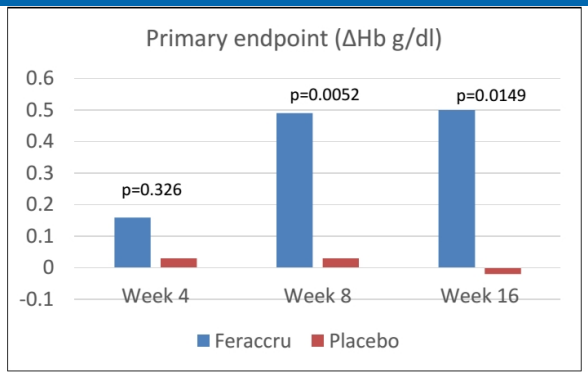
The AEGIS H2H multi-national Phase IIIb randomised, active-controlled trial in 242 IBD patients with IDA.

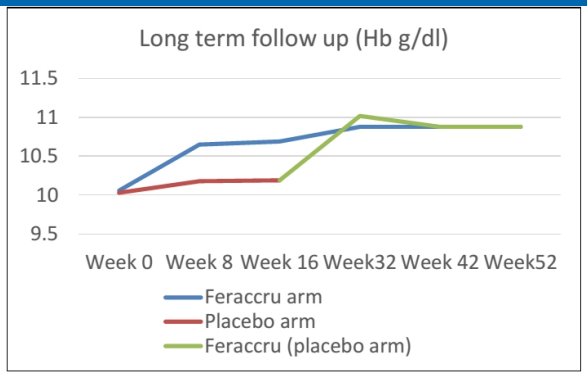
- This showed non-inferiority to a key comparator – Ferinject. So, Feraccru stands to challenge the current standard of care. This is measured as a rise or normalisation of haemoglobin (Hb) at week 12. The study was extended out to 52 weeks
- The positive outcomes triggered a €2.5m development milestone receivable from European license partner Norgine
- The full dataset is being analysed and peer-reviewed to form the basis of marketing information and to support reimbursement of Feraccru for current and potential partners
- Providing potentially compelling data to form the basis of ongoing partnering discussions for the US and China in the near-term and supporting commercialisation for current partners

Phase III AEGIS CKD long term follow-up outcomes

- The placebo-controlled study was conducted in patients with CKD - chronic kidney disease suffering from chronic IDA
- The original study reported in March 2018 met the primary endpoint – a statistically significant change in Hb from baseline at 16 weeks providing unequivocal evidence of efficacy
- At week 16 of the study placebo patients switched to open-label Feraccru and saw a similar rise in Hb as in the initial treatment group - the change in Hb was maintained through to 52 weeks

Phase III AEGIS CKD study outcomes





Source: Shield Therapeutics PLC

Feraccru has a clear clinical and commercial rationale

Outwardly simple, but with clinically proven equivalent efficacy to IV iron, Feraccru is an oral product absorbed in the gut. It is also an alternative for those unable to tolerate or unresponsive to first-line salt-based oral iron products.

Such patients have the second-line option of intravenous IV iron, which is invasive and inconvenient. So, Feraccru presents a much more convenient and potentially lower cost, safer alternative to IV iron, which

needs to be administered in hospital because it always carries the risk of a severe and potentially fatal allergic reaction.

The market leading IV iron delivered FY18 in-market revenues of CHF 898m (Vifor Pharma: VIFN) in a global IV iron market valued at $1.8bn, according to IQVIA. Vifor Pharma AG, a Switzerland-based company with a market capitalisation of CHF 8.7bn commercialises the market leading branded IV iron Ferinject, known as Injectafer in US. In Europe, Ferinject is indicated for ID when oral iron is ineffective or cannot be used. While in US, Injectafer is indicated for adults with IDA, for patients who have non-dialysis dependent CKD, and for patients who are intolerant to, or who have an unsatisfactory response to oral irons.

The ID patient pool in Europe alone is estimated to be up to 40m patients and with a similar size in US, although it might be logical to assume that CKD and IBD patients would form the initial targets. Active education, reimbursement and commercial roll-out could lead to an additional share of the wider markets, which includes the significant paediatric market of up to 1.6m patients in Europe and US.

Commercial prospects

Physicians report that the outcomes seen in clinical studies are reflected in real world use of Feraccru

We contend that Feraccru can command a high market share as well as branded pricing because of its convenience and, supported by emerging evidence from clinical studies, that it provides a long-term treatment for maintaining the body's iron stores. Its convenience is a very important differentiator as patients can take Feraccru at home, avoiding a hospital admission and the life-threatening risks of IV iron administration. Physicians report that the outcomes seen in clinical studies are reflected in real world use of Feraccru.

Vifor reports that the IV iron markets for ID/IDA are relatively poorly penetrated – except for its home market Switzerland – providing high growth potential for the overall market in line with commercial efforts and reimbursement. Current penetration rates reported by Vifor and market research data (Beige Market Intelligence) suggest an overall IV and oral iron market size of up to $3bn, and poor compliance with oral products is leading to a gradual switch to IV iron.

The ongoing commercialisation and education program being rolled out by Vifor is in some senses laying the way for Feraccru in terms of raising awareness of how many patients have ID/IDA and the potential benefits of alleviating and preventing IDA.

US opportunity on the horizon

Feraccru also has a full data package to support partnering discussions

STX is commercialising Feraccru through its global partners: Norgine in Europe, through AOP in Central Eastern Europe and Scandinavia and EWO in Switzerland. With a US filing on track for a PDUFA date of July 27, the company is short-listing potential partners ahead of the approval decision date so they are ready to go ahead if they receive the green light.

While it is never possible to second guess, existing approvals and industry averages suggest there is a likelihood of approval of over 80% from NDA filing (Biomed Tracker). Feraccru also has a full data package to support partnering discussions – indeed the latest head-to-head data

is compelling and presents a clear commercial challenge to market incumbents.

STX is seeking a US approval for a broad label, although it is possible that FDA will limit it initially to IDA in CKD and IBD since these are the studies included in the submission. The company states that its main option is partnering. Clearly, a late-stage asset such as Feraccru would likely command attractive royalties - upfront and commercial milestone payments.

While the shares have risen more than threefold in the year to date (the company had a market capitalisation of just £35m at the start of 2019), there is still a clear mismatch to both the February 2016 IPO valuation of 150p per share (which provided a market capitalisation of c £160m at that time) as well as the significant progress made since in both partnering activities and in positive clinical study outcomes.

News flow

We look forward to the upcoming news flow including:

- Further news on commercialisation progress, publication of peer reviewed Feraccru data from H2H study
- US PDUFA date 27 July
- Initiation of a paediatric study in infants over 1 month starting in H219
- News on next steps with PT20 including outcomes of ongoing re-formulation work
- News on partnering in new geographies – notably China in next 12 months.

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