Capital Network
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Pharma & Biotech

52-WEEK HIGH	185.00p
52-WEEK LOW	27.00p
PRICE	175.00p
MARKET CAP MLN	£205.00

Share Price

Major Shareholders

W Health LP 48.1%
Maru AG 10.8%
Carl A Sterritt 8.7%

Shares in issue	117,188,657
Avg Three-month trading volume	177,551
Primary Index	AIM
Next Key Announcement	Accufer deal

Company Information

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Shield Therapeutics PLC: FDA approves broad label for Feraccru

Shield Therapeutics (LON:STX) reports it has achieved the best possible outcome for Feraccru. The US Food & Drug Administration (FDA) has approved the treatment for a broad label to treat iron deficiency (ID) in adults, addressing a population many times wider than the iron deficiency anaemia (IDA) indications included in the submission data.

Feraccru, an oral treatment for iron deficiency with or without anaemia that will be marketed as Accrufer in the US, is now positioned to directly challenge the market-leading intravenous iron therapy. This is backed by clinical non-inferiority, as well as being a potentially safer and more convenient alternative. STX is well supported to negotiate attractive deal terms with prospective US commercial partners for Accrufer in a total US prescription iron replacement market worth more than US$1bn.

Feraccru, which will be marketed as Accrufer in the US, has obtained the broadest possible label for treating adults with iron deficiency with or without anaemia. There are around three times as many patients with ID than with IDA (source: STX). Adding these, the total addressable population could reach up to 40 million in the US. The announced label also took off the table the prospective limitation to just chronic kidney disease (CKD) and inflammatory bowel disease (IBD) patients as per the studies included in the FDA approval submission. In all Accrufer is poised to approach a US iron replacement therapy prescription market worth more than US$1bn.

The key commercial and clinical considerations supporting Accrufer are its greater convenience compared to intravenous (IV) iron therapy, for those patients unable to tolerate first-line salt-based oral iron treatments. Data from the AEGIS head-to-head (H2H) multi-national Phase IIIb randomised, active-controlled trial, showed non-inferiority to Vifor Pharma's market-leading IV iron Ferinject (marketed in the US as Injectafer). IV iron is invasive and inconvenient since it needs to be administered in a hospital because it always carries the risk of a severe and potentially fatal allergic reaction.

Furthermore, in the US, Injectafer has a more specific label than Accrufer – the former is indicated first 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. Accrufer's broader label, therefore, favours its commercial prospects.

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

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

Shield is therefore clearly on a very strong footing to advance its discussions with commercial partners for Accrufer based on this broad approval as well as a very sound data package. Evidence from clinical studies shows it provides long-term treatment for maintaining the body's iron stores. In our view, these factors provide a solid support for negotiating attractive deal terms.

The US label is equivalent to the extended label already obtained in the EU and Switzerland; Feraccru is approved and marketed in these geographies with a label that covers the treatment of adults with ID with or without anaemia through its licensing partners. We contend that Feraccru can command a high market share and potentially even challenge the treatment paradigm, because of its convenience and the favourable clinical evidence, in a global iron replacement market approaching US $3bn.

Conclusions

STX has clearly made very considerable strides since floating in February 2016 – it listed with a market capitalisation of £160mln at a share price of 150p. Since then it has achieved approval and out-licensed the lead product in Europe and Switzerland prior to the recent US approval. The current valuation is still mismatched in these respects particularly given the potential for ongoing US licensing discussions to lead to attractive terms.

STX has clearly made very considerable strides since floating in February 2016

We look forward to the upcoming news flow including:

- Outcomes from US commercial partner discussions for Accrufer
- Further news on commercialisation progress in partnered territories Europe, Switzerland, Central and Eastern Europe - first half (H1) business update
- Publication of peer-reviewed Feraccru data from the AEGIS H2H study
- 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 the next 12 months.

Background

Shield Therapeutics is a speciality 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 and was recently approved in the US to be marketed as Accrufer. It also has a pipeline of prescription pharmaceutical assets, the most advanced of which is PT20, a phase III-ready treatment for the electrolyte disorder, hypophosphataemia, which is extremely common in patients with chronic kidney disease.

Feraccru is approved and marketed in Europe and was recently approved in the US to be marketed as Accrufer

Unmet need in ID and IDA

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 (source: WHO) 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 in the blood through bleeding. Treating ID and IDA - which are common and often serious complications in people suffering from chronic heart or kidney disease, cancers or gastrointestinal diseases - can help improve patients' symptoms and quality of life.

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