EDISON

Shield Therapeutics

Corporate news

AEGIS-H2H update – non-inferiority at 24 weeks

Pharma & biotech

Shield Therapeutics (STX) has announced a technical update to findings from the AEGIS-H2H post-marketing study. The re-analysis demonstrates that Feraccru/Accrufer is a credible alternative to IV iron therapy for iron deficiency anaemia (IDA) in the long term. We note the product did not meet the primary endpoint of non-inferiority at 12 weeks vs IV iron, but did correct anaemia and maintain Hb levels over the long term phase (as defined by the 40-week extension phase of the trial). While we note AEGIS H2H was not required as a registration study (thus the regulatory status of the product is unaffected by the study), the headline results of long-term Hb correction is comparable to IV iron for chronic conditions of anaemia. We believe this will have positive implications for health economic outcomes, pricing strategies and partnering opportunities. The next key inflection point is a US partnering deal; we expect Accrufer launch later this year once a partner has been found. Our valuation of STX is unchanged at £381.7m or 326p/share.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/18	11.88	(5.15)	(1.5)	0.0	N/A	N/A
12/19	0.72	(9.07)	(7.5)	0.0	N/A	N/A
12/20e	12.66	1.14	2.0	0.0	N/A	N/A
12/21e	8.99	(4.31)	(3.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

AEGIS-H2H was a 52-week, open-label Phase III study in 242 inflammatory bowel disease patients with mild to severe IDA, randomised (1:1) onto either oral Feraccru or IV ferric carboxymaltose (Ferinject). The trial was a non-inferiority study, with the primary endpoint a non-inferior comparison between Feraccru and IV Iron as showing a 2g/dL improvement in Hb levels or achieving normalisation. Shield has announced that the re-analysis shows the primary endpoint of the study was not met after 12 weeks of treatment on Feraccru (the first phase of the study), although the average increase in Hb levels in Feraccru patients was~2.5g/dL which is clinically significant (vs ~3g/dL for IV). However, at the long-term phase (using the intention to treat population), by week 24, 65% of the Feraccru/Accrufer patients still being monitored had achieved normal levels of Hb, compared with 68% of IV patients. At weeks 24, 36 and 52, the mean increases in Hb levels in those patients still being monitored were 2.93 g/dL, 3.16 g/dL and 2.72 g/dL in the Feraccru/Accrufer arm compared with 2.84 g/dL, 2.70 g/dL and 2.79 g/dL in the IV arm respectively.

7 August 2020

Price	**127p**
Market cap	**£149m**
	£0.82/US$; £0.90/€
Unaudited net cash (£m) at 30 April 2020	10.4
Shares in issue	117.2m
Free float	32%
Code	STX
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

Business description

Shield Therapeutics is a commercial-stage pharmaceutical company. Its proprietary product, Feraccru, is approved by the EMA and FDA for the treatment of iron deficiency. Feraccru is marketed through partners Norgine, AOP Orphan and Ewopharma.

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