EDISON

Sequana Medical

DSR 2.0 update

CHIHUAHUA results clear path to MOJAVE

Pharma and biotech

Sequana Medical reported positive results from the CHIHUAHUA Phase I study of its second-generation DSR (direct sodium removal) product, DSR 2.0. This clears a key hurdle needed before filing a US Investigational New Drug (IND) application to start the MOJAVE US Phase I/IIa study in patients with diuretic-resistant congestive heart failure (CHF). CHIHUAHUA was conducted in 10 stable peritoneal dialysis (PD) patients in Mexico and showed that a single dose of DSR 2.0, administered via a PD catheter over a 24-hour dwell period, was safe and well-tolerated, with no serious adverse events or discontinuations due to adverse events. The positive safety data, in combination with favourable preclinical results, should support the IND filing, in our view. The company continues to expect to file the IND application for DSR 2.0 in Q123 and, if accepted by the US FDA, it plans to start enrolment for MOJAVE in Q223. Sequana continues to anticipate reporting interim results in H223, and top-line data in H224.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	0.4	(24.4)	(1.36)	0.0	N/A	N/A
12/22	0.9	(30.9)	(1.37)	0.0	N/A	N/A
12/23e	0.8	(28.1)	(1.18)	0.0	N/A	N/A
12/24e	3.0	(30.0)	(1.26)	0.0	N/A	N/A

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

DSR 2.0 is designed to provide an improved therapeutic and more favourable safety profile compared to DSR 1.0, which already showed in the SAHARA trial that it can restore euvolemia, improve diuretic response and resolve persistent congestion in diuretic-resistant CHF patients.

No patient in the CHIHUAHUA study showed a clinically relevant change in serum sodium levels or progressive hyponatremia (referring to abnormally low serum sodium). This is further evidence of DSR 2.0's anticipated safety profile, given that its longer dwell time (compared to DSR 1.0) had been expected to enable a more measured or gradual excretion of sodium. While not powered to show efficacy, patients in the CHIHUAHUA study experienced an average total fluid removal of approximately 3 litres, including 9g of sodium, following a single 0.5 litre treatment of DSR 2.0 and a 24-hour dwell period. This suggests proof-of-concept of the treatment's ability to remove sodium and treat fluid overload (congestion).

The MOJAVE study will have two study cohorts. In the safety cohort, three heart failure patients will receive DSR 2.0 via a PD catheter on top of usual care for up to four weeks. An independent data safety monitoring board will then determine whether the study can proceed to the efficacy cohort. The efficacy cohort is designed to enrol 30 diuretic-resistant CHF patients with persistent congestion, with 20 patients randomised to DSR 2.0 administered via a PD catheter on top of usual care for CHF for up to four weeks, and 10 patients randomised to intravenous loop diuretic treatment as part of usual care for CHF alone. There will also be a three-month safety follow-up period after the four weeks of DSR therapy. If results are positive, we believe Sequana will be in the enviable position of seeking favourable terms for commercial partnership or licensing transactions.

1 March 2023

Price	**€5.28**
Market cap	**€125m**
Net cash (€m) at 31 December 2022	2.2
Shares in issue	23.75m
Free float	45%
Code	SEQUA
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance

Business description

Based in Belgium, Sequana Medical develops products to treat diuretic-resistant fluid overload, a frequent complication of liver disease and heart failure. Its proprietary alfapump and DSR approaches aim to provide significant clinical and quality-of-life benefits in these fluid overload conditions.

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