Trinity Delta Lighthouse

Mereo BioPharma

Accelerated approval path for NAVI

16 July 2019

- Mereo BioPharma has agreed in principle the design of a Phase II study with navicixizumab in advanced ovarian cancer, which could potentially by used for the accelerated approval of the product, with the US FDA in a Type B meeting.
- Navicixizumab is a bispecific antibody that binds to DLL4 and VEGF, which was acquired by Mereo BioPharma during the merger with Oncomed. In a Phase Ib study in combination with paclitaxel in advanced platinum-resistant ovarian cancer, an unconfirmed overall response rate (ORR) of 41% (18/44 patients) was observed.
- The primary endpoint of the trial will be confirmed ORR, and the secondary endpoints will include duration of response, CA-125 response rate, PFS (progression free survival) and OS (overall survival), with the dosing regimen the same as in the current Phase Ib trial.
- There are currently limited treatment options for patients with advanced platinum-resistant ovarian cancer and an estimated 14,000 women will die from ovarian cancer in 2019.
- Mereo BioPharma has commenced partnering activities for navicixizumab.
- There is a contingent value right (CVR) for the former OncoMed shareholders linked to any partnering deal with navicixizumab; 70% of the net proceeds of any cash milestone payments received by Mereo BioPharma for five years post-completion will be received by the CVR holders (subject to a cap of c$80m), with the balance retained by Mereo BioPharma.

Price (UK share) (US ADS)	45.5p $2.63
Market Cap	£45m $60m
Exchanges	AIM London NASDAQ
Sector	Healthcare
Company Code	MPH.L MREO
Corporate client	Yes

Company description:

Mereo BioPharma develops and commercialises innovative therapeutics addressing rare and specialty diseases. These are acquired or licensed in at clinical stages from large pharmaceutical companies. The portfolio consists of four compounds that are progressing through late clinical development.

Trinity Delta view: The importance of navicixizumab to Mereo BioPharma from a DCF-valuation perspective is limited due to the linked CVR, but a deal would still be valuable to the company as it would strengthen its balance sheet and also demonstrate Mereo BioPharma's ability to out-license assets. The outline of the Phase II design and potential accelerated approval pathway, agreed with the FDA in principle, should facilitate any partnering discussions and increase the likelihood of navicixizumab being out-licensed within the next 12 months.

We value Mereo BioPharma at £541m ($704m), equivalent to 506p/share or $25.59/ADS (fully diluted). This is based on the company's four leading assets to be conservative, and excludes any contribution from navicixizumab.

Analysts

Mick Cooper PhD
mcooper@trinitydelta.org
+44 (0) 20 3637 5042

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Mick Cooper PhD CFA mcooper@trinitydelta.org
+44 (0) 20 3637 5042

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

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