

Mereo BioPharma

Additional ASTEROID data supports progression

15 January 2020

- Mereo Biopharma has released further positive data from the Phase IIb ASTEROID study. This pivotal trial evaluated setrusumab, a monoclonal antibody targetting sclerostin, in OI (osteogenesis imperfecta). OI, better known as [brittle bone disease](#), is an orphan disease with different genotypes characterized by varying degrees of skeletal fragility.
- The top-line data from the 112 adult patient study were announced in November 2019 (see [Update](#) note). This showed the outcomes for secondary endpoints were achieved, but a primary outcome was missed. HRpQCT, a novel method of measuring BMD, had been selected as a main endpoint; but heterogeneity in the base data meant significance was improbable.
- The detailed analyses, using pre-specified criteria, show a dose-dependent, statistically significant bone building effect at multiple anatomical sites in adult OI patients (irrespective of OI subtype). The results include Finite Element Analysis (FEA), used as a primary endpoint to measure bone strength, and Trabecular Bone Score (TBS), which was a secondary endpoint.
- FEA at the radius after 12 months saw an increase in failure load and an increase in stiffness in the high dose cohort (+2.0% $p < 0.037$ and +2.2% $p < 0.022$ respectively). TBS at the vertical spine showed an increase in the medium and high dose groups (+3.2% $p < 0.001$, +3.7% $p < 0.001$ respectively).
- The new data confirms the view, also seen in previous studies, that setrusumab improves trabecular and cortical bone, as well as overall bone structure, at peripheral and lumbar sites. The next stage will be finalising the planning for the pivotal multi-centre trial of setrusumab in OI children.
- These results have already been discussed with the European regulatory body (EMA) and a clinical programme pathway is agreed. A meeting with the FDA is currently planned to happen during Q120.

Price (UK share)	36.0p
(US ADS)	\$2.34
Market Cap	£35.3m
	\$48.6m
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: Setrusumab, previously known as BPS-804, is the largest element in our valuation of Mereo BioPharma; amounting to £389m or \$299m, equivalent to 305p per share or \$15.26/ADS (see our recent [Outlook](#) note for further details). These encouraging data support our positive stance and help underline the inherent value within the company. The strategy is to develop a portfolio of innovative rare disease products. We believe management is actively progressing further partnering discussions that will provide near-term funding, yet still retain a sizeable element of longer-term commercial upside.

We maintain our valuation of Mereo BioPharma at £442m (\$574m), equivalent to 412p/share or \$20.60/ADS (fully diluted).

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