Mereo BioPharma

Setrusumab partnered with Ultragenyx

18 December 2020

- Mereo Biophama has announced a licence and collaboration agreement with Ultragenyx for setrusumab (osteogenesis imperfecta, OI or brittle bone disease). The deal sees Ultragenyx pay $50m upfront and up to $254m on achievement of clinical, regulatory, and commercial milestones. Ultragenyx will lead the global development programme for both paediatric and adult patients, with a paediatric Phase II/III pivotal study expected to start in 2021.
- Under this deal, Ultragenyx has been granted an exclusive licence to develop and commercialise setrusumab in the US and rest of the world, with Mereo BioPharma retaining the commercialisation rights for Europe. Ultragenyx will pay tiered double-digit percentage royalties on net sales outside of Europe, and Mereo BioPharma will pay a fixed double digit percentage royalty to Ultragenyx on net sales in Europe. Setrusumab was acquired from Novartis in 2015; under the terms of this agreement Novartis is entitled to a percentage of proceeds (subject to certain deductions), with Mereo BioPharma retaining a substantial majority of the payments received from UltraGenyx.
- Setrusumab is a fully humanised monoclonal antibody targeting sclerostin (SOST) that has successfully completed a c 112 adult OI patient, double-blind, placebo controlled Phase IIb clinical trial (ASTEROID). Development in the paediatric indication is the initial priority, with regulatory discussions expected to guide the Phase II/III trial design. This will first determine the optimal dosing before the Phase III element evaluating fracture reduction over a 15 to 24 month period as the primary endpoint. If successful, this will form the basis of the regulatory filing. A similar Phase III adult trial is planned.
- Ultragenyx Pharmaceutical Inc. (Nasdaq: RARE) is a US-based company focused on novel products for serious rare and ultra-rare genetic diseases. It has a solid track record of commercialising and developing such treatments, working closely with patient groups and regulators. It is well capitalised, with a market cap of $10.85bn. Setrusumab appears to fit neatly into its product and clinical expertise.

Price (US ADS)	$2.21
Market Cap	$125.8m
Exchange	NASDAQ
Sector	Healthcare
Company Code	MREO
Corporate client	Yes

Company description:

Mereo BioPharma develops and commercialises innovative therapeutics addressing oncology and rare diseases. These are acquired or licensed in at clinical stages from large pharmaceutical companies. The portfolio consists of six compounds that are progressing through late-stage clinical development. One of these is a promising anti-TIGIT programme entering Phase Ib/II trials in a variety of solid tumours.

Trinity Delta view: Mereo BioPharma continues to deliver on its promises. We view Ultragenyx as an ideal partner to complete development of setrusumab, with its established infrastructure boding well for its commercialisation in the US and rest of the world. The terms of the deal reflect the quality of the clinical package to date and underscores the value of retaining commercialisation rights for Europe. Despite this positive news, we emphasise that investor attention will focus on its anti-TIGIT programme. Etigilimab will start a key Phase Ib/II PD-1 combination trial in a variety of solid tumours shortly, with top line results expected during H221. Pending an update following this deal, we suspend our valuation and forecasts with the intention of reinstating them as soon as practicable. For context, our prior valuation of Mereo BioPharma was $741m, equivalent to $5.06/ADS (fully diluted).

Analysts

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

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

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

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

Disclaimer

More information is available on our website: www.trinitydelta.org