Mereo BioPharma Announces Positive Feedback from Type B End-of-Phase 2 Meeting with the FDA and Outlines Pivotal Phase 3 Pediatric Study Design for Setrusumab in Osteogenesis Imperfecta

London and Redwood City, Calif., February 28, 2020 - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), "Mereo" or the "Company," a clinical stage biopharmaceutical company focused on rare diseases, today announced the successful completion of a Type B End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") to discuss the development of setrusumab, an anti-sclerostin antibody, for the treatment of children and adolescents with osteogenesis imperfecta ("OI"). OI is a genetic rare disorder characterized by reduced bone mass and fragile bones that break easily. There are currently no approved treatments for OI.

Following the review of the data from the Company's Phase 2b ASTEROID study with setrusumab in adults with OI, the FDA agreed on the design of a Phase 3 pediatric study in OI to be completed prior to the submission of a Biologics License Application ("BLA") in the United States. This is in line with Mereo's proposed pivotal pediatric study design that has already been agreed to in principle with the European Medicines Agency ("EMA"). The Phase 3 pediatric study will include the following elements:

- A single study with two cohorts in approximately 160 children and adolescents ages 2 to <18 years diagnosed with Type I, III or IV OI and a confirmed genetic mutation leading to a collagen defect;
- A safety cohort with a limited number of patients will confirm the dose of setrusumab based on safety and the efficacy cohort will be a two-arm, randomized, double-blind, active control design of 12 months duration;
- In the efficacy cohort, participants will be randomized to one of two double-blinded study arms: in one arm participants will receive setrusumab at a dose equivalent to the high-dose arm utilized in the Phase 2b ASTEROID study and in the other arm, participants will receive a standardized bisphosphonate;
- Primary endpoint of fracture rate versus active control following 12 months of treatment; and
- Secondary endpoints of bone mineral density (BMD) at the lumbar spine at 12 months over baseline measured using two-dimensional dual-energy X-ray absorptiometry (DXA), bone biomarkers, patient reported outcomes (PRO) and quality of life measures.

"We are pleased with the productive feedback we received from the FDA during our End-of-Phase 2 meeting," said Dr. Denise Scots-Knight, Chief Executive Officer of Mereo. "Overall, the final pivotal study design will be consistent with what we had previously agreed to in principle with the EMA. We now have a clear path forward to initiate a Phase 3 study of setrusumab in pediatric OI that incorporates feedback from both the FDA and EMA and is intended to support the filings of a BLA in the United States and a Marketing Authorization Application ("MAA") in the EU. This is an important milestone for Mereo and we are excited to continue to develop setrusumab as there are no currently approved therapies for OI and treatment options are greatly needed. Preparations for the Phase 3 study are underway."

About Osteogenesis Imperfecta

Osteogenesis Imperfects (OI) is a rare genetic disorder that is characterized by fragile bones and reduced bone mass resulting in bones that break easily, loose joints and weakened teeth. In severe cases, those with OI may experience hundreds of fractures in a lifetime. In addition, people with OI often suffer muscle weakness, early hearing loss, fatigue, curved bones, scoliosis, respiratory problems and short stature, leading to significant impacts on overall health and quality of life. The majority of cases of OI (estimated at approximately 90%) are caused by a dominant mutation in a gene coding for type I

collagen, a key component of healthy bone. Current treatment of OI is supportive, focusing on minimizing fractures and maximizing mobility, but to date, there are no FDA or EU approved treatments.

About Setrusumab

Setrusumab is a fully humanized monoclonal antibody that inhibits sclerostin, a protein which inhibits the activity of bone-forming cells. The mechanism of action of setrusumab could be particularly well suited for the treatment of OI and setrusumab has the potential to become the first approved treatment option that could reduce fractures and improve the quality of life for individuals with OI. Mereo has obtained orphan drug designation in OI for setrusumab in both the United States and the EU, in February 2017 setrusumab was accepted into the EMA's Adaptive Pathways program in the EU and, in November 2017 it was accepted into the EMA's Priority Medicines scheme (PRIME). In the Phase 2b ASTEROID study, setrusumab demonstrated a dose-dependent bone building effect and a trend of reduction in fractures in addition to being safe and well tolerated adults with OI. On January 14, 2020 Mereo announced additional positive prespecified endpoint data from the Phase 2b ASTEROID study.

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for patients with rare diseases. Mereo's strategy is to selectively acquire product candidates for rare diseases that have already received significant investment from pharmaceutical and large biotechnology companies and that have substantial preclinical, clinical and manufacturing data packages. Mereo's lead rare disease product candidate, setrusumab, has completed a Phase 2b dose ranging study in adults with osteogenesis imperfecta ("OI"). Mereo's second lead product candidate, alvelestat, is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency ("AATD"). Mereo's broader pipeline consists of four additional clinical-stage product candidates; acumapimod for the treatment of acute exacerbations of chronic obstructive pulmonary disease ("AECOPD"), leflutrozole for the treatment of hypogonadotropic hypogonadism ("HH") in obese men, and etigilimab ("Anti-TIGIT") for patients with advanced or metastatic solid tumors.

Additional Information

The person responsible for arranging the release of this information on behalf of the Company is Charles Sermon, General Counsel of Mereo.

Forward-Looking Statements

This Announcement contains "forward-looking statements." All statements other than statements of historical fact contained in this Announcement are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements usually relate to future events and anticipated revenues, earnings, cash flows or other aspects of our operations or operating results. Forward-looking statements are often identified by the words "believe," "expect," "anticipate," "plan," "intend," "foresee," "should," "would," "could," "may," "estimate," "outlook" and similar expressions, including the negative thereof. The absence of these words, however, does not mean that the statements are not forward-looking. These forward-looking statements are based on the Company's current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

All of the Company's forward-looking statements involve known and unknown risks and uncertainties (some of which are significant or beyond its control) and assumptions that could cause actual results to differ materially from the Company's historical experience and its present expectations or projections. The foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in its Annual Report on Form 20-F, Reports on Form 6-K and other documents filed from

time to time by the Company with the United States Securities and Exchange Commission (the "SEC") and those described in other documents the Company may publish from time to time should be carefully considered. The Company wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update or revise any of our forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise, except to the extent required by law.

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