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Mereo BioPharma Group plc

("Mereo" or the "Company" or the "Group")

Positive early 6 month data from the open label arm of the phase 2b clinical study in adult patients with Type I, III or IV Osteogenesis Imperfecta treated with the anti-sclerostin antibody, BPS-804 (setrusumab)

Clear and encouraging percentage changes over baseline in trabecular volumetric bone mineral density measured at the radius at an early readout

Expect topline 12 month data from the blinded arms of study to be available in fourth quarter 2019

A call for analysts and investors will take place at 1pm BST / 8am ET

London, May 30, 2019 - Mereo BioPharma Group plc (AIM: MPH, NASDAQ: MREO), a clinical stage biopharmaceutical company focused on rare diseases, today announced encouraging 6 month data from the open label arm of its phase 2b dose-ranging clinical study in adults with Type I, III or IV osteogenesis imperfecta (OI) treated with BPS-804 (setrusumab), the "ASTEROID" Study (ClinicalTrials.gov Identifier: NCT03118570). The primary endpoint of the study is the percentage change over baseline in trabecular volumetric bone mineral density (Tr vBMD) of the radius (the wrist) at 12 months, assessed using High Resolution peripheral Quantitative Computed Tomography (HR-pQCT), with a hierarchial analysis of change over baseline in radius bone strength on Finite Element Analysis (FEA). As announced in October 2018, the phase 2b study has completed patient enrollment with 112 patients, of which 69 have Type I, 29 have Type IV and 14 have Type III OI.

In the open label arm of the study, patients received the highest of the three prospectively defined doses of setrusumab used in the blinded arms of the study. The change over patients' baseline Tr vBMD was assessed at three and six months. Patients of all three major phenotypes were represented in the open label arm.

At the time of the interim data cut-off, 12 patients had Tr vBMD measurements of the radius available at baseline and 3 months and 11 at baseline and 6 months. These patients showed a mean increase of 1.4% over baseline in Tr vBMD at the radius at 3 months and 3.2% increase over baseline at 6 months. Thus increases in Tr vBMD in OI patients in this open label study compare very favourably to the increases seen in Tr vBMD at the radius in osteoporosis patients of approximately 1% at 24 months with alendronate[1] and approximately 1% and approximately 1.5% increases seen in Tr vBMD at the radius in osteoporosis patients at 12 months observed with teraparitide or denosumab, respectively.[2] Given the small sample size, the Company would not expect to see statistical significance and we will therefore perform and report the FEA when we report the 12 month data set in Q4 2019.

Change from baseline at 6 and 12 months for areal bone mineral density (BMD) at the lumbar spine, as measured by dual energy x-ray absorptiometry (DXA), is a secondary endpoint of the phase 2b study. In the open label arm, at the time of the interim data cut-off, there were 12 patients whose areal BMD at the lumbar spine DXA measurements at baseline and six months were available with a mean increase of 3.5% over baseline.

[1] Burghardt et al, JBMR Dec 2010, 2558-2571

[2] Tsai et al JBMR Jan 2015; 39-45

The Company will continue to analyse the results from the patients in the open label arm in the coming weeks and expects to see further increases in the Tr vBMD and BMD at the lumbar spine in the 12 month data.

Of the 112 patients enrolled in the phase 2b study, to date there have been nine discontinuations. At the time of the last Drug Monitoring Committee (DMC) evaluation, 33 patients had been on setrusumab for 12 months and 102 patients had been on setrusumab for more than 6 months. The most frequently reported adverse event (AE) to-date is headache. There have been no drug related cardiovascular serious adverse events (SAEs) or AEs.

The Company continues to expect 12 month headline data from the blinded arms of the study to be available in Q4 2019.

Dr Denise Scots-Knight, Chief Executive Officer of Mereo said:

"The data from this open label arm of our phase 2b study is clear and encouraging and in line with our expectations. With 11 patients, we would not expect to see statistical significance and we believe the improvements in bone mineral density observed across patients with all Osteogenesis Imperfecta subtypes included in the trial, bodes well for a positive outcome from the blinded dose arms of the study and we continue to expect headline data from these to be available in the fourth quarter of 2019."

"Osteogenesis Imperfecta is quite distinct from osteoporosis and is a rare and devastating orphan disease, where there exists a significant need for an effective treatment. We are committed to advancing setrusumab for both adult and paediatric patients with this condition. As we have previously announced, the European Medicines Agency has approved our Pediatric Investigation Plan for setrusumab and the drug candidate is now phase 3 ready, with a registration study design agreed for a pediatric population."

Professor Jay Shapiro, Active Medical Staff Endocrinology Suburban Hospital Bethesda, Maryland and ASTEROID Study chairperson commented:

"The measured improvements in Tr vBMD at the radius and areal BMD at the lumbar spine in adult patients with Osteogensis Imperfecta in this open label arm over three and six months are notable, and I believe may prove clinically meaningful. I look forward to seeing the results from the blinded portion of the phase 2b study at the 12 month primary endpoint."

Associate Professor Bettina Willie, McGill University Faculty of Medicine Department of Pediatric Surgery commented:

"Osteogenesis imperfecta, also known as brittle bone disease is a life-long condition. Adequate therapies, especially those that promote bone gains are lacking for osteogenesis imperfecta, which would be particularly helpful in adults who have reduced bone formation as well as increased bone loss. This is why my research group at McGill University and Shriners Hospitals for Children has been working with Mereo BioPharma to test setrusumab, a novel bone forming therapy. The results so far are promising for the treatment of adults with osteogenesis imperfecta."

About the study

In May 2017, Mereo initiated a phase 2b study with setrusumab for the treatment of OI, with the full enrollment of 112 patients announced in October 2018. The study is a phase 2b dose ranging study in adult patients clinically diagnosed with type I, III or IV OI and a confirmed COL1A1/COL1A2 mutation who have fractured over the previous 5 years. Patients in the trial had not been treated with bisphosphonates in the previous 3 months or other anabolic or anti-resorptive medications in the previous 6 months. The primary endpoint of the study is change from baseline of Bone Mineral Density (BMD) as measured by High Resolution

peripheral Quantitative Computed Tomography (HR-pQCT) with secondary endpoints of BMD using traditional two-dimensional dual-energy X-ray absorptiometry (DXA) measurement together with measurement of serum bone biomarkers. Mereo expects to report the 12-month data on all patients enrolled in the study in Q4 2019, following 12-month treatment with setrusumab.

Mereo's Pediatric Investigation Plan (PIP) has been approved by the European Medicines Agency and a study design has been agreed for a phase 3 registration trial in children, based on a primary endpoint of fracture rate over a 12-month period and will be conducted in approximately 165 children with severe disease aged 5-18 years old.

About BPS-804 (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 has the potential to become a treatment that could reduce fractures and improve patients' quality of life.

About OI

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 patients 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 90.0%) 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 EMA or FDA approved treatments.

About Mereo

Mereo 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 that have substantial preclinical, clinical and manufacturing data packages. Mereo's existing portfolio consists of six clinical-stage product candidates.

- Setrusumab for osteogenesis imperfecta (OI). In October 2018, the Company announced completion of enrollment of 112 adult patients in a Phase 2b dose ranging study with initial data announced in May 2019 and top-line dose ranging data in Q4 2019. A pediatric Phase 3 study design has also been approved by the EMA. BPS-804 has orphan designation in the U.S. and the EU and has been accepted into the PRIME and Adaptive Pathways in EU;
- Alvelestat for alpha-1 antitrypsin deficiency (AATD). The Company recently announced dosing of the first patient in a Phase 2 dose ranging study in the U.S. with data expected around the end of 2019;
- Acumapimod for severe exacerbations of COPD. The Company announced positive Phase 2 data from a 270 patient study in May 2018 and recently announced the outline of the pivotal Phase 3 study including the primary and key secondary endpoints following the successful end of Phase 2 Type B meeting with the FDA;
- Leflutrozole for hypogonadotropic hypogonadism (HH). The Company announced positive top-line Phase 2b data from a 260 patient study in March 2018 and positive results from the Phase 2b safety extension study in December 2018;
- Navicixizumab has completed a Phase 1a single-agent clinical trial in patients with advanced solid tumors and is currently in a Phase 1b trial in combination with a standard paclitaxel regimen in patients with platinum-resistant ovarian cancer. This study recently completed enrollment; and
- Etigilimab has completed a single-agent Phase 1a trial in patients with advanced or metastatic solid tumors and is currently in the safety monitoring period for a Phase 1b combination study with nivolumab. Etigilimab is part of OncoMed's prior collaboration with Celgene. Celgene has the option

to obtain an exclusive licence to develop and commercialize the product. If Celgene exercises such option, OncoMed (now a wholly-owned indirect subsidiary of Mereo) will be eligible to receive a $35 million opt in payment.

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The live webcast and a replay may be accessed by visiting the Company's website at https://www.mereobiopharma.com/news-and-events/events-and-conferences/.

Alternatively, to listen to the live conference call, please see dial-in details below:

(866) 688-2942 (U.S.)
08000288438 (UK)
(561) 569-9224 (International)

Conference ID number: 5599316

Please dial in approximately 10 minutes prior to the call.