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**Mereo BioPharma Group plc**  
*(“Mereo” or the “Company” or the “Group”)*

**Business Update**

*Continued clinical development progress across all programmes*

**London, 13 December 2017** – Mereo BioPharma Group plc (AIM: MPH), a multi-asset biopharmaceutical company focused on the acquisition, development and commercialisation of innovative therapies that aim to improve outcomes for patients with rare and specialty diseases, today provides an update on its clinical development pipeline in addition to a general corporate update. The Company also announces that it intends to publish preliminary results for its financial year ending December 31, 2017 by the end of March 2018.

**Highlights**

- Reported positive top-line data from BCT-197 (acute exacerbations of chronic obstructive pulmonary disease) Phase 2 study, with primary endpoint met; BCT-197 also demonstrated statistically significant reduction in number of rehospitalisations in high dose group and was reported to be safe and well tolerated in both high and low dose regimens
- Completed enrolment of BGS-649 (Hypogonadotropic Hypogonadism in obese men) Phase 2b study and on track to deliver top-line data in Q1 2018
- BPS-804 (osteogenesis imperfecta) granted EMA PRIME designation
  - Phase 2b trial in adult patients ongoing; following discussions with the regulators measurement of primary endpoint for the HRpQCT analysis changed from six to 12 months
  - Paediatric Investigational Plan has been submitted to the EMA based on a potential 12-month fracture endpoint and Phase 2b/3 study expected to start in 2018
- AZD-9668 (alpha-1 antitrypsin deficiency) licensed from AstraZeneca, transition progressing according to plan and Phase 2 study expected to start in 2018
- Balance sheet remains strong:
  - Unaudited cash and short term deposit balances of £46.8 million as at November 30, 2017
  - Second and final £10m (gross) tranche of £20m credit facility agreed with Silicon Valley Bank and Kreos Capital in August 2017 expected to be drawn down prior to end of 2017
- Continue to evaluate additional opportunities to expand portfolio especially in rare diseases

**Dr Denise Scots-Knight, Chief Executive Officer of Mereo BioPharma Group plc commented:**

*“We have continued to make strong progress on our diversified product candidate pipeline throughout the year. This has culminated in the recent release of positive headline results from the Phase 2 clinical study of BCT-197 in acute exacerbations of COPD and the recently announced license of AZD-9668. We look forward to delivering the top-line Phase 2b clinical data for BGS-649 in hypogonadotropic hypogonadism in Q1 2018 and to initiating the Phase 2b/3 paediatric study for our orphan product candidate BPS-804 in osteogenesis imperfecta and the Phase 2 proof of concept study for AZD-9668 for the treatment of alpha-1 antitrypsin deficiency.”*

## Pipeline update

### *BCT-197 (Acumapimod) for acute exacerbations of COPD (AECOPD)*

On December 11, 2017 the Company announced positive top-line data from the AETHER study, a Phase 2 double-blind, randomised, placebo-controlled trial investigating the use of BCT-197, a novel, orally active p38 MAP kinase inhibitor, on top of Standard of Care, for the treatment of patients with AECOPD. The primary endpoint was met on an ITT basis for both BCT-197 high and low dose regimens ( $p=0.012$ ,  $p \leq 0.001$ ) with no significant change from baseline ( $p=0.102$ ) shown for Standard of Care plus placebo. One of the study objectives was the comparison between all three groups. This was not statistically significant; however, the treatment arms were numerically superior to the Standard of Care plus placebo arm. Positive clinical and health economic outcomes were supported by other secondary measures; specifically, the study showed a statistically significant reduction of more than 50% ( $p \leq 0.027$  to  $0.05$ ) in the number of clinical treatment failures in the high dose group compared to Standard of Care plus placebo, as measured by the number of rehospitalisations for the treatment of COPD at days 90 through 150, and there was a trend seen as early as day 30. BCT-197 was reported to be safe and well tolerated in both high and low dose regimens. The Company now intends to seek a partner for future development and, if approved, commercialisation of BCT-197.

### *BGS-649 (leflutrolole) for the treatment of hypogonadotropic hypogonadism (HH) in obese men*

The Company is on track to announce top-line data in Q1 2018 from the randomised, placebo-controlled Phase 2b dose-confirmation study with BGS-649 for the treatment of HH in obese men, which successfully completed patient enrolment in September 2017. A total of 271 patients have been enrolled into the six-month study, assessing three different doses versus placebo. The primary endpoint of this study is to demonstrate the efficacy of BGS-649 to normalise total testosterone levels in over 75% of subjects after 24 weeks of treatment. A six-month extension study in up to 120 patients to confirm the safety of long term treatment with BGS-649 is well underway. In March 2017 the Company announced that the Independent Data Monitoring Committee recommended continuation of all the arms of the study based on a blinded interim review of the safety and efficacy of all three doses based on 93 patients who had received at least one month's treatment.

### *BPS-804 (setrusumab) for osteogenesis imperfecta (brittle bone disease, or OI)*

In November 2017, following acceptance into the EMA's adaptive pathways programme, our orphan product candidate BPS-804 was granted EMA PRIME designation for the treatment of OI. The potentially pivotal Phase 2b ASTEROID study with BPS-804 is currently underway in which we intend to enroll approximately 120 adult patients with OI. The primary endpoint is change in trabecular volumetric bone mineral density measured by high resolution peripheral quantitative CT (HRpQCT) and change in bone strength using finite element analysis (FEA). As previously announced, the Company is planning an additional study in paediatric OI patients and has recently submitted its Paediatric Investigation Plan (PIP) for BPS-804 to the Paediatric committee of the European Medicines Agency (PDCO), including an initial Phase 2b/3 potential 12-month fracture study in children 12 to less than 18 years old. As a result of these discussions, the Company has also changed the primary endpoint for the HRpQCT analysis in the ongoing adult clinical study from six months to 12 months.

### *AZD-9668 (alvelestat) for alpha-1 antitrypsin deficiency (AATD)*

In October 2017, the Company announced an exclusive license agreement with AstraZeneca for AZD-9668, an oral inhibitor of neutrophil elastase, with an option to acquire the product candidate following the initiation of pivotal studies. The transfer of the program from AstraZeneca is progressing as planned and Mereo expects to initiate a Phase 2 study for the treatment of severe AATD, a congenital orphan condition, in 2018. This Phase 2 study is expected to be a 12-week randomized, placebo-controlled study that will evaluate two doses of AZD-9668 in approximately 150 patients with the PiZZ and NULL genetic mutations.

These mutations are seen in the more severely affected AATD patients who have very low (PIZZ) or zero (NULL) alpha-1 antitrypsin levels. Following completion of the transaction, AstraZeneca has become a shareholder in Mereo.

## **Corporate update**

### *Strong balance sheet*

The Company's balance sheet remains strong, with sufficient cash resources to fund the key clinical development programmes. As at November 30, 2017, the Company had unaudited cash and short term deposit balances of £46.8 million. The Company has notified Silicon Valley Bank and Kreos Capital of its intention to draw down the £10m (gross) second and final tranche of the £20m credit facility finalised and previously announced in August 2017. This will increase our cash resources and is expected to complete prior to the year end. On drawdown, the Company will issue warrants giving the lenders the right to subscribe for shares representing 11% of the value of the drawn amount which is currently equivalent to approximately 0.5% of the issued share capital of the Company. These warrants, when issued, will be capable of exercise until August 7, 2027.

### *Continued evaluation of new product candidate opportunities*

Mereo is focused on building a leading commercial business in rare and orphan diseases. The Company continues look for opportunities to further expand and diversify its product portfolio and is evaluating a number of innovative clinical stage products for the potential treatment of rare diseases from large pharmaceutical and biotechnology companies.

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## **About Mereo**

Mereo is a multi-asset biopharmaceutical company focused on the acquisition, development and commercialisation of innovative therapeutics that aim to improve outcomes for patients with rare and specialty diseases. The portfolio consists of four clinical-stage product candidates, each of which we acquired from large pharmaceutical companies: BPS-804 for the treatment of osteogenesis imperfecta, or OI; AZD-9668 for the treatment of severe alpha-1 antitrypsin deficiency, or AATD; BGS-649 for the treatment of hypogonadotropic hypogonadism, or HH, in obese men; and BCT-197 for the treatment of acute exacerbations of chronic obstructive pulmonary disease, or AECOPD. Each of the company's product candidates has generated positive clinical data for the target indication or in a related disease. The company's strategy is to selectively acquire product candidates that have already received significant investment from pharmaceutical companies and that have substantial preclinical, clinical and chemistry, manufacturing and controls, or CMC, data packages. Since inception, the company has commenced large, randomized, placebo-controlled Phase 2 clinical trials for three of the product candidates. The company intends to commence additional late-stage clinical trials in 2018.