



## **Biomarker Data from Phase 1b/2 Investigator-sponsored Trial of Mereo's Alvelestat in Bronchiolitis Obliterans Syndrome (BOS) at the ASH Annual Meeting**

**London and Redwood City, Calif., December 13, 2021** - Mereo BioPharma Group plc (NASDAQ: MREO) ("Mereo" or the "Company"), a clinical stage biopharmaceutical company focused on oncology and rare diseases, today announced the presentation of data from the initial seven patients in an investigator-sponsored study of alvelestat in patients with BOS following hematopoietic stem cell transplantation ("HCT"). These data were presented at the 63rd American Society of Hematology (ASH) Annual Meeting in Atlanta, GA by Annie Im, MD, University of Pittsburgh, UPMC Hillman Cancer Center, Pittsburgh, PA.

The Phase 1b/2 study of alvelestat, an oral neutrophil elastase inhibitor (NCT02669251), is being conducted under a Clinical Trial Agreement between Mereo and the National Cancer Institute ("NCI"), part of the National Institutes of Health, led by the Principal Investigator Dr. Steven Pavletic, Immune Deficiency Cellular Therapy Program, Center for Cancer Research, NCI.

Patients received escalating doses of alvelestat over an 8-week period, from 60 mg twice daily to a maximum of 240 mg twice daily, which was tolerated in all patients.

Treatment with alvelestat was associated with improvement in biomarkers of mechanistic efficacy, with ex vivo zymosan stimulated elastase activity showing progressive decrease over the dose escalation period, with some subjects demonstrating 100% suppression. The first evidence of elevated elastase activity in BOS and chronic Graft vs. Host Disease ("GVHD") was demonstrated by the elevation of desmosine/isodesmosine (elastin breakdown fragments) at baseline mean 0.464 (SEM 0.0508) ng/ml, with 6 of 7 subjects above the Upper Limit of Normal (ULN, 0.280 ng/ml). Desmosine/isodesmosine levels progressively declined during the dose escalation period to 0.380 (SEM 0.0419) ng/ml by week 8, representing a mean within subject 16.2% (SEM 6.794) change from baseline. There was also reduction in the collagen synthesis biomarkers PRO-C3 and PRO-C6 following alvelestat treatment which is encouraging for its potential to impact progressive lung fibrosis in BOS. There was consistency of improvement across biomarkers of elastase activity, desmosine/isodesmosine and collagen synthesis in 6 of the 7 treated patients, all of whom had improved or stable lung disease. Six patients had stable disease (2 with an improvement of 9% in FEV1), while 4 had improved symptoms at end of study.

"These data, while early, are highly encouraging as this is the first evidence of elevated elastase activity in patients with BOS and GVHD that can be suppressed by a neutrophil elastase inhibitor," said Dr. Jackie Parkin, Senior Vice President and Therapeutic Head at Mereo. "The potential of alvelestat to impact the progression of lung fibrosis in this patient population is also exciting and warrants further evaluation. We are grateful to Dr. Pavletic and his team at NCI for their work in progressing this study."

BOS is an inflammatory condition that affects the bronchioles, the smallest airways in the lungs. As the disease progresses, the bronchioles may become damaged and inflamed, leading to extensive scarring and blockage of the airways. Allogenic HCT is associated with BOS related morbidity and mortality. BOS following a lung transplant is the leading cause of re-transplantation and mortality.

### **About Mereo BioPharma**

Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for oncology and rare diseases. The Company has developed a portfolio of six clinical stage product candidates. Mereo's lead oncology product candidate, etigilimab (anti-TIGIT), has advanced into an open label Phase 1b/2 basket study evaluating anti-TIGIT in combination with an anti-PD-1 in a range of tumor types including three rare tumors and three gynecological carcinomas, cervical, ovarian, and endometrial carcinomas. The Company's second

oncology product, navicixizumab, for the treatment of late line ovarian cancer, has completed a Phase 1 study and has been partnered with OncXerna Therapeutics, Inc., formerly Oncologie, Inc. The Company has two rare disease product candidates, alvelestat for the treatment of severe Alpha-1 antitrypsin deficiency (AATD) and setrusumab for the treatment of osteogenesis imperfecta (OI). Alvelestat has recently received U.S. Orphan Drug Designation for the treatment of AATD and is being investigated in an ongoing Phase 2 proof-of-concept study in the U.S. and Europe, with top-line data now expected in early Q2 2022. The Company's partner, Ultragenyx Pharmaceutical, Inc., is expected to initiate a pivotal pediatric study for setrusumab in OI before the end of 2021.

### **Forward-Looking Statements**

This press release contains "forward-looking statements." All statements other than statements of historical fact contained in this press release 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 relate to future events, including, but not limited to, statements regarding future clinical development, efficacy, safety and therapeutic potential of clinical product candidates, including expectations as to reporting of data, conduct and timing and potential future clinical activity and milestones and expectations regarding the initiation, design and reporting of data from clinical trials. 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 involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in the "Risk Factors" section of its latest Annual Report on Form 20-F, reports on Form 6-K and other documents furnished or filed from time to time by the Company with the Securities and Exchange Commission. You should not 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 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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