

Mereo BioPharma Announces Positive Desmosine Biomarker Data from an Interim Analysis of an Investigator Initiated Study of alvelestat in Bronchiolitis Obliterans Syndrome (BOS)

London and Redwood City, Calif., June 2, 2021 - Mereo BioPharma Group plc (NASDAQ: MREO) (“Mereo” or the “Company”), a clinical stage biopharmaceutical company focused on oncology and rare diseases, today announced positive data from an interim analysis of an investigator-initiated study of alvelestat in patients with Bronchiolitis Obliterans Syndrome (“BOS”) following hematopoietic stem cell transplantation (“HCT”).

The Phase 1b/2 study, being conducted under a Clinical Trial Agreement between Mereo and the National Cancer Institute, plans to recruit a total of 30 patients. The primary endpoints of the study are to define the safety and the optimal biological dose, based on neutrophil elastase inhibition measured using biomarkers at 8 weeks (Phase 1b, total of 10 patients) and clinical efficacy at 6 months (Phase 2, an additional 20 patients).

Interim data from the first seven patients in this open-label study were presented at the 2020 American Society of Hematology (ASH) Annual Meeting in December 2020. In this phase 1 study, maximum-tolerated dose (MTD) was not reached and alvelestat was well tolerated. Six patients had stable disease, while one patient had progression in the setting of pneumonia. Notably, two patients had improvement in forced expiratory volume in one second (FEV1) of 9%, and four patients experienced improvement in symptoms.

Subsequent analysis of the elastin breakdown biomarker desmosine, has recently been completed. This demonstrated that all six patients with elevated desmosine levels at baseline (pre- treatment) showed a reduction in desmosine the within subject dose escalation period by week 8. A median reduction of 13.9% from baseline was observed at week 8, with a maximum reduction of 52%, supporting an effect of alvelestat to inhibit elastase in this population.

These changes in plasma desmosine, were supported by additional analysis of peripheral blood neutrophil elastase release in response to zymosan stimulation and taken from patients during the study. These showed suppression of elastase release, with a signal of increasing suppression over the dose escalation period. In some patients, there was complete suppression of elastase production, confirming the effect of alvelestat on the target mechanism of human neutrophil elastase inhibition and consistent with the desmosine changes.

“We have demonstrated that neutrophil elastase inhibition is well tolerated and shows a signal of stabilizing disease in patients with advanced BOS,” said Dr. Jackie Parkin, Mereo SVP and Therapeutic Head, “Based on the data from these interim analyses, we believe that further study of the clinical efficacy of alvelestat in BOS after HCT is warranted, especially at an earlier stage of disease and longer duration of drug administration.”

Additional biomarker analyses of the first seven patients are being conducted by Dr. Pavletic and his team, supported by Mereo, and are expected to be presented at ASH 2021. These accumulating data in BOS associated with chronic Graft versus Host Disease following allogeneic HCT and the existing scientific data on the role of neutrophil activation and elastase in lung transplant related BOS, are expected to further inform the clinical development plan for alvelestat in BOS indications.

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. Allogeneic HCT is associated with significant morbidity and mortality and 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 recently 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 a number of gynecological carcinomas including 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), which is being investigated in an ongoing Phase 2 proof-of-concept study in the U.S. and Europe, for which the Company expects to report top line data in late 2021, and setrusumab for the treatment of osteogenesis imperfecta (OI). In September 2020, the FDA granted Rare Pediatric Disease designation to setrusumab for the treatment of OI. In December 2020, the Company signed a license and collaboration agreement for setrusumab in OI with Ultragenyx Pharmaceutical Inc.

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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