UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 or 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2022

Commission File Number: 001-38452

MEREO BIOPHARMA GROUP PLC

(Translation of registrant's name into English)

4th Floor, One Cavendish Place,
London, W1G 0QF, United Kingdom
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Exhibit Index

Exhibits

99.1	Press release dated September 12, 2022 titled "Mereo BioPharma Reports Clinical Update and Interim Biomarker Analysis Presented at ESMO 2022 from ACTIVATE Phase 1b/2 Open Label Study of Etigilimab (Anti-TIGIT Antibody MPH-313) plus Nivolumab (Anti-PD-1 Antibody) in Solid Tumors."

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 12, 2022

MEREO BIOPHARMA GROUP PLC

By: /s/ Charles Sermon
Name: Charles Sermon
Title: General Counsel

Exhibit 99.1

Mereo BioPharma Reports Clinical Update and Interim Biomarker Analysis Presented at ESMO 2022 from ACTIVATE Phase 1b/2 Open Label Study of Etigilimab (Anti-TIGIT Antibody MPH-313) plus Nivolumab (Anti-PD-1 Antibody) in Solid Tumors

Data support further evaluation of PVR, CD226, and TIGIT as potential biomarkers of enrichment for etigilimab plus anti-PD1 therapy

Continued clinical benefit observed with the combination of etigilimab and nivolumab, including in PD-L1 negative or low subjects

London and Mountain View, Calif., Sept. 12, 2022 - Mereo BioPharma Group plc (NASDAQ: MREO) ("Mereo" or the "Company"), a clinical stage biopharmaceutical company focused on rare diseases and oncology, today reported updated clinical data and promising biomarker data from ACTIVATE, a Phase 1b/ 2 study of anti-TIGIT antibody, etigilimab, in combination with nivolumab, in select recurrent advanced / metastatic solid tumors. These biomarker data were presented at a poster session at the 2022 European Society of Medical Oncology (ESMO) Annual Meeting on September 10, 2022.

The multicenter ACTIVATE study is designed to evaluate the efficacy, safety, tolerability, PK, and pharmacodynamics of etigilimab, Mereo's proprietary anti-TIGIT antibody, in combination with a PD-1 inhibitor, nivolumab, with dosing every two weeks. Biomarker analyses were included as exploratory endpoints.

As of September 12, 2022, there were 63 efficacy-evaluable checkpoint inhibitor-naïve (CPI-naive) subjects with a minimum of 1 staging scan at 8 (+/-1) weeks and RECIST 1.1 response assessment or documented clinical progression. Key updates:

Cervical cancer: 3/7 PD-L1 combined positive score CPS>1%, CPI-naïve cervical cancer subjects with confirmed complete responses (cCRs) ORR of 43%, 2 ongoing at >284 days and >142 days, and 1 withdrew consent with ongoing cCR at 163 days. Two additional patients had stable disease (SD) for a DCR rate of 71%. Of interest, biomarker analysis showed that the 2 cervical subjects with complete responses exhibited higher levels of PVR, TIGIT as well as high CD226+CD8+ co-expression. No evaluable tissue for biomarker analysis was available for the third patent with a complete response.

Uveal melanoma: 1/6 evaluable subjects, with confirmed partial response (cPR) at >347 days, ORR 17% and 2 patients were SD, for 175 and 294 days DCR 50%. The subject with cPR was noted to have high CD226+CD8+ co-expression, and was PVR positive and PD-L1 negative (CPS <1%).

Biomarker data presented at ESMO 2022 evaluated tumors for baseline expression of PVR, TIGIT, PD-L1 and CD226 by multiple modalities including validated IHC assays. Consistent with Mereo's previously reported data (Mereo BioPharma webcast, November 30, 2021), high PVR expression was observed in subjects with decreases in target lesions (TL) from baseline and RECIST 1.1 responses. Additional noteworthy responses observed in subjects with cancer types not typically responsive to CPI monotherapy, with tumors that had high PVR expression and were either PD-L1 negative (CPS <1%), or PD-L1 low (CPS≤3%) include, (i) an ovarian PR (-80% target lesion (TL) decrease, ongoing >255 days, PD-L1 negative), (ii) an endometrial PR (-69% TL decrease, ongoing >150 days, MMR proficient, PD-L1 CPS=3%), (iii) a dedifferentiated liposarcoma PR (-80% TL decrease, ongoing cPR >267 days, high TIGIT, PD-L1 CPS=1%), and (iv) a recurrent/metastatic testicular GCT patient with stable, near normalization of elevated tumor marker alpha feto protein (doing well clinically on study >127 days), PD-L1 negative. The presentation at ESMO 2022 demonstrated robust target engagement in patients as evidenced by significant decreases in peripheral T regulatory cells while maintaining circulation levels of CD8 cells. Increases in proliferating T-cells subsets (CD8, CD4), proliferating NK cells, and intracellular cytokines (IFNg, IL2, and TNFα) were observed and sustained longitudinally. Additionally, etigilimab plus nivolumab reduced TPEX cells (CD8+CCR7+PD1+TIGIT+), progenitor cells believed to be committed to an exhausted-like fate. Further data was reported showing reductions in circulating tumor DNA (ctDNA) measured at ~5-6 weeks post-treatment correlated with clinical benefit.

These data support the role of dual checkpoint inhibition of the TIGIT/PVR and PD-(L)-1 pathways and further evaluation of these biomarkers, including PVR and CD226, as a potential enrichment strategy for the treatment of etigilimab plus anti-PD1.

"We are encouraged by the totality of biomarker data from the ACTIVATE study. These data have the potential to provide a roadmap for future clinical studies of etigilimab and nivolumab, including the opportunity to incorporate a patient enrichment strategy, that could help to provide a benefit to patients in need of additional treatment options," said Dr. Ann Kapoun, Senior Vice President Translational Research & Development at Mereo BioPharma.

"We continue to observe evidence of clinical benefit across a range of tumors being evaluated in the ACTIVATE study," said Dr. Suba Krishnan, Senior Vice President Clinical Development, at Mereo BioPharma. "At this time, we have paused the ongoing Phase 1b/2 ACTIVATE trial for further enrollment; 30 patients previously enrolled currently remain on study. The totality of emerging data from ACTIVATE and other trials targeting the TIGIT axis will direct next steps for the etigilimab program."

About Mereo BioPharma

Mereo BioPharma is a biopharmaceutical company focused on the development of innovative therapeutics for rare diseases and in oncology and plans to commercialize selected rare disease programs. The Company has developed a portfolio of six clinical stage product candidates. The Company has two rare disease product candidates, setrusumab for the treatment of osteogenesis imperfecta (OI) and alvelestat for the treatment of severe Alpha-1 antitrypsin deficiency (AATD) and Bronchiolitis Obliterans Syndrome (BOS). The Company's partner, Ultragenyx Pharmaceutical, Inc., has initiated a pivotal Phase 2/3 pediatric study in young adults (5-25 years old) for setrusumab in OI and expects to initiate a study in pediatric patients (2-5 years old) in the second half of 2022. The partnership with Ultragenyx includes potential milestone payments of up to $254 million and royalties to Mereo on Ultragenyx territories. Mereo has retained EU and UK commercial rights and will pay Ultragenyx royalties on those territories. Alvelestat has received U.S. Orphan Drug Designation for the treatment of AATD and positive top-line data were recently reported from a Phase 2 proof-of-concept study in North America, Europe and the UK. Mereo's lead oncology product candidate, etigilimab (anti-TIGIT), is currently in 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 global licensing agreement with OncXerna includes payments of up to $300 million in milestones and royalties.

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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