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## **Mereo BioPharma Announces FDA Clearance to Proceed into a Phase 1b/2 study for Etigilimab (Anti-TIGIT)**

On track to initiate Phase 1b/2 basket study of etigilimab in combination with an anti-PD-1 in a series of tumor types in Q4 2020

Plans to host virtual R&D day to review etigilimab development program and rare disease product pipeline in November 2020

**London and Redwood City, Calif., October 19, 2020** - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH) ("Mereo" or "the Company"), a clinical stage biopharmaceutical company focused on oncology and rare diseases, today announced that the U.S. Food and Drug Administration has cleared an investigational new drug (IND) application to proceed with a Phase 1b/2 study for the Company's lead oncology product candidate etigilimab. Etigilimab is a novel IgG1 monoclonal antibody against TIGIT (T-cell immunoreceptor with Ig and ITIM domains), a next generation checkpoint receptor shown to block T-cell activation and the body's natural anti-cancer immune response.

Mereo is on track to initiate the Phase 1b/2 basket study in the fourth quarter of 2020. The study will evaluate etigilimab in combination with an anti-PD-1 initially in approximately 100 patients with a defined series of tumor types, including biomarker enriched and rare tumor cohorts. The study will incorporate flat dosing (for patients 50 kg and higher) which is based on data from Mereo's previous Phase 1a and Phase 1b combination studies with etigilimab.

Dr. John Lewicki, Chief Scientific Officer of Mereo, said: "Recent clinical data regarding anti-TIGIT therapies in combination with PDL-1/PD-1 inhibition have been promising. We designed etigilimab as a novel IgG1 which blocks TIGIT signalling while retaining an intact effector function and we believe our development approach is differentiated. We have selected the tumor types for our planned Phase 1b/2 basket combination study based on biomarker screening of large collections of different tumor samples and correlating these with suboptimal responses to anti- PDL-1/PD-1. We've also included tumor types where we saw evidence of activity in our previous Phase 1a/1b study. We look forward to initiating the study this quarter and providing additional details during our planned virtual R&D day."

In November 2020, Mereo plans to host a virtual R&D day featuring external experts to review the etigilimab development program, including the design and biomarker strategy of the Phase 1b/2 basket combination study. Mereo also plans to provide an overview of its rare disease product pipeline. Further information including the date/time of the virtual R&D day will be announced in the coming weeks.

### **About Etigilimab**

Etigilimab is an antibody against TIGIT (T-cell immunoreceptor with Ig and ITIM domains). TIGIT is a next generation checkpoint receptor shown to block T-cell activation and the body's natural anti-cancer immune response. Etigilimab is an IgG1 monoclonal antibody which binds to the human TIGIT receptor on immune cells with a goal of improving the activation and effectiveness of T-cell and NK cell anti-tumor activity. Mereo completed a Phase 1a dose escalation clinical trial with etigilimab in patients with advanced solid tumors and enrolled patients in a Phase 1b study in combination with nivolumab in selected tumor types.

23 patients were treated in the Phase 1a dose escalation study with doses up to 20 mg/kg Q2W. Tumor types included colorectal cancer, endometrial cancer, pancreatic cancer and other tumors. No dose limiting toxicities were observed. In the Phase 1b combination study, a total of ten patients, nine of

whom had progressed on prior anti-PD-1/PD-L1 therapies were enrolled at doses of 3, 10, and 20 mg/kg. Eight patients were evaluable for tumor growth assessment, and all of these patients had progressed on PD-1/PD-L1 therapies with best responses including one patient with a partial response another with stable disease. These patients remained on study for up to 224 days. No dose limiting toxicities (DLTs) were observed and the most common related adverse events included fatigue, rash, and pruritis.

Mereo plans to initiate a Phase 1b/2 study of etigilimab in combination with an anti-PD-1 in a series of tumor types in Q4 2020.

#### **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. Mereo's lead oncology product candidate, etigilimab (Anti-TIGIT), has completed a Phase 1a dose escalation clinical trial in patients with advanced solid tumors and has been evaluated in a Phase 1b study in combination with nivolumab in select tumor types. Mereo's rare disease product portfolio consists of setrusumab, which has completed a Phase 2b dose-ranging study in adults with osteogenesis imperfecta (OI), as well as alvelestat, which is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency (AATD) and in a Phase 1b/2 clinical trial in COVID-19 respiratory disease.

#### **Additional Information**

The person responsible for arranging the release of this information on behalf of the Company is Charles Sermon, General Counsel.

#### **Forward-Looking Statements**

This Announcement contains "forward-looking statements." All statements other than statements of historical fact contained in this Announcement are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended and Section 21E of the United States Securities Exchange Act of 1934, as amended. Forward-looking statements usually relate to future events and anticipated revenues, earnings, cash flows or other aspects of our operations or operating results. 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 business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

All of the Company's forward-looking statements involve known and unknown risks and uncertainties some of which are significant or beyond its control and involve assumptions that could cause actual results to differ materially from the Company's historical experience and its present expectations or projections. These forward-looking statements are subject to risks and uncertainties, including, among other things, those described in the Company's latest Annual Report on Form 20-F, Reports on Form 6-K and other documents filed from time to time by the Company with the United States Securities and Exchange Commission. The Company wishes to caution investors not to 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, whether as a result of new information, future events or otherwise, except to the extent required by law.

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