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Mereo BioPharma Group plc
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# Mereo BioPharma Receives FDA Fast Track Designation for Navicixizumab for the Treatment of Heavily Pretreated Ovarian Cancer

**London and Redwood City, Calif., October 7, 2019** - Mereo BioPharma Group plc (NASDAQ: MREO, AIM: MPH), "Mereo" or the "Company" or the "Group," a clinical stage biopharmaceutical company focused on rare diseases, today announces that the U.S. Food and Drug Administration ("FDA") has granted Fast Track designation to navicixizumab for the treatment of high grade ovarian, primary peritoneal or fallopian tube cancer in patients who have received at least 3 prior therapies and/or prior bevacizumab. Navicixizumab is an anti-DLL4/VEGF bispecific antibody and one of two product candidates Mereo acquired through its April 2019 merger with OncoMed Pharmaceuticals, Inc.

"We are pleased that the FDA continues to recognize the potential of navicixizumab to become a viable new treatment option for patients with platinum-resistant ovarian cancer who failed multiple other therapies," said Jill Henrich, Senior Vice President of Regulatory Affairs at Mereo BioPharma. "This designation follows our successful Type B End of Phase 1 meeting with the FDA held in July 2019 regarding a potential pathway for accelerated approval for navicixizumab where the FDA agreed in principle on an outline for a Phase 2 clinical trial that could potentially support accelerated approval of navicixizumab in patients with ovarian cancer who have become resistant to prior therapies."

Navicixizumab has completed a Phase 1a monotherapy study in patients with various types of refractory solid tumors and is currently being evaluated in an ongoing Phase 1b study in combination with paclitaxel in patients with advanced heavily pretreated ovarian cancer. In line with the Company's strategy, a range of strategic partnering discussions have been initiated to provide additional funding for the navicixizumab program.

**About FDA Fast Track Designation**
Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Fast Track designation enables a sponsor to engage in more frequent communications with the FDA throughout the entire development process and also provides eligibility for Priority Review and a rolling Biologics Licence Application ("BLA") submission.

**About Navicixizumab**
Navicixizumab is an anti-DLL4/VEGF bispecific antibody designed to inhibit both Delta-like ligand 4 ("DLL4") in the Notch cancer stem cell pathway as well as vascular endothelial growth factor ("VEGF") and thereby induce potent anti-tumor responses while mitigating certain angiogenic-related toxicities. In preclinical studies, navicixizumab demonstrated robust in vivo anti-tumor efficacy across a range of solid tumor xenografts, including colon, ovarian, lung and pancreatic cancers, among others. In a Phase 1a study with single-agent navicixizumab, 19 of 66 patients with various types of refractory solid tumors had tumor shrinkage following treatment with navicixizumab. Notably, 3 of the 12 (25%) ovarian cancer patients treated in the trial achieved an unconfirmed partial response with single-agent navicixizumab therapy.

A Phase 1b dose escalation and expansion study of navicixizumab plus paclitaxel has completed enrollment of 44 platinum resistant ovarian cancer patients who had failed >2 prior therapies and/or received prior bevacizumab. As of the last interim data analysis at the end of Q1 2019, the unconfirmed response rate was 41%. The unconfirmed ORR for bevacizumab-naïve patients was 64% and 30% for bevacizumab pre-treated patients. The median PFS for all patients was 7.3 months. The most common related adverse events of any grade were hypertension (68%), fatigue (46%), headache (25%), neutropenia (21%), diarrhea (18%), pulmonary hypertension (14%), dyspnea (14%) and peripheral edema (14%). Other related adverse events of special interest were one Grade 1 related heart failure, one Grade 3 and one Grade 4 related thrombocytopenia, and one Grade 4 related gastrointestinal perforation.

**About Mereo BioPharma**
Mereo BioPharma is a biopharmaceutical company focused on the development and commercialization of innovative therapeutics that aim to improve outcomes for patients with rare diseases. Mereo's strategy is to selectively acquire product candidates for rare diseases that have already received significant investment from pharmaceutical and large biotechnology companies and that have substantial preclinical, clinical and manufacturing data packages. Mereo's lead rare disease product candidate, setrusumab, is being developed for the treatment of osteogenesis imperfecta ("OI") with topline 12-month results from a Phase 2b dose ranging study expected in Q4 2019. Mereo's second lead product candidate, alvelestat, is being investigated in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency ("AATD") with topline data expected in mid-2020.

Mereo's broader pipeline consists of four additional clinical-stage product candidates; acumapimod for the treatment of acute exacerbations of chronic obstructive pulmonary disease ("AECOPD"), leflutrozole for the treatment of hypogonadotropic hypogonadism ("HH") in obese men, navicixizumab for the treatment of platinum-resistant ovarian cancer, and etigilimab for patients with advanced or metastatic solid tumors.

**Further Enquiries**

**Mereo** **+44 (0)333 023 7300**
Denise Scots-Knight, Chief Executive Officer
Richard Jones, Chief Financial Officer

**Cantor Fitzgerald Europe (Nominated Adviser and Broker to Mereo)** **+44 (0)20 7894 7000**
Phil Davies
Will Goode

**Burns McClellan (US Public Relations Adviser to Mereo)**
Lisa Burns **+01 (0) 212 213 0006**
Steve Klass

**FTI Consulting (UK Public Relations Adviser to Mereo)**
Simon Conway
Brett Pollard **+44 (0)20 3727 1000**
Ciara Martin



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