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Mereo BioPharma Announces Initiation of Placebo-Controlled Phase 1b/2 Clinical Trial with Alvelestat in COVID-19 Respiratory Disease

London and Redwood City, Calif., August 25, 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 the initiation of a Phase 1b/2 placebo-controlled clinical trial to evaluate the safety and efficacy of alvelestat in hospitalized, adult patients with moderate to severe COVID-19 respiratory disease. Alvelestat is a novel, oral small molecule designed to inhibit neutrophil elastase (NE), a key enzyme involved in the destruction of lung tissue. Alvelestat is already being investigated by Mereo in a Phase 2 proof-of-concept clinical trial in patients with alpha-1 antitrypsin deficiency ("AATD").

Acute Lung Injury (ALI) is a manifestation of systemic inflammation in the lungs that can result from SARS-CoV-2 infection. Neutrophil extracellular traps (NETs), involving the enzyme neutrophil elastase (NE), may contribute to the pathogenesis of ALI via cytokine and neutrophil activation. NET formation (NETosis) also plays an important role in arterial and venous thrombosis, which have been shown to be common complications of COVID-19. By inhibiting NE, alvelestat demonstrated efficacy in preclinical models of treating ALI driven by NETosis[1].

"As we learn more about COVID-19 from data now accumulated from patients worldwide, there is a rationale for blocking NE and therefore the use of alvelestat as a potential treatment for patients hospitalized with acute lung injury associated with COVID-19," said Dr. J. Michael Wells, Assistant Professor in Medicine at the University of Alabama at Birmingham. "NE is the key enzyme involved in NET formation, degrading intracellular proteins and triggering the release of fibres studded with inflammatory and tissue damaging enzymes. Inhibiting NE with alvelestat could target the disease to prevent NETs and also once NETosis is underway. By way of this unique mechanism of action, I believe alvelestat may have the potential to help address the needs of patients with moderate to severe COVID-19 respiratory disease."

The Phase 1b/2 trial is a randomized, double-blind, placebo-controlled study to assess the safety and efficacy of alvelestat in adult patients hospitalized with moderate to severe COVID-19 respiratory disease not yet receiving mechanical ventilation. The trial is led by Dr. J. Michael Wells and will be conducted at the University of Alabama. Approximately 15 patients will be randomized (2:1) to receive either alvelestat plus standard of care or placebo plus standard of care for 10 days. The primary endpoint of the trial is safety and tolerability of alvelestat at day 10, with a safety follow up to day 90. Additional endpoints include blood biomarkers (NETosis, inflammation and hypercoagulation) and oxygen deficit (as measured by the ratio of oxygen saturation to the fraction of inspired oxygen, SaO2/FiO2) at day 10. The trial will also assess clinical outcomes, including effect on disease progression measured by need for respiratory support and disease severity using the WHO 9-point ordinal scale at day 29.

"We believe alvelestat may have the potential to become an important therapeutic option for COVID-19-associated respiratory disease," said Dr. Jackie Parkin, Head of the Alvelestat Program at Mereo. "We look forward to working closely with our colleagues at the University of Alabama to investigate alvelestat in this patient population and to complete this study as rapidly as possible to help with the ongoing effort to solve the global COVID-19 crisis."

About Alvelestat
Alvelestat (MPH-966) is a novel, oral small molecule designed to inhibit neutrophil elastase (NE), a neutrophil protease, which is a key enzyme involved in the destruction of lung tissue. Mereo is conducting a Phase 2 proof-of-concept clinical trial with alvelestat for the treatment of severe alpha-1 antitrypsin deficiency ("AATD"), a potentially life-threatening, rare, genetic condition caused by a lack of effective alpha-1 antitrypsin ("AAT"), a protein that protects the lungs from enzymatic degradation. This degradation leads to severe debilitating diseases, including early-onset pulmonary emphysema, a disease that irreversibly destroys the tissues that support lung function. By inhibiting NE, Mereo believes alvelestat has the potential to protect AATD patients from further lung damage. Investigator-sponsored studies with alvelestat are also underway in AATD and in bronchiolitis obliterans syndrome (BOS).

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").

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 assumptions that could cause actual results to differ materially from the Company's historical experience and its present expectations or projections. The foregoing factors and the other risks and uncertainties that affect the Company's business, including those described in its 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 you 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 of our 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.

[1] Li, Haitao et al. "Neutrophil extracellular traps contribute to the pathogenesis of acid-aspiration-induced ALI/ARDS." Oncotarget vol. 9,2 1772-1784. 28 Nov. 2017, doi:10.18632/oncotarget.22744

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