Mereo BioPharma Group plc
(“Mereo” or “Mereo BioPharma” or the “Company” or the “Group”)

Mereo BioPharma announces agreement with AstraZeneca AB (“AstraZeneca”) for an exclusive license and option to acquire AZD9668

Highlights

- Potential novel oral therapy for the orphan disease alpha-1 antitrypsin deficiency
- Substantive and supportive clinical data package available from studies in linked respiratory diseases; c.1,000 patients have been treated with the drug with positive data on safety, tolerance and efficacy
- Initial upfront consideration and planned Phase II study to be funded from the Company’s existing resources
- AstraZeneca to become a shareholder in Mereo

London, 30 October 2017 – Mereo BioPharma Group plc (AIM: MPH), a clinical stage, UK-based, biopharmaceutical company focused on rare and specialty diseases, today announces that it has reached an agreement with AstraZeneca for an exclusive license, including an option to acquire, AZD9668, an oral inhibitor of neutrophil elastase. Under the exclusive license the Company plans to conduct a Phase II study for the treatment of alpha-1 antitrypsin deficiency (“AATD”), a congenital orphan condition. The Company has the right to exercise its option to acquire AZD9668 after the initiation of pivotal studies.

Denise Scots-Knight, CEO of Mereo BioPharma Group plc commented:

“We are delighted to have closed this agreement with AstraZeneca for AZD9668 in furtherance of our stated strategy of building a portfolio of products focussed on rare and speciality diseases. We believe that this neutrophil elastase inhibitor has potential as an effective, orally available treatment for alpha-1 antitrypsin deficiency, an untreated orphan condition that results in progressive lung destruction. The structure of this license and option agreement allows us to complete the Phase II study with our existing resources before triggering additional payments to acquire the asset outright.”

“AstraZeneca has generated a substantial clinical data package on AZD9668 which includes extensive Phase II studies in several respiratory conditions that will inform the initial Phase II clinical study we are planning for AATD. We believe that the neutrophil elastase inhibitor AZD9668 could provide a new innovative approach for the treatment of AATD, which affects approximately 100,000 patients in the US and 120,000 patients in Europe.”

“As part of this agreement, we also welcome AstraZeneca as another large pharma shareholder in the Company, alongside Novartis.”

Kumar Srinivasan, Vice President of Scientific Partnering & Alliances at AstraZeneca added:
“This transaction reaffirms AstraZeneca’s commitment to patients by re-positioning an asset into an orphan indication with a high unmet need. We will continue to divest or out-license deprioritized assets where we believe it will help accelerate the development of new medicines.”

Professor Sandy Sandhaus MD, PhD, FCCP said:

“Alpha-1 antitrypsin deficiency is a debilitating disease with limited treatment options. Available data to date suggests AZD9668 may be effective in treating this condition. I welcome Mereo’s clinical development programme that will evaluate its potential in this setting.”

Robert A. (Sandy) Sandhaus, MD, PhD, FCCP is Professor of Medicine at National Jewish Health in Denver CO and a leading expert in the treatment of AATD. He is also the Medical Director at AlphaNet, a patient advocacy organisation for patients with AATD, and Clinical Director of the Alpha-1 Foundation that promotes research and development of new therapies for the treatment of AATD.

A conference call for analysts will be held today at 1pm GMT see below for details.

Outline of deal terms

Mereo has acquired the license and option to acquire AZD9668 for an initial upfront payment totalling USD $5 million, in a combination of USD $3 million in cash and the issue of 490,798 new ordinary shares in the capital of the Company (“New Ordinary Shares”) to satisfy the balance of the upfront payment.

Additional deferred payments in cash and in new ordinary shares would be payable on certain milestones based on completion and success of the proof of concept study in AATD and upon the initiation of a potentially pivotal study in this indication.

Additional global filing and approval milestones are payable following successful pivotal data. Under the agreement, following product launch, if approved, the Company will pay AstraZeneca commercial milestones, sales-related payments and royalties, each in line with rates for analogous licensing deals for drugs at this stage of development.

The cash element of the upfront payment for the option purchase and the initial Phase II study will be funded from the Company’s existing financial resources.

Application will be made for the New Ordinary Shares to be admitted to trading on the AIM market operated by the London Stock Exchange and admission is expected to become effective and dealings in the New Ordinary Shares on the London Stock Exchange are expected to commence on or around 3 November 2017. The New Ordinary Shares, when issued, will rank pari passu with the existing ordinary shares in the capital of the Company.

Following the issue of the New Ordinary Shares, which is expected to take place later today, the total number of shares in issue will be 71,094,974 ordinary shares, each with voting rights. Therefore, the total number of voting rights in the Company with effect from such date will be 71,094,974. This figure may be used from such date by shareholders in the Company as the denominator for the calculations by which they will determine if they are required to notify their interest, or a change to their interest, in the Company under the Financial Conduct Authority’s Disclosure Guidance and Transparency Rules.

About AATD

AATD is a genetic disorder that affects approximately 100,000 patients in the United States and 120,000 patients in Europe [rarediseases.org/rare-diseases/alpha-1-antitrypsin-deficiency]. It can cause severe debilitating conditions such as chronic liver disease but, most notably, pulmonary emphysema, which is a
life-threatening disease. Pulmonary emphysema results in irreversible destruction of the tissues supporting the function of the lungs and causing severe shortness of breath and wheeze. Patients typically present between the ages of 20 and 50 and have both a significantly reduced quality of life and a reduced life expectancy.

The lung damage in AATD results from loss of the normal protective effect of alpha-1 antitrypsin against the damaging enzymes released during inflammation, specifically neutrophil elastase.

Current standard of care for AATD varies from country to country. Protein replacement therapy, involving weekly infusions of plasma-derived alpha 1 antitrypsin is approved but is only reimbursed in the United States and some European countries. By suppressing neutrophil elastase through a more easily administered oral treatment, Mereo believes AZD9668 has significant differentiation from the current protein replacement therapy.

AstraZeneca has conducted a number of Phase I and Phase II clinical studies with AZD9668 in respiratory conditions that share some common pathology with AATD, specifically chronic obstructive pulmonary disease ("COPD"), cystic fibrosis and bronchiectasis. Approximately 1,000 patients have been treated with the drug in clinical studies to date. These studies have shown AZD9668 to be safe and well-tolerated. They have also generated signals of efficacy in lung function and biomarker data that are consistent with an elastase-mediated mechanism of action.

Mereo intends to initiate a Phase II study in AATD in 2018. This Phase II study is expected to be a 12-week randomized, placebo controlled, study that will evaluate two doses of AZD9668 in approximately 150 patients with the PiZZ and NULL genetic mutations. These mutations are seen in the more severely affected patients who have very low (PiZZ) or zero (NULL) alpha-1 antitrypsin levels. Mereo expects to leverage the internal expertise and respiratory disease key opinion leader network that it has assembled for the development of acumapimod to develop AZD9668.

Analyst conference call

A conference call for analysts will be held today at 1pm GMT. To participate please dial:

United Kingdom: +44 3333000804
United States: +1 6319131422
PIN: 33714203#
About Mereo
Mereo BioPharma is an innovative biopharma company established to address the R&D and financial challenges faced by an increasing number of large pharma and biotech companies. Mereo focuses on developing and optimizing the value of novel medicines acquired from large pharma and biotech designed to address significant unmet medical needs in rare and specialty disease areas.

Mereo is comprised of a strong team with broad operational capabilities and the financial resources to conduct comprehensive clinical studies. The Company plans to build a rare and orphan commercial business combined with plans to partner where appropriate.

Mereo’s existing portfolio consists of three mid-late stage clinical assets that were acquired from Novartis in July 2015 each with proof of concept data in the indication that Mereo is now developing. BPS-804 is being developed for the prevention of fractures resulting from osteogenesis imperfecta (brittle bone disease); acumapimod (BCT-197), is being developed to treat inflammation in patients with an AECOPD; and BGS-649 is a once-weekly oral novel therapy that restores the patient’s own testosterone in men with hypogonadotropic hypogonadism.

In H1 2016 the Company initiated a Phase 2 study with acumapimod and a Phase 2b study with BGS-649. Mereo recently announced commencement of the first potentially pivotal Phase 2b trial for BPS-804 and completion of enrolment of both the acumapimod Phase 2 study and the BGS-649 Phase 2b study. The acquisition of AZD9668 is in furtherance of the Company’s objective to build a portfolio of additional rare and specialty products acquired from large pharmaceutical and biotechnology companies. The Company continues to actively evaluate other opportunities with this product profile.