BERGENBIO ANNOUNCES FIRST PATIENT DOSED WITH BEMCENTINIB IN RELAPSED MALIGNANT PLEURAL MESOTHELIOMA INVESTIGATOR SPONSORED PHASE IIA STUDY

Bergen, Norway, 7 October 2020 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that the first patient has been dosed and continues on therapy in a trial assessing bemcentinib in relapsed malignant mesothelioma patients, sponsored by the University of Leicester.

With the support of the British Lung Foundation, which has provided £2.5 million in funding, the University of Leicester is leading the development of the world's first molecularly stratified umbrella study in mesothelioma named Mesothelioma Stratified Therapy (MiST). The goal of MiST is to enable the acceleration of novel, effective personalised therapy as a basis for improving survival outcomes for patients with mesothelioma. The current study assessing bemcentinib, MiST3, is a part of this umbrella study and is an all-comers arm, with no requirement for molecular markers for eligibility.

MiST3 is a two-stage, single-arm Phase IIa clinical trial of bemcentinib and pembrolizumab for the treatment of relapsed malignant pleural mesothelioma patients. The study will enroll up to 26 patients at three sites in the United Kingdom. The primary endpoint of this trial is disease control rate at 12 weeks, with an analysis of complete or partial responses in patients. Other endpoints include safety and toxicity, objective response rate, and disease control rate at 24 weeks for bemcentinib in combination with pembrolizumab.

More information about the trial can be found here.

AXL is over-expressed in many solid tumours, including malignant pleural mesothelioma (MPM). Within mesothelioma, AXL expression has been shown in 74% of tissue samples analysed[1]. AXL has also been implicated in epithelial-to-mesenchymal transition (EMT), which promotes metastasis and the ability of cells to migrate through extracellular matrix and intravasate into blood vessels[2]. A strong association between EMT status and an inflammatory tumour micro-environment with an elevation of multiple targetable immune checkpoint molecules has been previously shown[3]. Bemcentinib has been shown to enhance the efficacy of checkpoint inhibitors, such as pembrolizumab, in preclinical cancer models and in patients with lung cancer (SITC 2019). Key effects of bemcentinib in this setting include activation of innate immunity in the tumour microenvironment, leading to activation of adaptive anti tumour T cell responses.

Professor Gavin Murphy, Director of the Leicester Clinical Trials Unit, commented:

"*Leicester Clinical Trials Unit are delighted to announce the opening and recruitment of the first participant to this important Phase IIa study. The collaboration includes the British Lung Foundation, BerGenBio, University of Leicester Professors Anne Thomas and Professor Dean Fennell and Dr. Matthew Krebs from The Christie, Manchester, and represents the culmination of three years' work. The ultimate output of this study will be the potential to provide benefit to the MPM population.*"

Richard Godfrey, Chief Executive Officer of BerGenBio, commented:

"We congratulate Professor Anne Thomas, Dr. Matthew Krebs and Professor Dean Fennel on the start of this novel clinical study. We believe this trial can provide an opportunity to potentially prolong the duration of response with a combination of bemcentinib and pembrolizumab to patients who currently have no standard option of care. With the UK having the highest global incidence of MPM, several patients are likely to benefit from this trial recruiting in Manchester, Leicester, and Newcastle. Data obtained from this trial will not only benefit the UK population but also benefit the MPM population globally as a result of the continued use of asbestos in the developing world."

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About BerGenBio ASA

BerGenBio is a clinical-stage biopharmaceutical company focused on developing transformative drugs targeting AXL as a potential cornerstone of therapy for aggressive diseases, including immune-evasive and therapy resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad Phase II oncology clinical development programme focused on combination and single agent therapy in lung cancer, leukaemia and COVID-19. A first-in-class functional blocking anti-AXL antibody, tilvestamab, is undergoing Phase I clinical testing. In parallel, BerGenBio is developing companion diagnostic tests to identify those patient populations most likely to benefit from bemcentinib or tilvestamab: this is expected to facilitate more efficient registration trials and support a precision medicine-based commercialisation strategy. For further information, please visit: www.bergenbio.com

About Investigator-Sponsored Trials

Investigator-sponsored clinical trials are clinical trials proposed by front-line patient-facing physicians who act as the regulatory sponsor and are supported by industry in bespoke clinical development partnerships. The industry partner does not assume the role of sponsor according to European or US regulatory guidelines but may offer support in a variety of different ways, such as providing investigational medicinal product at no cost and providing additional financial support as required.

About Malignant Pleural Mesothelioma

Malignant pleural mesothelioma (MPM) is a cancer that develops in the lungs. The cause of pleural mesothelioma is exposure to asbestos fibres, which are inhaled into the lungs. It usually takes from 20 to 50 years for mesothelioma to develop after a person's first exposure to asbestos. Because of this latency period, the disease usually affects people older than 75. (www.asbestos.com) In the UK, 65,000 people are expected to die by 2050 (after 2001), making mesothelioma one of the few predicted cancer epidemics. The average life expectancy for pleural mesothelioma is often less than 18 months.

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Forward looking statements

This announcement may contain forward-looking statements, which as such are not historical facts, but are based upon various assumptions, many of which are based, in turn, upon further assumptions. These assumptions are inherently subject to significant known and unknown risks, uncertainties, and other important factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this announcement by such forward-looking statements

This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.

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