



# **BERGENBIO COMPLETES ENROLMENT INTO LATEST COHORT OF PHASE II BEMCENTINIB COMBINATION STUDY IN REFRACTORY NSCLC**

**Bergen, Norway, 12 March 2021** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, is pleased to announce that it has completed enrolment into Cohort C1 of its Phase II study (BGBC008) of bemcentinib in combination with anti-PD-1 therapy Keytruda® (pembrolizumab) in refractory non-small cell lung cancer (NSCLC) patients.

The BGBC008 trial ClinicalTrials.gov Identifier: NCT03184571 is being conducted in three cohorts evaluating the safety and benefit of bemcentinib and pembrolizumab combination in refractory NSCLC patients. Cohort C is assessing second line patients refractory to first line treatment with checkpoint inhibitors in combination with chemotherapy. A total of 13 patients have been enrolled in Cohort C1 and the first efficacy data is expected within 24 weeks. If successful the trial will expand to Cohort C2, assessing a further 29 patients.

The study is being sponsored by BerGenBio in collaboration with MSD, a tradename of Merck & Co., Inc., Kenilworth, New Jersey, USA, who continue to supply Keytruda® (pembrolizumab) for use in the study, under a collaboration agreement signed in March 2017.

**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** "We are pleased to have completed enrolment into the first stage of the third cohort planned for this study. We are excited by the potential patient benefit of selective AXL inhibition with bemcentinib, to reverse acquired resistance to immune checkpoint inhibitors in cAXL-positive patients who have relapsed on immunotherapy and chemotherapy. There are currently limited treatment options for patients for whom first line therapies in NSCLC have been ineffective. If successful, this combination treatment could provide an important alternative to second line chemotherapy standard-of-care. I look forward to providing an update on the data from this cohort in due course."

**-End-**

## **About AXL**

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases.

In COVID-19, AXL has two synergistic mechanisms of action, it acts a co-receptor to ACE2, to which the spike protein of the SARS-CoV-2 virus attaches and enters the host cell, and AXL expression is upregulated that leads to suppression of the Type 1 Interferon immune response by host cells and in their environment. Research data

confirms bemcentinib inhibits SARS-CoV-2 host cell entry and promotes the anti-viral Type I interferon response.

In cancer, increase in AXL expression has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers. AXL suppresses the body's immune response to tumours and drives treatment failure across many cancers. High AXL expression defines a very poor prognosis subgroup in most cancers. AXL inhibitors, such as bemcentinib, therefore, have potential high value as monotherapy and as the cornerstone of cancer combination therapy, addressing significant unmet medical needs and multiple high-value market opportunities.

Research has also shown that AXL mediates other aggressive diseases including fibrosis.

### **About Bemcentinib**

Bemcentinib (formerly known as BGB324), is a potential first-in-class, potent and highly selective AXL inhibitor, currently in a broad phase II clinical development programme. It is administered as an oral capsule and taken once per day. Ongoing clinical trials are investigating bemcentinib in COVID-19, and multiple solid and haematological tumours, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent. Bemcentinib targets and binds to the intracellular catalytic kinase domain of AXL receptor tyrosine kinase and inhibits its activity.

### **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, therapy resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme focused on combination and single agent therapy in 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 a companion diagnostic test to identify patient populations most likely to benefit from AXL inhibition: this is expected to facilitate more efficient registration trials supporting a precision medicine-based commercialisation strategy.

BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK. The company is listed on the Oslo Stock Exchange (ticker: BGBIO). For more information, visit [www.bergenbio.com](http://www.bergenbio.com)

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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.

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