BERGENBIO COMPLETES RECRUITMENT OF PHASE II AML STUDY (BGBC003)

Bergen, Norway, 7 September 2021 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical needs, is pleased to announce the completion of patient recruitment into BGBC003 (ClinicalTrials.gov ID: NCT02488408), a Phase Ib/II multicenter open-label study of bemcentinib as a single agent and in combination with cytarabine or decitabine in patients with Acute Myeloid Leukemia (AML) or as a single agent in patients with myelodysplastic syndrome (MDS).

BerGenBio has recruited a total of 86 patients in cohort B, with between 14 and 18 patients in each of the cohorts B1-B4 and 20 patients in cohort B5, as per protocol.

In June 2021, the latest study data was published at the European Haematology Association (EHA) Meeting, which indicated that the combination of bemcentinib and low dose cytarabine (LDAC) is efficacious and well tolerated in relapsed elderly AML patients unfit for intensive chemotherapy, with an overall response rate of 31% (5/16) and median overall survival of 13.3 months. The encouraging preliminary survival data reported showed that the addition of bemcentinib more than doubled the historic survival rates seen with standard of care treatment in this patient population.

An in-depth translational research program to identify predictive molecular and biological factors associated with response is ongoing.

Dialogue continues with the regulatory agencies in the US and Europe to align on a pathway for a pivotal registration trial for the bemcentinib/LDAC combination in relapsed elderly AML patients unfit for intensive chemotherapy.

Rune Skeie, Interim Chief Executive Officer, said: *"We are pleased to have completed enrolment of the BGBC003 study and now look forward to delivering our full analysis of the data from this important trial. There is a significant unmet need for an effective therapy for relapsed elderly AML patients unfit for intensive chemotherapy, for whom there are currently few treatment options available. With encouraging data shown so far, we will continue dialogue with the regulators towards progressing bemcentinib in this indication."*

Prof. Dr. Sonja Loges, Chief Investigator of the trial, commented: *"We have been very encouraged by the positive responses observed so far in relapsed AML patients with many patients remaining on bemcentinib for extended durations. With the trial fully recruited, we hope that data gathered will prove useful in the continued exploration of bemcentinib's potential efficacy in AML, as well as helping us identify predictive biomarkers that may help identify patients most likely to benefit from this approach."*

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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 in infected organs with an activation of the signalling pathway leading to suppression of the Type 1 Interferon immune response by infected cells and neighbouring cells, in their environment. Pre-clinical research studies demonstrate that bemcentinib inhibits SARS-CoV-2 host cell entry and promotes 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

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Forward looking statements

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