



BERGENBIO CLOSES RECRUITMENT INTO TRIAL ASSESSING BEMCENTINIB IN COVID-19 PATIENTS

Bergen, Norway, 4th 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 it has closed recruitment into the company sponsored randomised Phase II clinical trial (BGBC020), assessing the efficacy and safety of bemcentinib for the treatment of hospitalised COVID-19 patients in South Africa and India.

A total of 114 out of the target 120 hospitalised COVID-19 patients have been recruited across five sites in South Africa and seven sites in India. 56 patients received bemcentinib (as monotherapy or in combination with standard of care medication) and 58 patients in a control group (receiving standard of care treatment only). The trial protocol permits co-administration with other medicines recommended for treatment of COVID-19, including remdesivir and dexamethasone. The integrity and statistical power of the data remains intact and top line clinical results are expected to read out around the end of Q1 2021.

The primary endpoint of the trial is time to clinical improvement of at least two points (from randomisation) on the WHO nine-point ordinal scale, or live discharge from the hospital, whichever comes first. Key secondary endpoints include viral load, clinical markers of disease progression and survival rate.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"The incidence of COVID-19 has fallen significantly in South Africa, so we have taken the decision to close the study for recruitment in a timely fashion, this allows us to analyse the data without loss of quality and maintain our momentum in the development of bemcentinib as a potential treatment for COVID-19. We aim to share initial data as soon as possible around the end of this quarter and remain hopeful that bemcentinib can play a role in treating COVID-19 patients and complement the global vaccination programmes."*

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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 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 suppresses 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.