

DATA MONITORING COMMITTEE RECOMMENDS CONTINUATION OF BERGENBIO'S BGBC020 TRIAL ASSESSING BEMCENTINIB IN COVID-19 PATIENTS

Bergen, Norway, 11th January 2021 – BerGenBio ASA (OSE:BGBO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, provides an update on the Company sponsored 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, following a meeting of the trial's independent Data Monitoring Committee (iDMC).

The iDMC, formed from a group of independent infectious disease clinical experts external to the study, has recommended that the trial should continue as planned with no changes, as no safety concerns were raised from the available data. The iDMC will continue to assess the safety data and critical efficacy endpoints of the trial, as it progresses.

The Phase II BGBC020 study will recruit 120 hospitalised COVID-19 patients across five sites in South Africa and seven sites in India. 60 patients will receive bemcentinib (as monotherapy or in combination with standard of care treatment) and 60 patients in a control group (receiving standard of care treatment only).

The primary endpoint of the trial will be time to clinical improvement of at least two points (from randomisation) on a nine-point ordinal scale, or live discharge from the hospital, whichever comes first. The trial protocol will permit co-administration with other medicines recommended for treatment of COVID-19, including remdesivir and dexamethasone.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"We continue to have confidence in the favourable safety profile of bemcentinib, and are pleased that the iDMC has recommended the continuation of the BGBC020 trial. We look forward to recording further data. We are hopeful that bemcentinib can play a role in the global effort to find an effective treatment option for hospitalised COVID-19 patients, particularly as we continue to see an increase in incidence of the virus in many areas of the world."*

– END –

About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases. In cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. AXL expression defines a very poor prognosis subgroup in most cancers. AXL inhibitors, therefore, have potential high value at the centre 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.

About Bemcentinib

Bemcentinib (formerly known as BGB324), is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in 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. Increase in AXL function has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers.

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 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 patient populations most likely to benefit from bemcentinib: 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: BGBO). For more information, visit www.bergenbio.com

Contacts

Richard Godfrey CEO, BerGenBio ASA
+47 917 86 304

Rune Skeie, CFO, BerGenBio ASA
rune.skeie@bergenbio.com
+47 917 86 513

International Media Relations

Mary-Jane Elliott, Chris Welsh, Lucy Featherstone, Carina Jurs

Consilium Strategic Communications
bergenbio@consilium-comms.com
+44 20 3709 5700

Media Relations in Norway

Jan Petter Stiff, Crux Advisers

stiff@crux.no
+47 995 13 891

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.