

BERGENBIO CONFIRMS FIRST PATIENT ENROLLED IN PHASE II TRIAL ASSESSING BEMCENTINIB AS A POTENTIAL TREATMENT FOR COVID-19 IN INDIA

Bergen, Norway – 24th November 2020: BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, today announces that the first patient in India has been enrolled in the company sponsored Phase II clinical trial (BGBC020), assessing the efficacy and safety of bemcentinib for the treatment of hospitalised COVID-19 patients.

The Phase II study will recruit 120 hospitalised COVID-19 patients across seven sites in India and five in South Africa. 60 patients will receive bemcentinib (as monotherapy or in combination with standard of care medication) 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. A Data Monitoring Committee (DMC) formed of a group of independent experts external to the study has been established. The DMC will assess the progress, safety data and, critical efficacy endpoints of the trial as it proceeds.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *“We are pleased to expand the BGBC020 study to patients in India, where incidences of COVID-19 remain high, following the commencement of dosing in South Africa in October. There are still no approved therapies for patients hospitalised as a result of COVID-19 infection and we are keen to continue exploring the profile of bemcentinib as a potential treatment.”*

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About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying many 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: BGBIO). For more information, visit www.bergenbio.com

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Forward looking statements

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