BERGENBIO RECEIVES APPROVAL TO COMMENCE PHASE II TRIAL OF BEMCENTINIB FOR COVID-19 IN SOUTH AFRICA

Bergen, Norway, 11 September 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that it has received regulatory approval from the South African Health Products Regulatory Authority (SAHPRA) to proceed with a company sponsored Phase II clinical trial to assess the efficacy and safety of bemcentinib for the treatment of COVID-19 in hospitalised patients.

The study will enrol 120 hospitalised COVID-19 patients. 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), across five sites in South Africa, with the first patients due to be treated imminently, pending clearance by the Norwegian Regional Ethics Committee.

The primary endpoint of the trial will be time to clinical improvement of at least two points (from randomisation) on a nine-point category 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.

BerGenBio also confirms it is in late stage set-up phase to expand the study to include additional hospital sites in India, and expects to be in a position to update the market in the near future.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"Preclinical data shows that bemcentinib holds great potential for the treatment of COVID-19. Based on our experience in the ACCORD study there is no reason for us to believe bemcentinib will not be of benefit to COVID-19 patients; with falling rates of COVID-19 incidence in Europe over recent months, we have moved quickly, shifting our focus in the interests of patients to geographies with a high number of cases in order to address this urgent unmet medical need. With infection rates still high in many countries including South Africa and India, we are reminded there is still no approved treatment or cure for this disease. We expect to dose the first patients in South Africa imminently, and accelerate patient recruitment rapidly with the planned expansion to include patients in India and look forward to providing further updates on our progress."*

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