

# BERGENBIO ANNOUNCES STOPPED RECRUITMENT TO THE BEMCENTINIB ARM IN UK ACCORD COVID PLATFORM TRIAL

**Bergen, Norway, 30 March 2021** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that recruitment to the bemcentinib arm of the Phase two COVID-19 trial platform ACCORD, has been stopped today following review by the Scientific Advisory Committee.

Due to the success of the vaccine roll out and public health measures taken in the UK, COVID-19 case incidence has fallen rapidly, and the decision has been made to halt UK recruitment at 30 patients and a similar number of matched controls, enabling a prompt analysis of results. No safety concerns have been identified.

BerGenBio's company sponsored Phase II trial (BGBC020), assessing the efficacy and safety of bemcentinib for the treatment of COVID-19 in hospitalised patients in South Africa and India, has completed recruitment. Data from the ACCORD study and BerGenBio's Phase II COVID-19 trial study will be analysed separately and in combination in a meta-analysis to inform next steps for this potential new treatment.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "We are grateful to the University of Southampton and the ACCORD clinical trial platform for evaluating bemcentinib in hospitalised COVID-19 patients in the UK, the cohort of 30 patients taking bemcentinib and matched controls will complement our data sets for our similar study conducted in South Africa and India. We look forward to closely reviewing the data generated from this trial, as well as from our own study. We believe bemcentinib has great promise as a treatment for COVID-19 complimentary to the ongoing global mass vaccination programs".

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### **About ACCORD**

The ACcelerating COVID-19 Research & Development (ACCORD) is a clinical trial platform sponsored by Southampton University Hospital and is being funded by the UK Research and Innovation (UKRI) with modest financial contribution by BerGenBio and the other drug candidate contributing companies, to test potential drugs through early stage clinical trials and feed them for consideration into the UK's large-scale COVID-19 studies such as the RECOVERY trial (<a href="https://www.nihr.ac.uk/urgent-public-health-research-studies-for-covid-19/randomised-evaluation-of-covid-19-therapy-recovery/24513">https://www.nihr.ac.uk/urgent-public-health-research-studies-for-covid-19/randomised-evaluation-of-covid-19-therapy-recovery/24513</a>).

### **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 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 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 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 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 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 <a href="https://www.bergenbio.com">www.bergenbio.com</a>

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