ACCORD CLINICAL STUDY ASSESSING BEMCENTINIB IN COVID-19 PATIENTS TO RECOMMENCE IN UK

Bergen, Norway, 28 September 2020 - BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for unmet medical need, notes that following a rise in the number of COVID-19 cases in the UK, UK Research and Innovation (UKRI) has decided to reinstate funding for the COVID-19 ACCORD clinical study in which BerGenBio's bemcentinib is the lead drug candidate to be tested.

The University Hospital Southampton NHS Trust remains the study sponsor, however the trial will be managed by the Medicines Evaluation Unit at Manchester University. Three drug candidates will be evaluated in the trial, it is anticipated that up to 25 UK sites in the ACCORD study will recruit patients into the trial and that patient recruitment will recommence within weeks.

The ACCORD study is a multicentre, seamless, Phase II adaptive randomisation platform trial to assess the efficacy and safety of multiple candidate agents, the first of which is bemcentinib, for the treatment of COVID-19 in hospitalised UK NHS patients. Funding for the study was suspended by UKRI in July due to the falling number of hospitalised COVID-19 patients across UK trial sites.

BerGenBio will make a modest financial contribution to the cost for the study and provide bemcentinib drug material. 60 hospitalised COVID-19 patients will receive bemcentinib and 60 patients in a control group will receive standard of care treatment. The trial protocol will permit enrolled patients with COVID-19, who meet the inclusion criteria for the study, to potentially receive bemcentinib plus one or both of the two recently recommended treatments for COVID-19: dexamethasone and remdesivir.

Data will be open source and freely available to enable global knowledge sharing and collaboration. Data previously gathered before the cessation of the trial in July will be included in the analysis.

BerGenBio has also received full regulatory and ethics clearance for its company sponsored Phase II trial (BGBC020) to assess the efficacy and safety of bemcentinib for the treatment of COVID-19 in hospitalised patients in South Africa and dosing is due to commence imminently. The Company is also 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: "In recent weeks COVID-19 infection rates have unfortunately increased rapidly in the UK. With still no approved treatment or cure in place, and the hospitalised patient population now becoming large enough to support the trial, the decision has been taken to reinstate the ACCORD programme to continue investigating the potential of bemcentinib and two other agents as treatments for COVID19 patients. We believe bemcentinib has great promise and welcome the opportunity to recommence participation in the UK trial. We also look forward to continuing our own studies, using a similar protocol, in South Africa and India."

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About ACCORD

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

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

About The Medicines Evaluation Unit (MEU)

The Medicines Evaluation Unit (MEU) is a leading specialist clinical research facility working with the pharmaceutical industry to identify potential new treatments for respiratory disease and conditions such as Asthma, COPD, Cystic Fibrosis, Hypertension, Psoriasis. MEU has an outstanding reputation within the industry for performing high quality clinical research complying with strict clinical trial legislation. MEU has successfully conducted over 360 clinical trials.

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