BERGENBIO ANNOUNCES UPDATE FROM INVESTIGATIONAL PHASE II TRIALS ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

- Day 29 follow-up of last patient enrolled has now occurred in BGBC020 and ACCORD2_002
- Data receipt is ongoing and evaluation of efficacy data is underway
- Exploratory analyses are looking to define subsets of patients with baseline markers indicative of increased disease severity with the potential for greater benefit
- Bemcentinib was well tolerated throughout both studies, in the ACCORD2 study there was a numerically lower number of deaths up to day 29 in the bemcentinib arm (1 of 28 with bemcentinib + standard of care vs 5 of 32 in patients treated with standard of care alone); in BGBC020 it was 2 vs 3 respectively
- More detailed top line data expected to report in May

Bergen, Norway, 19th April 2021 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, provides an update from the Phase II clinical study evaluating the efficacy and safety of bemcentinib in hospitalised COVID-19 patients (BGBC020).

The BGBC020 BerGenBio-sponsored trial completed 96% of its targeted enrolment with a total of 115 patients participating (60 in India and 55 in South Africa, with 58 receiving bemcentinib). In addition, the Investigator sponsored study ACCORD2–002 study stopped recruitment at 50% of the original recruitment target due to a reduction in UK COVID-19 case incidence, and to permit a prompt analysis. Both trials were undertaken with the same study design and clinical endpoints. As such data from the two studies will be analysed separately and in combination in a meta-analysis to inform next steps for this potential new COVID-19 treatment.

Throughout both studies, bemcentinib was well tolerated by patients and no safety signals of concern were reported. At day 29, there was a numerically lower number of deaths reported in the bemcentinib arm of both studies: In ACCORD2, 1 death in 28 patients treated with bemcentinib and SoC versus 5 in 32 patients treated with SoC alone, and 2 vs 3 in BGBC020.

BGBC020 is an investigational phase II study, which enrolled adult patients within a day of admission to hospital with COVID-19, who were not intubated and ventilated (grades 3-5 of the 9-point WHO ordinal scale for clinical improvement[1]). Patients were randomised to receive standard of care or bemcentinib plus standard of care. 81% of the COVID-19 patients were assessed as grade 4 within 24 hours of admission to hospital (requiring oxygen but not ventilatory assistance) according to the WHO ordinal scale; 75% of patients received steroids as part of their standard of care and 50% received remdesivir, this was evenly distributed between the two arms across both studies.

A thorough analysis of the entire patient population and subsets of the population will be undertaken on both the primary and key secondary endpoints. The primary endpoint of the trial is time to clinical improvement of at least two points (from randomisation) on the 9-point WHO ordinal scale, or live discharge from the hospital, whichever comes first. A preliminary analysis shows the primary endpoint is numerically in bemcentinib's favour, although in this small study, in a diverse population and demographic, it did not reach the pre-defined statistical threshold of $p<0.05$. Key secondary endpoints include avoidance of worsening of the WHO scale throughout hospitalisation up to day 29, duration for which patients required oxygen, and changes over time in levels of virus detected in different body fluids.

More detailed top line data expected to report in May and will be followed by preparation for presentation at a scientific conference and publication in a peer-review journal.

Professor Tom Wilkinson, MA Cantab MBBS PhD FRCP FERS, Professor of Respiratory Medicine and Chief Investigator on the ACCORD programme commented: "The COVID-19 pandemic persists as the most serious global health crisis we currently face and there is still an urgent need for safe, convenient and more effective treatment for a broad spectrum of patients. The novel mechanism of action of bemcentinib is independent of the SARS-CoV-2 spike protein and thus would be expected to retain its effect with the emergence of new, potentially vaccine-resistant, strains of the virus. The drug has a good safety profile and holds potential promise at this vital time."**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** "Our phase II studies have been completed in three distinct geographies, with differing demographics and ethnicities and evolving standards of care. Bemcentinib has shown to be generally safe and well-tolerated in hospitalised COVID-19 patients. We look forward to receiving further data and continuing our analysis of the patient populations and datasets, and subsequently discussing these results with the market, regulators, industry and Government partners and KOLs to determine next steps."

[1)] WHO R&D Blueprint novel Coronavirus COVID-19 Therapeutic Trial Synopsis; available at https://www.who.int/blueprint/priority-diseases/key-action/COVID-19_Treatment_Trial_Design_Master_Protocol_synopsis_Final_18022020.pdf; Accessed 18 April, 2021

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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 in infected organs with an activation of the signalling pathway leading to suppression of the Type 1 Interferon immune response by infected cells and neighbouring cells, in their environment. Pre-clinical research studies demonstrate that 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 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 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 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 www.bergenbio.com

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