BERGENBIO PRESENTS ENCOURAGING COMBINED DATA FOR BEMCENTINIB FROM TWO PHASE II COVID-19 STUDIES AT ECCMID

- *Survival 96.6% vs 91.2%*
- *Significantly reduced likelihood (69%) of progression to ventilation in higher severity cohort*
- *Significantly increased likelihood (88%) of shorter time to recovery or discharge in higher severity cohort*
- *Clinical evidence of anti-viral mechanism of action*
- *Preclinical analysis highlights bemcentinib's potential against COVID-19 variants*

Bergen, Norway, 12 July 2021 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, has presented a combined analysis of data from two Phase II studies investigating bemcentinib in hospitalised COVID-19 patients at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID).

Data was presented from the UKRI PhaseII ACCORD2 platform study, sponsored by University Hospital Southampton, UK and BGBC020, BerGenBio's open-label Phase II study conducted in South Africa and India. In total, 179 eligible patients were enrolled across both studies between May 2020 and March 2021, randomly allocated on an open-label basis to treatment with bemcentinib in addition to standard of care (SoC) compared to SoC alone. The two studies shared an identical design, and combined data presented today showed encouraging survival benefit of 96.5% vs 91.2%, with fewer deaths within 29 days of enrolment in bemcentinib treated patients (1 of 30 and 2 of 58, 3.4%) versus SoC (5 of 34 and 3 of 57, 8.8%), respectively.

As previously reported for BGBC020, a post-hoc analysis identified a sub-group of patients with higher disease severity on enrolment within 24 hours of admission to hospital in whom evidence of a treatment benefit with bemcentinib was observed. Patients in the subgroup were receiving oxygen (Grade 4) or non-invasive ventilation (Grade 5) and recorded serum levels of the inflammatory marker C-Reactive Protein (CRP) greater than 30mg/L. This subgroup represents more than 60% of the patients in the combined study population, and the previously reported treatment benefit in this group of patients in India and South Africa is reproduced in analysis of the patients studied in the UK.

Across both studies, evaluation of the primary endpoint of time to recovery or discharge, in this defined patient subgroup with higher baseline disease severity, showed there was a statistically significant greater likelihood of faster time to recovery or hospital discharge with bemcentinib added to SoC, compared to SoC alone; 88% greater than SoC, representing a hazard ratio of 1.88 95% confidence intervals (1.24, - 2.87) log-rank p=0.003 (not adjusted for multiple comparisons).

A 69% lower likelihood of progression of patients to need for any form of increased ventilatory assistance from enrolment, or to death, within 29 days, was also observed

with statistical significance in this higher severity subgroup treated with bemcentinib, compared to SoC alone. A hazard ratio of 0.31 (95% C.I. 0.12, 0.78), log-rank p=0.0088 unadjusted for multiple comparisons was shown. This benefit of bemcentinib on ventilator-free survival was observed in rates of admission to Intensive Care in the UK study; four patients (14%) treated with bemcentinib in addition to SoC, compared to ten (31%) of matched eligible patients treated with SoC alone.

Bemcentinib was well tolerated throughout both studies. An independent data monitoring committee has reviewed each study and concluded there is no evidence of safety concerns from the Phase II evaluation in COVID-19 patients.

In a separate preclinical analysis, bemcentinib's mechanism of action has been shown to be independent of the SARS-CoV-2 spike protein. In vitro analysis of alpha and beta COVID-19 virus variants has shown continued bemcentinib efficacy.

Professor Tom Wilkinson MA Cantab MBBS PhD FRCP FERS, Professor of Respiratory Medicine and Chief Investigator on the ACCORD programme commented: *"This encouraging data demonstrates bemcentinib's novel mechanism of action, which appears to have efficacy independent of the SARS-CoV-2 spike protein, which could be significant with the emergence of new and potentially vaccine resistant variants of the virus. The result of the combined analysis underlines the potential for bemcentinib to treat a substantial portion of hospitalised COVID-19 patients, offering a survival benefit."*

Richard Godfrey, CEO of BerGenBio, commented: *"We are pleased to present these encouraging data at ECCMID. As the data has matured, we can see that bemcentinib offered a survival benefit to patients and we remain confident that bemcentinib could prove a valuable treatment option for patients severely affected by COVID-19 and reduce their need for ventilation for recovery. We'll continue to provide updates as our development activities to treat COVID-19 patients evolve."*

Presentation details

Presenting author: Akil Jackson

Title: Bemcentinib, an oral AXL kinase inhibitor, results in lower mortality compared to standard of care (steroids with or without remdesivir) in hospitalised patients with COVID-19

Session name: LB: Interventions for improving COVID outcome

Session code: S191

Date: 12 July 2021

Recording will be available for registered attendees to the conference from the day after presentation for three months.

-Ends-

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

Contacts

ir@bergenbio.com

Richard Godfrey CEO, BerGenBio ASA

Rune Skeie, CFO, BerGenBio ASA
rune.skeie@bergenbio.com
+47 917 86 513

International Media Relations

Mary-Jane Elliott, Chris Welsh, Lucy Featherstone, Carina Jurs

Consilium Strategic Communications
bergenbio@consilium-comms.com
+44 20 3709 5700

Media Relations in Norway

Jan Petter Stiff, Crux Advisers

stiff@crux.no
+47 995 13 891

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