



BERGENBIO ANNOUNCES TOP LINE DATA FROM PHASE II TRIAL ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

The trial BGBC020 shows that Bemcentinib has the potential to increase the rate of ventilator free survival in more than 50% of hospitalised COVID-19 patients, addressing the greatest challenge faced by hospitals worldwide fighting the pandemic.

- Ventilator Free Survival observed in 90% in bemcentinib treated patients vs 72% in SOC treated patients, in a subgroup of patients with increased disease severity
- *Survival benefit numerically greater in bemcentinib treated patients*
- *Bemcentinib anti-viral mechanism of action supported by analysis*
- *Bemcentinib was well tolerated throughout*
- *BerGenBio continues discussions with international governments and regulators about next steps*
- *BerGenBio will be hosting a webcast at 10.00 CEST today (see details below)*

Bergen, Norway, 18 May 2021 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, provides top line data from BGBC020, a randomised Phase II clinical study evaluating the efficacy and safety of bemcentinib in hospitalised COVID-19 patients.

BGBC020 was conducted from October 2020 across multiple sites in South Africa and India, with 115 patients enrolled at the end of March 2021.

Baseline demographics were balanced between groups; 60 patients enrolled in India, and 55 in South Africa. The median age of enrolled patients was 54.0 years (range 19 - 89y) with 34% of them being female. The vast majority of patients were WHO OCS grade 4 at baseline, 93 of 115 (83%), with 11 enrolled in each of the grade 3 and grade 5 cohorts. The most common co-morbidities were diabetes (27%), cancer (8%), and heart disease (7%).

The patients were randomised to receive standard of care (SOC) only, or bemcentinib with SOC; 76% of patients received steroids and 51% also received remdesivir as part of their therapy. Patients were closely evaluated through 29 days following admission to assess efficacy endpoints, and to 90 days after randomisation to determine longer outcomes.

A post-hoc analysis (not specified in the protocol) identified a sub-group of patients with higher baseline severity (Grade 4 & 5) and C-Reactive Protein (CRP) >30mg/L, representing more than 50% of the patients in the study. This sub-group showed encouraging evidence of stronger treatment effect by bemcentinib across all end points evaluated. C-reactive protein (CRP) is an established biomarker, widely used in clinical practice to detect acute inflammation, rising within the first few hours of the acute phase response. In COVID-19, the rising level of CRP in the bloodstream correlates with increasing disease severity.

Bemcentinib was well tolerated by patients and no safety signals of concern were identified.

Ventilator Free Survival

Ventilator Free Survival is defined as the proportion of patients that survived to day 29 without admission to ICU and the need for ventilator assisted breathing. Patients treated with bemcentinib appeared to be protected from an early deterioration at day 2 or 3, compared to patients treated with SOC, with this effect being maintained through 29 days. In the sub-group of patients with increased disease severity, ventilator free survival was higher (90%) with bemcentinib treatment compared to SOC on its own (72%).

Primary endpoint

The primary endpoint (time to improvement by two WHO grades, from baseline, or time to discharge or fitness for discharge) marginally favoured bemcentinib treatment over SOC, but the difference was not statistically significant. This endpoint is subject to a broad range of subjective factors, including variation in clinician practice, local epidemic case rates, ensuing demand for bed occupancy in hospital, and resource availability. Therefore, this endpoint may not directly measure the individual patient's health, or the benefit from bemcentinib.

Overall Survival

Analysis of overall survival in the BGBC020 study was combined with that of the ACCORD2 study, conducted in the UK with an analogous phase 2 design. The ACCORD2 platform study recommenced enrolment in the UK winter wave of the local epidemic, enrolling patients between December 2020 and March 2021 (30 to the bemcentinib arm in both phases of the study, with 32 eligibility-matched control patients).

Mortality rates in ACCORD2 SOC treated patients were higher than those in BGBC020 at day 29; (5 of 32 patients (16%) in ACCORD2, versus 3 of 57 (5%) in BGBC020).

Overall in the combined studies, survival to day 29 was 96.5% (83 of 86 evaluable patients) in bemcentinib arm versus 91.0% (81 of 89) treated with SOC alone.

Anti-Viral mechanism of action

The evaluation of patients' viral load whilst hospitalised was an exploratory endpoint in the study, with bemcentinib treatment being associated with a shorter apparent time to SARS-CoV2 not being detected in body fluid samples, than in those treated with SOC alone.

Next steps

Full scientific analysis of BGBC020 will be combined with the ACCORD2 data set in a meta-analysis for presentation at a scientific conference and publication in a peer-reviewed journal.

The totality of data clearly informs a benefit from bemcentinib in treating a substantial subset of hospitalised COVID-19 patients. This will support ongoing engagement with regulatory agencies, Government partners and industry.

Professor emeritus Stener Kvinnsland MD PhD, Director of BerGenBio and former Chair of Norwegian Korona Commission commented: *“The greatest challenge faced by hospitals worldwide is an unmanageable demand for ICU capacity and ventilator support for COVID-19 patients. For the foreseeable future, in spite of recent progress with vaccinations, there remains a substantial global need for effective treatments for COVID-19 patients that offers survival benefit and relief for intensive care demand on hospitals. The totality of data for bemcentinib is very encouraging in this respect and warrants further confirmation.”*

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, and there remains 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: *“The potential of bemcentinib to increase the rate of ventilator free survival in more than 50% of hospitalised COVID-19 patients is very encouraging. This represents a meaningful outcome for both patients and healthcare systems and is of potential great value. This was an exploratory real world study completed in several global geographies, with differing demographics and ethnicities and evolving standards of care. Through diligent analysis of all the data collected, the totality of which supports the unique mechanism of action of bemcentinib in potentially treating hospitalised COVID-19 patients, we now have a clear clinical position for bemcentinib in this disease. We will continue our discussion of these results with the regulators, industry and Government partners to determine next steps.”*

Presentation and webcast information

BerGenBio will be hosting a live webcast and Q&A session at 10.00 CEST, 18 May:

Webcast link: https://channel.royalcast.com/hegnarmedia/#!/hegnarmedia/20210518_1

Dial-in numbers:

- NO: +47 2195 6342
- UK: +44 203 769 6819
- US: +1 646 787 0157

PIN: 712491

-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

Richard Godfrey CEO, BerGenBio ASA

ir@bergenbio.com

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

Forward looking statements

This announcement may contain forward-looking statements, which as such are not historical facts, but are based upon various assumptions, many of which are based, in turn, upon further assumptions. These assumptions are inherently subject to significant known and unknown risks, uncertainties, and other important factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this announcement by such forward-looking statements.

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