BERGENBIO PRESENTS ENCOURAGING UPDATED PRELIMINARY DATA FROM PHASE II STUDY IN RELAPSED AML PATIENTS AT EHA VIRTUAL MEETING

Encouraging updated preliminary survival data more than double standard of care reported in relapsed AML patients

Bergen, Norway, 11 June 2021 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, will present updated preliminary survival data from the ongoing Phase II study of bemcentinib (BGBC003) in combination with low dose cytarabine (LDAC) in elderly relapsed Acute Myeloid Leukaemia (AML) patients at the European Haematology Association (EHA) 2021 Virtual Meeting, taking place from 9-17 June 2021.

An update will be provided from an expansion cohort of 27 relapsed/refractory AML patients, who were assessed to explore safety and efficacy together with translational analysis.

The data indicate that the combination of bemcentinib, a once-daily oral AXL-inhibitor and LDAC is efficacious and well tolerated in the elderly and unfit relapsed AML population. Durable responses were observed in the relapsed AML setting, with an overall response rate of 31% (5/16) and median overall survival of 13.3 months, currently still immature and potentially subject to change.

In a subset of eleven relapsed AML patients, who received two or more cycles of the combination, an increased clinical benefit was demonstrated; a CR/CRi rate of 36% (4/11) was observed, coupled with encouraging overall survival to date (median OS not reached at >16 months) with several subjects continuing on the study. In contrast, historic controls of LDAC monotherapy suggest CR/CRi rates of 13-17% with median survival rates of 4.1-5.6 months, as reported by Sarkozy et al. (2015) and Wei et al. (2020).

An in-depth translational research program to identify predictive molecular and biological factors associated with response is ongoing.

Ongoing dialogue continues with the FDA and EMA regulatory agencies to align on a pathway for a pivotal registration trial for the combination of bemcentinib and LDAC in relapsed elderly AML patients unfit for intensive chemotherapy.

Dr. Sonja Loges, Principal Investigator of the trial, commented: ***"****We were impressed to see these positive responses in relapsed AML patients, for whom treatment options are very limited under the current standard of care. Interestingly, the first complete responses were reported at a relatively late stage in the trial, between*

week 13 and 15. These later onset responses could reflect the importance of AXL mechanisms in disease development as well as the potential immune promoting benefits of bemcentinib treatment. Further clinical investigation of this promising combination is therefore warranted."

Richard Godfrey, CEO of BerGenBio, commented: *"We are very encouraged by this promising preliminary response and survival data from the combination of bemcentinib and LDAC in this patient population. Effective treatments with meaningful survival benefit for relapsed AML patients is acknowledged as a critical unmet medical need, this being a significant and rapidly growing patient population as the first line treatment options improve. We continue to work closely with the regulators in Europe and the US to align on the way forward to embark on late-stage pivotal trial of bemcentinib in this combination and patient population."*

The e-poster presentations are now available to watch online for registered attendees here: https://ehaweb.org/congress/eha-congress-2021/program/featured-sessions/.

Details of the e-poster presentation are below.

E-poster Title: THE COMBINATION OF AXL INHIBITOR BEMCENTINIB AND LOW-DOSE CYTARABINE IS WELL TOLERATED AND EFFICACIOUS IN ELDERLY RELAPSED AML PATIENTS: UPDATE FROM THE ONGOING BGBC003 PHASE II TRIAL (NCT02488408)

Abstract Number: EHA-2859

Session: 04. Acute Myeloid Leukaemia – Clinical

Date/Time: Available from 9am CEST on 11 June

-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 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 the anti-viral Type I interferon response. Data from a Phase II in human clinical trial has shown that treatment with AXL inhibitor bemcentinib increased the rate ventilator free survival in hospitalised COVID-19 patients.

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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Forward looking statements

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