BERGENBIO RECEIVES FDA FAST TRACK DESIGNATION FOR BEMCENTINIB / ANTI-PD-(L)1 COMBINATION IN NSCLC

First recognition by a regulator of AXL-positive patients as a target population

Bergen, Norway, 08 June 2021– BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent for the treatment of patients with AXL-positive advanced/metastatic non-small cell lung cancer (NSCLC).

The FDA's decision represents the first recognition by a regulator of AXL-positive patients as a molecular targetable patient population. This designation has been granted for patients without actionable mutations, with disease progression on or after treatment with an anti-PD-(L)-1 agent, with or without chemotherapy as their first line of therapy.

Fast Track designation is intended to facilitate the development and review of drugs used to treat serious conditions and to fill an unmet medical need. It will enable BerGenBio to have more frequent interactions with the FDA throughout the drug development process, so that an approved product can reach the market faster.

The designation also provides Eligibility for Accelerated Approval, enabling approval based on a surrogate clinical endpoint; Priority Review, which allows New Drug Application (NDA) review in six months instead of 10, if relevant criteria are met; and eligibility for Rolling Review, whereby the Company will be able to submit completed sections of its NDA for review by the FDA before complete application is submitted.

BerGenBio has developed proprietary biomarkers and companion diagnostic assays for selection of AXL positive patients, the cAXL assay is validated for clinical trial use. Retrospective analysis of patients in clinical trials suggest approximately 50% of patients are cAXL positive, and it is these patients that achieve the clinical responses and extended survival benefit previously reported.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"Building on our encouraging clinical and translational data, we are excited to receive Fast Track designation from the FDA for the promising combination of bemcentinib in combination with a checkpoint inhibitor. This regulatory milestone is particularly meaningful for BerGenBio, as it represents the first formal recognition by a regulator of AXL-positive patients as a discernible patient population and serves as further validation of our belief that AXL inhibition has high potential as a cornerstone of cancer combination therapy. We look forward to working closely with the FDA on the continued clinical development of the combination."*

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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 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

Composite AXL (cAXL) is a proprietary biomarker developed by BerGenBio that simultaneously scores AXL expression on tumour cells and immune cells in the tumour microenvironment, as determined by Immune Histo Chemistry (IHC) assay. Data from on-going clinical trials suggest ca. 50% of patients are high cAXL and this is predictive of improved clinical outcomes for patients receiving bemcentinib.

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, visitwww.bergenbio.com

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Forward looking statements

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This information is considered to be inside information pursuant to the EU Market Abuse Regulation and is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.