

# PRECLINICAL BEMCENTINIB AND TILVESTAMAB DATA PRESENTED AT EAU 2021

**Bergen, Norway, 10 July 2021** – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that preclinical data from a study investigating the anti-tumor efficacy of BerGenBio's AXL-inhibitors bemcentinib and tilvestamab in renal cell carcinoma (RCC) was presented at the European Association of Urology 2021 virtual congress.

Data from the study, conducted by researchers at the University of Bergen, Department of Clinical Medicine, showed that both bemcentinib and tilvestamab prevented Gas6-induced AXL phosphorylation in vitro and effectively prevented tumour growth in an orthotopic RCC xenograft model in vivo.

Tony J. Chen, Principal Investigator of the study commented: "Our data shows that AXL-inhibitors effectively reduce tumor size in an orthotopic RCC model. Following these encouraging results, we believe AXL-inhibition represents a promising strategy in treatment of RCC and warrants further investigation."

Details of the presentation are as follows:

**Title**: The Successful therapy of experimental, orthotopic renal cell carcinoma with two different types of AXL-inhibiting agents

Date/Time: 10th July at 13-14.00 CET

The presentation can be found at the company website www.bergenbio.com

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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.

# **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 <a href="https://www.bergenbio.com">www.bergenbio.com</a>

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# 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.