



# BERGENBIO PRESENTS DATA FROM PHASE I/II BEMCENTINIB/ERLOTINIB COMBINATION TRIAL IN NSCLC AT ASCO MEETING

**Bergen, Norway, 04 June 2021** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, today presents end-of-trial data from a Phase I/II study of bemcentinib in combination with erlotinib in patients with advanced non-small cell lung cancer (NSCLC) at the American Society of Clinical Oncology (ASCO) Annual Meeting.

## Study Design

Phase I of the study was a dose escalation arm designed to confirm the safety and tolerability of bemcentinib in NSCLC patients as both monotherapy and in combination with erlotinib in patients whose disease had previously progressed on erlotinib alone.

Phase II assessed patients in two groups; those whose disease had progressed on an approved EGFR inhibitor, and those who were responding/stable on erlotinib as a first line treatment. Both groups were treated with bemcentinib and erlotinib to evaluate the safety and activity of the combination, while assessing reversal or prevention of resistance to EGFR inhibition.

## Conclusions

Data from the study found that Bemcentinib in combination with erlotinib was well tolerated over extended periods of time, with the longest ongoing patients having been dosed for over 46 months.

The combination led to disease stabilisation and durable tumour responses in a proportion of patients who had previously progressed on EGFR targeted therapy and who were negative for the T790M resistance mutation. In patients who were responding to first line treatment with erlotinib, either stable disease or partial response, the addition of bemcentinib led to further deepening of responses and prolonged the duration of responses beyond 30 months in 4 out of the 13 patients evaluated. At the time of data cut-off, 2 patients are still participating in the study beyond 34 months of treatment. Ongoing patients at the time of study closure, who wish to continue receiving study treatment, will be offered the drug via an expanded access program.

**Presenting author Lauren Byers, M.D., associate professor of Thoracic/Head and Neck Medical Oncology at the University of Texas MD Anderson Cancer Center, in Houston, said** *"We are encouraged by the responses observed both in patients whose disease was progressing on EGFRi alone, as well as patients already in remission with erlotinib. In particular we were pleased to see durable responses exhibited by a number of patients on the study, with two patients continuing to be dosed with bemcentinib beyond 36 months. This is a good indicator that bemcentinib offers excellent tolerability as well as the potential for anti-tumour activity and we look*

*forward to following their progress as their treatment continues.”*

*Byers reports past advisory board participation for BerGenBio.*

**Richard Godfrey, CEO of BerGenBio** said *“This end of study data shows the potential of bemcentinib as a combination treatment alongside EGFR inhibitors such as erlotinib and osimertinib, which are established treatments and widely used in indications such as NSCLC in patients with the EGFR driver mutation. We believe that further clinical investigation is needed to fully explore this potential, and look forward to discussing our findings further with our colleagues at ASCO.”*

Details of the presentation, also available on the investor section of BerGenBio’s website, are as follows:

**Title:** Ph I/II study of oral selective AXL inhibitor bemcentinib (BGB324) in combination with erlotinib in patients with advanced EGFRm NSCLC: end of trial update

**Session:** Lung Cancer – Non-Small Cell Metastatic

**Abstract ID:** 9110

**Date/Time:** Friday, June 4, 2021 at 9:00 AM (EDT)

**Author:** Byers et al.

**-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 of 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](http://www.bergenbio.com)

## **Contacts**

[ir@bergenbio.com](mailto:ir@bergenbio.com)

Richard Godfrey CEO, BerGenBio ASA

Rune Skeie, CFO, BerGenBio ASA

[rune.skeie@bergenbio.com](mailto: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](mailto:bergenbio@consilium-comms.com)

+44 20 3709 5700

## **Media Relations in Norway**

Jan Petter Stiff, Crux Advisers

[stiff@crux.no](mailto: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.**