BERGENBIO MEETS EFFICACY ENDPOINT FOR FIRST STAGE OF PHASE II TRIAL WITH AXL INHIBITOR BEMCENTINIB IN COMBINATION WITH KEYTRUDA® IN NSCLC PATIENTS PROGRESSING ON IMMUNE CHECKPOINT INHIBITORS

- First stage clinical efficacy endpoint met for the Phase II trial cohort evaluating selective AXL inhibitor bemcentinib in combination with Keytruda® in patients with advanced NSCLC who have failed checkpoint inhibitor therapy.
- Criteria were met for expansion of this cohort to a second stage.

Bergen, Norway, 15 January 2019 – BerGenBio ASA (OSE: BGBIO) a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces meeting the clinical efficacy endpoint of stage 1 of Cohort B in the phase II trial (BGBC008) evaluating bemcentinib in combination with MSD's Keytruda® (pembrolizumab) in previously treated non-small cell lung cancer (NSCLC) patients with confirmed progression on prior immune checkpoint therapy. The trial will advance into the second stage.

The company reports that the Cohort B, stage 1 efficacy analysis has met the confirmed response of one or more patients therefore continuation to stage two evaluation is planned.

The second stage will enroll a further 16 patients to confirm the safety and clinical efficacy of the combination in NSCLC patients that have confirmed progression on prior immune checkpoint therapy.

Comprehensive exploratory biomarker studies of tumor and blood samples are ongoing to measure of AXL expression and immune modulation. Further results from the trial are expected during 2020 and will be presented at appropriate scientific conferences.

The BGBC008 trial (ClinicalTrials.gov Identifier: NCT03184571) is being sponsored by BerGenBio. MSD, a tradename of Merck & Co., Inc., Kenilworth, New Jersey, USA, will continue to supply Keytruda® for use in the study under a collaboration agreement signed in March 2017.

Richard Godfrey, Chief Executive Officer of BerGenBio, said: "Reversing resistance to immune checkpoint inhibitors in patients who have relapsed on immunotherapy is a highly desirable alternative to the second-line chemotherapy standard-of-care. We are very excited with these early results in this challenging setting and look forward to expanding the study to confirm these findings and reporting comprehensive translational insight. Furthermore, Cohort C in NSCLC patients having failed 1L chemo-checkpoint inhibitor combination is now recruiting, and top line data should be available in the coming months."

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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 cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. AXL inhibitors, therefore, have potential high value at the centre 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.

About Bemcentinib

Bemcentinib (formerly known as BGB324), is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in 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. Increase in AXL function has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers.

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, drug resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad Phase II oncology clinical development programme focused on combination and single agent therapy in lung cancer and leukaemia. A first-in-class functional blocking anti-AXL antibody is undergoing Phase I clinical testing. In parallel, BerGenBio is developing a companion diagnostic test to identify those patient populations most likely to benefit from bemcentinib: 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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