BERGENBIO'S BEMCENTINIB MEETS PRIMARY ENDPOINT IN FIRST COHORT OF PHASE 2 NSCLC STUDY IN COMBINATION WITH KEYTRUDA®

- Primary endpoint, Overall Response Rate, has been met in predominantly PD-L1 negative/low patients
- Secondary endpoint, median Progression Free Survival, exceeds expectations in AXL positive patients
- Data to be presented at Society for Immunotherapy of Cancer 34th Annual Meeting on 8 November 2019

Bergen, Norway, 6 November 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces today that the primary endpoint of Overall Response Rate (ORR) has been met in Cohort A of its Phase II clinical trial (BGBC008) evaluating bemcentinib, its first in class selective AXL inhibitor, in combination with the MSD's, (a tradename of Merck & Co., Inc., Kenilworth, NJ., USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab), as a potential new treatment regimen for previously treated advanced non-small cell lung cancer (NSCLC). The primary efficacy endpoint requires that at least 25% evaluable patients achieve a clinical response when treated with the novel drug combination, defined as either complete or partial response, as measured by Response Evaluation Criteria in Solid Tumors (RECIST).

A secondary endpoint of median Progression Free Survival (mPFS) reported significant 3-fold improvement in AXL positive vs negative patients, as defined by BerGenBio's composite AXL tumor-immune score.

These data will be presented during at the Society for Immunotherapy of Cancer in the High Impact Clinical Trials session on Friday 8 November in a presentation entitled: ***A phase II study of bemcentinib (BGB324), a first-in-class selective AXL inhibitor, in combination with pembrolizumab in patients with advanced NSCLC: Updated analysis***.

Professor Hani Gabra MD PhD, Chief Medical Officer of BerGenBio, commented: "I am impressed by these results that clearly demonstrate the durable clinical benefits in this difficult to treat low PD-L1 patient population. Importantly the patients that benefit most match gene signatures that predict poor prognosis and a lack of response to immunotherapy in NSCLC".

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "I am delighted to see continued significant patient benefit from bemcentinib in combination with Keytruda. This is the first of three cohorts where we are evaluating this combination in previously treated lung cancer patients and I look forward to reporting data from these additional cohorts in the coming months."

Presentation details

A phase II study of bemcentinib (BGB324), a first-in-class selective AXL inhibitor, in combination with pembrolizumab in patients with advanced NSCLC: Updated analysis

- Matthew G. Krebs, MD, PhD –*The University of Manchester*
- Concurrent Session 206: High Impact Clinical Trials
- Oral Session
- 08 November 2019: Prince George's Exhibition Hall C, 4:50 – 6:15 p.m. EST

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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. Tumour AXL expression is associated with poor prognosis in NSCLC and most other cancer types. 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, therapy 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 AXL antibody (BGB149) and an AXL-ADC (ADCT-601) are 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). www.bergenbio.com

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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.