BERGENBIO PRESENTS UPDATED PHASE 2 NSCLC CLINICAL AND TRANSLATIONAL DATA FOR BEMCENTINIB IN COMBINATION WITH KEYTRUDA®

- BerGenBio's proprietary Composite AXL Tumor-Immune Score predicts patients that have significantly prolonged clinical benefit
- Primary endpoint of ORR in cohort A met, in predominantly PD-L1 low/negative patients
- Combination is 5-fold more active in composite AXL positive patients (33% ORR) vs AXL negative patients (7% ORR)
- Secondary endpoint, median Progression Free Survival of 8.4 months in composite AXL score positive patients, exceeds expectations, 3-fold longer than for composite AXL negative patients.

Bergen, Norway, 8 November 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, today presents comprehensive clinical and translational data from Cohort A of its Phase II clinical trial (BGBC008) evaluating bemcentinib, its first in class selective AXL inhibitor, in combination with 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) at an oral presentation at the prestigious High Impact Clinical Trial session at the Society for Immunotherapy of Cancer (6-10 November 2019) conference in Washington DC.

In cohort A, 44 patients were evaluable for response; of IHC evaluable patients: 50% were composite AXL positive, 52% were PD-L1 negative (<1%TPS), and 38% patients were PD-L1 low positive (1-49% TPS). The primary endpoint of Overall Response Rate (ORR) was met, with 33% ORR in AXL positive patients; five times the response rate of AXL negative patients (7%).

A secondary endpoint of median Progression Free Survival (mPFS) reported significant 3-fold improvement in AXL positive vs negative patients – 8.4 months in composite AXL positive patients significantly surpassing what has been shown historically in second line treatment with PD-1 inhibitor monotherapy.

Dr. Matthew Krebs, MD, PhD, the lead investigator who will give the presentation at SITC said: "The clinical benefit seen with the drug combination in AXL positive patients is impressive and provides a potential new treatment approach for patients with low or negative PD-L1 status. The mPFS observed for the AXL positive patients is far higher than that seen with pembrolizumab monotherapy results from earlier clinical trials for patients with PD-L1<50%. Furthermore, the combination is well tolerated by patients."

RNA sequence analysis of pretreatment patient biopsies revealed that clinical benefit from the combination therapy correlates with total tumor AXL expression. A proprietary predictive signature for response to bemcentinib and pembrolizumab combination derived from the transcriptional analysis is enriched for genes associated with epithelial-to-mesenchymal transition (EMT) and myeloid cell activation. "This is exactly where we know AXL is important." **added Professor James Lorens PhD, Chief Scientific Officer of BerGenBio**.

The gene expression measured in responding patients correlates with gene signatures known to be associated with poor prognosis and lack of response to immunotherapy. This indicates that previously treated patients are particularly benefiting despite exhibiting these adverse traits. **Professor Hani Gabra MD PhD, Chief Medical Officer of BerGenBio said**: "This indicates that bemcentinib is conditioning the tumor microenvironment in AXL positive patients and optimizing pembrolizumab response in these previously treated patients."

Multispectral immunofluorescence analysis detected tumor infiltrating AXL-expressing macrophages closely adjacent to T cells in the tumors of patients who responded to the combination therapy. “Seeing the AXL expressing macrophages interacting with T regulatory cells in the tumor of a patient who responded to the treatment really underscores the potential.” **added Dr. Krebs**.

Prof. Lorens added: “Previously we only considered AXL expression in the tumor cells, ignoring the immune cell compartment of the tumor. Our deeper biomarker analysis clearly shows that our earlier tumor cell-only score did not fully capture the population of patients who benefit from the combination.” A proprietary composite AXL tumor-immune score has now been developed, derived from gene expression and immunohistochemistry analysis that selects patients likely to benefit from bemcentinib.

Richard Godfrey, Chief Executive Officer of BerGenBio, said: “Our improved ability to select and predict patients with durable clinical benefit with a refined AXL composite biomarker is an important development for our AXL targeting clinical programs. Importantly for patients is the prolonged duration of benefit or mPFS and improved Overall Survival (mOS), which is still maturing, these are also critical regulatory end points. I look forward to reporting mOS and data from 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
- 5:10 – 5:25 p.m. EST (Session runs from 4:50 – 6:15 p.m.)

Presentation will be available at www.bergenbio.com in the section: Investors/Presentations when the presentation starts.

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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

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This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.