

BERGENBIO PRESENTS UPDATES FROM ONGOING PHASE II BEMCENTINIB COMBINATION STUDY IN REFRACTORY NSCLC AT WCLC 2020

- *Bemcentinib in combination with pembrolizumab was well-tolerated and showed promising clinical activity in refractory lung cancer*

Bergen, Norway, 29 January 2021– BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, will today present an update from its Phase II study of bemcentinib in combination with anti-PD-1 therapy pembrolizumab (BGB008) in refractory non-small cell lung cancer (NSCLC) patients at an oral presentation at the 2020 World Conference on Lung Cancer Singapore (WCLC).

The presentation will provide updated data from Cohort B of the study, assessing the safety and efficacy of bemcentinib in combination with anti-PD-1 therapy pembrolizumab, in 16 refractory NSCLC patients previously treated with a PD-L1 or PD-1 checkpoint inhibitor (CPI) as a monotherapy. Recruitment is ongoing in these patient populations.

The primary endpoint of the study is Overall Response Rate, with pre-defined criteria to proceed from the first to second stage in each cohort. Secondary endpoints include Disease Control Rate, Progression Free Survival, Overall Survival and safety.

Interim data from Cohort B showed that the overall response rate among the seven evaluable cAXL positive patients was 14% with a disease control rate of 86% and a 2.5-fold improvement in progression free survival rate in the cAXL positive patients. In the seven cAXL negative patients, all showed clinical progression with 29% of patients demonstrating clinical benefit following treatment. The interim data shows that bemcentinib in combination with pembrolizumab was well-tolerated and shows promising clinical activity in refractory lung cancer. Furthermore, whole tumour gene expression analysis identified an AXL positive gene signature characteristic of an immune suppression mechanism, in patients with acquired (Cohort B) resistance to CPIs.

Dr. Matthew Krebs, who will deliver the presentation at WCLC commented: *“These promising interim data suggest that bemcentinib is well tolerated in these vulnerable patient groups and may reverse acquired resistance to checkpoint inhibition by targeting AXL positive macrophages and regulatory dendritic cells. These findings support further development of AXL inhibition with bemcentinib to extend efficacy of immunotherapy in biomarker-selected refractory NSCLC.”*

The full abstract can be found on the WCLC [website](#), and details of the presentation are below.

Title: A phase II study of the oral selective AXL inhibitor bemcentinib with pembrolizumab in refractory patients with advanced NSCLC

Presenting Author: Dr. Matthew G. Krebs PhD.

Session/Abstract ID: Immunotherapy (Phase II/III Trials) / # 3647

Date/Time: Friday 29th January 2021 at 09.50 Singapore Time / 02.50 CET

The presentation will be available on BerGenBio's website from 29th January 2021.

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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 expression defines a very poor prognosis subgroup in most cancers. 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, 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 companion diagnostic tests to identify 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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