BERGENBIO PRESENTS PHASE II BEMCENTINIB COMBINATION STUDY IN NSCLC AT ANNUAL SITC MEETING

Bergen, Norway, 11 November 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, will today present an updated clinical & translational analysis from its Phase II bemcentinib and pembrolizumab combination study (BGBC008) in advanced non-small cell lung cancer (NSCLC), at an oral presentation at the Society for Immunotherapy of Cancer (SITC) 35th Annual Meeting.

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.

"AXL is implicated in resistance to immunotherapy and this study is based around the hypothesis that blocking AXL signalling represents a novel approach to prevent cancer survival mechanisms and to improve the efficacy of immuno-oncology drugs," **commented Professor James Spicer, PhD, who will give the presentation at SITC.** *"Our findings from this interim analysis suggest that bemcentinib has potential to reverse acquired resistance to checkpoint inhibitors among previously treated NSCLC patients by targeting AXL expressing macrophages and regulatory dendritic cells. These encouraging results support the further development of AXL inhibition as a means to extend the efficacy of immunotherapy in biomarker-selected NSCLC patients."*

The combination of bemcentinib and pembrolizumab was overall shown to be well tolerated and clinically active in CPI-refractory composite AXL (cAXL) positive NSCLC. Of the evaluable patients in Cohort B 58% were cAXL-positive, 25% were PD-L1 negative (<1%TPS), and 42% patients were PD-L1 low positive (1-49% TPS). 86% of cAXL-positive patients achieved clinical benefit (one partial response, five stable disease) while none was observed in cAXL negative patients.

The study demonstrated a median progression-free survival among cAXL positive patients in Cohort B patients of 4.73 months, compared with 1.87 months among cAXL-negative patients.

Full details of the presentation are as follows:

Title: A PhII study of bemcentinib, a first-in-class selective AXL kinase inhibitor, in combination with pembrolizumab in pts with previously-treated advanced NSCLC: Updated clinical & translational analysis

Author: Professor James Spicer, Professor of Experimental Cancer Medicine at King's College London

Session/Abstract ID: Combinatorial Therapies, 362

Date/Time: 11 November 2020, 11.40am EST

The presentation will be made available on BerGenBio's website, under 'Presentations'.

– END –

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

Contacts

Richard Godfrey CEO, BerGenBio ASA
+47 917 86 304

Rune Skeie, CFO, BerGenBio ASA
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
+44 20 3709 5700

Media Relations in Norway

Jan Petter Stiff, Crux Advisers

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.