



BERGENBIO PRESENTS PRE-CLINICAL AND CLINICAL DATA ON BEMCENTINIB IN STK11-POSITIVE NSCLC AT SITC ANNUAL MEETING 2021

Bergen, Norway, 9 November 2021 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL inhibitors for severe unmet medical needs, is pleased to announce that it will deliver an e-poster presentation at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting, taking place online from 10th-14th November 2021.

The e-poster presentation provides pre-clinical and clinical data suggesting that bemcentinib restored response to anti-PD-1 treatments in non-small cell lung cancer (NSCLC) patients harboring STK11 mutations. STK11 is an important tumor suppressor gene reported in some studies to confer immunotherapy resistance in NSCLC. STK11 mutations are present in about 10-20% of NSCLC patients.

In pre-clinical NSCLC mouse models harboring STK11 mutations, sensitivity to PD-1 blockade was evaluated in the absence and presence of bemcentinib. Systemic inhibition of AXL with bemcentinib resulted in the expansion of tumor-associated T cells and restored therapeutic response to anti-PD-1 check point inhibition.

In parallel, data from BerGenBio's Phase II bemcentinib and pembrolizumab combination study (BGBC008) in advanced NSCLC showed that 3 of 3 evaluable patients with identified STK11 mutations demonstrated objective clinical response / clinical benefit to the combination of bemcentinib and pembrolizumab.

Martin Olin, Chief Executive Officer at BerGenBio, commented: "While the data are limited, they suggest a mechanism by which treatment with bemcentinib could restore sensitivity to anti-PD-1 treatment in NSCLC patients harboring STK11 mutations. Up to 20% of the NSCLC patient population has been reported to harbor STK11 mutations representing a large subgroup of NSCLC."

Mutations in the tumor suppressor STK11/LKB1 have in some studies been reported as associated with negative predictive and prognostic impact in NSCLC patients receiving anti-PD-1/PD-L1 treatments. STK11 mutant tumors are characterized by a suppressive tumor micro-environment devoid of cytotoxic T cells. The study hypothesized that targeting the receptor tyrosine kinase AXL, a known driver of an innate immune suppressive microenvironment, would restore sensitivity to PD-1 blockade in pre-clinical models as well as in patients harboring STK11 mutated NSCLC.

Full abstracts are available on the SITC website here:
<https://www.sitcancer.org/2021/home>

Full details of the presentation are below.

Title: *AXL targeting with bemcentinib restores PD-1 blockade sensitivity of STK11/LKB1 mutant NSCLC through innate immune cell mediated expansion of*

TCF1⁺ CD8 T cells

Author: Rolf A. Brekken et al.

Session/Abstract ID: 602

The presentation will be made available on BerGenBio's website, under '[Presentations](#)'.

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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 clinical development programme focused on combination and single agent therapy in cancer 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 potentially identify patient populations most likely to benefit from AXL inhibition. 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

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.

