BERGENBIO ANNOUNCES PUBLICATION IN CELL REPORTS MEDICINE JOURNAL INDICATING EFFICACY OF BEMCENTINIB IN STK11/LKB1 LUNG CANCER POPULATION

The article identifies the key role of AXL inhibition in restoring response to immune checkpoint blockade therapy in lung cancer with mutations in the STK11/LKB1 gene

Bergen, Norway – 17 March 2022 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL inhibitors for severe unmet medical needs, today announces the publication of a peer-reviewed article entitled "AXL targeting restores PD-1 blockade sensitivity of STK11/LKB1 mutant NSCLC through expansion of TCF1$^+$ CD8$^+$ T cells" in the journal *Cell Reports Medicine*.

The article reports on research that identifies AXL as a critical targetable driver of immune suppression in *STK11/LKB1* mutated non-small cell lung cancer (NSCLC). Mutations in *STK11/LKB1* in NSCLC occur in approximately 20% of patients and are associated with poor outcomes and limited response to immune checkpoint blockade, commonly utilized treatments for lung cancer.

This article and its accompanying material are accessible here:
https://www.science.org/doi/10.1126/science.abg5827

The research was led by Professor Rolf A. Brekken, in the Hamon Center for Therapeutic Oncology Research at the UT Southwestern Medical Center. The group introduced a *STK11/LKB1* mutation into a preclinical murine model of lung adenocarcinoma, resulting in immune checkpoint blockade refractory tumors. The group posits that the lack of response occurred because the *STK11/LKB1* mutated tumors lacked a specific population of immune cells (TCF1-expressing CD8$^+$ immune T cells). This immune cell population was also reduced in human NSCLC tumors carrying *STK11/LKB1* mutations.

Systemic inhibition of AXL by the BerGenBio molecule bemcentinib led to increased type I interferon secretion from AXL-expressing dendritic cells, resulting in expansion of the TCF1$^+$ T cell population and restored therapeutic response to immune checkpoint blockade treatment. These results were observed in both an immunocompetent mouse model and in mice bearing human *STK11/LKB1* mutant NSCLC tumors along with a humanized immune system. The paper also summarizes clinical data in NSCLC patients with identified *STK11/LKB1* mutations receiving bemcentinib and immune checkpoint blockage (pembrolizumab), who demonstrated objective clinical response to combination therapy.

In November 2021 BerGenBio announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent as a treatment for patients with STK11/LKB1 altered advanced/metastatic NSCLC patients without actionable mutations.

Martin Olin, Chief Executive Officer of BerGenBio, commented: *"We are pleased to receive this strong preclinical validation of the potential role of bemcentinib to treat STK11/LKB1 mutated NSCLC patients. Data suggests that this significant patient population is underserved by current immune checkpoint blockade therapies, and we hope that the combination with bemcentinib can restore the immune response in these patients. The identification of a new druggable biomarker segment such as the STK11/LKB1 mutations may offer significant hope for improved patient outcomes in combination with the current standard of care therapies. We look forward to initiating a clinical trial this year to advance bemcentinib into development for this patient population."*

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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.