



BerGenBio Announces Initiation of Phase 1b/2a Trial Evaluating Bemcentinib in 1st line Non-Small Cell Lung Cancer Patients Harboring STK11 Mutations

- Study will assess *bemcentinib* in combination with current standard of care for 1st line NSCLC -
- Approximately 20% of NSCLC patients have STK11 mutations -
- First patient is expected to be dosed in 4Q22 -

BERGEN, Norway, October 11, 2022— BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical needs, today announced the initiation of a Phase 1b/2a trial evaluating *bemcentinib* in combination with the current standard of care, checkpoint inhibitor pembrolizumab and doublet chemotherapy, for the treatment of 1st line (1L) Non-Small Cell Lung Cancer (NSCLC) patients harboring STK11 mutations (STK11m).

“Real-world data continues to reinforce that the presence of STK11m currently result in particularly poor outcomes for NSCLC patients,” said Martin Olin, Chief Executive Officer of BerGenBio. “We believe that *bemcentinib*’s proficiency in blocking AXL overexpression may result in the reversal of an immunosuppressive tumor microenvironment leading to activation of immune response, restoration of sensitivity to immune checkpoint therapy and potentiation of chemotherapy effects in this large, underserved patient population.”

Bemcentinib, is a potent, first-in-class highly selective inhibitor of the receptor tyrosine kinase AXL, which is overexpressed in response to cellular stress, inflammation, hypoxia and chemotherapy. STK11 mutations are detected in approximately 20% of non-squamous NSCLC patients and are known to create a more immunosuppressive tumor microenvironment limiting the response to checkpoint inhibition. Preclinical data have demonstrated that by selectively blocking AXL activation, *bemcentinib* restores sensitivity to immune checkpoint inhibitor therapy, enhances chemotherapy, while also, pertinently, driving the expansion of CD8+ T cells in STK11m models. Early clinical data also point to the activity of bemcentinib in NSCLC patients, including those harboring STK11m.

The global, open-label Phase 1b/2a trial is designed to determine the safety, tolerability and efficacy of *bemcentinib* with standard of care in untreated advanced/metastatic non-squamous NSCLC patients with STK11 mutations and no actionable mutations. The Phase 1b portion of the study will evaluate the safety and feasibility of bemcentinib in combination with pembrolizumab and doublet chemotherapy in 1L advanced/metastatic non-squamous NSCLC patients, regardless of STK11 status. The Phase 2a expansion part will assess the efficacy of *bemcentinib* in the same treatment combination in 1L advanced/metastatic non-squamous NSCLC patients with STK11 mutations. The first patient is expected to begin treatment in the fourth quarter of 2022.

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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 cancer and severe respiratory infections. The Company is focused on its proprietary lead candidate, bemcentinib, a potentially first-in-class selective AXL inhibitor in development for STK11 mutated NSCLC and COVID-19.

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.