# BerGenBio Announces Positive Data From Phase 2 Trial of Bemcentinib in Combination with Pembrolizumab in 2L + NSCLC Patients

*- The Company will discuss the topline results during its Q4 2022 results presentation on Thursday, February 16, 2023, at 10:00 AM CET -*

**BERGEN, Norway, February 15, 2023** – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical needs, today announced topline data from BGBC008, a phase 2 trial evaluating its lead compound bemcentinib in combination with MSD's anti-PD-1 therapy pembrolizumab in 2L+ Non-Small Cell Lung Cancer (NSCLC) patients.

***BGBC008 Topline Data***

The open-label, multi-center, single arm, multi-cohort, international phase 2 trial conducted in collaboration with MSD (Merck and Co., Inc. Rahway, NJ, USA), enrolled 90 evaluable patients with disease progression at study entry, who had received at least one prior line of chemotherapy, immunotherapy, or the combination. Enrolled patients received the combination of bemcentinib and pembrolizumab until disease progression as assessed by investigators. Topline results from the total evaluable population:

- A clinically meaningful survival benefit and evidence of disease control was demonstrated with bemcentinib in combination with pembrolizumab regardless of prior therapy, providing a median overall survival (mOS) of 13.0 months (95% CI: 10.1, 16.7), median progression free survival (mPFS) of 6.2 months (95% CI: 4.6, 9.8), disease control rate (DCR) of 51.1% (95% CI: 40.3, 61.8) and overall response rate (ORR) of 11.1% (95% CI: 6.2, 18.1).

- A significant (p-value < 0.05) and clinically meaningful improvement in mOS based on AXL tumor proportion score (TPS) was observed. Patients with AXL TPS > 5 (46% of evaluable patients) achieved a mOS of 14.8 months (95% CI: 12.4, 29.6) compared to patients with AXL TPS $\leq$ 5, who achieved a mOS of 9.9 months (95% CI: 6.7, 17.4). In addition, patients with an AXL TPS > 5 had a mPFS of 8.7 months (95% CI: 6.0, 14.8) compared to 4.6 months (95% CI: 2.7, 8.1) for patients with AXL TPS $\leq$ 5. The ORR for AXL TPS > 5 was 21.9%.

- The observed mOS was similar regardless of patient PD-L1 status.

- Treatment with bemcentinib in combination with pembrolizumab was well-tolerated.

*"We are very encouraged by the topline data"* said Martin Olin, Chief Executive Officer of BerGenBio. *"Treatment with bemcentinib in combination with pembrolizumab demonstrated long survival benefit and sustained disease control, particularly in patients with AXL TPS > 5, substantiating the relevance of AXL as a target and bemcentinib's selective inhibition capabilities in NSCLC. Notably, the survival benefit was observed regardless of PD-L1 status. The data support our ongoing phase 1b/2a trial in 1L STK11m NSCLC patients, of whom approximately 80% have AXL expression. This subgroup of NSCLC represents more than 30,000 patients in the US and five largest European countries, for whom there is currently no effective targeted therapy available."*

James Spicer, PhD, FRCP, Professor of Experimental Cancer Medicine at King's College London and Principal Investigator of the BGBC008 trial, remarked, *"The reported data shows that the combination of bemcentinib and pembrolizumab is well-tolerated in patients with NSCLC, and is particularly active in patients with tumour AXL expression. Other evidence suggests that current therapies are less effective in NSCLC with loss of the tumour suppressor gene STK11, and that AXL inhibition can restore susceptibility. Further investigation is warranted to confirm the role of AXL inhibition in STK11-mutated NSCLC patients, who are under-served by currently available therapeutic options."*

The Company plans to present further details of the BCBG008 trial at an upcoming medical conference.

***First-Line STK11m NSCLC Trial (BGBC016)***

BerGenBio is studying bemcentinib in a global, open-label, phase 1b/2a trial evaluating bemcentinib in combination with the current standard of care of pembrolizumab and platinum doublet chemotherapy, for the treatment of 1L NSCLC patients with mutations in the STK11 gene. More than 30,000 NSCLC patients (US and EU5) harbor STK11 mutations which are associated with poor prognosis with currently available therapies. The Company believes that STK11 mutations create a severely immunosuppressed tumor microenvironment associated with AXL expression and activation, resulting in the development of drug resistance, immune evasion, and metastases.

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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. The Company is focused on advancing its lead candidate, bemcentinib, a potentially first-in-class, oral, selective AXL inhibitor in STK11 mutated NSCLC and severe respiratory infections including 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

## About Bemcentinib

BerGenBio's lead compound, bemcentinib, is a potentially first-in-class, oral, selective inhibitor of the receptor tyrosine kinase AXL, which is expressed and activated in response to oxidative stress, inflammation, hypoxia, and drug treatment, resulting in a number of deleterious effects in cancer and severe respiratory infections. Bemcentinib selectively inhibits AXL activation to prevent the progression of serious diseases through the modulation of resistance mechanisms

and the adaptive immune system.

Bemcentinib is currently being developed in STK11 mutated NSCLC and severe respiratory infections including COVID-19. Its novel mechanisms of action and primary accumulation in the lungs uniquely position it to address these severe lung diseases.

## 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 considered to be inside information pursuant to the EU Market Abuse Regulation and subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.**