BERGENBIO RECEIVES FDA FAST TRACK DESIGNATION FOR BEMCENTINIB IN STK11-MUTATED ADVANCED/METASTATIC NON-SMALL LUNG CANCER (NSCLC)

Bergen, Norway, 9 November 2021 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL inhibitors for severe unmet medical needs, today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent as treatment for patients with STK11 altered advanced/metastatic NSCLC patients without actionable mutations.

Fast Track designation is intended to facilitate the development and review of drugs used to treat serious conditions and to fill an unmet medical need. It will enable BerGenBio to have more frequent interactions with the FDA throughout the drug development process so that an approved product can potentially reach the market faster.

In a separate release today 9 November 2021, BerGenBio announced that 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.

Further, 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/LKB1 mutations demonstrated objective clinical response / clinical benefit to the combination of AXL inhibitor bemcentinib and pembrolizumab.

Martin Olin, Chief Executive Officer of BerGenBio, commented: *"We are very pleased to receive Fast Track designation from the FDA for the second time this year and look forward to continuing to explore bemcentinib's potential as a treatment option for NSCLC patients. It has been reported that patients habouring STK11 mutations represents up to 20% of the total NSCLC patient population, representing a large, identifiable subgroup of patients who may benefit from treatment with an AXL inhibitor such as bemcentinib.*"

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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 a potential companion diagnostic test to 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

About FDA Fast Track

Fast Track designation is intended to facilitate the development and review of drugs used to treat serious conditions and to fill an unmet medical need. The designation provides Eligibility for Accelerated Approval, enabling approval based on a surrogate clinical endpoint; Priority Review, which allows New Drug Application (NDA) review in six months instead of 10, and eligibility for Rolling Review, whereby the Company will be able to submit completed sections of its NDA for review by the FDA before the complete application is submitted.

Contacts

Martin Olin, CEO, BerGenBio ASA
ir@bergenbio.com

Rune Skeie, CFO, BerGenBio ASA
rune.skeie@bergenbio.com

International Media Relations

Mary-Jane Elliott, Chris Welsh, Lucy Featherstone

Consilium Strategic Communications
bergenbio@consilium-comms.com
+44 20 3709 5700

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 is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.