



BERGENBIO ANNOUNCES START OF PHASE 1B TRIAL OF ANTI-AXL ANTIBODY TILVESTAMAB (BGB149)

Bergen, Norway, 5th March 2021– BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces the first patient dosed in an international Phase 1b trial investigating its first-in-class fully humanised anti-AXL monoclonal antibody, tilvestamab (BGB149).

The objective of the study is to confirm safety, tolerability and determine a recommended phase II dose (RP2D) for use in subsequent clinical trials. It is a multiple ascending dose study, that will focus on establishing tilvestamab's safety profile, tolerability and provide an insight into the dose proportional response with respect to its effectiveness at modulating AXL expression, as determined by BerGenBio's proprietary cAXL biomarker diagnostic assay.

The study will be conducted in patients with platinum resistant high-grade serous ovarian cancer, in which AXL is frequently strongly over expressed. The research will be conducted at specialist ovarian cancer centres able to perform serial biopsies in these patients, and thereby providing a comprehensive understanding of how tilvestamab modulates AXL expression in real time during a treatment period.

Richard Godfrey, Chief Executive Officer of BerGenBio, said: "We understand that AXL plays an important role in mediating the aggressive nature of this treatment resistant cancer. From our Phase Ia study with tilvestamab that was completed last year, we have an insight into its safety profile, and a safe starting dose for this first-in-patient study. I am particularly excited that we are able to conduct this state-of-the-art study collecting serial biopsies from patients with a similar disease, which will provide high quality data on how tilvestamab modulates AXL expression. This will inform how we can best use tilvestamab in a future Phase II program.

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About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases.

In COVID-19, AXL has two synergistic mechanisms of action, it acts a co-receptor to ACE2, to which the spike protein of the Sars-Cov-2 virus attaches and enters the host cell, and AXL expression is upregulated that leads to suppression of the Type 1 Interferon immune response by host cells and in their environment. Research data confirms bemcentinib inhibits SARS-CoV-2 host cell entry and promotes the anti-viral Type I interferon response.

In cancer, increase in AXL expression has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers. AXL suppresses the body's immune response to tumours and drives treatment failure across many cancers. High AXL expression defines a very poor prognosis subgroup in most cancers. AXL inhibitors, such as bemcentinib, therefore, have potential high value as monotherapy and as the cornerstone of cancer combination therapy, addressing significant unmet medical needs and multiple high-value market opportunities. Research has also shown that AXL mediates other aggressive diseases including fibrosis.

About tilvestamab

Tilvestamab (BGB149) is a first-in-class, fully humanised, therapeutic anti-AXL function blocking monoclonal antibody, discovered and developed by BerGenBio. A Phase Ia study in healthy volunteers has been completed. Pre-clinical data has shown that tilvestamab prevents AXL mediated cell signalling in cancer models, reduces cell migration and invasion and shows anti-tumour efficacy.

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 lung cancer, leukaemia 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 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

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