

BerGenBio receives regulatory approval to commence phase II trial of bemcentinib for COVID-19 in India

Bergen, Norway, 30 September 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that it has received regulatory approval from the India Regulatory Authority to proceed with a company sponsored Phase II clinical trial to assess the efficacy and safety of bemcentinib for the treatment of COVID-19 in hospitalised patients.

Patient dosing in India is due to commence in the next few weeks and the Company will provide an update in due course.

The study will enrol 120 hospitalised COVID-19 patients. 60 patients will receive bemcentinib (as monotherapy or in combination with standard of care medication) and 60 patients in a control group (receiving standard of care treatment only), across five sites in South Africa and seven sites in India.

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About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying many life-threatening diseases. In cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. AXL expression defines a very poor prognosis subgroup in most cancers. AXL inhibitors, therefore, have potential high value at the centre 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.

About Bemcentinib

Bemcentinib (formerly known as BGB324), is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in multiple solid and haematological tumours, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent. Bemcentinib targets and binds to the intracellular catalytic kinase domain of AXL receptor tyrosine kinase and inhibits its activity. Increase in AXL function has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers.

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 oncology 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 companion diagnostic tests to identify patient populations most likely to benefit from bemcentinib: 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

Contacts

Richard Godfrey CEO, BerGenBio ASA
+47 917 86 304

Rune Skeie, CFO, BerGenBio ASA
rune.skeie@bergenbio.com
+47 917 86 513

International Media Relations

Mary-Jane Elliott, Chris Welsh, Lucy Featherstone, Carina Jurs

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

Media Relations in Norway

Jan Petter Stiff, Crux Advisers
stiff@crux.no
+47 995 13 891

Forward looking statements

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