BERGENBIO TO PRESENT PRECLINICAL DATA ON TILVESTAMAB IN CHRONIC KIDNEY DISEASE AT ERA-EDTA VIRTUAL CONGRESS 2021

Bergen, Norway, 7 June 2021 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, is pleased to present preclinical data on its first-in-class, fully humanised, therapeutic anti-AXL function blocking monoclonal antibody, tilvestamab, in chronic kidney disease at the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress.

This preclinical study was conducted to characterise AXL as a target in chronic kidney disease (CKD) and to investigate the anti-fibrotic efficacy of tilvestamab using an ex vivo model of human Precision Cut Kidney Slices (PCKSs).

The study results showed that AXL expression was induced in key cell populations during the development of kidney fibrosis in the unilateral ureteric-outflow obstruction (UUO) model of kidney fibrosis in mice. In an ex vivo model using human Precision Cut Kidney Slices (PCKSs), tilvestamab dose-dependently reduced the levels of αSMA, a marker of myofibroblast activation. When combined with the ACE inhibitor enalapril, tilvestamab synergized to reduce αSMA levels further as well as reducing secreted Collagen 1a1. This data supports AXL as a novel target in CKD and highlights the potential of tilvestamab as a promising candidate for pharmacologic intervention in kidney fibrosis, with potential synergies with current reno-protective therapies warranting further exploration.

Read the full abstract on the ERA-EDTA website here: https://www.era-edta.org/en/virtualcongress2021/ndt-abstracts-book/

Details of the presentation are as follows:

Title: Tilvestamab, a function-blocking monoclonal antibody inhibitor of AXL RTK signalling, limits the onset of renal fibrotic changes in human kidneys ex vivo

Session: Renal pathology. Experimental and clinical

Abstract ID: MO074

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Author: Linn Hodneland Nilsson

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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. Data from a Phase II in human clinical trial has shown that treatment with AXL inhibitor bemcentinib increased the rate of ventilator free survival in hospitalised COVID-19 patients.

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, 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.

An international Phase Ib first-in-patient trial investigating tilvestamab (BGB149) is currently ongoing with the objective to confirm safety, tolerability and determine a recommended phase II dose (RP2D) for use in subsequent clinical trials.

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, 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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Forward looking statements

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