

BerGenBio Receives FDA Approval of Fast Track Designation for Bemcentinib

Bergen, Norway 22nd October 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, today announces that the U.S. Food and Drug Administration (FDA) has approved Fast Track Designation for bemcentinib for the treatment of elderly patients with acute myeloid leukaemia (AML) whose disease has relapsed. There are currently no marketed drugs specifically approved for all relapsed AML patients, representing a significant unmet medical need. BerGenBio has ongoing phase 2 trials in this indication and plans to seek regulatory advice from the FDA and European Medicines Agency (EMA) to determine the optimal regulatory path for bemcentinib in relapsed AML.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. A drug that receives Fast Track designation is eligible for the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: “We are thrilled that bemcentinib has been granted Fast Track Designation. Not only does this make us eligible for accelerated approval and priority review, but it serves as an important validation of bemcentinib in this significant unmet medical need we are trying to address. Currently, bemcentinib is in expanded Phase II trials in the U.S. and Europe for the treatment of AML and the Company has recently announced positive interim top line data.”

About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases. In cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. 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, as monotherapy and in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy). 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 AML

Acute myeloid leukemia (AML) is the most common type of aggressive leukemia in adults, which has the lowest survival rate for all types of leukemia. In 2018, it is estimated there will be nearly 20,000 new cases of AML diagnosed in the United States. Many AML patients older than age 60 are unable to tolerate intensive induction chemotherapy treatment.

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 and leukaemia. A first-in-class functional blocking AXL antibody (BGB149) and an AXL-ADC (ADCT-601) are undergoing phase I clinical testing. In parallel, BerGenBio is developing a companion diagnostic test to identify those 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). 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.