BERGENBIO PRESENTS PRELIMINARY CLINICAL DATA FROM PHASE II COMBINATION TRIAL OF BEMCENTINIB AND LDAC IN ELDERLY AML PATIENTS AT ASH 2019

- Phase II trial evaluating bemcentinib in combination with low-dose cytarabine (LDAC) in elderly AML patients unfit for intensive therapy is well tolerated and shows promising efficacy
- Long duration of response (>9.9 mo, still maturing) with 50% CR/CRi in 6 evaluable newly diagnosed patients receiving the bemcentinib-LDAC combination.
- Clinical benefit demonstrated in >2L relapsed and refractory AML patients with 1 CR/CRi and 3 SD out of 6 evaluable patients
- Pretreatment sAXL holds as predictive of response

Bergen, Norway, December 9, 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, will today provide an update from the Company's phase II study of bemcentinib (BGB324), a first-in-class highly selective oral AXL inhibitor, in combination with low-dose cytarabine (LDAC) in elderly AML patients in a poster presentation at the 61st Annual American Society of Hematology (ASH) Meeting, being held from 7-10 December in Orlando, Florida.

The bemcentinib-LDAC combination was safe and well tolerated in elderly AML patients and showed promising efficacy among both newly diagnosed and relapsed/refractory AML patients. The overall response rate and duration surpass historical benchmarks and compare favorably to other LDAC combinations. Pretreatment sAXL holds as a predictive biomarker in AML patients treated with the combination, and a new novel blood based predictive biomarker is identified and associated with clinical benefit in AML and Lung cancer patients receiving bemcentinib.

Professor Sonja Loges, attending physician and principal investigator, University Medical Centre Hamburg Eppendorf, Germany commented: "I am very encouraged by these early results. The duration of response and successful treatment beyond progression are consistent with the previously reported immunomodulatory activity of bemcentinib. I look forward to conducting a deeper analysis of AXL signalling in tumor and immune cells from patient biopsy samples to further elucidate this unique mechanism-of-action."

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "This combination trial of bemcentinib with low-dose cytarabine continues to show promising results in AML patients who are unable to tolerate intensive chemotherapy and have limited treatment options. The current data further highlight the novel tumor-immune effects of bemcentinib observed in previous cohorts and in other cancer types. Although these are early findings, we are encouraged by the response rate and duration, and we are focused on advancing our late stage development programme."

Details of the presentation are below.

Title: Durable responses observed in elderly AML patients unfit for intensive chemotherapy with first-in class selective AXL inhibitor bemcentinib (BGB324) in combination with LDAC: Phase II open-label study

Date: Monday 9th December 2019

Session Name: 616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster III

Time, Location: 6:00 PM – 8:00 PM, Orange County Convention Center, Hall B

The poster will be available at www.bergenbio.com in the section: Investors/Presentations from 14.00 CET Monday 9th December 2019.

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About AML and the BGBC003 trial

Acute myeloid leukaemia (AML) is a rapidly progressing blood cancer. AML is the most common form of acute leukaemia in adults, where malignant AML blasts interfere with the normal functioning of the bone marrow leading to a multitude of complications like anaemia, infections and bleeding. AML is diagnosed in over 20,000 patients in the US annually and is rapidly lethal if left untreated. Successful treatment typically requires intensive therapy or bone marrow transplantation, and relapse and resistance are common. Consequently, there is an urgent need for effective novel therapies in relapsed/refractory patients, particularly those that are ineligible for intensive therapy or bone marrow transplant.
The BGBC003 trial is a phase Ib/II multi-centre open label study of bemcentinib in combination with cytarabine (part B2) and decitabine (part B3) in patients with AML who are unsuitable for intensive chemotherapy as a result of advanced age or existing-co-morbidities. Up to 28 patients will be enrolled at centres in the US, Norway, Germany and Italy.

For more information please access trial NCT02488408 at www.clinicaltrials.gov.

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, 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, drug 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 anti-AXL antibody is 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). 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, Nicholas Brown, 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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This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.