BERGENBIO PRESENTS UPDATED CLINICAL DATA FROM TWO PHASE II STUDIES OF BEMCENTINIB IN AML AND MDS PATIENTS AT ASH 2020

- *Clinical benefit rate of 73% reported in second line relapsed AML patients. Overall Response OOR 45%, CR/CRi rate of 36%*
- *Median treatment duration exceeding 6 months with some patients remaining on study*

Bergen, Norway, 6 DECEMBER 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, will present updated clinical data from two Phase II studies of bemcentinib in acute myeloid leukemia and high-risk myelodysplastic syndrome, in two poster sessions at the American Society of Hematology (ASH) Annual Meeting being held virtually from 5-8 December 2020.

Dr Sonja Loges will provide an update from the Company's Phase II study of bemcentinib (BGBC003) in combination with low dose cytarabine (LDAC) in elderly previously treated, relapsed and refractory AML patients.

The data indicates that treatment with the bemcentinib-LDAC combination shows promising efficacy in relapsed patients who are unfit for intensive chemotherapy. Of 11 evaluable relapsed patients a response rate of 45% to date has observed. CR/CRi rate was 36% with durable responses observed, and clinical benefit observed in eight patients (73%) to date. Although the study is ongoing, patients remain on drug, with median treatment of 6.2 months in CR patients.

The Company is currently undertaking an in-depth translational research program aiming to identify predictive molecular and biological factors associated with response.

Dr Sonja Loges, Principal Investigator on the trial commented *"The current prognosis for relapsed AML patients is very bleak, so we are pleased to see such a positive clinical benefit rate in relapsed second line patients with many patients remaining on drug for extended durations. We are currently undertaking an analysis to identify the suspected immune based factors that potentiate the effects of the drug in certain patients. We hope that this will enable us to identify specific biomarkers that will help us decide which patients may benefit most from treatment with bemcentinib."*

Details of this Poster presentation as follows:

Title: *The Combination of AXL Inhibitor Bemcentinib and Low Dose Cytarabine Is Well Tolerated and Efficacious in Elderly Relapsed AML Patients: Update from the Ongoing BGBC003 Phase II Trial (NCT02488408)*

Date: *Sunday, December 6, 2020*

Session name: *613. Acute Myeloid Leukemia: Clinical Studies: Poster II*

Time: *7.00am - 3.30pm (Pacific Time) / 4.00pm - 12.30am (CET)*

Abstract: *https://ash.confex.com/ash/2020/webprogram/Paper136566.html*

An update will also be presented from the fully recruited investigator sponsored BERGAMO Phase II Trial investigating bemcentinib monotherapy in patients having relapsed treatment with hypomethelating agents (HMAs) with High Risk Myelodysplastic Syndromes (HR-MDS) or Acute Myeloid Leukemia (AML).

The primary endpoint of overall response rate (ORR) was met, with the MDS cohort achieving a 36% response rate, while 8.3% of patients with AML achieved stable disease. Three patients remain on drug, with median treatment exceeding 8 months. A comprehensive translational research program is ongoing to identify and verify soluble plasma biomarkers, including sAXL, that continue to be predictive of response.

Richard Godfrey, Chief Executive Officer of BerGenBio, said: *"We are pleased to continue sharing updates from our phase II clinical studies assessing bemcentinib with the scientific and medical community. Data from both of the studies being presented at ASH continue to show encouraging results in patients with a very poor prognosis with current treatment options. We believe these data provide further validation for our clinical development strategy in these indications as we prepare to progress bemcentinib into late stage randomised trials."*

Details of this Poster presentations as follows:

Title: *Efficacy and Safety of Bemcentinib in Patients with Myelodysplastic Syndromes or Acute Myeloid Leukemia Failing Hypomethylating Agents*

Date: *Saturday, December 5, 2020*

Session name: *637 Myelodysplastic Syndromes - Clinical Studies: Poster I Hematology Disease Topics & Pathways: Diseases, Therapies, MDS, Myeloid Malignancies, Clinically relevant*

Time: *7.00am - 3.30pm (Pacific Time) / 4.00pm - 12.30am (CET)*

Abstract: *https://ash.confex.com/ash/2020/webprogram/Paper140240.html*

Presentations will be made available at our website www.bergenbio.com under Investors/Presentations at the date of the conference.

-End-

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 chemotherapy 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 low dose decitabine (part B3 & B5) in patients with AML who are unsuitable for intensive chemotherapy as a result of advanced age or existing-co-morbidities.

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

About MDS

Myelodysplastic syndromes (MDS) are stem cell disorders characterised by a decreased ability of the bone marrow to produce normal blood cells and platelets. MDS is associated with increased risk of developing AML and immune dysfunctions are seen in patients both with lower and higher-risk MDS. Hypomethylating agents (HMAs) are the standard of care for patients with higher-risk myelodysplastic syndrome not eligible for intensive chemotherapy or allogeneic stem cell transplantation. However, the majority of patients do not respond to these agents or relapse, and face a dismal outcome with very limited treatment options available. Hence, there is an urgent need for novel therapies to treat MDS

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, 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

This announcement may contain forward-looking statements, which as such are not historical facts, but are based upon various assumptions, many of which are based, in turn, upon further assumptions. These assumptions are inherently subject to significant known and unknown risks, uncertainties and other important factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this announcement by such forward-looking statements.

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