Selective AXL inhibitor bemcentinib meets pre-specified efficacy endpoint in stage 1 of NSCLC phase II combination trial with KEYTRUDA®

- *Clinical response merits initiation of stage 2 of the Phase II combination trial*
- *24 patients treated to date, 48 patients to be treated in total*
- *Responses will be correlated with AXL and PD-L1 biomarkers*

Bergen, Norway, June 26, 2018 – BerGenBio ASA (OSE:BGBIO) announces today that on a top-line, preliminary basis, the first efficacy endpoint has been met in its Phase II clinical trial (BGBC008) evaluating bemcentinib, a first-in-class oral selective AXL inhibitor, in combination with the Merck & Co., Inc., Kenilworth, N.J., USA[1] anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as a potential new treatment regimen for advanced non-small cell lung cancer (NSCLC). The primary efficacy endpoint requires at least four patients (out of the first 22 treated patients) to achieve clinical responses when treated with the novel drug combination, defined as either complete or partial response, as measured by Response Evaluation Criteria in Solid Tumors (RECIST).

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "Immunotherapy has become a major component of the treatment of many cancers – patients who respond to immune checkpoint inhibitors like KEYTRUDA enjoy long-term disease control with excellent quality of life. Unfortunately, only a minority of lung cancer patients receiving KEYTRUDA monotherapy in second-line respond to treatment. The BGBC008 combination trial of bemcentinib with KEYTRUDA evaluates whether the addition of our selective AXL inhibitor will improve the outcome of immunotherapy.

"Clearing the first efficacy threshold in this ongoing Phase II trial is very encouraging and we intend to begin enrolment for Stage 2 of this study in which 24 further patients will be enrolled under the same protocol. Thus far, we are delighted to see activity in a number of patients receiving this novel treatment regimen. A particularly encouraging finding is that we see responses in patients who are negative for the PD-L1 biomarker, for whom KEYTRUDA monotherapy is not indicated. The second stage of the trial is intended to confirm activity and biomarker correlation in a larger group of patients – comprehensive analysis of the Phase II data will continue and will be presented at a future scientific conference.

"Successfully completing this important milestone further supports our belief in the potential of bemcentinib to become a cornerstone of cancer therapy. We look forward to sharing more details from our Phase II clinical programme during major clinical conferences in the coming months."

About the BGBC008 trial combining bemcentinib with KEYTRUDA (pembrolizumab) conducted in collaboration with Merck & Co., Inc.

Design

The BGBC008 trial is a Phase II multi-centre open-label study of bemcentinib in combination with KEYTRUDA (pembrolizumab) in previously treated, immunotherapy naïve, patients with advanced adenocarcinoma of the lung, the most common form of non-small cell lung cancer (NSCLC). The objective of the trial is to determine the anti-tumour activity of this novel drug combination and responses will be correlated with biomarker status (including AXL kinase and PD-L1 expression).

A pre-defined efficacy endpoint was set at four or more responses observed in the first 22 patients based on previously reported response rates to KEYTRUDA monotherapy in the second line setting in NSCLC.

Status June 2018

To date, 4 responses (partial responses as per RECIST v1.1) have been observed in the first 22 patients. A number of patients remain ongoing and are awaiting the confirmation of their best response.

Patients generally tolerated the novel drug combination well – no new safety events were reported from the combination of bemcentinib with KEYTRUDA at full dose.

A preliminary interim analysis of the trial (from 15 patients evaluable for response) was presented at ASCO 2018, where tumour shrinkage was observed in about half of the patients analysed to date. Results looked particularly promising in patients who did not express the PD-L1 biomarker, i.e. representing 1/3 of NSCLC patients, a group for whom KEYTRUDA monotherapy as a second line is not indicated.

For more information please access trial NCT03184571 at www.clinicaltrials.gov.

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About BerGenBio ASA

BerGenBio ASA is a clinical-stage biopharmaceutical company focused on developing a pipeline of first-in-class AXL kinase inhibitors as a potential cornerstone of combination cancer therapy. The Company is a world leader in understanding the essential role of AXL kinase in mediating cancer spread, immune evasion and drug resistance in multiple aggressive solid and haematological cancers.

BerGenBio's lead product, bemcentinib, is a selective, potent and orally bio-available small molecule AXL inhibitor in four Company sponsored Phase II clinical trials in major cancer indications, with read-outs anticipated during 2018. It is the only selective AXL inhibitor in clinical development.

The Company sponsored clinical trials are:

- Bemcentinib with TARCEVA® (erlotinib) in advanced EGFR mutation driven non-small cell lung cancer (NSCLC)
- Bemcentinib with KEYTRUDA in advanced adenocarcinoma of the lung, and
- Bemcentinib with KEYTRUDA in triple-negative breast cancer (TNBC).
- Bemcentinib as a single agent and combination therapy in acute myeloid leukaemia (AML) / myeloid dysplastic syndrome (MDS)

The clinical trials combining bemcentinib with KEYTRUDA in adenocarcinoma of the lung and TNBC are conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA, through a subsidiary.

In addition, a number of investigator-sponsored trials are underway, including a trial to investigate bemcentinib with either MEKINIST® (trametinib) plus TAFINLAR® (dabrafenib) or KEYTRUDA in advanced melanoma, as well as a trial combining bemcentinib with docetaxel in advanced NSCLC.

BerGenBio is simultaneously developing a companion diagnostic test to identify patient subpopulations most likely to benefit from treatment with bemcentinib. This will facilitate more efficient registration trials and support a precision medicine based commercialisation strategy.

The Company is also developing a diversified pre-clinical pipeline of drug candidates, including BGB149, an anti-AXL monoclonal antibody.

For further information, please visit: www.bergenbio.com

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. TARCEVA® is a registered trademark of OSI Pharmaceuticals, LLC., marketed by Roche-Genentech. TAFLINAR® is a registered trademark of Novartis International AG and MEKINIST® is a registered trademark of GSK plc.

Contacts

Richard Godfrey
CEO, BerGenBio ASA
+47 917 86 304

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

Media Relations in Norway

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

International Media Relations

David Dible, Mark Swallow, Marine Perrier
Citigate Dewe Rogerson
bergenbio@citigatedewerogerson.com
+44 207 638 9571

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.

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[1] Known as MSD outside the United States and Canada