BerGenBio completes recruitment into first stage of Phase II breast cancer trial with selective AXL inhibitor bemcentinib combined with KEYTRUDA®

Bergen, Norway, 19 February 2018 – BerGenBio ASA (OSE: BGBIO) announces that it has completed enrolment, ahead of schedule, of the planned 28 patients into the first stage of its Phase II clinical trial evaluating its investigational oral selective AXL inhibitor bemcentinib (BGB324) in combination with the Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) as a potential new treatment regimen for advanced breast cancer.

The Phase II trial (BGBC007) follows a two-stage design: it is an open label, multi-centre study of bemcentinib in combination with KEYTRUDA in patients with previously treated, locally advanced and unresectable or metastatic triple negative breast cancer (TNBC) or triple negative inflammatory breast cancer (TN-IBC). Up to 56 patients in total will be included in the study (NCT03184558).

The trial is designed to evaluate efficacy and safety of the combination, and to correlate the patient response with biomarker status (AXL kinase and PD-L1 expression). In parallel, companion diagnostics using these biomarkers, and others, are being developed for the identification of patients predicted to be most suitable for treatment with the bemcentinib / KEYTRUDA combination. Interim results are expected mid-year 2018.

The trial, which began in October 2017, is being conducted under a clinical collaboration with Merck & Co., Inc., Kenilworth, N.J., USA, through a subsidiary, and is taking place at more than 16 clinical sites in the US and Europe.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "We are delighted to have completed patient enrolment into the first part of this Phase II trial in such a short time and ahead of schedule. Immuno-oncology therapies, such as KEYTRUDA, are now established as a major treatment option for cancer patients and we are excited with the progress being seen across our clinical trials exploring if bemcentinib in combination with KEYTRUDA can result in significantly improved patient outcomes. Positive results from these trials, and from our broader Phase II development programme will help confirm the great potential we see for bemcentinib as a cornerstone therapy across multiple cancer indications and in combination with existing and emerging modalities of cancer treatment. We look forward to interim results from this and other studies during 2018."

Preliminary safety data, reported at the ASCO-SITC Clinical Immuno-Oncology Symposium (January 2018), found that the bemcentinib / KEYTRUDA combination was well tolerated in a sample of patients across three cancer indications in which it is being studied (advanced breast cancer, lung cancer and melanoma) with a safety profile similar to KEYTRUDA alone. Nineteen of the 34 patients evaluated in this analysis were from the BGBC007 breast cancer trial.

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About TNBC

Breast cancer is the most common cancer in women – it is estimated that more than 250,000 new cases will be diagnosed in the US in 2018. 20% of breast cancers lack receptors for three common hormones (oestrogen, progesterone and HER2) and are thus called triple-negative breast cancers (TNBC). Treatment options for TNBC are limited to intense chemotherapy, but disease recurrence is frequent and aggressive. Consequently, novel treatment strategies for TNBC are urgently needed.

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 (BGB324), 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 commercialization 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

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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.