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

Bergen, Norway, 10 April 2018 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors as a potential cornerstone of combination cancer therapy in NSCLC, AML/MDS, TNBC and melanoma, announces that it has completed enrolment of the planned 22 patients into the first stage of its Phase II clinical trial evaluating bemcentinib (formerly BGB324), its investigational oral selective AXL inhibitor, 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 lung cancer.

The Phase II trial (BGBC008) follows a two-stage design: it is an open label, multi-centre study of bemcentinib in combination with KEYTRUDA in patients with previously treated advanced adenocarcinoma of the lung (non-small cell lung cancer, NSCLC) whose disease is progressing. Up to 48 patients in total will be included in the study (NCT03184571).

The trial is designed to evaluate the anti-tumour activity, objective response rate and safety of the combination, and to correlate the patient response with biomarker status (including AXL kinase and PD-L1 expression). In parallel, companion diagnostics using these and other biomarkers are being developed for the identification of patients predicted to be most suitable for treatment with the bemcentinib / KEYTRUDA combination. Interim results are expected during 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 12 clinical sites in the US, UK, Norway and Spain.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "Immuno-oncology therapies, such as KEYTRUDA, are now established as a major treatment option for lung cancer patients alongside targeted and chemo-therapies. This trial forms an important part in our strategy to provide proof of concept that selective AXL inhibition in combination with established and emerging cancer therapies may improve patient outcomes. We are encouraged by strong pre-clinical data combining bemcentinib with immune-therapy to increase and deepen responses as well as early clinical data suggesting that bemcentinib in combination with KEYTRUDA has a favourable safety profile across several cancer indications. We are looking forward to report interim results from the BGBC008 trial as well as our other combination trials in the coming months.

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About NSCLC

It is estimated that more than 220,000 new cases of lung cancer were diagnosed in the US in 2017 and it is the leading cause of cancer deaths. 65% of NSCLCs are of adenocarcinoma pathology. Although various treatments exist for NSCLC, they are often curtailed by acquired resistance to therapy and immune evasion. Novel treatments overcoming these mechanisms in NSCLC are urgently required.

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 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

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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.