BerGenBio Announces Start of Ph II Trial Assessing Selective AXL Inhibitor BGB324 in Combination with KEYTRUDA® for Patients with Advanced Lung Cancer

Bergen, Norway, 24 Oct 2017 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company focused on developing a pipeline of first-in-class Axl kinase inhibitors to treat multiple cancer indications, announces that the first patient has been dosed in a Phase II trial evaluating the Company's lead product BGB324 in combination with KEYTRUDA® (pembrolizumab) in patients with previously treated advanced adenocarcinoma of the lung (non-small cell lung cancer, NSCLC) whose disease is progressing. The trial is being sponsored by BerGenBio. MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA) will supply KEYTRUDA, an anti-PD-1 therapy, for use in the study under a collaboration agreement signed between the two companies in March 2017. The trial plans to enrol up to 48 patients at hospitals in Norway, Spain, the UK and the US (ClinicalTrials.gov Identifier: NCT03184571).

The clinical study will primarily evaluate the anti-tumour activity, objective response rate, and safety profile of the combination. Additionally, the study will assess the pharmacokinetic profile of BGB324 when given with KEYTRUDA. Comprehensive exploratory studies will evaluate biomarkers in tumour and blood indicative of immune modulation and Axl signalling, including expression levels of PD-L1 and Axl. The trial is expected to deliver preliminary results around the end of 2018.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "This is the second trial under our collaboration agreement with MSD to evaluate the combination of our selective Axl inhibitor BGB324 with MSD's approved anti-PD-1 therapy, KEYTRUDA. With this study in advanced NSCLC and our other BGB324/KEYTRUDA study in advanced breast cancer, we hope to generate compelling clinical evidence that blocking Axl signalling can reverse and prevent tumour resistance to anti-PD-1 therapies and lead to improved clinical outcomes. The results from these studies and those from our broader Phase II programme with BGB324, which we expect to read-out in 2018, will be crucial to establishing its potential as a key factor in the treatment of many aggressive cancers."

About NSCLC

It is estimated that more than 220,000 new cases of lung cancer will be 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 to treat multiple cancer indications. 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 haematological and solid cancers.

BerGenBio's lead product, 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 in the second half of 2018. It is the only selective Axl inhibitor in clinical development.

The Company sponsored clinical trials are:

- BGB324 as a single agent and combination therapy in acute myeloid leukaemia (AML) / myeloid dysplastic syndrome (MDS)
- BGB324 with TARCEVA® (erlotinib) in advanced EGFR mutation driven non-small cell lung cancer (NSCLC)
- BGB324 with KEYTRUDA® (pembrolizumab) in advanced adenocarcinoma of the lung, and
- BGB324 with KEYTRUDA® in triple negative breast cancer (TNBC).

The clinical trials combining BGB324 with KEYTRUDA in adenocarcinoma of the lung and TNBC are conducted in collaboration with Merck & Co. Inc. (MSD), through a subsidiary.

In addition, a number of investigator-sponsored trials are underway, including a trial to investigate BGB324 with either MEKINIST® (trametinib) plus TAFINLAR® (dabrafenib) or KEYTRUDA in advanced melanoma, as well as a trial combining BGB324 with docetaxel in advanced NSCLC.

BerGenBio is simultaneously developing a companion diagnostic test to identify patient subpopulations most likely to benefit from treatment with BGB324. 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.

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