BerGenBio Presents BGB324 and KEYTRUDA® (pembrolizumab) Clinical Trial at the 2017 San Antonio Breast Cancer Symposium

Bergen, Norway, 14 Nov 2017 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective Axl kinase inhibitors for multiple cancer indications, is pleased to announce that the Company will present its recently initiated Phase II clinical trial investigating 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), in patients with triple negative breast cancer (TNBC) at the 2017 San Antonio Breast Cancer Symposium in San Antonio, USA (5-9 Dec 2017).

The poster presentation will describe the rationale and design of the combination study with KEYTRUDA and BGB324, a first-in-class and highly selective small molecule Axl kinase inhibitor, which is being developed to target tumour immune evasion and resistance.

The poster will be presented by Murray Yule (MD, PhD) Clinical Development Officer at BerGenBio, and is entitled: A Phase II multi-center study of BGB324 in combination with pembrolizumab in patients with previously treated, locally advanced and unresectable or metastatic triple negative breast cancer (TNBC) or triple negative inflammatory breast cancer (TN-IBC)

Abstract ID#: 851840 – Henry B. Gonzalez Convention Center, San Antonio, USA, 9-12 Dec 2017
Session: Ongoing Trials – Immunotherapy, OT1 – Wednesday, 6 Dec 2017, 5pm-7pm
ClinicalTrials.gov identifier: NCT03184558

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 solid and haematological 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 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., Kenilworth, N.J., USA.

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 GBB149, 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. TAFINLAR® is a registered trademark of Novartis International AG and MEKINIST® is a registered trademark of GSK plc.

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