BerGenBio Announces Start of PhII Trial Assessing Selective AXL Inhibitor BGB324 in Combination with KEYTRUDA for Patients with Advanced Breast Cancer

Bergen, Norway, 19 October 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, locally advanced and unresectable or metastatic triple-negative breast cancer (TNBC) or triple negative inflammatory breast cancer (TN-IBC). 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 56 patients in hospitals in Norway, Spain, the UK and the US (ClinicalTrials.gov Identifier: NCT03184558).

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 at the end of 2018.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "The role of Axl in driving mechanisms that enable tumour cells to evade the immune system and to gain resistance to therapies is well documented. Pre-clinical and early clinical data show that BGB324 counteracts tumour aggressiveness and drug resistance in a wide range of cancers, and support the rationale for testing BGB324 in combination with anti-cancer therapies. KEYTRUDA and anti-PD-1 therapies have created excitement due to the high response rates and durable benefit for patients. Unfortunately, a large number of patients develop resistance to anti-PD-1 therapies and the oncology community is urgently seeking combination strategies to improve patient outcomes. BerGenBio believes that combining BGB324 to counteract immune evasion and acquired resistance, with KEYTRUDA has the potential to improve overall and progression-free survival in cancer patients. This trial will evaluate the combination in TNBC patients and we are planning to start another Phase II trial in advanced lung cancer patients in the coming weeks."

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 2017. 20% of breast cancers lack receptors for three common hormones (estrogen, progesterone and HER2) and are thus called triple-negative breast cancers (TNBC). Treatment options for TNBC are limited to intense chemotherapy, but therapy recurrences are frequent and aggressive. Consequently, novel treatment strategies for TNBC are of high need.

About BerGenBio ASA

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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

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Contacts

Richard Godfrey

CEO, BerGenBio ASA

+47 917 86 304

Tom Henrik Sundby

Finance Director, BerGenBio ASA

+47 477 54 415

tom.sundby@bergenbio.com

Media Relations

David Dible, Mark Swallow, Marine Perrier

Citigate Dewe Rogerson

bergenbio@citigatedr.co.ukl

+44 207 638 9571

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