

BGB324, BerGenBio's Selective First-in-Class AXL Inhibitor, Featured in 3 Clinical Presentations at 18th World Conference on Lung Cancer in Yokohama

Bergen, Norway, October 16, 2017 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective Axl kinase inhibitors for multiple cancer indications, announces presentations on three ongoing Phase 2 clinical trials with BGB324 in lung cancer patients at the 18th World Conference on Lung Cancer in Yokohama, Japan.

BGB324, a first-in-class selective Axl inhibitor, is being investigated in three Phase 2 clinical trials across the three standard-of-care treatment regimens available to patients with non-small-cell lung cancer (NSCLC): these trials seek to demonstrate the potential of BGB324:

- 1) as a monotherapy and in combination to enhance the effect of TARCEVA® (erlotinib), a targeted therapy for patients with advanced NSCLC driven by an EGFR mutation
- 2) in combination to improve response rates of KEYTRUDA® (pembrolizumab), an anti-PD1 immuno-therapy
- 3) in combination to improve response rates to docetaxel chemotherapy in all other NSCLC patients.

BerGenBio's rationale for these studies is based on compelling preclinical and clinical evidence that BGB324, by selectively blocking Axl signalling, can prevent tumour cells from evading the immune system and acquiring resistance to anti-cancer therapies, and target critical anti-tumour immune suppression. Therapy with BGB324 therefore aims to render tumour cells more susceptible to cancer treatment and tumour-killing effectors of the immune system.

An oral presentation by Don L. Gibbons (MD, PhD), physician and Associate Professor, Department of Thoracic/Head and Neck Medical Oncology at the MD Anderson Cancer Center, Houston (US), entitled: **A Ph I/II Study of BGB324, a Selective AXL Inhibitor as Monotherapy and in Combination with Erlotinib in Advanced NSCLC** provided updated clinical results confirming the safety of combining BGB324 with erlotinib in heavily pre-treated NSCLC patients. Dr Gibbons also highlighted an outstanding response from one patient receiving BGB324 and erlotinib whose disease has been stable for over 20 months.

Additionally, two posters featuring BGB324 combination trials with anti-PD1 therapy and chemotherapy, respectively, are being presented during the conference:

- Murray Yule (MD, PhD), Clinical Development Officer at BerGenBio, highlights key pre-clinical results and the design of the recently opened trial of BGB324 in combination with KEYTRUDA in collaboration with Merck in a poster entitled: **A Phase II Study of BGB324 in Combination with Pembrolizumab in Patients with Previously Treated Advanced Lung Adenocarcinoma**, and
- David E. Gerber (MD, PhD), physician and Associate Professor Internal Medicine, Department of Clinical Science Integrative Biology at the University of Texas Southwestern Medical Center (US) reports disease stabilisation over nine months in one out of the first three patients treated in the investigator sponsored phase Ib/II clinical trial entitled: **Trial of BGB324 in combination with docetaxel for previously treated advanced NSCLC**.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "We believe that our selective Axl inhibitor BGB324 has potential to become a cornerstone of therapy in multiple cancer indications by making tumour cells more susceptible to treatment and attack by the immune system. This is exemplified by our broad clinical development strategy in lung cancer, which is designed to address the three major routes of treatment currently available to patients. These trials are all ongoing and we look forward to providing updates at clinical conferences during the next 12 months."

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 death. 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 the 18th World Conference on Lung Cancer

The World Conference on Lung Cancer (WCLC) is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting over 6,000 researchers, physicians and specialists from more than 100 countries. The goal is to disseminate the latest scientific achievements; increase awareness, collaboration and understanding of lung cancer; and to help participants implement the latest developments across the globe. Organized under the theme of "Synergy to Conquer Lung Cancer," the conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit <http://wclc2017.iaslc.org/>.

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

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