

BerGenBio to present recent highlights from its clinical trials with selective AXL inhibitor BGB324 at DNB's 8th Annual Nordic Healthcare Conference

- Six phase II clinical trials ongoing with first-in-class highly selective AXL inhibitor BGB324.
- Monotherapy data at 19% RR in relapsed/refractory AML and high-risk MDS reported at ASH.
- 50% CBR with BGB324 in combination with erlotinib in NSCLC reported at World Lung.
- BGB324 in combination with docetaxel as last line therapy in NSCLC showing very promising early efficacy at 66% CBR.

Bergen, Norway, 14 December 2017 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective Axl kinase inhibitors for multiple cancer indications, announces that the Company will be presenting recent clinical highlights at the DNB's 8th Annual Nordic Healthcare Conference in Oslo, Norway, today at 11:15-11:40 CET.

The presentation will be delivered by Richard Godfrey, CEO, and the presented slides are available on the Company's website: www.bergenbio.com.

The talk will focus on recent clinical highlights from BerGenBio's broad clinical development programme:

- At the recent 2017 American Society of Hematology Annual Meeting, an ongoing phase II study reported encouraging early signs of efficacy of BGB324 as a monotherapy in difficult to treat relapsed/refractory AML and high risk MDS patients (BGBC003, NCT02488408). 35 patients have been treated with the AXL inhibitor as a single agent at a response rate of 19% and showing high correlation with three novel, predictive biomarker candidates.
- At the recent 2017 World Conference on Lung Cancer, an ongoing phase II study showed a 50% clinical benefit rate of BGB324 in combination with erlotinib in advanced EGFRm positive non-small cell lung cancer (NSCLC) patients who had previously progressed on erlotinib (BGBC004, NCT02424617).
- The Company furthermore announces that very encouraging early efficacy is seen in an investigator initiated phase I/II trial of BGB324 in combination with docetaxel in previously treated advanced NSCLC (BGBIL005, NCT02922777). Of six patients who completed at least one cycle of treatment, two experienced a partial response and two experienced stable disease (up to ten cycles). All four patients had progressed on prior platinum as well as checkpoint inhibitor therapy.

Richard Godfrey, CEO of BerGenBio commented: "BGB324 targets the fundamental mechanisms that cancers exploit to evade the patient's immune system and develop resistance to immune, targeted and chemotherapy. Our broad programme of phase II clinical trials seeks to evaluate the potential of BGB324 to become a cornerstone of therapy to improve patient outcomes and I am looking forward to provide an overview of the significant progress we have made over the past few months. I am particularly delighted to share for the first time, early signs of efficacy we are seeing with our AXL inhibitor in combination with docetaxel in heavily pre-treated NSCLC patients. All of these trials, in addition to combinations with Keytruda in TNBC, NSCLC and melanoma, are ongoing and I am looking forward to share further progress in due course."

About the BGBC003 trial

The BGBC003 trial is a phase Ib/II multi-centre open label study of BGB324 as a single agent in patients with AML or high-risk MDS or in a combination with cytarabine and decitabine in AML patients. Up to 75 patients will be enrolled at centres in the US, Norway, Germany and Italy. For more information please access trial NCT02488408 at www.clinicaltrials.gov.

About the BGBC004 trial

The BGBC004 trial is a phase I/II multi-centre open-label study of BGB324 in combination with erlotinib in patients with previously treated, EGFR mutation driven Stage IIIB or Stage IV non-small cell lung cancer. Up to 66 patients will be enrolled at centres across in the US. For more information please access trial NCT02424617 at www.clinicaltrials.gov.

About the BGBIL005 trial

The BGBIL005 trial is an investigator initiated phase I/II open-label study of BGB324 in combination with docetaxel in patients with previously treated Stage IV non-small cell lung cancer. Up to 30 patients will be enrolled at centres in Texas, USA. For more information please access trial NCT02922777 at www.clinicaltrials.gov.

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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