BerGenBio announces first patient dosed in BGB324 AML trial

Bergen, Norway, November 4, 2014 – BerGenBio AS ("BerGenBio" or the "Company"), an oncology biopharmaceutical company, today announces that the first patient has been dosed in its multi-centre Phase 1b trial (BGBC003) of BGB324, a selective inhibitor of Axl, in patients with acute myeloid leukaemia (AML) at Haukeland University Hospital in Bergen, Norway.

The two part Phase 1b trial will primarily investigate the safety and tolerability of BGB324 when administered as a single agent and in combination with standard of care drug (cytarabine) in patients with AML; secondary endpoints will also explore evidence of clinical response and assess novel biomarkers. The study will be conducted at six sites in Norway, Germany and the United States. The Company expects data to be available from this trial in 2015.

Professor Bjørn Tore Gjertsen, Principal Investigator at Haukeland University Hospital said:
"BGB324 is a potential breakthrough treatment for patients with aggressive AML, and it is particularly encouraging that a forward-thinking biotech company like BerGenBio prioritised a trial for patients with this aggressive blood cancer. I am delighted that I am able to offer this experimental drug to my patients and to allow us to test a novel therapeutic concept in patients that have limited treatment options."

Richard Godfrey, Chief Executive Officer of BerGenBio, commented:
"We continue to progress BGB324, our first-in-class selective Axl inhibitor, through early clinical development; recently we also received FDA clearance and this trial will open imminently in the United States and at sites in Germany. The novel mechanism of action of this class of drugs holds great potential as a treatment for many aggressive drug resistant cancers; we will also investigate BGB324 in non-small cell lung cancer (NSCLC). Therefore we see successful completion of this study as a key value inflection point for the Company. We expect preliminary data from these studies in 2015."

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About the BGBC003 trial
BGBC003 is a multi-centre Phase 1b trial of BGB324, a selective inhibitor of Axl, in patients with acute myeloid leukaemia (AML) The two part Phase 1b trial will investigate dose escalation and expansion of BGB324 in patients with refractory/relapsed AML an aggressive form of cancer in which certain types of white blood cells (granulocytes or monocytes) become cancerous, at six sites in three countries. The primary objective of the first part of the trial is to identify the maximum tolerated dose (MTD) of BGB324 and the secondary objectives are to identify the dose limiting toxicity (DLT), safety and tolerability and confirm the pharmacokinetics of the drug candidate. The primary objective of the second part of the trial is to identify the safety, and tolerability of BGB324, as a single agent and in combination with low dose cytarabine, with a secondary objective of determining the efficacy of BGB324 as a single agent and in combination with low dose cytarabine.

About BGB324

BGB324 is a first-in-class, highly selective small molecule inhibitor of the Axl receptor tyrosine kinase. It blocks the epithelial-mesenchymal transition (EMT), which is a key driver in drug-resistance and metastasis.

About Acute myeloid leukaemia

Acute myeloid leukaemia (AML) is an aggressive cancer of the blood and bone marrow. It is characterised by the rapid growth of abnormal white blood cells that accumulate in the bone marrow and prevent the production of other normal blood cells. It is estimated that 1 in 243 people will be diagnosed with AML during their lifetime. In the United States, the five-year overall survival is 24%. It is estimated that 40-45% of patients younger than 65 years can be cured with current therapies, however only 10% of older patients achieve long-term survival. BerGenBio has shown that more than 50% of AML patients have elevated levels of Axl and by inhibiting Axl with BGB324 in preclinical studies a substantial and potentially therapeutic reduction in leukaemic burden can be achieved.

About BerGenBio AS

BerGenBio AS is a clinical stage biopharmaceutical company. The company is committed to developing innovative therapeutics that inhibit EMT, prevent the formation of cancer stem cells and disrupt the cellular mechanisms that drive acquired cancer drug resistance. The company is founded on proprietary platform technology, CellSelect™, which uses information from RNAi screening studies to identify and validate novel drug targets and biomarkers. BGB324 is the first compound in BerGenBio's pipeline to enter clinical trials in AML and NSCLC, with additional compounds and drug targets at different stages of preclinical development. www.bergenbio.com