BERGENBIO ANNOUNCES FIRST PATIENT DOSED IN RECURRENT GLIOBLASTOMA INVESTIGATOR SPONSORED PHASE I/II STUDY ASSESSING SELECTIVE AXL INHIBITOR BEMCENTINIB

Bergen, Norway, 20 July 2020 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces that the first patient has been dosed and continues on therapy in a trial assessing bemcentinib in recurrent glioblastoma (GBM). The trial is sponsored by Prof. Ichiro Nakano, MD, Professor in the Department of Neurosurgery and co-leader of the Neuro-Oncology Program at University of Alabama at Birmingham and funded by the National Cancer Institute (NCI).

This is an open label, multi-centre, intra-tumoral tissue pharmacokinetic (PK) study of bemcentinib in patients with recurrent glioblastoma for whom a surgical resection is medically indicated. The study will enrol up to 20 recurrent GBM patients, at up to 15 sites in the USA. 10 patients will be treated prior to surgery and 10 patients will have no pre-surgical treatment. However, all patients will receive treatment with bemcentinib following surgery. The endpoints of the study include an evaluation of bemcentinib's ability to cross the blood brain barrier, AXL expression, pharmacokinetics, safety and tolerability, as well as efficacy assessments including Progression Free Survival and Overall Survival. More information about the trial can be found at https://clinicaltrials.gov/ct2/show/NCT03965494

Increased expression of the receptor tyrosine kinase AXL is significantly correlated with poor prognosis in GBM patients and preclinical data has suggested that bemcentinib may be a promising therapeutic agent for GBM, particularly in post-irradiation mesenchymal-transformed GBM tumors[1]. A comprehensive translational research programme will run in parallel with the clinical trial, this will be conducted by Prof. Jeff Supko, Harvard Medical School and Director of the Clinical Pharmacology Laboratory, Massachusetts General Hospital (Boston, USA)

Prof. Burt Nabors MD, the Chairman of the trial and Director of Neuro-Oncology at University of Alabama at Birmingham (UAB) and Director of UAB's Centre for Clinical Translational Science's Clinical Research Unit, commented: "GBM is among the most lethal of adult cancers. The median survival of patients remains less than two years despite the current available therapies, including surgery, radiation, and chemotherapy; development of more effective therapies is urgently needed. We welcome the opportunity to offer patients access to the investigational AXL inhibitor bemcentinib in this pilot study and look forward to initiating additional trial sites across the Adult Brain Tumour Consortium in the USA later this year."

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "We congratulate Prof. Nakano and Prof. Nabors on the start of this exciting clinical study, which we believe will provide us with important data regarding the ability of

[1] 3. Sadahiro H, Kang KD, Gibson JT, et al. Activation of the Receptor Tyrosine Kinase AXL Regulates the Immune Microenvironment in Glioblastoma. Cancer Res. 2018;78(11):3002-3013.

bemcentinib to cross the blood-brain barrier and potentially treat GBM patients. This clinical trial is based on pioneering preclinical research carried out by our collaborators, conducted at high profile research hospitals in the USA and is funded by National Cancer Institute (NCI). We look forward to reporting the potential of bemcentinib to improve patient outcomes in this very aggressive cancer."

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About BerGenBio ASA

BerGenBio is a clinical-stage biopharmaceutical company focused on developing transformative drugs targeting AXL as a potential cornerstone of therapy for aggressive diseases, including immune-evasive and therapy resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad Phase II oncology clinical development programme focused on combination and single agent therapy in lung cancer, leukaemia and COVID-19. A first-in-class functional blocking anti-AXL antibody, tilvestamab, is undergoing Phase I clinical testing. In parallel, BerGenBio is developing companion diagnostic tests to identify those patient populations most likely to benefit from bemcentinib or tilvestamab: this is expected to facilitate more efficient registration trials and support a precision medicine-based commercialisation strategy. For further information, please visit: www.bergenbio.com

About Investigator-Sponsored Trials

Investigator-sponsored clinical trials are clinical trials proposed by front-line patient-facing physicians who act as the regulatory sponsor and are supported by industry in bespoke clinical development partnerships. The industry partner does not assume the role of sponsor according to European or US regulatory guidelines but may offer support in a variety of different ways, such as providing investigational medicinal product at no cost.

About Glioblastoma

Glioblastoma (GBM) ranks among the deadliest of all human cancers with no curative options available[2]. It is the most aggressive of the gliomas, a collection of tumors arising from glia or their precursors within the central nervous system. Gliomas are divided into four grades, grade 4 or glioblastoma multiforme (GBM) is the most aggressive of these and is the most common in humans. Most patients with GBMs die of their disease in less than a year.[3]

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[2] [3] 1. Cloughesy, T., Finocchiaro, G., Belda-Iniesta, C., et al. (2016). Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase II Study of Onartuzumab plus Bevacizumab versus Placebo plus Bevacizumab in Patients with Recurrent Glioblastoma: Efficacy, Safety, and Hepatocyte Growth Factor and O6-Methylguanine-DNA Methyltransferase Biomarker Analyses. J Clin Oncol, JCO2015647685. Gilbert, M.R., Sulman, E.P., and Mehta, M.P. (2014). Bevacizumab for newly diagnosed glioblastoma. N Engl J Med 370, 2048-2049.

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This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.