BerGenBio – US Clinical Trial Update

Bergen, Norway, 15 March 2018 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective Axl kinase inhibitors for multiple cancer indications, provides an update on BGBC004, an ongoing, company sponsored USA only phase Ib/II clinical trial evaluating bemcentinib in combination with TARCEVA® (erlotinib) in first and second line patients with non-small cell lung cancer (NSCLC).

In November 2017, BerGenBio informed that the Company was in voluntary discussions with the Regional Ethics Committee (REK) in Bergen and the Norwegian Board of Health about gaining retrospective approval for the study; the Company can confirm that it has now received a notice of non-acceptance from the Norwegian National Ethics Committee (NEM) for the retrospective approval for the conduct of this clinical trial outside Norway.

In accordance with international good clinical practice BerGenBio secured all necessary approvals from the US Food & Drug Administration (FDA) and from the ethics committees at the participating USA hospitals prior to initiating the study in 2014.

To date 33 NSCLC patients have been enrolled in the trial and ten patients have reported clinical benefit (four partial responses and six stable disease) from taking the combination of bemcentinib and erlotinib. In some cases, the patient benefit is observed for more than two years. This preliminary outcome is viewed as very promising at this stage in the clinical development of bemcentinib.

The clinical trial remains ongoing in the USA, BerGenBio maintains the view that the study qualifies for retrospective approval and will formally ask NEM to reconsider their decision. There is currently uncertainty what implications the decision may have for the study (if the decision is upheld), as no research activities are carried out in Norway and all necessary foreign approvals have been acquired. BerGenBio will attempt to secure a meeting with the authorities to determine the future next steps.

BerGenBio has relevant approvals for all of the other Phase II clinical trials with bemcentinib that are currently ongoing in multiple cancer indications, alone and in combination with other cancer therapies.

Richard Godfrey, BerGenBio CEO: commented: “We are disappointed and perplexed that NEM has not provided us with a clear explanation for its decision not to provide retrospective approval for the bemcentinib-erlotinib combination study. This trial has all the necessary approvals in the USA where it is being conducted and is generating promising clinical results in patients with advanced lung cancer. We are strongly committed to working towards a solution with the relevant authorities in Norway, and in the meantime the clinical trial remains ongoing in the USA, with an interim readout expected in mid-2018.”

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About the BGBC004 trial

The BGBC004 trial is a Phase I/II multi-centre open-label study of bemcentinib in combination with erlotinib in patients with EGFR mutation driven Stage IIIb or Stage IV NSCLC. The trial is designed to evaluate reversal of resistance to EGFR targeted therapy in later line patients who are negative for the T790M mutation as well as prevention of resistance in patients receiving the EGFR inhibitor erlotinib first line. Patients are currently being enrolled at centres across in the US. For more information please access trial NCT02424617 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 as a potential cornerstone of combination cancer therapy. 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 solid and haematological cancers.

BerGenBio’s lead product, bemcentinib (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 during 2018. It is the only selective AXL inhibitor in clinical development.

The Company sponsored clinical trials are:

- Bemcentinib with TARCEVA® (erlotinib) in advanced EGFR mutation driven non- small cell lung cancer (NSCLC)
- Bemcentinib with KEYTRUDA in advanced adenocarcinoma of the lung, and
- Bemcentinib with KEYTRUDA in triple-negative breast cancer (TNBC).
- Bemcentinib as a single agent and combination therapy in acute myeloid leukaemia (AML) / myeloid dysplastic syndrome (MDS)

The clinical trials combining bemcentinib with KEYTRUDA in adenocarcinoma of the lung and TNBC are conducted in collaboration with Merck & Co., Inc., Kenilworth, NJ, USA, through a subsidiary.

In addition, a number of investigator-sponsored trials are underway, including a trial to investigate bemcentinib with either MEKINIST® (trametinib) plus TAFINLAR® (dabrafenib) or KEYTRUDA in advanced melanoma, as well as a trial combining bemcentinib with docetaxel in advanced NSCLC.

BerGenBio is simultaneously developing a companion diagnostic test to identify patient subpopulations most likely to benefit from treatment with bemcentinib. This will facilitate more efficient registration trials and support a precision medicine based commercialization 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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Contact

Richard Godfrey, CEO, BerGenBio ASA
+47 917 86 304

Rune Skeie, CFO, BerGenBio ASA
rune.skeie@bergenbio.com
+47 917 86 513

Media Relations

Jan Petter Stiff, Crux Advisors
stiff@crux.no
+47 995 13 891

David Dible, Mark Swallow, Marine Perrier; Citigate Dewe Rogerson
bergenbio@citigatedewerogerson.com
+44 207 638 9571

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