

# BerGenBio announces strong recruitment and encouraging safety profile for AXL Inhibitor BGB324 in a melanoma study at 9th World Congress of Melanoma

**Bergen, Norway, October 18, 2017** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective Axl kinase inhibitors for multiple cancer indications, announces that the randomised Phase 1b/2 clinical study of BGB324 in combination with either the MAPK inhibitors MEKINIST® (trametinib) plus TAFINLAR® (dabrafenib) or the immune checkpoint inhibitor KEYTRUDA® (pembrolizumab) in patients with advanced melanoma is recruiting well at four sites in Norway and reports a favourable safety profile. The results and analysis from this dose-finding part of the study (NCT02872259) have been presented in a poster at the 9th World Congress of Melanoma in Brisbane, Australia.

Dr Oddbjørn Straume, consultant oncologist at Haukeland University Hospital and Professor at the University of Bergen Centre for Cancer Biomarkers and sponsor of the trial, reported that the recommended Phase 2 dose (RP2D) of BGB324 in combination with trametinib and dabrafenib had been established. In addition, Dr Straume presented early data demonstrating that BGB324 is well tolerated in combination with either dabrafenib and trametinib or pembrolizumab.

Patient recruitment in all three arms of the Phase 2 study is ongoing and seeks to demonstrate safety and efficacy of BGB324 in combination with pembrolizumab or dabrafenib and trametinib in the first-line and second line setting. A parallel biomarker study is ongoing in collaboration with MIT and Harvard Medical School.

**Dr Straume, commented:** “Although novel immune- and targeted therapies show high initial response rates they are curtailed by the development of treatment resistance. Combination strategies therefore are being widely explored to further improve patient outcomes. Axl is a combination target of particularly high interest as it has been shown to be a key driver of resistance in melanoma to both anti-PD-1 therapy and MAP kinase inhibitors as well as playing a role in anti-tumour immune suppression. BGB324 is the most advanced selective Axl inhibitor in clinical development. It is very encouraging to see that BGB324 thus far has been tolerated well in patients with metastatic melanoma and I look forward to continue enrolling patients into the randomised arms of the study.”

**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** “We greatly appreciate the opportunity to work with physician-scientists at the forefront of their research areas such as Dr Straume and his international collaborators. This randomised trial in patients with melanoma is of great interest as it explores BGB324 as a potential cornerstone therapy across the whole patient population. BGB324 has specifically been developed as a selective Axl inhibitor to allow such strategic combinations and we are encouraged by the strong patient recruitment and that the combination with the MAP kinase inhibitors or the anti-PD1 therapy pembrolizumab so far has been well tolerated. This is especially important as we advance two additional Phase 2 studies of BGB324 in combination with pembrolizumab in lung and breast cancer.”

## About melanoma

Melanoma is the most serious type of skin cancer as it may spread to lymph nodes and distant organs if not discovered in time. Melanoma occurs when the cells that colour the skin, the so-called melanocytes, start to divide uncontrollably. It is estimated that in 2016, there have been almost 150,000 melanoma diagnoses in the US alone. If detected very early, melanoma has a good prognosis; for patients with advanced melanoma, however, the probability of surviving 5 years or longer is less than 20%.

## About the 9th World Congress of Melanoma - A Joint Meeting with the Society for Melanoma Research

This global summit is a joint congress consisting of the 9th World Congress of Melanoma and 14th International Congress of the Society for Melanoma Research and brings together the world's leading melanoma researchers and clinicians to showcase the latest developments in melanoma diagnosis, treatment and research. The congress is held in Brisbane, Australia, October 18 – 21st 2017.

## 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](http://www.bergenbio.com)

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