

BerGenBio: Encouraging I-O clinical data with selective AXL inhibitor bemcentinib (BGB324) supports its potential as cornerstone of cancer therapy

- Favourable interim safety data reported across three phase II clinical trials with bemcentinib in combination with KEYTRUDA® (pembrolizumab)
- Immune response demonstrated in AML patients treated with bemcentinib monotherapy in phase II clinical trial
- Two posters featuring four of BerGenBio's six phase II clinical trials with selective AXL inhibitor bemcentinib presented at the ASCO-SITC Clinical Immuno-Oncology Symposium

Bergen, Norway, January 29, 2018 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company focused on developing bemcentinib as a potential cornerstone therapy for multiple cancer indications, today announced the presentation of data from its broad phase II clinical development programme with its selective AXL inhibitor bemcentinib (BGB324) in two posters at the ASCO-SITC Clinical Immuno-Oncology Symposium (January 25-27, San Francisco, CA, USA).

One poster outlined favourable interim safety data from three phase II clinical trials with bemcentinib in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the US and Canada). Furthermore, an AXL immunohistochemistry (IHC) method developed and validated by the Company was shown to clearly detect the presence of AXL on tumour and immune cells in patient samples thus holding promise as a potential future companion diagnostic.

The second poster provided translational analyses from BerGenBio's phase II trial in acute myeloid leukaemia (AML), with bemcentinib used as a single agent. The results showed a clear immunomodulatory effect as a result of selective AXL inhibition, as evidenced by increased immune activity characterised by diversification of patients' T-cell receptor repertoire.

The data presented strengthens the Company's proposition that its selective, first-in-class and orally bioavailable AXL inhibitor bemcentinib may hold promise as an immunomodulatory agent, both as backbone to current and emerging immune checkpoint inhibitor regimens as well as a monotherapy by demonstrating the following:

(1) Combining bemcentinib with KEYTRUDA has thus far been well tolerated:

In a poster presentation entitled: "*Combination of bemcentinib (BGB324) – a first-in-class selective, oral AXL inhibitor – with pembrolizumab in patients with triple negative breast cancer and adenocarcinoma of the lung,*" Murray Yule (MD, PhD), Clinical Development Officer at BerGenBio, detailed:

- A total of 34 patients across the Company's three trials combining bemcentinib with KEYTRUDA (Trial ref. BGBC007 in triple-negative breast cancer, trial ref. BGBC008 in non-small cell lung cancer and trial ref. BGBIL006 in melanoma) have thus far been evaluable for safety of the drug combination
- The spectrum of observed serious adverse events was similar to that reported for KEYTRUDA alone.

(2) Treatment with bemcentinib has immunomodulatory effect:

In a poster presentation entitled: "*The immunomodulatory activity of bemcentinib (BGB324) – a first-in-class selective, oral AXL inhibitor in patients with relapsed/refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome.*", Professor Sonja Loges (MD, PhD), attending physician at the University Hospital in Hamburg-Eppendorf and lead investigator of the BGBC003 trial, detailed the following:

- 35 patients with relapsed/refractory (R/R) AML or myelodysplastic syndrome (MDS) received bemcentinib monotherapy as part of the BGBC003 trial. Two patients achieved complete responses with incomplete recovery of peripheral counts (CRi) and five achieved partial responses (PR). Eight patients reported disease stabilisation for more than four months. Three patients remain on study at the time of data cut-off (Jan 17th 2018).
- Six out of nine patients analysed showed a diversification of the T-cell receptor repertoire in their peripheral blood, bone marrow or both indicative of increased immune activity as a result of AXL inhibition.

Richard Godfrey, CEO of BerGenBio commented: "I am pleased that the data presented at ASCO-SITC demonstrate that our first-in-class, selective AXL inhibitor bemcentinib is well tolerated in combination with the anti-PD-1 therapy KEYTRUDA. This is fundamental data supporting the positioning of AXL inhibition as a future cornerstone of cancer therapy. I am also extremely encouraged by the data reported showing that bemcentinib can generate a positive immune response, particularly in R/R AML and MDS patients who tend to be a severely immunocompromised patient population. These data build on the recently reported favourable safety data of bemcentinib in combination with chemo- and targeted therapy as well as the first evidence of bemcentinib's ability to reverse acquired resistance to these treatments. I look forward to reporting continued progress across our broad phase II development programme with bemcentinib at medical and scientific congresses during the upcoming months."

-ENDS-

About TNBC and the BGBC007 trial

Breast cancer is the most common cancer in women – it is estimated that more than 250,000 new cases will be diagnosed in the US in 2018. 20% of breast cancers lack receptors for three common hormones (oestrogen, progesterone and HER2) and are thus called triple-negative breast cancers (TNBC). Treatment options for TNBC are limited to intense chemotherapy, but disease recurrence is frequent and aggressive. Consequently, novel treatment strategies for TNBC are urgently needed.

BGBC007 is a phase II multi-centre open label study of bemcentinib (BGB324) in combination with KEYTRUDA in patients with previously treated, non-resectable TNBC or triple negative inflammatory breast cancer. Up to 56 patients will be included in the study. For more

information, please access trial NCT03184558 at www.clinicaltrials.gov.

About NSCLC and the BGBC008 trial

It is estimated that more than 220,000 new cases of lung cancer will be diagnosed in the US in 2018 and it is the leading cause of cancer deaths. 65% of NSCLCs are classed as adenocarcinoma of the lung. Although various treatments exist for NSCLC, they are often curtailed by acquired resistance to therapy. Novel treatments overcoming this resistance in NSCLC are urgently required.

BGBC008 is a phase II multi-centre open label study of bemcentinib (BGB324) in combination with KEYTRUDA in patients with previously treated advanced adenocarcinoma of the lung. Up to 48 patients will be included in the study. For more information, please access trial NCT03184571 at www.clinicaltrials.gov.

About melanoma and the BGBIL006 trial

Melanoma is the most serious type of skin cancer and may spread to lymph nodes and distant organs if not discovered in time. Melanoma occurs when the pigment cells in the skin (melanocytes), divide uncontrollably. It is estimated that in 2016, there were 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 five or more years is less than 20%.

BGBIL006 is an investigator initiated, randomised phase II trial combining bemcentinib with either KEYTRUDA or dabrafenib/trametinib in patients with advanced non-resectable or metastatic melanoma who are naïve for systemic treatment. Up to 92 patients will be enrolled across three arms. For more information, please access trial NCT02872259 at www.clinicaltrials.gov.

About AML and the BGBC003 trial

AML is the most common form of acute leukaemia diagnosed in over 20,000 patients in the US annually and is rapidly lethal if left untreated. Successful treatment typically requires intensive therapy or bone marrow transplantation, and relapse and resistance are common. Consequently, there is an urgent need for effective novel therapies in R/R patients, particularly those that are ineligible for intensive therapy.

BGBC003 is a phase Ib/II multi-centre open label study of bemcentinib (BGB324) as a single agent in patients with AML or MDS or in a combination with chemotherapy (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 2018 ASCO-SITC Clinical Immuno-Oncology Symposium

The ASCO-SITC Clinical Immuno-Oncology Symposium is an international conference focused on clinical and translational research in immuno-oncology and the implications for clinical care. <https://immunosym.org/>

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:

- leukaemia BGB324 with TARCEVA® (erlotinib) in advanced EGFR mutation driven non-small cell lung cancer (NSCLC)
- BGB324 with KEYTRUDA in advanced adenocarcinoma of the lung, and
- BGB324 with KEYTRUDA in triple-negative breast cancer (TNBC).
- BGB324 as a single agent and combination therapy in acute myeloid leukaemia (AML) / myeloid dysplastic syndrome (MDS)

The clinical trials combining BGB324 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 BGB324 with either MEKINIST® (trametinib) plus TAFILINAR® (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 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

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Kenilworth, NJ, USA). TARCEVA® is a registered trademark of OSI Pharmaceuticals, LLC., marketed by Roche-Genentech. TAFILINAR® is a registered trademark of Novartis International AG and MEKINIST® is a registered trademark of GSK plc.

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