BerGenBio ASA: Results for the Third Quarter 2018

- ***Phase II data in NSCLC with bemcentinib/KEYTRUDA combination:*** *First stage of trial in previously treated patients reported 40% ORR and ca. 6 months median PFS in AXL positive patients, stage 2 actively enrolling patients*
- ***Additional NSCLC data:*** *Bemcentinib/TARCEVA phase II combination trial in first line EGFRm patients reported that median PFS has surpassed that of TARCEVA monotherapy, encouraging efficacy reported in combination trial with docetaxel in later line patients*
- ***Pipeline update:*** *IND filed for AXL antibody BGB149*

Bergen, Norway, 13 November 2018 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces its results for the third quarter 2018. A presentation of the results by the Company's management will take place today at 10.00 am CET in Oslo – details below.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"We are pleased with the progress of our phase II clinical development programme with our selective AXL inhibitor bemcentinib, particularly in NSCLC. The observed correlation between patient response and positive AXL status in our combination trial with KEYTRUDA gives us confidence in bemcentinib's proposed mode of action and its broad appeal as a promising new agent treating aggressive cancer. The next six to nine months will be an exciting time for the company as we anticipate further clinical data from our phase II trials, particularly in NSCLC and acute myeloid leukaemia."*

Highlights – Third Quarter & 2018

Bemcentinib/KEYTRUDA® combination in advanced non-small cell lung cancer (NSCLC) delivers highly promising phase II clinical results

- 40% overall response rate & 70% clinical benefit rate observed in AXL-positive, previously treated NSCLC patients, including PD-L1 negative patients (data presented at World Conference on Lung Cancer (WCLC))
- 5.9 months median progression-free-survival (PFS) in AXL positive vs. 3.3 months in AXL negative patients presented as late breaking abstract at Society Immunotherapy of Cancer congress (SITC, post-period)
- Efficacy endpoint met and stage two of the trial actively enrolling

Additional lung cancer phase II trials show promise for bemcentinib in combination with chemo- and targeted agents

- Median PFS of NSCLC patients receiving the bemcentinib/TARCEVA® combination in first line has surpassed that of TARCEVA monotherapy (data presented at WCLC)
- Encouraging efficacy reported for bemcentinib in combination with docetaxel chemotherapy in patients who had exhausted all available therapy options (data presented at WCLC)

Tissue- and blood-based biomarkers with potential for development as companion diagnostics

- Novel biomarkers identified and qualified across multiple clinical trials with bemcentinib, presented as poster discussion at European Society for Medical Oncology meeting (ESMO) and SITC 2018 (post period)

Arbitration process with Rigel Pharma Inc.

- The Company is seeking clarification of interpretation and application of certain provisions of the 2011 bemcentinib license agreement

Anticipated data and news flow in the coming months

- AML and MDS mono- and combination therapy at ASH 2018
- Stage 2 of bemcentinib/KEYTRUDA combination trial in H1 2019
- IND filed for BGB149, first in class AXL function blocking antibody (post period)

Financial Highlights
(Figures in brackets = same period 2017 unless otherwise stated)

- Total operating expenses for the third quarter were NOK 38.1 million (NOK 36.6 million). Total operating expenses for the first nine months of 2018 amounted to NOK 143.6 million (NOK 136.2 million)
- Research and development expenses accounted for 75.3 % of total operating expenses in Q3, and 72.3 % for the first nine months of 2018
- Comprehensive loss for the third quarter amounted to NOK 37.7 million (loss of NOK 35.4 million). Comprehensive loss for the first nine months of 2018 was NOK 140.7 million (loss of NOK 134.6 million)
- Cash and cash equivalents amounted to NOK 398.2 million at the end of September 2018 (NOK 440.3 million at 30 June 2018 and NOK 370.3 million at 31 December 2017)

Presentation and Webcast Details

A presentation by BerGenBio's senior management team will take place at 10.00 am CET at:

Hotel Continental, Stortingsgaten 24/26, 0117 Oslo

The presentation will webcast live and the link will be available at www.bergenbio.com in the section Investors/ Financial Reports. A recording will be available shortly after the webcast has finished.

The results report and the presentation will be available at www.bergenbio.com in the section: Investors/ Financial Reports from 7:00 am CET the same day.

-End-

About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms that drive aggressive and life-threatening diseases. In cancer, AXL drives tumour survival, treatment resistance and spread, as well as suppressing the body's immune response to tumours. AXL expression has been established as a negative prognostic factor in many cancers. AXL inhibitors, therefore, have potential value at the centre of cancer combination therapy, addressing significant unmet medical needs and multiple high-value market opportunities.

About BerGenBio ASA

BerGenBio is a clinical-stage biopharmaceutical company focused on developing transformative drugs targeting AXL as a potential cornerstone of therapy for advanced and aggressive cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in multiple solid and haematological tumours, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent.

In parallel, BerGenBio is developing a companion diagnostics test to identify patient populations most likely to benefit from bemcentinib: this is expected to facilitate more efficient registration trials and support a precision medicine-based commercialisation strategy.

BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK. The company is listed on the Oslo Stock Exchange (ticker: BGBIO). www.bergenbio.com

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Forward looking statements

This announcement may contain forward-looking statements, which as such are not historical facts, but are based upon various assumptions, many of which are based, in turn, upon further assumptions. These assumptions are inherently subject to significant known and unknown risks, uncertainties and other important factors. Such risks, uncertainties, contingencies and other important factors could cause actual events to differ materially from the expectations expressed or implied in this announcement by such forward-looking statements.

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