BerGenBio ASA: Results for the Second Quarter and First Half 2019

- Acute Myeloid Leukaemia (AML): Preliminary Phase II clinical shows promising efficacy for bemcentinib in combo with low-intensity chemo in elderly AML patients unfit for intensive therapy
- Non small cell lung cancer (NSCLC): Phase II clinical data continues to show promising clinical activity and improved overall survival, particularly in patients with AXL positive tumours including those with low or no PD-L1 expression.
- Recruitment completed for second stage Phase II bemcentinib and KEYTRUDA® combo trial in patients with advanced NSCLC (BGB008)
- Private placement completed, raising gross proceeds of NOK 74.2 million
- Cash and Cash equivalents at end of Q2 2019 NOK 324.4 million
- Operating loss of NOK 52.0 million in Q2 2019 (NOK 50.7 in Q2 2018) and NOK 97.1 million in H1 2019 (NOK 105.5 H2 2018).

Bergen, Norway, 19 August 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces its results for the second quarter and first half 2019.

A presentation and live webcast by the Company's management will take place today at 10.00 am CEST in Oslo, please see below for details.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented:

"*We are pleased to report a period of continued encouraging clinical data and validation of our lead candidate bemcentinib in our AML and NSCLC programmes. We are particularly excited by the LDAC combination data in second line AML patients.*
Our focus is now on refining and preparing our late stage clinical trials in light of our recent clinical data and emerging market opportunities, as we continue to leverage our significant scientific and R&D leadership to develop this potentially transformative therapy. We are committed to progressing bemcentinib through to regulatory approval and, in turn, addressing the significant unmet need among AML and NSCLC patients in order to improve outcomes for these patients and create value for stakeholders."

Operational Highlights – second quarter and first half 2019

Acute Myeloid Leukaemia (AML)

- Preliminary Phase II clinical data from AML trial presented at EHA 24 and ASCO 2019

- Phase II trial evaluating bemcentinib in combination with low-intensity chemotherapy in elderly AML patients unfit for intensive therapy shows promising efficacy
- 6 out of 14 patients receiving LDAC combination achieved an Overall Response Rate (ORR) of 43%, with encouraging duration of response - this data is still maturing.
- ORR significantly higher than previously reported/historical benchmarks (18%) with single-agent low dose cytarabine
- Favourable safety profile continues to be seen in LDAC combination
- Initiated preparation of expansion cohort to confirm the clinical signal from bemcentinib in combination with LDAC in elderly relapse/refractory AML patients.

Non-Small Cell Lung Cancer (NSCLC)

- New clinical data from BGB324 in NSCLC presented at ASCO 2019

- Completed recruitment for second stage of Phase II trial evaluating bemcentinib and KEYTRUDA in previously treated NSCLC patients post chemotherapy (NCT03184571 (BGB008, cohort A)
- First stage previously met efficacy endpoint, and reported encouraging median overall survival of 12.2 months
- Preliminary Overall Response Rate of 40% continues to be seen in patients with AXL positive tumours including those with weak or no PD-L1 expression
- Encouraging safety profile continues to be seen in combination

- Initiation of additional cohort in combination with KEYTRUDA in previously treated NSCLC patients post immunotherapy (NCT03184571, BGB008, cohort B)

Completed private placement, raising gross proceeds of NOK 74 million

- Net proceeds from the Private Placement to be used to advance the Company's clinical programs in AML and lung cancer, as well as for general corporate purposes
- The Private Placement attracted strong interest from existing shareholders and new specialist institutional investors

Presentation and Webcast Details

A presentation by BerGenBio's senior management team will take place today at 10:00 am CEST at:

Carnegie AS
Fjordalleen 16, 5. floor,
Aker Brygge,
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 presentation will be available at www.bergenbio.com in the section: Investors/Financial Reports from 7:00 am CET the same day.

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About BerGenBio

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, 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 and leukaemia. A first-in-class functional blocking anti-AXL antibody is undergoing Phase I clinical testing. In parallel, BerGenBio is developing a companion diagnostic test to identify those patient populations most likely to benefit from bemcentinib: this is expected to facilitate more efficient registration trials supporting 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). For more information, visit 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.