

BERGENBIO ASA: RESULTS FOR THE THIRD QUARTER 2019

- FDA granted Fast Track Designation for 2L Acute Myeloid Leukaemia (AML)
- High Impact oral presentation of 2L NSCLC clinical data at SITC
- Met primary and secondary endpoints in non-small cell lung cancer (NSCLC) Phase II clinical trial in patients previously treated with chemotherapy (cohort A)
- Proprietary composite AXL tumor immune score (cAXL) identified patients that have shown very durable response and significantly prolonged median Progression Free Survival (mPFS)
- Proprietary gene signature identified 2L NSCLC patients that had durable benefit and was independent of PD-L1
- Phase Ib/II interim safety data with bemcentinib in combination with pembrolizumab or BRAF/MEK inhibitors in 1L Melanoma confirmed the combinations are well tolerated by patients
- Cash and Cash equivalents at end of Q3 2019 NOK 289.5 million (NOK 398.2 million in Q3 2018)
- Operating loss of NOK 47.5 million in Q3 2019 (NOK 38.1 million in Q3 2018) and NOK 145.3 million YTD 2019 (NOK 143.6 million YTD 2018)

Bergen, Norway, 19 November 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 third quarter 2019.

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

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: “During the quarter we have continued working to expand our proof of concept trials in AML and NSCLC. Our goal is to confirm that the addition of our selective AXL inhibitor bemcentinib can substantially improve patient outcomes across both these indications. This will inform clinical strategy and position for late stage clinical development, and we remain committed to progressing bemcentinib through to regulatory approval.”

Operational Highlights – Third quarter 2019

Non-Small Cell Lung Cancer (NSCLC)

- Cohort A of the Phase II clinical trial (BGBC008) evaluating bemcentinib in combination with KEYTRUDA in patients with NSCLC met its primary endpoint.
 - Primary endpoint of Overall Response Rate (ORR) was met, with 33% ORR in cAXL positive patients; five times the response rate of cAXL negative patients (7%)
 - Response rate three times greater than that seen with Keytruda monotherapy reported in earlier clinical trials in similar patients.
 - Secondary endpoint of median Progression Free Survival (mPFS) reported significant 3-fold improvement in cAXL positive vs negative patients,
 - Data were presented at the prestigious High Impact Clinical Trial session at the Society for Immunotherapy of Cancer (6-10 November 2019) conference in Washington DC.
- Proprietary Composite AXL Immune Score (cAXL) suggests patients that express AXL in both their tumor and immune cells report significantly improved clinical benefit from bemcentinib combination with Keytruda.

- Data from Cohort A of BGBC008 was also presented in an oral presentation at the 2019 World Conference on Lung Cancer (WCLC) and as a poster the European Society of Medical Oncology Congress (ESMO).
- Data suggest bemcentinib has potential to enhance patient responses and overall survival, when treated in combination with a PD-1 inhibitor, particularly in patients with no or limited expression of PD-L1, this is a very significant patient population, and a very encouraging development.
- The clinical trial BGBC008 is ongoing in two additional cohorts; B) in Check Point Inhibitor refractory patients and C) in CPI/chemotherapy combination refractory patients. Preliminary data read out is anticipated in the first half of 2020.

Acute Myeloid Leukaemia (AML)

- U.S Food and Drug Administration (FDA) has granted bemcentinib Fast Track Designation for the treatment of elderly patients with AML whose disease has relapsed.
 - The purpose of the Fast Track designation is to get important new drugs to the patients earlier
 - The Fast Track program is designed to facilitate the development and expedite the regulatory review of new drugs to treat serious conditions without any treatment options.
- Phase IIa clinical trial data has shown that bemcentinib in combination with low-intensity chemotherapy (LDAC) in elderly AML patients is well tolerated and efficacious.
 - Preliminary responses were reported in 43% of evaluated patients, with complete responses in a substantially higher percentage of patients compared to previously observed/historical benchmarks in single-agent cytarabine.
 - Trial has been expanded to include an additional 28 patients to verify this early proof of concept, preliminary data from this expanded trial will be reported in the first half of 2020.

Financial highlights

- Revenue for the third quarter 2019 and the nine months ended 30 September 2019 respectively amounted to NOK 0 million (NOK 0 million) and NOK 8.7 million (NOK 0 million). The revenue was received in Q1 2019 from ADCT as a clinical milestone payment.
- Total operating expenses for the third quarter and the nine months ended 30 September 2019 respectively amounted to NOK 47.5 million (NOK 38.1 million) and NOK 154.0 million (NOK 143.6 million).
- Cash and Cash equivalents at end of Q3 2019 NOK 289.5 million (NOK 398.2 in Q3 2018).

Presentation and Webcast Details

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

Arctic Securities
Haakon VIIIs gate 5
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.

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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, drug 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.