

## **BERGENBIO ASA: RESULTS FOR THE SECOND QUARTER AND FIRST HALF OF 2020**

**Bergen, Norway, 18 August 2020** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for unmet medical need indications, announces its results for the second quarter and first half of 2020.

A presentation and live webcast by BerGenBio’s senior management will take place at 10.00 am CET today, please see below for details.

**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** “Set against the unprecedented backdrop of a global pandemic, this has been an eventful period for BerGenBio. During this time we have continued our focus on progressing clinical trials of our lead candidate bemcentinib in non-small cell lung cancer (NSCLC) and Acute Myeloid Leukaemia (AML) and more recently COVID-19, while ensuring that the safety and wellbeing of our staff and the patients participating in our clinical trials has been and remains our top priority.

“The COVID-19 crisis has and will likely continue to delay clinical trials throughout the sector and as anticipated has impacted patient recruitment into BerGenBio clinical studies and extended previously anticipated timelines. The impact of the pandemic on our clinical trials has continued through the second quarter, but we are pleased that new patients continue to be recruited into our clinical studies with bemcentinib, and already enrolled patients have been able to continue their treatment throughout the restrictions.

“We continue to make progress, with a latest milestone in NSCLC trial presented at the Next Gen Immuno-Oncology Congress conference where 6 of the 7 identified AXL positive patients reported clinical benefit and data showed a 2.5-fold improvement in median Progression-free Survival.

“The Company remains in a strong cash position, with two drug candidates backed by pioneering biology, continued favourable clinical results and important data readouts on the horizon in two major cancer indications, as well as a potential COVID-19 treatment. This is an exciting time for us.”

### **Operational Highlights – second quarter and the first half of 2020 (including post-period end)**

- **Positive interim clinical and translational phase II data with bemcentinib in combination with KEYTRUDA® in checkpoint inhibitor refractory NSCLC patients**
  - In June, BerGenBio presented positive data from its Cohort B, stage 1, in the phase II trial evaluating bemcentinib in combination with KEYTRUDA® in patients with advanced non-small cell lung cancer (NSCLC) and with confirmed progression on prior immune checkpoint therapy.
  - The trial included 12 evaluable patients for cAXL, BerGenBio’s proprietary composite-AXL (cAXL) immunohistochemistry biomarker. 7 of these 12 patients were cAXL-positive whereby 6 of these 7 patients reported clinical benefit and 2.5-fold improvement in mPFS.
  - BerGenBio also reported an update on Overall Survival data from Cohort A, where cAXL-positive patients reported 12-month Overall Survival of 79% and median Overall Survival of 17.3 months, whereas cAXL-negative reported 60% and 12.4 months respectively.
  - Data was presented at the NextGen Immuno-Oncology Congress, 25 June
  
- **First patient dosed in bemcentinib COVID-19 study in June 2020**

- In April, BerGenBio announced the selection of bemcentinib as the first candidate in a UK Government-backed national ACCORD study.
  - The study was a multicentre, seamless, Phase II adaptive randomisation platform trial to assess the efficacy and safety of multiple candidate agents for the treatment of COVID-19 in hospitalised UK NHS patients, and the first patient was dosed in June.
  - At the end of July, the incidence of COVID-19 in the UK had drastically reduced and the UK Research and Innovation's (UKRI) decided to cease grant funding. Subsequently, the University Hospital Southampton NHS Trust notified all sites in the ACCORD programme to cease the recruitment of new patients into the trial for all candidate agents. Patients already recruited, including those dosed with bemcentinib, will continue on treatment as per the protocol.
  - The decision to halt the study reflected the significant decrease in the incidence of COVID-19 in the UK and difficulty recruiting a sufficient number of patients and in no way reflected any interpretation of the efficacy or safety of any of the candidate agents.
  - BerGenBio is now in the late stage set-up phase to sponsor a similar study to ACCORD in a country of high COVID-19 incidence.
- **First patient dosed in bemcentinib Glioblastoma study in July 2020 (post-period)**
    - In July, BerGenBio announced the first patient was dosed in an investigator-initiated trial (IIT) assessing bemcentinib in recurrent glioblastoma (GBM). The study will enrol up to 20 recurrent GBM patients, at up to 15 sites in the USA.
    - Increased expression of the receptor tyrosine kinase AXL is significantly correlated with poor prognosis in GBM patients and preclinical data has suggested that bemcentinib may be a promising therapeutic agent for GBM, particularly in post-irradiation mesenchymal-transformed GBM tumors.
    - A comprehensive translational research programme will run in parallel with the clinical trial.

## Q2 2020 Financial Highlights

*(Figures in brackets = same period 2019 unless otherwise stated)*

- Revenue for the second quarter amounted to NOK 0.0 million (NOK 0.0 million) and for the six months ended 30 June NOK 0.0 million (NOK 8.7 million). The revenue in 2019 reflects clinical milestone payments from ADCT.
- Total operating expenses for the second quarter amounted to NOK 64.7 million (NOK 52.0 million) and for the six months ended 30 June NOK 121.0 million (NOK 106.5 million). NOK 7.5 million (NOK – 2.5 million) of operating expenses was non cash accruals for option cost.
- The operating loss for the quarter came to NOK 64.7 million (NOK 52.0 million) and for the six months ended 30 June NOK 121.0 million (NOK 97.8 million), reflecting the level of activity related to the clinical trials BerGenBio are conducting.
- Cash and cash equivalents increased to NOK 828.4 million by 30 June (NOK 419.4 by 31 March 2020).
- Private placement completed in May 2020, with gross proceeds NOK 520 million (including NOK 20 million from repair issue in July). Net proceeds to be used to take full advantage of clinical development opportunities stemming from the Company's technology and to progress readiness for early commercialisation possibilities and general corporate purposes.

## **Presentation and Webcast Details**

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

Webcast link: [https://channel.royalcast.com/webcast/hegnarmedia/20200818\\_6/](https://channel.royalcast.com/webcast/hegnarmedia/20200818_6/)

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The second quarter report and presentation is available on the Company's website in the Investors/Financial Reports section and a recording of the webcast will be made available shortly after the webcast has finished.

-Ends-

## **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 and 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, leukaemia and COVID-19. A first-in-class functional blocking anti-AXL antibody, tilvestamab, is undergoing Phase I clinical testing. In parallel, BerGenBio is developing companion diagnostic tests to identify those patient populations most likely to benefit from bemcentinib or tilvestamab: 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).

For further information, please visit: [www.bergenbio.com](http://www.bergenbio.com)

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***Forward looking statements***

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