

### **BERGENBIO ASA: THIRD QUARTER 2020 RESULTS**

**Bergen, Norway, 17 November 2020** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces its results for the third quarter 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.

Operational Highlights – third quarter of 2020 (including post-period end)

## Oncology

- Primary endpoint met in BERGAMO Phase II Trial investigating bemcentinib in patients with High Risk Myelodysplastic Syndromes (HR-MDS) or Acute Myeloid Leukaemia (AML)
  - The multicenter Phase II study evaluated the safety and efficacy of bemcentinib monotherapy in 45 patients with HR-MDS or AML who had relapsed following multiple rounds of prior treatment with hypomethylating agents (HMAs)
  - The primary endpoint overall response rate (CR, Cri, PR or SD) assessed after 4 treatment cycles was met,
  - o Data from this trial will be presented at ASH in December 2020.
- First patient dosed in investigator led study assessing bemcentinib in recurrent glioblastoma (GBM)
  - 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
  - The study will enroll up to 20 recurrent GMB patients, at up to 15 sites in the US
- First patient dosed in MiST3 trial assessing bemcentinib in relapsed malignant pleural mesothelioma patients
  - The investigator led study, sponsored by the University of Leicester, is funded by the British Lung Foundation, and is in collaboration with MERCK; forms part of the world's first molecularly stratified umbrella study in mesothelioma designed to enable the acceleration of novel, effective personalised therapy as a basis for improving survival outcomes for patients with mesothelioma
  - o The study will enroll up to 26 patients at three sites in the United Kingdom
- Pre-clinical data on humanized anti-AXL antibody tilvestamab, presented at virtual 32<sup>nd</sup>
  EORTC NCI AACR (ENA) Symposium
  - The data, presented in an ePoster at ENA in October, showed that tilvestamab prevents AXL mediated cell signalling in cancer cell lines, reduces cell migration and invasion and shows anti-tumor efficacy in a panel of mouse xenograft models
  - Tilvestamab is currently being evaluated in a Phase I clinical study to evaluate safety, tolerability and pharmacokinetics
- Selected for an oral presentation at the Society for Immunotherapy of Cancer (SITC) 35<sup>th</sup>
  Annual Meeting
  - BerGenBio presented clinical translational research updates from its Phase II bemcentinib and pembrolizumab combination study (BGBC008) in advanced nonsmall cell lung cancer (NSCLC)



- First patient enrolled in BerGenBio-sponsored Phase II clinical trial in South Africa and India, assessing the efficacy and safety of bemcentinib for the treatment of hospitalised COVID-19 patients
  - The first patient was enrolled in South Africa in October. The Phase II study will recruit 120 hospitalised COVID-19 patients across five sites in South Africa and seven sites in India
  - The primary endpoint of the trial will be time to clinical improvement of at least two points (from randomisation) on a nine-point ordinal scale, or live discharge from the hospital, whichever comes first
- UK Research and Innovation (UKRI) has reinstated funding for the COVID-19 ACCORD clinical study in which BerGenBio's bemcentinib is one of three drug candidates to be evaluated
  - The University Hospital Southampton NHS Trust remains the study sponsor, and the trial will be managed by the Medicines Evaluation Unit at Manchester University
  - Several substantial administrative amendments were made, and these required regulatory approval.

# **Q2 2020 Financial Highlights**

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

- Revenue for the third quarter of 2020 and the nine months ended 30 September 2020, respectively, amounted to NOK 0.0 million (NOK 0.0 million), and NOK 0.0 million (NOK 8.7 million).
- Total operating expenses for the third quarter and the nine months ended 30 September 2020, respectively, amounted to NOK 68.3 million (NOK 47.5 million) and NOK 189 million (NOK 154.0 million).
- Cash and cash equivalents at the end of the third quarter amounted to NOK 777.9 million (NOK 289.5 million)

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "In this quarter we have made solid progress with BerGenBio's primary development objectives to confirm clinical safety and proof of concept efficacy for bemcentinib in lung cancer and leukaemia. While the COVID-19 crisis has continued to delay clinical trials, including our own, we are pleased that hospitals have opened again for clinical trials and new patients continue to be recruited. Already enrolled patients remain on study.

"Overall, we remain well positioned. With a NOK 520 million fundraising completed in May this year our cash position is strong. We have a promising pipeline with two drug candidates backed by pioneering biology and a growing bank of favourable clinical data with further important readouts anticipated in two major cancer indications, and strong science supporting ongoing COVID-19 trials in the UK, India and South Africa. As always, I am grateful to the patients and their families for their trust in participating in our clinical trials, our staff and collaborators for their dedication and to our shareholders for their continued support. I look forward to providing further updates on our progress in the coming months."



#### **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/hegnarmedia/#!/hegnarmedia/20201117 1

Dial-in numbers: NO: +47-21-956342 SE: +46-4-0682-0620 DK: +45 78768490 UK: +44-203-7696819 US: +1 646-787-0157

Pin: 712491

The third quarter report and presentation are 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 ASA**

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, leukaemia and COVID-19. A first-inclass functional blocking anti-AXL antibody, tilvestamab, is undergoing phase I clinical testing. In parallel, BerGenBio is developing companion diagnostic tests to identify 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 <a href="https://www.bergenbio.com">www.bergenbio.com</a>

### **Contacts**

Richard Godfrey CEO, BerGenBio ASA +47 917 86 304

Rune Skeie, CFO, BerGenBio ASA rune.skeie@bergenbio.com +47 917 86 513

## **International Media Relations**

Mary-Jane Elliot, Chris Welsh, Lucy Featherstone, Carina Jurs Consilium Strategic Communications bergenbio@consilium-comms.com +44 20 3709 5700

**Media Relations in Norway** 



Jan Petter Stiff, Crux Advisers stiff@crux.no +47 995 13 891

## 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.