BERGENBIO ASA: RESULTS FOR THE SECOND QUARTER AND FIRST HALF OF 2021

Bergen, Norway, 17 August 2021 – 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 second quarter and first half of 2021.

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

Operational Highlights – second quarter of 2021 (including post-period end)

COVID-19

Update from Phase II trials assessing bemcentinib in hospitalised COVID-19 patients (April)

- Data from BGBC020 and ACCORD2 showed bemcentinib was well tolerated by patients with no safety concerns
- In both studies there was a numerically lower number of deaths in the bemcentinib arm vs. standard of care (1 vs 5 and 2 vs 3 respectively)

Pre-clinical COVID-19 data presented at Virtual Immunology Conference 2021 (May)

- Data from a preclinical COVID-19 study conducted by Professor Wendy Maury showed that SARS-CoV-2 utilizes TIM1 and AXL as key pathways for virus entry and that inhibition of AXL signalling by BerGenBio's selective inhibitor bemcentinib reduces infection

Top line data from Phase II (BGBC020) trial assessing bemcentinib in hospitalised COVID-19 patients (May)

- Post-hoc analysis identified more than 50% of patients with the most severe disease showed evidence of treatment effect by bemcentinib, although the primary endpoint did not achieve statistical significance
- Data from BGBC020 trial showed that bemcentinib has the potential to increase the rate of ventilator free survival to 90% compared to 72% with SOC on its own in more than 50% of COVID-19 patients
- Overall, in the combined studies, survival to day 29 was 96.5% (83 of 86 evaluable patients) in bemcentinib arm versus 91.0% (81 of 89) treated with SOC alone
- Bemcentinib anti-viral mechanism of action supported by analysis
- Bemcentinib was well tolerated throughout

Encouraging combined bemcentinib data from Phase II COVID-19 studies presented at ECCMID (July)

- Data from BGBC020 and ACCORD2 showed increased survival of 96.6% in bemcentinib arm vs. 91.2% in standard of care arm

- Significantly reduced likelihood (69%) of progression to ventilation in higher severity cohort
- Significantly increased likelihood (88%) of shorter time to recovery or discharge in higher severity cohort
- Clinical evidence of anti-viral mechanism of action
- Preclinical analysis highlights bemcentinib's potential against COVID-19 variants

COVID-19 data presented at The Annual American Society For Virology (July)

- Presentation given by BerGenBio's collaborator, Mr. Dana Bohan, a PhD candidate from the University of Iowa, who outlined previously announced findings from preclinical studies conducted in the Lab of Professor Wendy Maury
- New data investigating bemcentinib against SARS-CoV-2 mutations showed that bemcentinib is also efficacious in preventing SARS-CoV-2 infection by carrying circulating mutations

Non-Small Cell Lung Cancer

FDA fast track designation received for bemcentinib / anti-PD-(L)1 combination in NSCLC (June)

- Fast track designation received for the treatment of patients with AXL-positive advanced/metastatic non-small cell lung cancer (NSCLC)
- First recognition by a regulator of AXL-positive patients as a target population

Acute Myeloid Leukaemia

Encouraging updated preliminary data from Phase II relapsed AML study presented at EHA (June)

- Preliminary survival data with bemcentinib more than doubles historic survival data with standard of care
- Durable responses were observed in the relapsed AML setting, with an overall response rate of 36% (4/11) and median overall survival not achieved at data cut off, but 12 month survival at 70%.

Tilvestamab

Preclinical bemcentinib and tilvestamab data presented at European Association of Urology 2021 (July)

- Preclinical data from study investigating bemcentinib and tilvestamab in renal cell carcinoma (RCC) showed that both drugs prevented Gas-6-induced AXL phosphorylation *in vitro* and effectively prevented tumour growth in an orthotopic RCC xenograft model *in vivo*

Financial Highlights – second quarter of 2021

(Figures in brackets = same period 2020 unless otherwise stated)

- Revenue amounted to NOK 0.0 million (NOK 0.0 million)
- Total operating expenses for Q2 were NOK 92.3 million (NOK 64.7 million), and for the first half NOK 175.7 million (NOK 121.0 million)
- Operating loss for Q2 of NOK 92.3 million (NOK 64.7 million), and for the first half NOK 175.7 million (NOK 121.0 million), reflecting the level of activity related to the clinical trials BerGenBio is conducting
- Cash and cash equivalents decreased to NOK 574.0 million by 30 June 2021 (NOK 659.4 by 31 March 2021 and NOK 828.4 by 30 June 2020)

Richard Godfrey, Chief Executive Officer of BerGenBio, commented:

"The second quarter of 2021 has seen BerGenBio continue to make progress across its oncology programs, with significant updates from our ongoing trial in Acute Myeloid Leukaemia (AML). Given the strong data obtained so far, we have continued our dialogue with EU and US regulators on the potential initiation of a pivotal registration trial for the combination of bemcentinib and LDAC in relapsed elderly AML patients unfit for intensive chemotherapy.

"In addition to our lead programmes in oncology, we remain hopeful that bemcentinib could be an effective treatment for COVID-19. The need for effective therapeutic interventions against COVID-19 remains high and is driven by the continuous threat of new, potentially vaccine resistant strains of the virus.

"With ongoing interaction with regulators, Government and industry partners, with positive clinical data, and a clear business strategy in place, we are looking forward to the year ahead."

Presentation and Webcast Details

A presentation by BerGenBio's senior management team will take place today at 10:00 am CET and be webcast live.

Webcast link: https://channel.royalcast.com/landingpage/hegnarmedia/20210817_3/

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The Q2 and HY 2021 Financial 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.

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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 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

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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 considered to be inside information pursuant to the EU Market Abuse Regulation and is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.