BerGenBio reports second quarter and half year 2022 financial results and provides business update

- Commenced bemcentinib Phase 2b trial in hospitalized COVID-19 patients -
- Initiation of Phase 1a/2b STK11 mutated NSCLC trial planned for 2H22 -
- BerGenBio to host conference call and webcast today at 10:00 AM CEST/4:00 AM EDT -

BERGEN, Norway, August 23, 2022 – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical needs, today announced financial results for the second quarter and half year ended June 30, 2022 and provided a business update.

"The prioritization of bemcentinib development in two key areas in the second quarter has created momentum entering the second half of the year," said Martin Olin, Chief Executive Officer of BerGenBio. "By following strong scientific rationale, clinical and preclinical data, and areas of significant unmet medical need, we are confidently enthusiastic about bemcentinib's potential in aiding patients in two indications of focus: STK11 mutated Non-Small Cell Lung Cancer and patients hospitalized by COVID-19. The initiation of the next phase of clinical development for both indications in 2H22 moves us a meaningful step closer to addressing two large patient populations that are in need of better treatments."

Clinical Development

Bemcentinib

BerGenBio's lead compound, bemcentinib, is a potent, first-in-class, oral, small molecule, highly selective inhibitor of the receptor tyrosine kinase AXL, which is overexpressed in response to cellular stress, inflammation, hypoxia and chemotherapy. Bemcentinib inhibits the host cells' ability to propagate the progression of serious disease through the modulation of resistance mechanisms and the adaptive immune system.

The Company is advancing bemcentinib development in two lung indications, STK11 mutated (STK11m) Non-Small Cell Lung Cancer (NSCLC) and Hospitalized COVID-19 patients, where bemcentinib's novel mechanisms of action and primary accumulation in the lungs make it uniquely positioned to address severe lung diseases.

First-Line STK11m NSCLC

BerGenBio is preparing a Phase 1b/2a trial of bemcentinib in 1L STK11m NSCLC, a group that represents approximately 20% of NSCLC patients. Mutations in the STK11 gene are highly correlated with poor treatment response and survival with today's standard of care treatments, including immune checkpoint inhibitors in NSCLC. Through inhibition of AXL, bemcentinib seeks to prevent AXL activation, consequently removing the innate immunosuppression that it causes and driving the proliferation of immune cells to restore sensitivity to immune checkpoint therapy. UT Southwestern Medical Center in Texas has shown that bemcentinib in models of NSCLC has the ability to restore the sensitivity of checkpoint inhibitors. Further bemcentinib is also believed to delay the development of chemoresistance.

- The detrimental effect of mutations in the STK11 gene on clinical outcomes was further highlighted by several academic groups at the American Society of Clinical Oncology (ASCO) meeting in June 2022. In a retrospective study funded by Roche, Spain (Abstract #9047), of real-world outcomes in 1L NSCLC patients, STK11m was identified as having

the poorest prognosis in all effectiveness outcomes, including lower response, progression free survival and overall survival, of 185 detected mutations.

- The Company is preparing and has post period filed an IND with the purpose to initiate a Phase 1b/2a trial evaluating bemcentinib in combination with a checkpoint inhibitor and doublet chemotherapy in 1L STK11m NSCLC patients in the second half of 2022.

- In parallel with the preparation of the Phase 1b/2a trial, the Company is evaluating the role of STK11 mutations in combination with other relevant co-mutations such as TP53, KRAS and KEAP1 to further characterize the potential of bemcentinib is this area of high unmet medical need.

Hospitalized COVID-19 Patients
Bemcentinib is currently being studied in a Phase 2b clinical trial in hospitalized COVID-19 patients. AXL, when induced by an infection, such as COVID-19, is known to play a variety of key roles in transporting the virus into cells, aiding replication, and dampening immune responses. Bemcentinib selectively inhibits AXL to block viral entry, stimulate the innate immune system and facilitate tissue repair regardless of known variants or mutations.

- In the ACCORD2 UK platform study of hospitalized COVID-19 patients, bemcentinib treatment resulted in a clear reduction in clinical deterioration, causing: a significant reduction in deaths, patients requiring less supplementary oxygen, a significant reduction in the need for intubation or ventilation and a shortening of hospital stays compared to the control group.

- Bemcentinib has been selected by an expert group to be studied in a Phase 2b trial under the EU-SolidAct platform through a sub-protocol enrolling 500 hospitalized COVID-19 patients across Europe.

Mipasetamab Uzoptirine
Post period, ADC Therapeutics announced that the first patient was dosed in a Phase 1 clinical trial evaluating mipasetamab uzoptirine as a single agent and in combination with gemcitabine in patients with selected advanced solid tumors. Mipasetamab uzoptirine contains an AXL-targeting humanized monoclonal antibody licensed from BerGenBio.

Corporate Activities
BerGenBio strengthened its leadership team in April 2022 with the addition of Cristina Oliva, M.D., as Chief Medical Officer. Dr. Oliva is a Board-certified oncologist with over 20 years of senior clinical development experience across large pharmaceutical, biotechnology and CROs, including her most recent position as Vice President, Oncology and Head of Oncology Centre of Excellence at IQVIA, Ltd.

Second Quarter 2022 Financial Highlights

(Figures in brackets = same period 2021 unless otherwise stated)
- Revenue amounted to NOK 0.0 million (NOK 0.0 million) for the second quarter 2022
- Total operating expenses for the second quarter were NOK 88.2 million (NOK 92.3 million)
- The operating loss for the second quarter came to NOK 88.2 million (NOK 92.3 million)
- Cash and cash equivalents amounted to NOK 292.1 million (NOK 367.8 million at the end of the first quarter 2022).

Presentation and Webcast Details
The live webcast link is available at www.bergenbio.com in the Investors/Financial Reports section. A recording will be available shortly after the webcast has finished.

Webcast link: https://channel.royalcast.com/landingpage/hegnarmedia/20220823_9/

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The first 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.

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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 cancer and severe respiratory infections. The Company is focused on its proprietary lead candidate bemcentinib a potentially first-in-class selective AXL inhibitor in development for STK11 mutated NSCLC and COVID-19.

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

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 subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.