BERGENBIO ANNOUNCES COMPLETE DATA ANALYSIS OF ACCORD2 PHASE II BEMCENTINIB STUDY IN HOSPITALIZED COVID-19 PATIENTS – PRIMARY EFFICACY ENDPOINT MET

Complete data analysis confirms that the primary endpoint of improved clinical response and key secondary endpoints were met in a subprotocol under the platform ACCORD2 study where bemcentinib was added to standard of care therapy

BerGenBio to confirm the ACCORD2 data by progressing bemcentinib into EU-SolidAct, a pan-European platform COVID-19 study enrolling up to 500 patients

Bergen, Norway, April 26, 2022 - BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL inhibitors for severe unmet medical needs, announced today that a complete data analysis of a randomized phase II study of bemcentinib in combination with standard of care (SoC) therapy, ACCORD2 (BGBIL019), in hospitalized COVID-19 patients confirms that the primary efficacy endpoint was met.

At the July 2021 European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) meeting, the Company previously presented preliminary data from the ACCORD2 study in combination with a second COVID-19 study (BGBC020) showing evidence of therapeutic benefit on meaningful clinical endpoints in a total of 177 patients. Today's announcement is the first time complete ACCORD2 data in a total of 61 treated patients has been separately reported.

Overall, 90% of patients treated with bemcentinib + SoC (26 of 29) experienced a clinical response by day 29 (median 7.0 days), as defined by either a two-point improvement in World Health Organization (WHO) category from baseline score, or discharge from hospital, whichever arose sooner. This compared to 69% (22 of 32 patients) with a clinical response to SoC treatment alone (median 9.5 days), showing statistical significance.

The data was generated under a sub-protocol of the platform ACCORD2 study (ACCORD2; EudraCT 2020-001736-95 - BGBIL019), a multi-center phase II randomized study designed to assess the efficacy and safety of candidate agents as add-on therapies to SoC for the treatment of COVID-19 in hospitalized patients.

Overall, 98% of patients received dexamethasone or an equivalent steroid in their SoC, and 18% received immunomodulatory treatment with tocilizumab. The antiviral remdesivir was used in 53% of those randomized to SoC alone, and in 21% of patients treated with bemcentinib.

In addition, key secondary endpoints saw statistically significant improvements for the bemcentinib + SoC arm compared to SoC alone, including avoidance of any deterioration by ≥1-point increase in WHO score (including death) and ventilator-free survival over 29 days. At day 29, 97% of bemcentinib + SoC treated patients were alive compared to 81% of SoC-alone.

Bemcentinib treatment was well tolerated in this patient population, with no clinically relevant safety signals in comparison to standard of care treatment.

These latest results underline bemcentinib's potential in COVID-19 and other severe respiratory infections. As previously announced, bemcentinib will be studied in the EU-SolidAct trial in up to 500 hospitalized COVID-19 patients.

Professor Tom Wilkinson MA Cantab MBBS PhD FRCP FERS, Professor of Respiratory Medicine and Chief Investigator on the ACCORD program commented: *"With COVID-19 still driving hospital admissions globally it is key that new, more effective treatments are being developed. These results from the ACCORD2 program indicate that bemcentinib has demonstrated real promise as a new therapeutic option for hospitalized patients and it now warrants testing in larger studies. These results are a testament to the great collaboration between the NHS, NIHR, the MEU and our Southampton research teams with more exciting results to follow from the platform."*

Martin Olin, Chief Executive Officer of BerGenBio, commented: *"We are highly encouraged by the final data from our ACCORD2 study in hospitalized COVID-19 patients. The ability of bemcentinib to add a statistically significant benefit in clinical response over standard of care therapy is promising. We look forward to moving to the next step in the development of bemcentinib for COVID-19 through our participation in the EUSolidAct platform study, designed to enrol up to 500 hospitalized COVID-19 patients."*

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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, therapy resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme focused on combination and single agent therapy in cancer and COVID-19. A first-in-class functional blocking anti-AXL antibody, tilvestamab, is undergoing phase I clinical testing.

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

About ACCORD2 study
Under the bemcentinib sub-protocol of the ACCORD2 study, patients were enrolled within a calendar day after being admitted to hospital. Eligible patients were categorized by the WHO 9-point clinical scale and ranged from patients who did not require supplementary oxygen (grade 3) to those requiring non-invasive ventilation or high-flow nasal oxygen, but not intubated (grade 5). In the bemcentinib sub-protocol 29 patients were randomized and received bemcentinib treatment in addition to SoC.
For further details: https://clinicaltrials.gov/ct2/show/NCT04890509

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.

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