BERGENBIO ANNOUNCES POSITIVE INTERIM CLINICAL AND TRANSLATIONAL DATA FROM PHASE II TRIAL OF BEMCENTINIB IN COMBINATION WITH KEYTRUDA® IN CHECK POINT INHIBITOR REFRACTORY NSCLC PATIENTS

- 6 of 7 checkpoint inhibitor refractory cAXL-positive patients report clinical benefit
- 12 evaluable patients for cAXL status, 7 of whom were cAXL-positive
- 2.5 fold improvement in mPFS in cAXL-positive patients
- Cohort A data-update mOS in cAXL-positive patients of 17.3 months.
- Data presented today at the virtual Next Gen Immuno-Oncology Congress

Bergen, Norway, 25 June 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for severe unmet medical need, announces positive clinical and translational data from Cohort B, stage 1 of in the phase II trial (BGBC008). This cohort of the trial is evaluating bemcentinib in combination with MSD's Keytruda® (pembrolizumab) in previously treated non-small cell lung cancer (NSCLC) patients with confirmed progression on prior immune checkpoint therapy. The trial is recruiting the second stage of the cohort.

The data was presented today by Professor Hani Gabra M.D. Ph.D., Chief Medical Officer of BerGenBio ASA, at the Next Gen Immuno-Oncology Congress, a virtual event, see: https://events.marketsandmarkets.com/3rd-annual-marketsandmarkets-next-gen-immuno-oncology-congress/#. The presentation will be available on the Company website in the Presentations section www.bergenbio.com/investors/presentations/

BerGenBio announced on 15th January 2020 that stage 1 of this trial cohort had met its primary end point of overall response rate and criteria were met for expansion of this cohort to a second stage.

The Company reports that Cohort B, stage 1 included 12 evaluable patients for cAXL, BerGenBio's proprietary composite-AXL (cAXL) immunohistochemistry biomarker. Seven of these 12 patients were scored cAXL positive, six of these seven patients reported clinical benefit, including1 PR and 1 PRi (unconfirmed) and 2.5 fold improvement in mPFS. Further, an update was presented for Overall Survival data from cohort A, where cAX-postive patients reported 12-month OS of 79% and mOS of 17.3 months (data still maturing), whereas cAXL-negative 60% and 12.4months respectively and in-line with historic controls.

The BGBC008 trial (ClinicalTrials.gov Identifier: NCT03184571) is conducted in three cohorts evaluating the safety and benefit of bemcentinib and Keytruda combination in refractory NSCLC patients. Cohort A (fully recruited, patients that are refractory to first line chemotherapy), Cohort B (enrolling second line patients who have received single agent checkpoint inhibitor in the first line) and Cohort C (that enrols second line patients refractory to the first line treatment of checkpoint inhibitor in combination with chemotherapy), cohorts B2 and C are actively recruiting patients. The study is being sponsored by BerGenBio in collaboration with MSD, a tradename of Merck & Co., Inc.,

Kenilworth, New Jersey, USA, who continue to supply Keytruda® for use in the study under a collaboration agreement signed in March 2017.

Richard Godfrey, Chief Executive Officer of BerGenBio, said: "This interim clinical and translational data adds further confidence to the potential patient benefit of selective AXL inhibition with bemcentinib, to reverse resistance to immune checkpoint inhibitors in selected cAXL-positive patients who have relapsed on immunotherapy. This would be a highly desirable alternative to the second-line chemotherapy standard-of-care. Top line data from expansion cohorts B2 and cohort C should be available towards the end of 2020."

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About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases. In cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. AXL expression defines a very poor prognosis subgroup in most cancers. AXL inhibitors, therefore, have potential high value at the centre of cancer combination therapy, addressing significant unmet medical needs and multiple high-value market opportunities. Research has also shown that AXL mediates other aggressive diseases.

About Bemcentinib

Bemcentinib (formerly known as BGB324), is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in multiple solid and haematological tumours, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent. Bemcentinib targets and binds to the intracellular catalytic kinase domain of AXL receptor tyrosine kinase and inhibits its activity. Increase in AXL function has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers.

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 COVID19. 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 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 www.bergenbio.com

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