

BerGenBio Presents Phase II Trial Updates with Selective AXL Inhibitor Bemcentinib at the European Society for Medical Oncology (ESMO) 2019 Congress

Bergen, Norway, 27 September 2019 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, is to provide study updates in two poster presentations from its Phase II clinical development programme with bemcentinib (BGB324), a first-in-class highly selective oral AXL inhibitor, at the European Society for Medical Oncology (ESMO) 2019 Congress, in Barcelona (27 September – 01 October 2019).

The first poster outlines data from BerGenBio's Phase II clinical trial (BGB008) with bemcentinib and Merck's anti-PD-1 therapy pembrolizumab (KEYTRUDA) in patients with advanced non-small cell lung cancer (NSCLC). Data shows that the combination is well tolerated and showed promising efficacy in previously treated NSCLC patients, particularly in those with AXL expression in tumour, immune and stromal cells, including PDL-1 low/negative patients. The poster also highlights the identification of a new novel predictive plasma protein biomarker.

The second poster provides a trial update on a randomized Phase Ib/II study of bemcentinib in combination with either dabrafenib/trametinib (D/T) or pembrolizumab in patients with metastatic melanoma. Data from the trial shows that bemcentinib is well tolerated in combination with both D/T and pembrolizumab, with adverse effect profiles consistent with those reported for either therapeutic approach alone.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "AXL mediates aggressive traits when expressed on tumour, immune and stromal cells in cancers. Bemcentinib inhibits this, and we see encouraging and very durable clinical benefit in patients who otherwise would not be expected to respond to PD-1 inhibitors. Our comprehensive translational research program is yielding novel biomarkers and validation of the mode of action of bemcentinib. We look forward to providing updates as data from our ongoing investigations becomes available."

Presentation details

Full abstracts are available online at <https://www.esmo.org/Conferences/ESMO-Congress-2019/Abstracts> and details of the presentations are below. The posters presented at ESMO will be made available at www.bergenbio.com in the Investors / Presentations section following the sessions.

Preliminary efficacy results of selective AXL inhibitor bemcentinib with pembrolizumab following chemo in patients with NSCLC (ID 2041)

- Jose M. Trigo Perez et al
- 1576P - Poster Display session 1
- 28 September 2019: Poster Area (Hall 4), 12:00 – 13:00

Trial update: A randomized Phase Ib/II study of the selective small molecule Axl inhibitor bemcentinib (BGB324) in combination with either dabrafenib/trametinib (D/T) or pembrolizumab in patients with metastatic melanoma (ID 2131)

- Oddbjørn Straume et al
- 1336P - Poster Display session 3
- 30 September 2019: Poster Area (Hall 4), 12:00 - 13:00

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 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 and leukaemia. A first-in-class functional blocking AXL antibody (BGB149) and an AXL-ADC (ADCT-601) are undergoing phase I clinical testing. In parallel, BerGenBio is developing a companion diagnostic test to identify those 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). www.bergenbio.com

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 Elliott, Chris Welsh, Nicholas Brown, 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.