

# BerGenBio ASA: Results for the Second Quarter and First Half 2018

- Encouraging clinical data emerging from several phase II trials with highly selective AXL inhibitor bemcentinib (BGB324)
- Advanced lung cancer (NSCLC): First stage fully recruited, and first efficacy endpoint met in phase II trial of bemcentinib in combination with anti-PD-1 therapy KEYTRUDA®
- Advanced leukaemia (AML/MDS): Encouraging bemcentinib single agent activity in hard to treat relapsed / refractory (R/R) leukaemia
- Pipeline update: AXL antibody preparing for Phase I clinical trial

**Bergen, Norway, 21 August 2018** – BerGenBio ASA (OSE: BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces its results for the second quarter and first half 2018. A presentation of the results by the Company's management will take place today at 10.00 am CET in Oslo – details below.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: "We are pleased with the progress of our clinical development programme for bemcentinib in the first half 2018. The emerging results in several clinical trials, which we showcased at our successful satellite reception coinciding with the ASCO meeting in June, are very encouraging and continue to support our view that bemcentinib could become a cornerstone of future cancer therapy. These data provide further evidence of bemcentinib's activity in patients whose cancer progression is mediated by AXL. In addition, we are making good progress with our studies to identify predictive biomarkers that could be developed as companion diagnostics for personalized therapy with bemcentinib. We look forward to advancing these studies to completion and defining the future development strategy of bemcentinib with the greatest value for patients."

# Highlights - Second Quarter & First Half 2018

- Advanced lung cancer (NSCLC): First stage fully recruited, and first efficacy endpoint met in trial of bemcentinib in combination with KEYTRUDA®. Clinical responses seen following treatment with bemcentinib/KEYTRUDA in patients negative for PD-L1 for whom KEYTRUDA monotherapy is not effective.
- Advanced leukaemia (AML/MDS): Encouraging single agent activity in hard to treat relapsed / refractory (R/R) leukaemia: Superior response rates of > 40% observed in biomarker subgroup analyses.
- Triple negative Breast cancer (TNBC): First stage fully recruited, patients negative for Axl and PDL1 and first efficacy endpoint not met.
- Tissue- and blood-based biomarkers with potential for development as companion diagnostics: AXL IHC method reporting encouraging correlation data. Low plasma soluble AXL predicts patient benefit in R/R AML/MDS.
- Pipeline update: AXL antibody preparing for Phase I clinical trial.
- Cash position NOK441m.

# **Presentation and Webcast Details**

A presentation by BerGenBio's senior management team will take place at 10.00 am CET at:

Felix Konferansesenter, Bryggetorget 3, 0125 Oslo

The presentation will webcast live and the link will be available at <a href="www.bergenbio.com">www.bergenbio.com</a> in the section Investors/ Financial Reports. A recording will be available shortly after the webcast has finished.

The results report and the presentation will be available at <a href="www.bergenbio.com">www.bergenbio.com</a> in the section: Investors/ Financial Reports from 7:00 am CET the same day.

-End-

# About BerGenBio ASA

BerGenBio ASA is a clinical-stage biopharmaceutical company focused on developing a pipeline of first-in-class AXL kinase inhibitors as a potential cornerstone of combination cancer therapy. The Company is a world leader in understanding the essential role of AXL kinase in mediating aggressive disease, including immune evasive, drug resistant, metastatic solid and haematological cancers.

BerGenBio's lead product, bemcentinib (BGB324), is a selective, potent and orally bio-available small molecule AXL inhibitor in four Company sponsored Phase II clinical trials in major cancer indications, with read-outs anticipated during 2018. It is the only selective AXL inhibitor in clinical development.

The Company sponsored clinical trials are:

- Bemcentinib with TARCEVA® (erlotinib) in advanced EGFR mutation driven non-small cell lung cancer (NSCLC)
- Bemcentinib with KEYTRUDA in advanced adenocarcinoma of the lung, and
- Bemcentinib with KEYTRUDA in triple-negative breast cancer (TNBC).
- Bemcentinib as a single agent and combination therapy in acute myeloid leukaemia (AML) / myeloid dysplastic syndrome (MDS)

The clinical trials combining bemcentinib with KEYTRUDA in adenocarcinoma of the lung and TNBC are conducted in collaboration with Merck & Co., Inc. (Kenilworth, NJ, USA), through a subsidiary.

In addition, a number of investigator-sponsored trials are underway, including a trial to investigate bemcentinib with either MEKINIST®

(trametinib) plus TAFINLAR® (dabrafenib) or KEYTRUDA in advanced melanoma, as well as a trial combining bemcentinib with docetaxel in advanced NSCLC.

BerGenBio is simultaneously developing a companion diagnostic test to identify patient subpopulations most likely to benefit from treatment with bemcentinib. This will facilitate more efficient registration trials and support a precision medicine based commercialization strategy.

The Company is also developing a diversified pre-clinical pipeline of drug candidates, including BGB149, an anti-AXL monoclonal antibody.

For further information, please visit: www.bergenbio.com

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, TARCEVA® is a registered trademark of OSI Pharmaceuticals, LLC., marketed by Roche-Genentech. TAFLINAR® is a registered trademark of Novartis International AG and MEKINIST® is a registered trademark of GSK plc.

#### **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

David Dible, Mark Swallow, Marine Perrier Citigate Dewe Rogerson bergenbio@citigatedewerogerson.com I +44 207 638 9571

## 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.