

# BerGenBio ASA: Results for the Fourth Quarter and Full Year 2017

**Bergen, Norway, 13 February 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 fourth quarter and full year 2017. A presentation of the results by the Company's senior management team will take place today at 10.00 am CET in Oslo – details below.

**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** “BerGenBio has made solid progress during 2017 and achieved all of the milestones we outlined at the time of our IPO in April. We have advanced, as planned, our clinical development strategy for bemcentinib, the recently accepted generic name for our lead candidate BGB324, such that it is now being evaluated in six Phase II clinical studies in multiple cancer indications. These trials are designed to deliver initial proof-of-concept of bemcentinib's potential as a future cornerstone of cancer therapy in combination with immuno-oncology drugs, chemo- and targeted therapy. Initial clinical data presented during the year continue to give us confidence that bemcentinib is a very exciting drug candidate with broad application across many types of cancer, and in combination with existing and emerging modalities of cancer treatment. We will continue to drive these trials towards interim read outs in mid-2018 and look forward to an exciting year ahead.”

## Q4'17 highlights

- First patients enrolled and dosed in Phase II trials of bemcentinib (BGB324) in combination with KEYTRUDA® (pembrolizumab) in non-small cell lung cancer (NSCLC) and triple negative breast cancer (TNBC)
- Clinical data presentations at global cancer conferences continue to highlight bemcentinib's safety and promising efficacy profile

## FY'17 highlights

- Successful initial public offering (IPO) raising NOK 400m has enabled BerGenBio to fund and advance its broad and ambitious Phase II clinical development programme with bemcentinib
- BerGenBio enters clinical collaborative agreement with Merck & Co., Inc. (MSD) for two immunotherapy trials in patients with advanced NSCLC and TNBC
- Six clinical trials open and recruiting to establish clinical proof-of-concept of bemcentinib's potential to be a cornerstone of cancer therapy across multiple cancer indications
- Clinical and scientific data updates at global conferences consistently show improved clinical benefit and immune modulatory effect of bemcentinib-containing therapy
- Good progress advancing the development of companion diagnostics in parallel with all clinical trials to identify patients who are most likely to benefit from bemcentinib treatment
- BGB149 anti-AXL antibody programme on track to enter the clinic in H2 2018

## Post FY events

- First efficacy endpoint met in Phase II trial of bemcentinib/TARCEVA® (erlotinib) combination in NSCLC
- Bemcentinib was well tolerated in all patients enrolled across three combination trials with KEYTRUDA thus far (n=34)
- Single agent therapy with bemcentinib led to a diversification of the T-cell receptor repertoire in relapsed / refractory acute myeloid leukaemia (AML) and myeloid dysplastic syndrome (MDS) patients indicative of immune activation

## Financial Summary

Key Figures (NOK million)	Q42017	Q42016	FY2017	FY2016
Operating revenues	-	-	-	-
Operating expenses	47.5	28.0	183.7	131.6
Operating profit (loss)	(47.5)	(28.0)	(183.7)	(131.6)
Profit (loss) after tax	(47.6)	(27.9)	(182.2)	(129.8)
Basic and diluted earnings (loss) per share (NOK)	(0.96)	(82.81)	(4.01)	(419.68)
Net cash flow in the period	(28.8)	(25.4)	208.5	87.8
Cash position end of period	370.3	161.8	370.3	161.8

## 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 [www.bergenbio.com](http://www.bergenbio.com) in the section Investors/Reports and presentations/Webcasts. A recording will be available shortly after the webcast has finished.

The results report and the presentation will be available at [www.bergenbio.com](http://www.bergenbio.com) in the section: Investors/Reports and presentations 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 cancer spread, immune evasion and drug resistance in multiple aggressive 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 TAFLINAR® (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](http://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.*

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## **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.*