

# BerGenBio ASA: Results for the First Quarter 2019

- Advanced leukaemia (AML/MDS): Phase II trial fully recruited and combination trial with low-intensity chemotherapy meets efficacy endpoint in hard to treat relapsed / refractory (R/R) leukaemia
- Advanced lung cancer (NSCLC): Additional cohort added in trial of bemcentinib in combination with anti-PD-1 therapy KEYTRUDA®
- Anti-AXL antibody, BGB149, commenced phase I safety and pharmacokinetic clinical trial.

**Bergen, Norway, 08 May 2019** – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for multiple cancer indications, announces its results for the first quarter 2019.

A presentation and live webcast by the Company's management will take place today at 10.00 am CET in Oslo, please see below for details.

**Richard Godfrey, Chief Executive Officer of BerGenBio, commented:** "We are pleased to see the positive strategic and clinical momentum generated in the last year continue into 2019. We have continued to see promising initial data emerging from the clinical development programme with bemcentinib, particularly in AML and NSCLC. We believe that this data provides us with sufficient evidence to begin the initiation of late stage clinical development in these indications during 2019. We are looking forward to providing an update on these data at the forthcoming American Society of Clinical Oncology (ASCO) meeting in June."

## Operational Highlights

### Lead candidate bemcentinib meets efficacy endpoint in combination with cytarabine in AML patients unfit for intensive therapy

- Phase II trial evaluating bemcentinib in combination with low-intensity chemo-therapy in AML patients unfit for intensive therapy fully recruited
- Bemcentinib in combination with Low-dose Cytarabine (LDAC) meets efficacy endpoint: Three out of 10 evaluable LDAC patients (30%) had CR/CRI
- Combos warrant further expansion, meanwhile, company prepares for late stage bemcentinib monotherapy trial in later line elderly AML patients unfit for intensive chemotherapy

### Phase II trial with bemcentinib and KEYTRUDA® in NSCLC made important progress

- Additional cohort (Cohort B) added under collaboration agreement with Merck & Co extending eligibility to patients who have disease progression on prior immune checkpoint inhibitors

### Start of Phase II Investigator-Initiated Trial Evaluating Selective AXL Inhibitor bemcentinib in high-risk MDS

- Up to 43 patients to be enrolled at leading MDS centres across Europe

### Start of Phase I trial evaluating first-in-class anti-AXL antibody BGB149

- BGB149, a wholly owned asset, is the first therapeutic anti-AXL monoclonal antibody to enter clinical development
- Phase I study will investigate safety and pharmacokinetics in healthy volunteers

### Start of phase I trial evaluating ADCT-601, a novel anti-AXL antibody drug conjugate (ADC), in patients with advanced solid tumours

- ADCT-601 uses a proprietary AXL antibody developed by BerGenBio and licensed to ADC Therapeutics for ADC development
- Phase I dose escalation and expansion trial will evaluate ADCT-601 in 75 cancer patients
- Trial managed and sponsored by ADC Therapeutics
- First clinical milestone met and milestone payment received

### Preclinical data presented at AACR reinforces bemcentinib's potential to reverse tumour immunosuppression and therapy resistance

- Extensive data in pre-clinical models of non-small cell lung cancer (NSCLC) and pancreatic cancer demonstrating AXL's role in reversing tumour-mediated immunosuppression and therapy resistance presented at AACR
- bemcentinib shown to reverse AXL's effects, thus acting synergistically with immune cells and anti-cancer therapies

### Key appointments to executive team and Board to prepare organisation for next phase of development

- Key appointments to executive team and Board to prepare organisation for next phase of development; Board of Directors strengthened. Grunde Eriksen, Debra Barker and Pamela Trail elected as new board members.
- Dr Dominic Smethurst appointed as permanent Chief Medical Officer (CMO)
- Favourable outcome of arbitration brought by BerGenBio against Rigel Pharmaceuticals clarifying the extent of Rigel's entitlement to receive compensation in the event of a sale of BerGenBio, its assets, or a license to Bemcentinib
- R&D grant of up to NOK 11 m awarded by Research Council of Norway

## Financial highlights

- Total operating expenses for the first quarter were NOK 54.5 million (Q1 2018 NOK 54.8 million)
- Research and development expenses accounted for 70% of total operating expenses in Q1
- Comprehensive loss for the first quarter amounted to NOK 44.3 million (Q1 2018 a loss of NOK 53.8 million)
- Cash and cash equivalents amounted to NOK 306.7 million at the end of March 2019

## Presentation and Webcast Details

A presentation by BerGenBio's senior management team will take place today 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/Financial Reports. A recording will be available shortly after the webcast has finished.

The results report and presentation will be available at [www.bergenbio.com](http://www.bergenbio.com) in the section: Investors/Financial Reports from 7:00 am CET the same day.

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## About BerGenBio

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 anti-AXL antibody is 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). For more information, visit [www.bergenbio.com](http://www.bergenbio.com)

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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.