



# BERGENBIO ANNOUNCES LAUNCH OF BUSINESS STRATEGY FOCUSED ON NSCLC AND COVID-19

- *BerGenBio to focus on two key opportunities for its lead compound bemcentinib*
- *Strategic focus anchored in strong scientific rationale, supported by dataset from over 600 patients demonstrating bemcentinib's biological and clinical activity matched with significant unmet medical needs*

Bergen, Norway, 4 May 2022 - BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL inhibitors for severe unmet medical needs, announces today an update on its business strategy. BerGenBio will now focus on two key indications; 1st line non-small cell lung cancer (NSCLC) and COVID-19, which the Company believes offer the optimal path towards translating BerGenBio's strong scientific foundation into significant value generation from marketed products to address unmet medical needs.

## The opportunity

BerGenBio has for many years pioneered research into AXL inhibition, with its lead development candidate bemcentinib showing clinical potential in oncology and infectious disease. With over 600 patients dosed (approx. 400 in oncology and approx. 200 in COVID-19), the Company has built a large dataset demonstrating biological and clinical activity while simultaneously defining dosing regimens to identify an appropriate balance of safety and efficacy.

The updated business strategy announced today builds on bemcentinib's mode of action and data gathered from a broad clinical exploration to progress two distinct opportunities with the potential to significantly improve the lives of patients: NSCLC and COVID-19. Both indications show strong evidence of bemcentinib activity, with the advantage of accumulation in target organs, options for accelerated registration, compelling competitive advantages, and both represent high unmet medical needs.

**Martin Olin, Chief Executive Officer of BerGenBio, commented:** *"BerGenBio has been at the forefront of understanding of AXL biology and, having pioneered this area, we remain confident that selective AXL inhibition holds significant potential as a transformative treatment modality for several serious diseases. A rapidly evolving treatment landscape, with improved standards of care in areas such as oncology requires BerGenBio to be nimble and identify specific opportunities where we can address unmet needs in a competitive manner.*

*With this in mind we believe that by introducing a laser focus and rightsizing the organization on two key areas where we see our pipeline has the greatest impact, we are efficiently advancing BerGenBio's potential; building on our strong scientific foundation to deliver new drugs to market resulting in better outcomes for patients and the generation of significant value for our shareholders."*

## NSCLC

Despite advances in treatment, lung cancer remains the leading cause of cancer-related deaths throughout the world. Approximately 85% of lung cancers are classified as NSCLC. BerGenBio is targeting 1<sup>st</sup> Line STK11 mutated Non-Squamous NSCLC patients, an extremely large patient population with very limited response to the standard of care treatments. STK11 is an important tumor suppressor gene reported to confer immunotherapy resistance in NSCLC and is present in up to 20% of NSCLC patients.

Pre-clinical and clinical studies have suggested a mechanism by which bemcentinib may restore response to immune checkpoint inhibitor therapy and enable the avoidance of chemoresistance in NSCLC patients harboring STK11 mutations, thus potentially offering a treatment option to those patients who respond poorly to existing therapies. Data from the subset of STK11mutated patients treated in the Company's BGB008 study in 2<sup>nd</sup> line NSCLC also provides early indications of efficacy in this biomarker driven patient population.

The FDA has recognized that STK11 is currently a "non-actionable" mutation – one that confers poor outcome and has no specific therapeutic approaches today and have granted BerGenBio a Fast Track Designation for bemcentinib in this setting. To date, bemcentinib is to the Company's knowledge the only selective AXL inhibitor in development for patients with STK11 mutation. BerGenBio has a strong proprietary position for treatment of this population and believes there may be a potential for an accelerated approval pathway in this patient sub-set.

## **COVID-19**

Despite the success of vaccines, there is still a large number of hospitalized patients that remain in need of improved therapeutic options for COVID-19. Research into bemcentinib's potential in hospitalized COVID-19 patients began in 2020, in response to the emergence of the pandemic, and based on the Company's understanding of AXL's role in mediating aggressive diseases.

Recently, BerGenBio announced results from the Phase II sub-protocol of the platform ACCORD2 study, which met its primary and key secondary endpoints, with demonstrable efficacy in patients on top of current standard-of-care treatments including remdesivir and corticosteroids. Further, bemcentinib has been selected to be studied under the EUSolidAct platform trial through a sub-protocol enrolling 500 patients across European sites. Given the ongoing need for new treatment options for hospitalized COVID-19 patients, the novel mechanism of action of bemcentinib (independent of the spike protein), along with potential to confirm the ACCORD2 data in the EUSolidAct trial, the Company believes that this could warrant Emergency Use Authorizations based on precedents.

The Company believes that the unique mechanism of action and properties of bemcentinib positions it well as a novel treatment modality within severe respiratory infections beyond COVID-19.

With a focused strategy and rightsized organization BerGenBio plans to unlock significant potential value related to the two indications selected and define the path to market.

An investor call will take place today at 1pm CEST (7am ET), full details below.

Web link: [https://channel.royalcast.com/hegnarmedia/#!/hegnarmedia/20220504\\_12](https://channel.royalcast.com/hegnarmedia/#!/hegnarmedia/20220504_12)

### **Dial-in details:**

PIN Code: 712491

NO: +47-21-956342

UK: +44-203-7696819

US: +1 646-787-0157

SE: +46-4-0682-0620

DK: +45 78768490

### **Contacts:**

For BerGenBio:  
Martin Olin CEO, BerGenBio ASA  
[ir@bergenbio.com](mailto:ir@bergenbio.com)

Rune Skeie, CFO, BerGenBio ASA  
[rune.skeie@bergenbio.com](mailto:rune.skeie@bergenbio.com)

#### **International Media Relations**

Mary-Jane Elliott, Chris Welsh, Lucy Featherstone  
Consilium Strategic Communications  
[bergenbio@consilium-comms.com](mailto:bergenbio@consilium-comms.com)  
+44 20 3709 5700

#### **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 cancer and severe respiratory infections. The Company is focused on its proprietary lead candidate bemcentinib a potentially first-in-class selective AXL inhibitor in development for STK11 mutated NSCLC and COVID-19.

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)

#### **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.

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