BERGENBIO'S BEMCENTINIB SELECTED TO BE FAST-TRACKED AS POTENTIAL TREATMENT FOR COVID-19 THROUGH NEW NATIONAL UK GOVERNMENT CLINICAL TRIAL INITIATIVE

- *Bemcentinib selected as first candidate to be tested through new ACCORD study*
- *The Phase II clinical trial initiative to rapidly investigate bemcentinib's efficacy and safety in hospitalised COVID-19 patients*
- *Study to be funded by the UK Department of Health and Social Care and UK Research and Innovation*
- *Study to be managed by CRO, IQVIA*
- *BerGenBio will be hosting a webcast at 10.00 CEST tomorrow (see details below)*

Bergen, Norway, 29 April 2020 – BerGenBio ASA (OSE:BGBIO), a clinical-stage biopharmaceutical company developing novel, selective AXL kinase inhibitors for unmet medical need, announces that bemcentinib has been selected as the first potential treatment to be fast-tracked in a new UK national multi-centre randomised Phase II clinical trial initiative that aims to save lives and get an early indication of bemcentinib's effectiveness in treating the most vulnerable patients with COVID-19.

The **AC**celerating **CO**VID-19 **R**esearch & **D**evelopment platform (ACCORD) study is being funded by the Department of Health and Social Care (DHSC) and UK Research and Innovation (UKRI). ACCORD brings together a single, UK-wide clinical trial platform provided by the clinical research company IQVIA and the UK's leading research expertise through the National Institute for Health Research, to rapidly test potential drugs through early stage clinical trials and feed them into the UK's large-scale COVID-19 studies such as the RECOVERY trial, currently the world's largest randomised controlled clinical trial for COVID-19 treatment.

ACCORD COVID-19 trial

The ACCORD study is a multicentre, seamless, Phase II adaptive randomisation platform trial to assess the efficacy and safety of multiple candidate agents, the first of which is bemcentinib, for the treatment of COVID-19 in hospitalised UK NHS patients.

The study, with drug material and trial resources provided by BerGenBio, will rapidly commence testing in 120 subjects (60 hospitalised COVID-19 patients and 60 control group patients receiving standard of care treatment) across 6 UK NHS hospital trusts, with the first patients due to be treated imminently. BerGenBio anticipates that top line data will readout within a few months. Data will be open source and freely available to enable global knowledge sharing and collaboration. If positive results are seen, bemcentinib will advance rapidly into the large-scale Phase III trials currently in progress across the UK.

Bemcentinib's applicability to treat COVID-19

COVID-19 is the clinical disease manifested as a result of SARS-CoV-2 coronavirus infection, responsible for the current COVID-19 pandemic. Preclinical data suggest that bemcentinib is potentially useful for the treatment of early SARS-CoV-2 infection. There are currently no approved medical treatments for, or vaccines against, COVID-19.

Bemcentinib is a once-a-day, oral, highly selective and potent inhibitor of AXL kinase being developed by BerGenBio. Bemcentinib has previously demonstrated a key role in cancer treatment: preventing immune evasion, drug resistance and metastasis in a variety of cancer trials. The drug has to date been shown to be safe and well-tolerated in hundreds of patients and in many cases taken daily for several years.

Bemcentinib has previously been reported to exhibit potent anti-viral activity in preclinical models against several enveloped viruses, including Ebola and Zika virus. Recent data have expanded this to SARS-CoV-2.[1, 2]

Bemcentinib selectively inhibits AXL kinase activity, blocking viral entry and enhancing the anti-viral type I interferon response, a key cellular defence mechanism against viral infection.

Richard Godfrey, Chief Executive Officer of BerGenBio, commented: *"We are delighted to be part of this initiative which is a ground-breaking partnership between government, academia and industry. We are hopeful that bemcentinib can play a significant role in the global effort to find suitable treatment options for COVID-19 patients, which has had such serious implications for so many people and thereby ease pressures on hospital intensive care units, and ultimately treat thousands of patients. We are poised to commence dosing in the coming days and will provide results as soon as is practically possible."*

Health and Social Care Secretary, Matt Hancock, said: *"Currently no drugs in the world have been clinically proven to treat Covid-19. But our Therapeutics Taskforce has identified a number of promising candidates. Currently, six different treatments have been entered into national clinical trials and the first is ready to enter the next stage: a new early phase clinical trial platform that we are launching today. This is a national effort made possible by government, academia and industry working together."*

Professor Tom Wilkinson, ACCORD clinical academic lead based at the National Institute for Health Research (NIHR) Southampton Biomedical Research Centre, said: *"There has been a tremendous effort to pull this initiative together so rapidly. ACCORD is a national effort and will be key to developing effective new treatments which are needed so desperately. The ACCORD platform will be able to rapidly test potential new treatments, advancing the most promising through Phase 2 clinical trials into the NHS. This unique national platform for developing new COVID-19 drug candidates will access the world-class expertise and resources of the NIHR Respiratory Translational Research Collaboration and allied centres nationwide."*

ACCORD is part of a co-ordinated therapeutic development pathway that the Government has put in place, overseen by the Department for Business, Energy and Industrial Strategy and delivered by UKRI, as part of the overall Therapeutics Taskforce.

References

[1] Dowall SD et al. Antiviral Screening of Multiple Compounds against Ebola Virus. Viruses 2016, 8:27
[2] Meertens L et al. Axl mediates ZIKA virus entry in human glial cells and modulates innate immune responses. Cell Rep 2017 18:324

Presentation and webcast tomorrow

BerGenBio will be hosting a live webcast and Q&A session at 10.00 CEST today, 29 April:

Webcast link: https://channel.royalcast.com/webcast/hegnarmedia/20200429_9/

Dial-in numbers:

- **NO:** +47 2195 6342
- **UK:** +44 203 769 6819
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PIN: 569168

The presentation will also be made available at www.bergenbio.com/investors, and the recording will be available shortly after the webcast has finished.

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, tilvestamab, is undergoing Phase I clinical testing. In parallel, BerGenBio is developing companion diagnostic tests 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

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This information is subject to the disclosure requirements pursuant to section 5-12 of the Norwegian Securities Trading Act.