

# Promising pre-clinical data supporting BerGenBio's pipeline to be published and presented at upcoming leading conferences

- *Bemcentinib active in pre-clinical models of IPF and NASH*
- *IPF and cirrhotic NASH patients with aggressive disease identified by AXL blood based biomarker*
- *BGB601 (partnered AXL ADC drug candidate) anti tumour pre-clinical data to be presented at AACR.*

**Bergen, Norway, 13 April 2018** – BerGenBio ASA (OSE: BGBIO) announces that promising pre-clinical data demonstrating that selective AXL inhibition counteracts the progression of aggressive fibrosis in the lung and liver has been published in the international peer-reviewed journal *American Journal of Respiratory and Critical Care Medicine* (AJRCCM, (1)) and accepted for presentation at the 53rd annual meeting of the European Association for the Study of the Liver (EASL), respectively.

Additionally, pre-clinical data of BerGenBio's out-licensed AXL ADC candidate BGB601 has been accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting 2018.

The details of the publications are as follows:

## **Potential of selective AXL inhibition as a mechanism for treating the progressive, rare, and frequently fatal lung disease idiopathic pulmonary fibrosis (IPF):**

Milena Espindola and colleagues from Cedars-Sinai in Los Angeles, CA, published evidence in the *American Journal of Respiratory and Critical Care Medicine* (AJRCCM) that AXL receptor expression is significantly elevated in patient cells, tissues and models of IPF. Consistent with the pathological role of AXL in fibrosis, selective inhibition of AXL using bemcentinib (BGB324) impacted IPF fibroblast functions and the development of fibrosis in pre-clinical models of IPF. The data also show a clear distinction in AXL levels between fast and slow progressing IPF patients, highlighting the potential of using AXL levels as a biomarker to (i) identify patients with a poor prognosis and who may respond to treatment with an AXL inhibitor, and (ii) enrich patient populations in future clinical trials.

The article in press is entitled: "*Targeting of TAM Receptors Ameliorates Fibrotic Mechanisms in Idiopathic Pulmonary Fibrosis*" and can be accessed at the AJRCCM's website - [click here](#).

## **Potential of selective AXL inhibition for treating advanced form of non-alcoholic steatohepatitis (NASH)**

Anna Tutusaus *et al.* will be presenting a poster on AXL targeting in NASH entitled "AXL increase in NASH patients and anti-fibrotic efficacy of AXL inhibition in experimental NASH" (abstract: FRI-074) at the European Association for the Study of the Liver (EASL) Annual Meeting in Paris, France, on Friday 13 April between 9 and 17:00 CET.

The abstract is available online - [click here](#).

## **Pre-clinical data in models of aggressive, AXL expressing, tumours supporting clinical development of AXL ADC BGB601 (ADCT-601)**

Lorenzo Zammarchi *et al.* will be presenting a poster on the *in vitro* and *in vivo* anti-tumour activity of BGB601 (ADCT-601) in human cancer cell lines and animal models as well as data on its safety and tolerability entitled "*Preclinical activity of ADCT-601, a novel pyrrolobenzodiazepine (PBD) dimer-based antibody-drug conjugate (ADC) targeting AXL-expressing tumors*" (abstract: 2792A) at the American Association of Cancer Research (AACR) Annual Meeting in Chicago, IL, on Monday 16 April between 13:00 and 17:00 CDT.

The abstract is available online at the AACR Annual Meeting website – [click here](#).

**Richard Godfrey, CEO of BerGenBio commented:** "This patient data and pre-clinical findings in IPF and cirrhotic NASH are very compelling and suggest that selective AXL inhibition may have potential as a new approach to treating life-threatening fibrotic diseases. While our focus remains clearly on completing our phase II clinical programme with bemcentinib and to establish proof of concept for its role as a cornerstone of cancer therapy, we are intrigued by the possibility of therapeutic benefit from our AXL inhibitors in fibrotic diseases. We will continue to support this research and look forward to integrating it into our pipeline development strategies. Furthermore, we are encouraged by pre-clinical data supporting the advancement of BGB601, our out-licensed AXL ADC drug candidate, towards the clinic."

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## **About fibrosis, IPF and NASH**

Fibrosis is an exaggerated healing response that fails to terminate appropriately causing almost half of fatalities across all non-communicable diseases combined.

Idiopathic Pulmonary Fibrosis (IPF) is a severe, progressive disease characterised by fibrosis in the lung. Approximately 12 in 100,000 people will develop IPF each year, the current approved treatments may slow down progression of the disease but are not curative. Prognosis for those diagnosed with IPF is poor, with median survival of only 2-3 years (2).

Non-alcoholic steatohepatitis (NASH) is a type of fatty liver disease characterised by fibrosis, inflammation and liver cell damage for which there is no approved treatment. Across the US and EU5, approximately 25 million people are believed to have NASH – a proportion of whom will experience significant worsening of their condition eventually leading to fatal liver failure.

## **About BGB601 (ADCT-601)**

BGB601 (ADCT-601) is an Antibody Drug Conjugate (ADC) drug, composed of a humanised IgG1 antibody against human AXL, discovered at BerGenBio and out-licensed for further development by [ADC Therapeutics SA](#).

## About the EASL and AACR Annual Meetings

The EASL Annual Meeting is the largest congress dedicated to hepatology. 10,000 international delegates from a wide range of scientific disciplines gather to present the latest research at this highly regarded event. The 2018 EASL Annual meeting will take place in Paris, France, 11 - 15 April. For more information please visit: <https://ilc-congress.eu>.

The AACR is the largest professional organisation in the world dedicated to advancing cancer research and its mission to prevent and cure all cancers. During the 2018 annual meeting, thousands of oncology researchers and clinicians will gather in Chicago, IL, April 14 – 18. For more information, please visit: <http://www.aacr.org>

## 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 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](http://www.bergenbio.com)

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## References

(1) Espindola MS *et al* AJRCC 2018

(2) Raghu G *et al* AJRCCM 2011

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