EDISON

BerGenBio

Strategy update

Focusing in on 1L NSCLC and COVID-19

Healthcare & biotech

BerGenBio (BGBIO) has announced an updated business strategy for its lead drug candidate, oral AXL inhibitor bemcentinib, which will focus on first-line (1L) non-squamous non-small cell lung cancers (NSCLCs) carrying the STK11 mutation and on hospitalised COVID-19 patients. The decision to move bemcentinib to the 1L setting could significantly broaden its target population among NSCLCs, given that c 20% of such cancers carry the STK11 mutation (~30,000 patients). Following encouraging data from the Phase II ACCORD2 study, BGBIO will continue to pursue bemcentinib in the treatment of hospitalised COVID-19 patients, with the EU-SolidAct platform trial set to begin recruitment shortly in a sub-protocol arm designed to enrol 500 patients across European sites. With this news we expect the company to deprioritise the current clinical development of bemcentinib in second-line (2L) NSCLC and 2L AML to focus on these new opportunities, which management sees as offering significant value potential. Our forecasts are under review.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/20	0.6	(257.0)	(3.43)	0.0	N/A	N/A
12/21	0.8	(309.4)	(3.52)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

BerGenBio sees significant opportunities for lead asset bemcentinib in two indications where the drug has already demonstrated potential. Firstly, NSCLCs with SKT11 loss-of-function mutations are associated with impaired patient responses to PD-1/PD-L1 immunotherapies and poor outcomes. Preclinical data showed systemic inhibition of AXL by bemcentinib restored therapeutic response to immune checkpoint inhibitor treatment. The company's Phase II BGB008 study in 2L NSCLC has already shown some efficacy in STK11 mutant patients when combined with pembrolizumab. Secondly, BerGenBio will pursue bemcentinib's use in the treatment of hospitalised COVID-19 patients after recently completing the data analysis from its Phase II ACCORD2 study. In this, 90% (26 of 29) of patients experienced a clinical response by day 29 (median 7 days) when treated with bemcentinib + standard of care, compared to only 69% on standard-of-care alone. These results have also shown that bemcentinib provides broad inhibition across COVID-19 variants due to its unique mode of action.

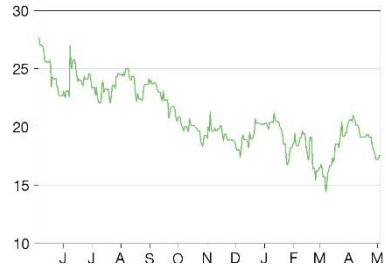
As PD-1/PD-L1 immunotherapy is often the 1L standard of care in NSCLC and the 1L population is significantly larger, we see the progression of bemcentinib to 1L as a considerable opportunity for BerGenBio. The identification STK11m as a biomarker for bemcentinib treatment will de-risk further clinical trials and we note that STK11m is routinely screened for in commercial diagnostic panels such as FoundationOne CDx and Guardant 360 CDx.

5 May 2022

Price	**NOK17.57**
Market cap	**NOK1.56bn**

Net cash (NOKm) at 31 Dec 2021	436
Shares in issue	88.7m
Free float	61.6%
Code	BGBIO
Primary exchange	Oslo Stock Exchange
Secondary exchange	N/A

Share price performance



Business description

BerGenBio is a clinical stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune-evasive cancers and COVID-19. It focuses on AXL inhibitors bemcentinib (small molecule) and tilvestamab (mAb).

Analysts

Dr Pooya Hemami, CFA +44 (0)20 3077 5700

Dr Harry Shrives +44 (0)20 3077 5700

healthcare@edisongroup.com

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia