Trinity Delta Lighthouse

BerGenBio

Efficacy endpoint met in Phase II AML study

2 April 2019

- In the Phase II trial in AML with bemcentinib in combination with low-dose cytarabine (LDAC), the pre-specified efficacy endpoint has been met; at least three patients out of the first 14 patients (21%) were required to achieve a clinical response.
- Of the 15 patients enrolled, 10 patients were evaluable for response to date with 4 newly diagnosed and 6 relapsed/refractory (R/R) patients. Among the newly diagnosed patients, there was one complete remission (CR) and one CR with incomplete haematologic recovery (CRi) observed; and among the R/R there was one CR observed. So, overall 3 of the 10 evaluable patients (CR/CRi rate of 30%) have achieved a clinical response.
- The responses had an early onset (after 1-2 cycles), were durable, and deepened over time.
- The combination treatment was well tolerated with no overlapping or new toxicities observed; all responders were over the age of 75 and included patients with poor risk prognosis.
- More detailed results from the trial, including biomarker data, will be presented at upcoming medical conferences.
- BerGenBio expects to start a late-stage bemcentinib monoterhapy trial in R/R AML patients in H219.

Price	NOK25.00
Market Cap	NOK1,371m
Primary exchange	Oslo
Sector	Healthcare
Company Code	BGBIO
Corporate client	Yes

Company description:

BerGenBio is a clinical-stage, drug development company based in Bergen, Norway and Oxford, UK. It is developing innovative anti-cancer therapies that act on the promising Axl signalling pathway. The lead oncology compound, bemcentinib, is in a number of Phase II trials.

Trinity Delta view: BerGenBio has already reported promising bemcentinib monotherapy data from this Phase II trial (CR/CRi/CRp rate of 22% from all 27 patients treated and 43% from the 14 patients with low levels of the sAxl biomarker, see Outlook note from January 2019). This data suggests that bemcentinib can also increase the activity of LDAC, the current standard of care for elderly AML patients and that has an ORR of only c18%.

Our valuation of BerGenBio is NOK3,143m ($370m) or NOK57.45/share and data from the Phase II study in NSCLC with pembrolizumab due in the coming months could be important share price catalysts. The overall survival data from the first stage of the Phase II study in NSCLC with pembrolizumab and initial results from the trial's second stage are due in Q219.

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