

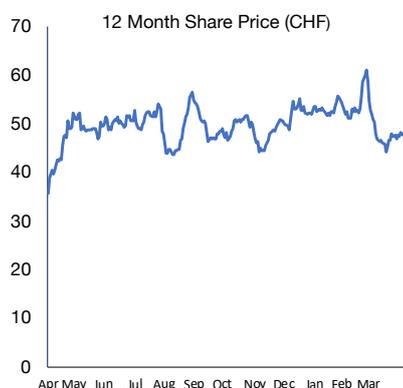
Basilea Pharmaceutica

24 March 2021

Share Price	CHF 48
CP Fair Value	CHF 120

Market Cap (CHFm)	569
Cash (CHFm)	207
EV (CHFm)	680

Country	Switzerland
Code	BSLN
Exchange	SIX



Source: Calvine Partners Research

Derazantinib differentiation apparent

Much of the recent focus at Basilea has involved securing the promise of the oncology portfolio and the FGFR inhibitor derazantinib. The FGFR class has been successfully validated elsewhere through the approvals of Balversa and Pemazyre in bladder and biliary cancer respectively. The key for Basilea in the competitively challenging environment is to identify appropriate positioning for derazantinib to ensure optimal positioning once approved and commercialised. As we have highlighted previously, we believe that the key data will be the combination with the checkpoint inhibitors, particularly in those cancers where the performance of the CKIs has been underwhelming.

Derazantinib delivering on its potential

Basilea has a comprehensive programme ongoing evaluating the potential of derazantinib in both monotherapy and in relevant combinations in difficult to treat cancers. While the clinical risk in monotherapy has been reduced thanks to the positive outcome of FIDES-01 (cohort 1), this was in biliary cancer (iCCA) patients with FGFR2 gene fusions. The interim results today from FIDES-01 (cohort 2) have effectively demonstrated that the activity of derazantinib lies beyond gene fusions to include other aberrations including gene mutations or amplifications. Overall, the data suggest activity broadly in line with FGFR2 gene fusion iCCA patients with a disease control rate (DCR) of 79% although the numbers were small (n=14). With derazantinib delivering on its pre-specified PFS objective of 3 months (or more) in at least 8 patients (median PFS not yet mature), this positive outcome has facilitated further patient enrolment to reach the target of 43 patients. Topline data from the completion of cohort 2 will be reported in H1 2022.

Differentiation becoming more apparent

These data are important since they demonstrate the relevance of derazantinib beyond FGFR2 gene fusions and provide an initial insight into its true potential while delivering important differentiation from its peers in this emerging new class of anti-cancer therapies. Further differentiation from existing competition could also come from ongoing studies evaluating its combination with the checkpoint inhibitor Tecentriq (atezolizumab). Of the approved FGFR inhibitors, derazantinib appears to have the sole ability to help reverse the immunosuppressive state found in many cancers thanks to its activity against the CSF-1/CSF1R axis. Basilea is seeking to capitalise on this activity with FIDES-02 in urothelial cancer and FIDES-03 in gastric cancer. Important data on these trials will emerge over the next 12-18 months helping to optimally position derazantinib and confirming the oncology ambitions of Basilea.

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