Calvine Partners

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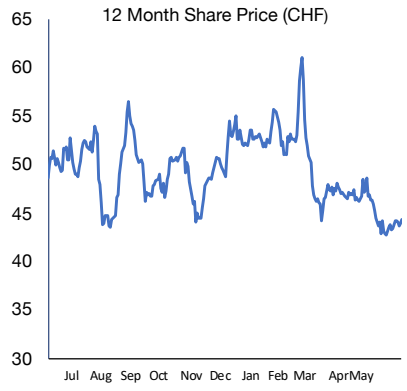
Basilea Pharmaceutica

31 May 2021

Share Price	**CHF 44.4**
CP Fair Value	**CHF 120**
Market Cap (CHFm)	580
Cash (CHFm)	160
EV (CHFm)	670
Country	Switzerland
Code	BSLN
Exchange	SIX



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Establishing derazantinib optimum positioning

Much of the recent focus at Basilea has involved securing the promise of 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 once approved and commercialised. As we have highlighted previously, we believe that ultimately the key data will be in 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. The data reported today in iCCA gene fusions is particularly important to the extent that the PFS data is now sitting at 7.8 months which is highly competitive compared with peers. When combined with a more benign tolerability profile (low rates of retinal side effects, stomatitis, hand-foot syndrome, nail toxicity), and its additional potential in gene mutations and amplifications, derazantinib should represent a differentiated and highly attractive addition for physicians and patients in bile duct cancer.

Study modifications should ensure clinically and commercially relevant data

Basilea is progressing derazantinib in other difficult to treat FGFR driven cancers including urothelial (FIDES-02) and gastric cancer (FIDES-03) in monotherapy and combination. The release today suggests a recognition that although data at the initial dose of 300mg may well have proven to be successful clinically, in order to fulfil the true potential of derazantinib in these important patient populations and to maximise commercial relevance, a higher dose of 400mg may be more suitable. As a result, FGFR naïve urothelial cancer patients in 2nd line or later will now receive derazantinib at this higher dose, as will gastric cancer patients. Monotherapy and combination data (FIDES-02) will be available starting in H1 2022 providing an important insight into this dose intensification strategy. FGFR refractory patients will continue to receive 300mg dose in monotherapy and in combination with Tecentriq, with data available later this year providing a helpful insight into the potential utility of this combination approach, albeit in a very challenging patient population. As Basilea seeks to differentiate derazantinib and to maximise its clinical and commercial potential, it is worth remembering that, 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. As a result, we believe the combination with the CKIs (Tecentriq for now) offers a unique competitive advantage.

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