BRYAN, GARNIER & CO

Healthcare

1st July 2019

BASILEA PHARMACEUTICA

Healthcare
Pharmaceuticals

BUY

Fair Value	CHF73 (+105%)
Share price	CHF35.60
EPS 3Y Cagr	NM

A broader population in iCCA to further differentiate Derazantinib

Derazantinib's phase II extended to additional FGFR2 aberration

Basilea has just announced the extension of the ongoing Derazantinib's phase II program in intrahepatic cholangiocarcinoma (iCCA) to patients with FGFR2 gene mutations or amplifications through an additional cohort of 40 patients. While the clinical program previously focused on the most common type of aberrations (gene fusions), the company is looking to assess the potential of Derazantinib in a broader range of FGFR2-driven tumors in order to expand its therapeutic potential. It could indeed be a way to further differentiate itself from the competitors currently looking to unlock the FGFR pathway in iCCA.

iCCA: A proof of concept indication

As reported in our initiation report, Cholangiocarcinoma is a heterogenous group of malignancies emerging at any level from the biliary tree. It is the second most common malignancy arising from the liver, representing up to 10% of all cholangiocarcinomas, and accounting for 3% of all case of gastrointestinal cancer. While the incidence of iCCA appears to be increasing and may be as high as 2.1 per 100,000 person/year in western countries, five-year survival remains dismal at approximately 8%. While current first-line SoC consists of combination of gemcitabine plus cisplatin, there is no proven effective treatment for patients who progress first-line chemotherapy, so second-line treatment is a high unmet need.

Preliminary results from the pivotal phase II are promising

In the beginning of the year, a pre-planned interim analysis of the FGFR fusion-positive cohort of the study reported promising efficacy results alongside manageable safety profile. It has indeed achieved a 21% overall response rate (three times the rate observed with chemotherapy) and an 83% disease control rate. This cohort is expected to enroll up to 100 patients with FGFR2 gene fusions and should read-out mid-2020. In the meantime, we are anticipating Derazantinib to be evaluated in bladder cancer through an interesting combination with Tecentriq.

A combination with Tecentriq based on a novel rationale

Back in January, Basilea announced a clinical supply agreement with Roche to explore a combination of derazantinib and Tecentriq in patients with bladder cancer and confirmed FGFR aberrations. While others are also assessing this type of combination, the rationale of Basilea's combination lies on a unique feature of derazantinib: its CSF1R inhibition activity. It has been described that CSF1R inhibition improves susceptibility to PD-L1/PD1 inhibitors. We believe that, based on this rationale, Basilea's combination could go one step further in terms of clinical outcome than the other combinations currently evaluated. It should start soon.

In a nutshell, we believe that this new cohort in iCCA and the future bladder combination will help derazantinib to further differentiate itself from competition.

Market Data

Bloomberg / Reuters	BSLN SW/BSLN.S
Market Cap.	CHF423m
E.V.	CHF396m
Free Float	-
Avg. Daily volume (6m)	48.40
12m high / low	CHF69.1 / CHF34.1
Ytd Perf.	-10.9%

CHFM	12/18	12/19e	12/20e	12/21e
Sales	132.6	134.7	177.8	233.4
% Change		*1.6%*	*31.9%*	*31.3%*
EBITDA	-22.2	-25.9	5.7	55.8
% Change		*-16.4%*	*NS*	
EBIT	-24.1	-27.7	4.0	54.2
% Change		*-14.8%*	*NS*	
Net Income	-31.4	-34.0	-2.3	43.6
% Change		*-8.3%*	*93.3%*	*NS*
ROE	NM	NM	NM	NM

	12/18	12/19e	12/20e	12/21e
EV/Sales	3.0x	3.2x	2.6x	1.9x
EV/EBITDA	NS	NS	80.5x	7.8x
EV/EBIT	NS	NS	113.9x	8.0x
EPS	-2.89	-3.13	-0.21	4.02
% change		*-8.3%*	*93.3%*	*NS*
P/E	NM	NM	NM	8.8x
Div Yield	NM	NM	NM	NM

Next Catalyst : Half-year results (Aug 20, 2019)

Last Reports:

2019-6-3, BASILEA PHARMACEUTICA (Buy, FV CHF73) | Promising results for oral BAL101553 from a phase I study

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