5th December 2016

Healthcare

Roche

Price CHF220.60

More detailed results from GALLIUM supportive of Gazyva use in 1L iNHL

Fair Value CHF285 (+29%) **BUY**

Bloomberg	ROG VX
Reuters	ROG.VX
12-month High / Low (CHF)	278.5 / 220.1
Market Cap (CHFm)	154,985
Avg. 6m daily volume (000)	1 303

	1 M	3 M	6 M	31/12/15
Absolute perf.	-1.6%	-9.2%	-15.1%	-20.2%
Healthcare	0.9%	-8.6%	-10.1%	-15.5%
DJ Stoxx 600	2.4%	-3.2%	-1.4%	-7.2%

	2015	2016e	2017e	2018e
P/E	16.4x	14.1x	13.5x	13.4x
Div yield (%)	3.7%	4.3%	4.4%	4.5%

ANALYSIS

- GALLIUM phase III study had been stopped early after the IDMC stated at an interim analysis in May 2016 that the primary endpoint had been reached. The study was comparing Gazyva/CT (i.e. CHOP or CVP or bendamustine) followed by maintenance therapy with Gazyva alone for up to 2 years to rituximab/CT and then rituximab for the same period of time in 1,401 patients with indolent NHL previously untreated.
- The primary endpoint was investigator-assessed PFS and risk reduction was 34% in favour of Gazyva (HR=0.66, p=0.0012). It was 29% under an independent review, which was a secondary endpoint (p=0.0138). Secondary endpoints overall delivered mixed results with positive data with time to next treatment (HR=0.68, p=0.0094), but less positive ones with OS (94% vs 92.1% at 3 years) and response rates (ORR: 88.5% vs 86.9%). The exploratory endpoint of minimal residual disease reported good results with MRD negativity in 92% vs 84.9% of the patients, however only measured in less than 60% of the total number of patients treated in the two arms.
- Somewhat surprising is the overall safety profile because compared to rituximab, Gazyva is a humanised CD20 antibody and could have therefore been expected to show less infusion-related reactions and overall side effects. But the opposite happened and Gazyva showed a rate of grade 3 or more side effects of 74.6% vs 67.7% for rituximab.

VALUATION

- It is hard to say where Gazyvo will be able to go at peak. It is fair to say that we see no momentum in reported quarterly sales so far. The drug should end slightly below the CHF200m mark in 2016. So far our peak sales are CHF1.5bn in 2022, but will adjust in the course of 2017 depending on how the drug picks up with new data shared in congresses. GALLIUM data still have to be filed.

NEXT CATALYSTS

- By year-end: first phase III data with ACE910 in haemophilia
- 28 December 2016: PDUFA date for Ocrevus in PPMS and RRMS

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BUY ratings 72% NEUTRAL ratings 0% SELL ratings 28%

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