

18th May 2016

Healthcare

Novartis

Price CHF73.35

LEE011 so successful in trial that DMC calls for an early ending

Fair Value CHF89 vs. CHF88 (+21%)

NEUTRAL

Bloomberg	NOVN VX
Reuters	NOVN.VX
12-month High / Low (CHF)	102.3 / 68.5
Market Cap (CHFm)	192,699
Ev (BG Estimates) (CHFm)	196,264
Avg. 6m daily volume (000)	6 046
3y EPS CAGR	5.7%

DMC is recommending early stop of MONALEESA-2 phase III trial investigating LEE011+letrozole vs letrozole alone in HR+/HER2- BC patients after convincing interim efficacy results. This could accelerate filing of LEE011 in this setting. Our FV is adjusted by CHF1.

ANALYSIS

- There could not be better piece of news to try offset bad taste left by the announcement of the departure of David Epstein (see sector mail) than an early interruption of the MONALEESA-2 trial based on interim results at the request of the DMC. The overwhelming efficacy of CDK4/6 inhibitor LEE011 in HR+/HER2- breast cancer in combination with letrozole vs letrozole alone was so strong at the pre-planned interim analysis that the committee has recommended that the trial be stopped as primary endpoint (PFS) had already been met. Safety-wise, LEE011 was very much as expected as we understand it.
- That said, positivity of clinical results with LEE011 made little doubt considering that palbociclib (Ibrance, Pfizer) already demonstrated the benefit of the mechanism of action in the same setting previously in PALOMA-1 and is already in market. To note is that PALOMA-3, investigating palbociclib in combination with fulvestrant, was also stopped early due to efficacy. So, CDK 4/6 inhibition looks definitely like a very interesting approach to HR+/HER2- BC and part of future SOC as illustrated by the strong ramp-up of Ibrance in its first year (USD429m in sales in Q1 2016 o/w USD422m in the US alone).
- As a consequence of these positive interim results, Novartis will start discussing with healthcare authorities about filing of LEE011 which may come earlier than expected i.e. sometimes in Q3. As to whether it is differentiated to Ibrance, unlike past statements, this is unclear to us. We do not see superior selectivity for CDK4/6 receptors vs palbociclib whereas Pfizer is moving quickly forward with aggressive clinical programme, including in adjuvant breast (PALLAS, 4,600 patients, FPI August 2015), offering it 12-15 months head start vs Novartis. To note however is that Novartis has a long experience in this setting with Femara and Afinitor.
- Let's see, maybe at ESMO, the PFS results of MONALEESA-2 and how they compare to Ibrance's similar results in PALOMA-1 i.e. 20.2m median PFS (vs 10.2m for comparator), HR=0.488 (see below)

	1 M	3 M	6 M	31/12/15
Absolute perf.	0.3%	0.8%	-18.2%	-15.5%
Healthcare	-2.4%	1.1%	-12.1%	-11.0%
DJ Stoxx 600	-2.4%	1.8%	-11.9%	-8.5%

YEnd Dec. (USDm)	2015	2016e	2017e	2018e
Sales	49,414	50,145	52,551	55,856
% change		1.5%	4.8%	6.3%
EBITDA	13,119	12,996	13,822	15,372
EBIT	7,544	7,496	8,322	9,872
% change		-0.6%	11.0%	18.6%
Net income	6,017	6,568	7,603	9,133
% change		9.2%	15.8%	20.1%

	2015	2016e	2017e	2018e
Operating margin	15.3	14.9	15.8	17.7
Net margin	12.2	13.1	14.5	16.4
ROE	8.1	8.5	9.9	11.6
ROCE	14.4	13.4	14.6	16.9
Gearing	21.4	22.5	20.8	16.4

(USD)	2015	2016e	2017e	2018e
EPS	5.01	4.96	5.28	5.92
% change	-	-1.1%	6.5%	12.1%
P/E	15.0x	15.2x	14.2x	12.7x
FCF yield (%)	0.6%	3.2%	4.8%	5.2%
Dividends (USD)	2.75	3.00	2.64	2.96
Div yield (%)	3.7%	4.0%	3.5%	3.9%
EV/Sales	4.1x	4.0x	3.8x	3.5x
EV/EBITDA	15.3x	15.5x	14.5x	12.8x
EV/EBIT	26.6x	26.8x	24.0x	19.9x

Table 8. Efficacy Results – Study 1 (Investigator Assessment, Intent-to-Treat Population)

	IBRANCE plus Letrozole (N=84)	Letrozole (N=81)
Progression-Free Survival (PFS)		
Number of PFS Events (%)	41 (48.8%)	59 (72.8%)
Hazard ratio (95% CI)	0.488 (0.319, 0.748)	
Median PFS [months] (95% CI)	20.2 (13.8, 27.5)	10.2 (5.7, 12.6)

CI=confidence interval; N=number of patients.

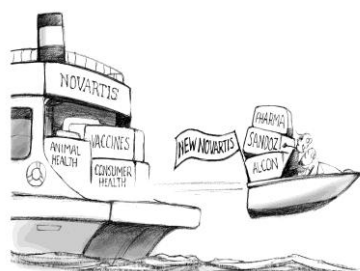
VALUATION

- As a consequence of today's announcement, we are increasing our PoS for LEE011 from 60% to 90% and, based on Ibrance's early success, we are also beating on a stronger take-off in 2016-17. The impact on our FV is CHF1.

NEXT CATALYSTS

- 24-25 May 2016: Meet The Management Meeting in Basel

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