9th August 2016

Healthcare

Ablynx

Price EUR12.96

Vobarilizumab differenciate from the crowd (despite study design helping placebo)

Fair Value EUR18 (+39%) **BUY**

Bloomberg	ABLX BB
Reuters	ABLX.BR
12-month High / Low (EUR)	16.1 / 10.4
Market Cap (EURm)	789
Ev (BG Estimates) (EURm)	942
Avg. 6m daily volume (000)	174.4
3y EPS CAGR	15.0%

	1 M	3 M	6 M	31/12/15
Absolute perf.	12.6%	-4.7%	7.6%	-18.5%
Healthcare	1.5%	9.6%	10.2%	-4.0%
DJ Stoxx 600	5.3%	2.6%	4.7%	-6.7%

YEnd Dec. (EURm)	2015	2016e	2017e	2018e
Sales	77.5	81.6	39.6	54.2
% change		*5.2%*	*-51.4%*	*36.7%*
EBITDA	-15.6	-21.9	-64.3	-44.4
EBIT	-17.0	-23.3	-65.0	-45.4
% change		*-37.6%*	*NS*	*30.2%*
Net income	-54.5	-60.9	-102.6	-83.0
% change		*-11.7%*	*-68.4%*	*19.1%*

	2015	2016e	2017e	2018e
Operating margin	-21.9	-28.6	-164.1	-83.8
Net margin	-70.3	-74.7	-258.9	-153.1
ROE	-195.4	184.5	75.7	38.0
ROCE	NM	NM	NM	NM
Gearing	NM	NM	NM	NM

(EUR)	2015	2016e	2017e	2018e
EPS	-1.01	-1.13	-1.90	-1.53
% change	-	*-11.7%*	*-68.4%*	*19.1%*
P/E	NS	NS	NS	NS
FCF yield (%)	NM	NM	NM	NM
Dividends (EUR)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	9.1x	11.5x	23.5x	17.3x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS

Ablynx reported results from its second phase IIb trial comparing voba on top of MTX to placebo. Results bodes well with what we observed in the first phase IIb trial. Primary endpoint is reached with a 81% ACR20 responder rate at 12w. Despite high placebo effect favoured by the study design, continuous improvement is seen in ACR50 and ACR70 with responder rates of up to 59% and 43% at week24. Safety profile looks clean. While surprisingly high placebo effect could make it difficult to assess the benefit of voba, and mute share price reaction, DAS28 remission rate stands out with up to 49% of patients in remission at the end of the study. We believe that voba would be a strategic fit in ABBV post-Humira portfolio. Note that ABBV might opt-in before year-end. We reiterate our BUY rating and EUR18 fair value.

ANALYSIS

- Vobarilizumab's 2nd phase IIb trial was carried out in 345 moderate to severe RA patients randomized to either SC vobarilizumab + MTX (at the 75mg/Q4W, 150mg/Q4w, 150mg/Q2W or 225mg/Q2W doses) or placebo + MTX. Primary endpoint was reached at 12w with ACR20 reponder rate reaching 81%. At the end of the 24w treatment course, voba reported ACR20, ACR50 and ACR70 reponder rates of up to 79%, 59% and 43% repectively. ACR20 reponder rate plateaued from week 12 to 24. However, we see a continuous improvement in ACR50 and ACR70 responder rates trought week 24 which was expected by management following the results from the first phase IIb trial (please see our comment here). While results at the 225mg/Q2W results are clearly higher than others active arms group, the once-monthly dosing compares well with scores from other IL-6 either commercialized or under development. High placebo rates might be due to ABBV and ABLX's decision to exclude all patients who did not reach a 20% improvement on swollen or tender joints at week 12, 16 and 20. This has been prompted by limited SC data for voba (despite bioequivalence data from IV to SC available).
- Results in terms of DAS28 remission score, less dependant on placebo effect, clearly stands out from the crowd with up to 49% and 68% of patients in remission or with low disease activity/remission at 24w (p<0.0001). Note that the roll-over rate in the follow-up stands at 94%.
- Safety-wise, voba profile is clean (voba's AEs 6.5% vs 4.3% for placebo, SAEs of 1.8% vs 2.9% for placebo. We would look forward to infection rates which are not mentionned in the press release.

% responders based on ITT analysis with non-responder imputation

Efficacy parameter	placebo (N=69)		vobarilizumab 75mg, Q4W (N=69)		vobarilizumab 150mg, Q4W (N=70)		vobarilizumab 150mg, Q2W (N=68)		vobarilizumab 225mg, Q2W (N=69)	
	W12	W24	W12	W24	W12	W24	W12	W24	W12	W24
ACR20[1]	62%	74%	75%	74%	81%*	79%	78%	72%	72%	74%
ACR50[1]	28%	39%	29%	48%	44%	56%	41%	54%	45%	59%*
ACR70[1]	9%	17%	14%	23%	21%	33%	19%	22%	17%	43%**
Clinically meaningful improvement in HAQ-DI score (≥ 0.25)[2]	71%	71%	68%	68%	71%	67%	69%	68%	65%	65%
DAS28$_{CRP}$ remission[3]	9%	17%	10%	23%	37%***	37%*	35%***	38%**	25%*	49%***
DAS28$_{CRP}$ low disease activity or remission[3]	23%	29%	25%	38%	53%***	57%**	47%**	60%***	57%***	68%***

*nominal p<0.05 vs. placebo; **nominal p<0.01 vs. placebo; ***nominal p<0.001 vs. placebo

- Having one JAK-inhibitor currently studied in a large phase III program (ABT-494), we do not see particular reasons for ABLX' partner, ABBV, not to opt-in for vobarilizumab at this stage. Indeed, ABLX' compound would be a strategic fit into ABBV's post-Humira RA portfolio in our view.

VALUATION

- We reiterate our BUY rating and EUR18 fair value.
- Upon ABBV's opt-in which decision is expected before year-end (USD75m milestone), we would raise our PoS from 40% to 60%. Indeed, such decision would be the guarantee of the fast progression of the compound in phase III.

NEXT CATALYSTS

- Today 10:00amEST/4:00pmCET : conference call (+32 2 404 06 60: code 3494034)

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