12th December 2016

Healthcare

AstraZeneca

Price 4,280p

Unexpected good news for durvalumab

Fair Value 5100p (+19%) **BUY**

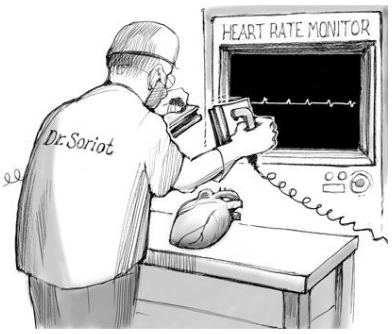
Bloomberg	AZN LN
Reuters	AZN.L
12-month High / Low (p)	5,220 / 3,774
Market Cap (GBP)	54,144
Ev (BG Estimates) (GBP)	66,336
Avg. 6m daily volume (000)	2 979
3y EPS CAGR	-8.3%

	1 M	3 M	6 M	31/12/15
Absolute perf.	-6.5%	-11.2%	8.3%	-7.3%
Healthcare	-0.8%	-4.4%	-6.4%	-13.0%
DJ Stoxx 600	4.6%	2.9%	4.1%	-2.9%

YEnd Dec. (USDm)	2015	2016e	2017e	2018e
Sales	23,641	21,375	19,695	20,463
% change		*-9.6%*	*-7.9%*	*3.9%*
EBITDA	5,937	4,232	5,493	5,633
EBIT	4,114	3,168	4,529	4,491
% change		*-23.0%*	*43.0%*	*-0.8%*
Net income	5,390	5,337	4,185	4,165
% change		*-1.0%*	*-21.6%*	*-0.5%*

	2015	2016e	2017e	2018e
Operating margin	17.4	14.8	23.0	21.9
Net margin	6.8	0.8	7.0	7.4
ROE	8.6	1.2	9.9	12.9
ROCE	16.2	14.5	10.8	10.6
Gearing	47.7	101.1	139.1	192.8

(USD)	2015	2016e	2017e	2018e
EPS	4.26	4.22	3.31	3.29
% change	-	*-1.1%*	*-21.6%*	*-0.5%*
P/E	12.6x	12.8x	16.3x	16.3x
FCF yield (%)	NM	NM	2.2%	1.7%
Dividends (USD)	2.80	2.80	2.80	2.80
Div yield (%)	5.2%	5.2%	5.2%	5.2%
EV/Sales	3.3x	3.9x	4.4x	4.4x
EV/EBITDA	12.9x	19.7x	15.7x	15.9x
EV/EBIT	18.7x	26.3x	19.0x	19.9x



On Friday last week the FDA surprisingly accepted durvalumab's BLA in second line bladder cancer for review based on phase I/II results. The data was indeed very good but stemmed from a pretty small trial including a wide variety of different tumour types. And earlier this year, Tecentriq (Roche) was approved in a similar indication, leaving limited hope for BLA acceptance and approval. Actually AstraZeneca suggested it might get approval for all-comers and this is where the difference with Tecentriq might come from although we do not understand which clinical data supports this claim. Anyway, the PDUFA date is therefore in Q2 2017 and once the first indication is approved will make life easier for the following ones that will use the shorter sBLA route. 2L bladder cancer per se represents a limited commercial opportunity however and pressure is still on MYSTIC to succeed.

ANALYSIS

- Anything positive on durvalumab is of meaningful significance for AstraZeneca and its Oncology franchise for sure. So, the FDA's first BLA acceptance for the drug, in bladder cancer, is relevant, positive and somewhat surprising news. The surprise comes from the fact that durvalumab in bladder cancer only presented limited data so far out of a multi-tumour open-label phase I/II trial out of which only 61 patients had advanced urothetial bladder cancer whereas a PD-L1 targeting agent had already been approved earlier this year in about the same indication (Tecentriq, Roche), based on a much larger study including 310 patients. In our view, very few people if any expected under these circumstances to act on durvalumab in bladder cancer before it reports phase III data in 1L from DANUBE, sometimes in 2018. Even AstraZeneca had limited hopes we believe.
- Our understanding is that AstraZeneca succeeded in differentiating durvalumab from atezolizumab by sharing new data (so far undisclosed?) that would allow their drug to be offered to all-comers rather than only to PD-L1 positive patients. That is what we understood from our interactions with the company. Based on study 1108, we do not see the rationale behind this since what was reported in *The Lancet* in July 2016 was that ORR was 46.4% in PD-L1 positive patients and 0% in PD-L1 negative patients. The editorial reported comments from Dr Bellmunt from Dana Institute: "in this study, 25% or more expression of PD-L1 in either tumour or immune cells was predictive of efficacy, which gives us strong information". There should be additional data from other sources we are not aware of that support such a belief and FDA's decision to accept a filing.
- In terms of the consequences of the news, we consider them fairly limited in the end. Bladder cancer will represent a meaningful opportunity if and only if DANUBE is positive. So the commercial opportunity so far is modest. This BLA acceptance does not remove any pressure from durvalumab to succeed in head&neck and in lung cancer, starting with PFS data from MYSTIC that is expected in H1 2017. The combination between durvalumab and tremelimumab is where AZN can make a difference with existing drugs. That said, beyond the symbolic aspect of the news that can make possible to have durvalumab on the market in Q2 2017 (that's when the PDUFA date is), the positive aspect of the BLA acceptance is to be able to file any other following indication under the sBLA route and to save a bit of time.

VALUATION

- We have no sales for durvalumab in 2017 so far and it is now fair to say that there is a meaningful probability to have some, based on this BLA acceptance and PDUFA date in Q2 2017. However, over half a year, this will be modest. Tecentriq reported CHF77m in sales for the first two quarters and this is the top-end of what can be achieved. So we will make the change at a later stage but the impact on our FV would be minimal.

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- 2nd February 2017: Full-year results

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