Genmab

Price DKK763.50

Is Darzalex (daratumumab) guidance too conservative?

Fair Value DKK1170 (+53%) **BUY-Top Picks**

Bloomberg	GEN DC
Reuters	GEN.CO
12-month High / Low (DKK)	954.0 / 466.2
Market Cap (DKK)	45,292
Ev (BG Estimates) (DKK)	41,912
Avg. 6m daily volume (000)	389.0
3y EPS CAGR	-12.3%

	1 M	3 M	6 M	31/12/15
Absolute perf.	-9.0%	-9.1%	22.7%	-16.8%
Healthcare	-4.9%	-12.9%	-15.7%	-12.0%
DJ Stoxx 600	-2.0%	-14.3%	-14.4%	-10.8%

YEnd Dec. (DKKm)	2015	2016e	2017e	2018e
Sales	1,133	866.7	906.4	1,306
% change		*-23.5%*	*4.6%*	*44.1%*
EBITDA	554	50.1	2.7	351
EBIT	730.4	50.1	2.7	351.2
% change		*-93.1%*	*-94.5%*	
Net income	587.3	85.1	42.7	396.2
% change		*-85.5%*	*-49.8%*	

	2015	2016e	2017e	2018e
Operating margin	64.5	5.8	0.3	26.9
Net margin	67.4	9.8	4.7	30.3
ROE	21.9	2.4	1.2	9.9
ROCE	-15,400	44.2	11.1	69.2
Gearing	-100.2	-94.6	-89.4	-85.8

(DKK)	2015	2016e	2017e	2018e
EPS	9.71	1.41	0.71	6.55
% change	-	*-85.5%*	*-49.8%*	
P/E	78.6x	NS	NS	NS
FCF yield (%)	0.4%	0.1%	0.1%	NM
Dividends (DKK)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	36.9x	48.4x	46.4x	32.0x
EV/EBITDA	75.4x	835.7x	15302.4x	119.2x
EV/EBIT	57.2x	835.7x	15302.4x	119.2x

We had the opportunity to talk to Genmab's top management during a breakfast meeting in London. Unsurprisingly, most of the questions revolved around Darzalex (daratumumab) and its sales guidance for 2016 (USD250-300m)… and we now think this figure could be beaten if a European approval takes place in coming weeks. Apart from that, we understand that JNJ is already talking with other big pharmas, and this may lead to the initiation of clinical studies evaluating Darzalex with checkpoint blockers (which validates the scenario we put forward in our recent report). BUY reiterated with a FV of DKK1,170.

ANALYSIS

- **2016 sales guidance for Darzalex (daratumumab) looks very realistic**. While the compound was approved solely in the US on the 16th November, net sales during December 2015 amounted to approximately USD15-20m… thus already implying an annual run rate of USD180-240m. Since 1/ a European approval could be given by the end of H1 2016 (and knowing that the CHMP granted an accelerated assessment to the marketing authorisation application back in September), and 2/ we cannot rule out an off-label use of the drug in other settings (in combination with pomalidomide in R/R patients for example, as some data involving this setting have recently been presented), the low-end of the guidance (USD250m) looks entirely achievable.

- **Under what conditions could the USD300m threshold could be attained?** A cautious assumption for monthly sales of USD10-15m for Europe starting from June, and some growth in the US (which is very likely as the company is already seeing rising demand following the ASH meeting), means the high-end looks already at hand. But given how fast the FDA was (two months), we guess the EC could give its green light in coming weeks… If so, this would increase the likelihood of a rise in guidance when Q2 or Q3 results are released. Besides, we think JNJ will quickly reallocate a part of its marketing efforts to Darzalex as Velcade will continue to lose ground 1/ vs Amgen's Kyprolis and Takeda's Ninlaro (the first one being more potent and safer, while the second one is patient-friendlier), and 2/ with the advent of generics.

- **Management also reiterated its confidence in the outcome of the POLLUX and CASTOR studies.** Why should we be positive about this? Because 1/ dara already exhibited best-in-class data in R/R patients either as a monotherapy or along with the current standard of care; 2/ BMS' Empliciti (elotuzumab) got positive Phase III results in a similar setting with a far less impressive efficacy/toxicity profile as a monotherapy. As such, we are expecting a quite broad label expansion as of 2017, and thus a strong increase in revenues.

  Note that CASTOR – which evaluates dara along with Velcade (bortezomib) and dexamethasone – may come first as this proteasome inhibitor is much less potent than the agent used in POLLUX (Celgene's Revlimid (lenalidomide)).

- **JNJ is already talking with other pharmas to test Darzalex in combination with checkpoint blockers;** and this validates the scenario we put forward in our latest report (here). Of course, the timing of such a deal remains uncertain… but we'd say its probability will certainly increase once the (positive) results of the POLLUX and CASTOR studies are available. In any case, we see a strong rationale behind such a combo: 1/ dara is said to increase the CD8+/CD4+ T cells ratio thanks to its immune-modulation properties (some Tregs and myeloid-derived suppressor cells exhibiting CD38 at their surface + adenosine being produced through a CD38-mediated pathway); 2/ our hypothesis that dara could lead to an upregulation of PD-L1 remains to be confirmed, but if so this would only make it more appealing.

- Who would be the best partner in a perfect world? We'd say Celgene because of their deep knowledge of multiple myeloma, and their obtention of durvalumab (anti-PD-L1)'s rights from AstraZeneca… but also because we're assuming the big biotech will expand its collaboration agreement with AZN to obtain the rights to Innate Pharma's monalizumab (here). And if so, a mona/dara combo may see the light whereby mona may enhance the dara-mediated ADCC, while dara would augment the number of NKG2A CD8+ T cells. But of course, all this remains our conjecture.

VALUATION

- **Buy reiterated with a FV of DKK1,170**.
- To our eyes, the recent fall in the share price has opened a window of opportunity as the current level is even lower than that seen prior to daratumumab's first approval; 2/ **based on our SOTP valuation, the street gives nearly no value to daratumumab as a first and second-line treatment for patients with multiple myeloma** (these accounting for roughly DKK500 of our FV). In other words, the risk-reward profile is very attractive and should allow us to play serenely the upcoming publication of Phase III results.

NEXT CATALYSTS

- Q1 2016: European approval of daratumumab for the treatment of double-refractory patients.
- Q2 2016: Phase III results for daratumumab (anti-CD38) for the treatment of MM patients who received ≥ 1 prior line of therapy.
- H2 2016: Read-across from the approval of Roche's ocrelizumab (anti-CD20) in multiple sclerosis.
- 2016: collaboration agreement between JNJ and another big pharma to evaluate daratumumab in combination with a PD-1/PD-L1 checkpoint blocker.

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