Genmab

Price DKK816.50

Daratumumab to be combined with Roche's anti-PD-L1 in myeloma AND a solid tumor

Fair Value DKK1170 (+43%) **BUY-Top Picks**

Bloomberg	GEN DC
Reuters	GEN.CO
12-month High / Low (DKK)	954.0 / 466.2
Market Cap (DKK)	48,727
Ev (BG Estimates) (DKK)	45,347
Avg. 6m daily volume (000)	411.5
3y EPS CAGR	-12.3%

	1 M	3 M	6 M	31/12/15
Absolute perf.	6.9%	-10.6%	23.3%	-11.0%
Healthcare	-0.9%	-10.1%	-12.4%	-12.8%
DJ Stoxx 600	4.4%	-4.6%	-4.8%	-6.8%

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	84.1x	NS	NS	NS
FCF yield (%)	0.4%	0.0%	0.1%	NM
Dividends (DKK)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	39.9x	52.3x	50.2x	34.7x
EV/EBITDA	81.6x	904.2x	16552.0x	129.0x
EV/EBIT	61.9x	904.2x	16552.0x	129.0x

Genmab announced that daratumumab (an anti-CD38) will be investigated in early-stage clinical studies (Phase Ib) in combination with Roche's atezolizumab (an anti-PD-L1) in solid tumour, and multiple myeloma. We see this as 1) a strong validation of the best-in-class status of daratumumab as a treatment for MM… and we think the novel triplet combo (dara/atezo/lena) could bring the bar even higher, and 2) potentially as another step towards the enlargement of the addressable market with other malignancies (be it prostate cancer or non-hodgkin's lymphomas). BUY reiterated with a FV of DK1,170.

ANALYSIS

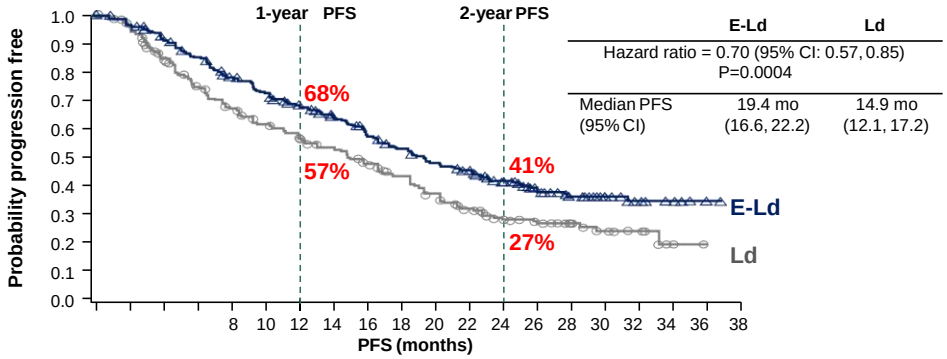
- As we expected (see our latest report here), **JNJ has found a partner (Roche in this case) to assess the potential of daratumumab in combination with an anti-PD-L1 (atezolizumab)** AND an immunomodulatory (lenalidomide or pomalidomide) in R/R multiple myeloma… But we have to admit that 1) the timing of the announcement was much earlier than we anticipated (we thought that a partner would only ink a collaboration agreement once the (positive) results of the POLLUX and CASTOR studies were available); 2) we had not anticipated the assessment of dara/atezo in a solid tumour (prostate?)… which of course is a very nice surprise.
- **We see this as a validation of the best-in-class status of daratumumab as a treatment for multiple myeloma**… and we think this novel triplet combo could bring the bar even higher as 1) we know that Merck's pembrolizumab (anti-PD-1) in combination with Celgene's pomalidomide generated an ORR of 76% in heavily pre-treated patients; 2) daratumumab is known to increase the CD8+/CD4+ T cells ratio thanks to its immune-modulation properties (and we assume it may lead to a stronger upregulation of PD-L1). In other words, we assume dara's market penetration could be enchanced should such development prove to be positive.
- **Daratumumab is currently seen as a myeloma drug… but this collaboration should change this image (for the better)**. We've said it several times: CD38 is a very interesting therapeutic target for several types of haematological malignancies (like non-hodgkin lymphomas and chronic lymphocytic leukemia to name just two); and we're pretty sure "dara"'s addressable market should be enlarged to some of them. But announcing the initiation of a new trial involving a solid tumour could be a step towards a new (and perhaps more lucrative) venue… and potentially more royalties for Genmab.
- **What's next ?** No study involving dara/atezo in NHL and other blood cancers has been initiated... but we can't rule out that 1) JNJ is willing to test dara along with ibrutinib (a BTK inhibitor - which is known to favour a Th1 response and is synergistic with immunotherapies) in these indications; 2/ another big pharma may have shown its interest (Merck & Co?) in replicating Roche's strategy in other malignancies (the press release does specify it, but we guess the deal is not an exclusive one).
- **Read-across: we see this is as another validation for the concept of Cellectis' UCART38** (the first one news being the recent announcement of a collaboration agreement between Roche and Kite Pharma; the objective to evaluate the safety and efficacy and KTE-C19 in combination with "atezo" in R/R NHL) as 1) not only this allogeneic CAR-T candidate has been designed to target cancerous cells exhibiting CD38; 2) but its anti-tumoral activity should theoretically be strengthen by the knock-out of the PD-1 gene (see our recent initiation report here for more details).

Fig. 1: Single-agent therapies in R/R multiple myeloma

Drugs	Settings	Responses
Carfilzomib	R/R patients (median of 5 prior lines)	ORR: 23.7%, CR: 0.4%, VGPR: 5.0%, PR: 18.3%
Carfilzomib	R/R patients (median of 5 prior lines)	ORR: 19.1%
Daratumumab	Double refractory (median of 5 prior lines)	ORR: 29.2%, CR: 3%, VGPR: 9%, PR: 17%
Daratumumab	R/R patients (median of 4 prior lines)	ORR: 35%, CR: 10%, VGPR: 5%, PR: 20%
SAR650984	R/R patients (median of 5 prior lines)	ORR: 33%, CR: 11%, PR: 22%
MOR202	R/R patients (median of 4 prior lines)	ORR: 33% (PR and VGPR) with dexamethasone
Pomalidomide	R/R patients (median of 5 prior lines)	ORR: 18%, CR: 2%, PR: 16%
Elotuzumab	R/R patients (median of 5 prior lines)	ORR: 0%, SD: 26.5%

Source : Company Data; Bryan Garnier & Co. ests.

Fig. 2: BMS' elotuzumab in combination with lenalidomide/dexamethasone (ELOQUENT-2)



- **Next catalyst: top-line results from two Phase III trials (CASTOR and POLLUX).** As a reminder, 1/ daratumumab has so far exhibited best-in-class data in relapsed/refractory patients with multiple myeloma either as a monotherapy, or as part of a combination regimen with the current standard of care (in particular with Celgene's lenalidomide); 2/ BMS' elotuzumab has generated positive Phase III results in a similar setting (see Fig. below)… while it was quite inefficient as a single-agent.

VALUATION

- **BUY reiterated with a FV of DKK1,170**. To our eyes, the recent fall in the share price has opened an interesting window of opportunity. Based on our SOTP valuation, the street gives little value to daratumumab as a first and second-line treatment for patients with myeloma (these two settings accounting for roughly DKK500 of our FV). In other words, the risk-reward profile looks quite attractive… and allows us to play serenely the upcoming publication of key Phase III data.

NEXT CATALYSTS

- Q2: Phase III results for daratumumab for the treatment of patients with multiple myeloma who received more than one prior therapy.
- H2: Read-across from the approval of Roche's ocrelizumab (anti-CD20) as a therapy for multiple sclerosis.

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