26th July 2016

Healthcare

Genmab

Price DKK1,148

Another BTD for "dara" - on the way to a label extension by year end

Fair Value DKK1600 (+39%) **BUY**

Bloomberg	GEN DC
Reuters	GEN.CO
12-month High / Low (DKK)	1,266 / 548.0
Market Cap (DKKm)	68,689
Avg. 6m daily volume (000)	485.6

	1 M	3 M	6 M	31/12/15
Absolute perf.	-0.9%	18.3%	36.4%	25.1%
Healthcare	6.2%	4.5%	2.7%	-3.2%
DJ Stoxx 600	-0.3%	-2.3%	0.6%	-7.0%

	2015	2016e	2017e	2018e
P/E	NS	NS	NS	73.2x
Div yield (%)	NM	NM	NM	NM

ANALYSIS

- Genmab and JNJ have announced that Darzalex (daratumumab) received a breakthrough therapy designation from the FDA. This BTD 1) covers Darzalex' use as part of a combination therapy with lenalidomide/dexamethasone or bortezomib/dexamethasone in myeloma patients who received at least one prior therapy; 2) follows the outstanding publication of the CASTOR and POLLUX studies in March and May this year (please see here and here).
- Obviously this is good news as 1) a BTD is an explicit acknowledgement of the quality of the clinical package by the US regulator and 2) paves the way for a potential priority review (which could be obtained in coming weeks). As such, we reiterate our belief that the compound should obtain a label expansion in 2L patients by the end of the year.
- Note that this is the second designation of this kind that "dara" has received since the beginning of its development, and we are not ruling out that others might be attributed (whether for the first-line of myeloma, or perchance other haematological malignancies such as non-Hodgkin's lymphomas).

VALUATION

- We reiterate our BUY recommendation and DKK1,600 Fair Value.
- While we have not changed our probability of success (80%) linked to the use of daratumumab in this setting (2L) yet, note that potential approval by the FDA towards late 2016/early2017 would add DKK150 to our Fair Value.

NEXT CATALYSTS

- August 2016: Potential FDA priority review given to daratumumab 1) as a treatment for patients with myeloma who received at least one prior therapy, and 2) as part of a combination regimen (bort/dex or len/dex)… which would pave the way for a label expansion by the end of the year.
- Q4 2016: Phase II results involving daratumumab in Non-Hodgkin Lymphomas.
- Q4 2016: Presentation of follow-up data from the POLLUX and CASTOR trials during the ASH meeting.
- Q4 2016: Read-across from the approval of Roche's ocrelizumab (anti-CD20) as a treatment for relapsing-remitting multiple sclerosis (RRMS).

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