# Genmab

Price DKK850.00

## The CASTOR study is positive… A first step towards large market expansion!

**Fair Value DKK1300 vs. DKK1170 (+53%)** **BUY-Top Picks**

| | |
|---|---|
| Bloomberg | GEN DC |
| Reuters | GEN.CO |
| 12-month High / Low (DKK) | 954.0 / 514.0 |
| Market Cap (DKKm) | 50,726 |
| Ev (BG Estimates) (DKKm) | 47,346 |
| Avg. 6m daily volume (000) | 413.3 |
| 3y EPS CAGR | -12.3% |

| | 1 M | 3 M | 6 M | 31/12/15 |
|---|---|---|---|---|
| Absolute perf. | 0.8% | -8.0% | 41.3% | -7.4% |
| Healthcare | -2.7% | -13.6% | -6.4% | -12.8% |
| DJ Stoxx 600 | 0.9% | -8.9% | -0.7% | -7.9% |

| 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%* | *NM* |
| Net income | 587.3 | 85.1 | 42.7 | 396.2 |
| *% change* | | *-85.5%* | *-49.8%* | *NM* |

| | 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%* | *NM* |
| P/E | 87.5x | 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 | 41.7x | 54.6x | 52.4x | 36.2x |
| EV/EBITDA | 85.2x | 944.1x | 17279.3x | 134.7x |
| EV/EBIT | 64.7x | 944.1x | 17279.3x | 134.7x |


**Genmab has announced that its Phase III trial evaluating daratumumab in combination with bortezomib and dexamethasone (namely CASTOR) was stopped early for benefit, and met its primary endpoint of improving progression free survival (PFS) vs bortezomib/dexamethasone. This is of course very positive as 1) JNJ (which retains dara's rights) should be able to obtain a first label expansion from the FDA to second-line patients with such data, 2) we are not ruling out increased off-label use of daratumumab in combo with a proteasome inhibitor, whether bortezomib or carfilzomib, in coming months. The next step would be the publication of top-line results for another Phase III study (POLLUX), which this time is evaluating "dara" in combination with lenalidomide and dexamethasone. And once again, we are quite confident in its outcome… BUY reiterated with a FV of DKK1,300 vs DKK1,170.**

## ANALYSIS

- **Genmab has announced that the Phase III evaluating daratumumab (anti-CD38) in combination with bortezomib and dexamethasone (CASTOR) met its primary endpoint of improving progression free survival** (PFS) in a pre-planned interim analysis (p≤0.0001). We have no details regarding the extent of this enhancement, but we note that **an IDMC (Independent Data Monitoring Committee) recommended to stop the trial early due to benefit**… So we would not be surprised to see a hazard ratio or HR ranging from 0.5 to 0.7, as seen with BMS's nivolumab in some solid tumors (irrespectively of the PD-L1 status), or even Amgen's carfilzomib in multiple myeloma.

**Fig. 1: Data from drugs for which the trial was stopped early**

| Drug | Indication | Setting | Median PFS |
|---|---|---|---|
| Nivolumab | 1L BRAF Melanoma | Monotherapy vs dacarbazine | 5.1 vs 2.2 months (HR: 0.43) |
| Nivolumab | 2L NSCLC | Monotherapy vs docetaxel | 3.5 vs 2.8 months (HR: 0.62) |
| Nivolumab | 2L Advanced RCC | Monotherapy vs everolimus | 4.6 vs 4.4 months (HR: 0.88) |
| Carfilzomib | 2/3L Myeloma | Combo with len/dex vs len/dex | 26.3 vs 17.6 mpnths (HR: 0.69) |
| Carfilzomib | 2/3L Myeloma | Combo with dex vs bort/dex | 18.7 vs 9.4 months (HR: 0.53) |

*Source : Companies Data; Bryan Garnier & Co. ests.*

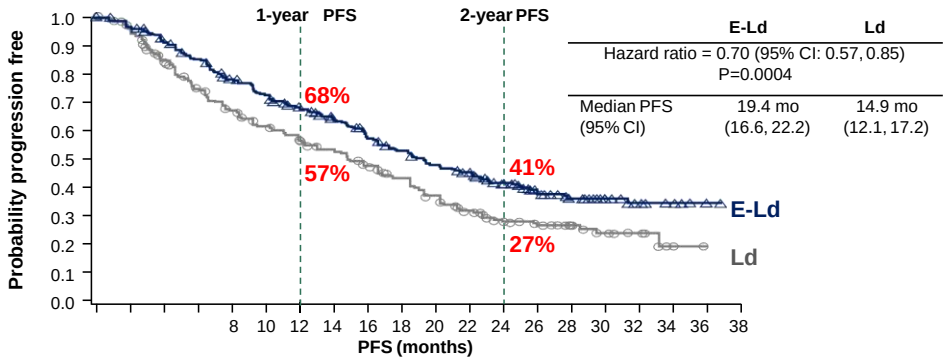
- Obviously, this is very positive news as 1/ with such data, JNJ (which retains dara's WW rights) should then be able to get a first label expansion from the FDA to second-line patients (whereas the previous label was "limited" to double-refractory ones as a single-agent); 2/ we think approval could be obtained by the end of this year, assuming a priority review by the FDA in the next three months; 3/ we are not ruling out increased off-label use of daratumumab in combo with a proteasome inhibitor, whether bortezomib or carfilzomib, in coming months…. and notably following the presentation of detailed results (perhaps at the ESMO conference?). As a consequence, **FY2016 sales guidance of USD250-300m now looks even more conservative to us…**
- **The next step would be the publication of top-line results for another Phase III study (POLLUX)**, which this time is evaluating "dara" in combination with lenalidomide and dexamethasone. And here again, we are confident in its outcome given that 1/ this anti-CD38 has so far generated best-in-class data in heavily pre-treated patients either as a single-agent (See Fig. 2), or as part of a combination regimen (and remarkably with immunomodulatory agents like lenalidomide – given the strong(er) synergies between these two approaches); 2/ even BMS's elotuzumab (an anti-CS1), which we consider a much less potent therapeutic option, has yielded positive Phase III results in a similar setting (see Fig. 3).
- **We think this data could be the most important from a market penetration point of view…** especially if it were to show a stronger improvement in PFS and OS compared to Amgen's carfilzomib in a similar setting, along with a more satisfying safety profile (and we think they could do, given what we saw in the GEN503 study – see our latest report here for more details). **As such, we are sticking to our peak sales of EUR5.5bn for dara in multiple myeloma… at least for the moment.**

**Fig. 2: 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 : Companies Data; Bryan Garnier & Co. ests.*

**Fig. 3: BMS' elotuzumab in combination with lenalidomide/dexamethasone (ELOQUENT-2)**




*Source : BMS*

## VALUATION

- **We have raised our FV from DKK1,170 to DKK1,300** after having 1/ slightly increased our probability of success (70% vs 60%) for daratumumab as a second-line treatment for patients with multiple myeloma, and 2/ decreased our WACC for this very same setting (9.0% vs 10.0% previously). **BUY recommendation reiterated.**
- Importantly, **our FV could be further increased by +DKK50-100 should POLLUX be positive**.

## NEXT CATALYSTS

- **Q2 2016**: European approval of daratumumab as a monotherapy for the treatment of double-refractory or heavily pre-treated patients (who have received at least three prior lines of therapy) with multiple myeloma.
- **H1 2016**: Top-line results from the POLLUX study (Phase III evaluating daratumumab in combination with lenalidomide and dexamethasone in with myeloma who received more than one therapy).
- **H2 2016**: Read-across for ofatumumab (an anti-CD20) from the likely approval of Roche's ocrelizumab (another anti-CD20) in multiple sclerosis (and notably in RRMS).

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BUY ratings 64% NEUTRAL ratings 28.7% SELL ratings 7.4%

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