

EQUITY RESEARCH | INSTANT INSIGHTS

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Daratumumab forging ahead; still undervalued within JNJ's oncology portfolio. Second molecule receiving "breakthrough therapy designation:"

Stock Rating/Industry View: JNJ

Price Target: USD 95.00

Price (30-Apr-2013): USD 85.23 Potential Upside/Downside: +11%

Ticker: JNJ

The News: Today, Genmab (OMX:GEN) and partner Johnson and Johnson (NYSE:JNJ) announced that the FDA has granted a breakthrough therapy designation for daratumumab. This designation was awarded specifically for the treatment of multiple myeloma. Daratumumab is in clinical trials for a variety of hematological cancers. Two Phase I/II trials are underway in multiple myeloma in conjunction with Reviimid and dexamethasone and in a separate trial in combination with Velcade and dexamethasone according to clinicaltrials.gov. This is the second such designation for a JNJ developed molecule. In February, the FDA also granted breakthrough therapy designation to the Pharmacyclics/JNJ co-developed molecule ibrutinib for a number of other hematological cancers. This anti-CD38 molecule is being developed and commercialized through a worldwide license by JNJ.

Quick Take:

Could daratumumab enter the market as early as late 2015? With the breakthrough designation as well as the recent track record of the FDA with regards to fast approvals (i.e. PFE's Xalkori, ARIA's Iclusig), we believe it is possible that daratumumab may be available for patients in the US with an approval in multiple myeloma by late 2015. This is ahead of our previous expectation of late 2016/2017.

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