

Quick Take

Johnson & Johnson — Outperform (1)

JNJ: \$70.60

Quick Take: Zytiga Gets FDA OK For Use In Pre-Chemo Setting On rPFS Data

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Analysts

Josh Jennings, M.D.
(646) 562-1333
josh.jennings
@cowen.com

**Christopher Hamblett,
Ph.D.**
(617) 946-3950
chris.hamblett
@cowen.com

Denis Kelleher
(646) 562-1389
denis.kelleher
@cowen.com

Yesterday afternoon, the FDA approved Zytiga (abiraterone acetate) for use in treating men with metastatic castration-resistance prostate cancer prior to receiving chemotherapy. The approval in the pre-chemo setting was based on Phase III data that showed a statistically significant improvement in radiographic progression-free survival (rPFS) in patients receiving Zytiga plus prednisone compared to the placebo plus prednisone (HR=0.43; <0.0001). Zytiga failed to achieve statistical significance on the pre-specified overall survival endpoint (p=0.0097 vs the pre-specified p-value of p=0.0008) in this setting, but we expected the drug to be approved on the rPFS data and strong hazard ratio for overall survival (HR = 0.75; 95% CI = [0.61, 0.93]; p=0.0097). Median overall survival data in chemotherapy naive patients receiving Zytiga was 35.3 months compared to 30.1 months in patients receiving placebo plus prednisone, a net improvement of 5.2 months. We view Zytiga's label expansion based on rPFS data as a positive for JNJ.

The approval comes a few days ahead of its scheduled mid-December PDUFA date. The pre-chemo CRPC market opportunity is estimated to be approximately three times the size of the post-chemo CRPC opportunity. Our global Zytiga sales estimates of \$975MM in 2012, \$1,120MM (+15%) in 2013, \$1,165MM (+4%) in 2014, \$1,220MM (+5%) in 2015, \$1,300MM (+7%) in 2016, and \$1,380MM (+6%) in 2017 assume competitive pressures from Medivation's Xtandi (enzalutamide) and assume Xtandi achieves regulatory approvals in both settings as well.

Phase III interim data for Medivation/Astellas' androgen receptor antagonist Xtandi in chemotherapy-naive prostate cancer are expected in 2013. Xtandi was approved for use in post-chemo CRPC patients in September 2012. Xtandi acts similarly to Zytiga and has roughly equivalent efficacy (based on overall survival data in the post-chemo setting), but offers potential convenience and tolerability advantages over Zytiga in being administered without prednisone. However, prior to today's label expansion, Zytiga had already gained off-label use in the pre-chemo setting (likely among Medical Oncologists), which supports our clinical consultants' views that co-administration with prednisone, while perceived as a potential disadvantage, is not a major barrier to Zytiga's use.

Addendum

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Ticker	Company Name
JNJ	Johnson & Johnson

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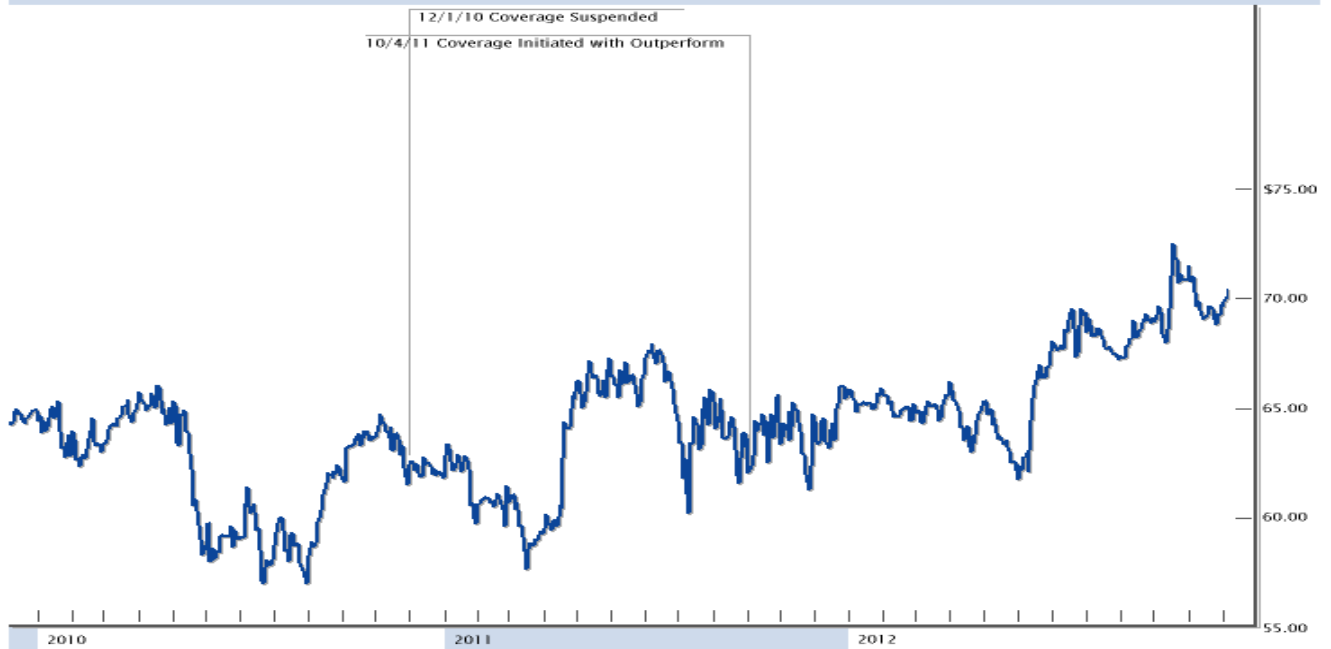
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Johnson & Johnson - JNJ



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