

Novartis: Zometa Sales Likely to Continue Until March 2013; Confident in Afinitor Approval Given Strong Data in pNET and High Unmet Need in Metastatic Carcinoid

Novartis offers a wide pipeline with many shots at goal. The recent approval of Tasigna in first-line Chronic Myeloid Leukemia and the positive FDA AdCom vote for Multiple Sclerosis drug Gilenia substantially de-risks over \$3bn of revenues to the company providing greater visibility to outer year earnings. Looking ahead with further data and understanding, we see the potential for the pipeline (QAB149, Afinitor, Ilaris and Gilenia upgrades) to drive consensus outer year earnings expectations and lead to outperformance of the share versus peers.

Oncology Products Update:

Zometa relief – sales likely until March 2013. Novartis has settled the patent litigation with Teva on Zometa/Aclasta removing a low risk threat to \$750m of sales until the drugs' patent expiration in 2013. Further detail on the call demonstrated the strength of the patent as generic challenger Teva changed its application from a paragraph IV challenge to a paragraph III application (approval once patents expired).

Afinitor misses in carcinoid tumors. The one blight on the quarterly report comes from a study of cancer drug Afinitor that narrowly failed to meet its primary endpoint in carcinoid tumors (HR=0.77, p=0.26 vs. predefined endpoint of p=0.24). Novartis will now enter discussions with regulatory bodies with the hope of filing for both carcinoid and pancreatic neuroendocrine tumours (pNET) during 2H10.

Our forecasts currently hold \$350m risk-adjusted 2015E sales for Afinitor in carcinoid tumors. We remain reasonably confident of approval given 1) the strong data in pNET a mechanistically similar tumor, 2) the narrow miss being explained by an imbalance in base-line groups, with the Afinitor arm suffering from a higher level of poor prognosis foregut (lungs) tumors. 3) the high unmet need in metastatic carcinoid with no effective therapy available other than somatostatin analogues (primarily for symptom control).

Source: Deutsche Bank/Race, July 15, 2010

Oncology Indication: Multiple

Keyword: Clinical Trials/Pipeline