

Bristol-Myers: Yervoy (Phase III/Adjuvant Melanoma) Expected to Show a Significant Improvement in Relapse Free Survival

We anticipate that EORTC-run 950-patient Phase 3 Yervoy adjuvant melanoma trial will show a very significant improvement in relapse free survival for Yervoy 10mg/kg dose compared with placebo in high-risk stage III melanoma patients. We anticipate outcome measures to look materially superior and better tolerated compared with historic controls with IFN alpha, the current and meager gold standard. As with Roche's Avastin in breast cancer, we assume Bristol-Myers (BMY) will adopt patient price caps to offset 3-year treatment duration and higher 10mg/kg dosing.

What do we expect? We anticipate that Yervoy will demonstrate at least a 30- 40% improvement in relapse free survival compared with the placebo treated patients. The historical improvement with IFN is a dubious c.10%. The anticipated clinical benefit of Yervoy will likely offset the expected immune related adverse event profile typical for Yervoy, even with prolonged usage. The predictive relevance of baseline tumor ulceration for Yervoy is unclear.

What next? We anticipate BMY to initiate a three-arm trial with Yervoy, nivolumab and the combination in a similar adjuvant melanoma setting. A trial evaluating two different doses of Yervoy (3mg/kg and 10mg/kg) in adjuvant melanoma is ongoing. We anticipate competitors AstraZeneca, Merck & Co. and Incyte to follow suit with various combinations but we don't expect Yervoy to face significant competition until 2019.

\$3bn opportunity for Yervoy, with c.95% margins. We estimate a total commercial opportunity for Yervoy of \$3bn in the adjuvant melanoma indication, on top of the opportunity in metastatic melanoma. There are c.45,000 patients with Stage III melanoma diagnosed every year in the U.S. and EU-5 (roughly 2.5x Stage IV metastatic melanoma patients) with stage IIIB and IIIC constitute a third of all Stage III patients. BMY is evaluating Yervoy 10mg/kg dose over a maximum duration of 3 years (15 injections in total). We have conservatively assumed only a year of treatment (7 injections) and model the same pricing for the 10mg/kg dose as for the 3mg/kg dose approved for the metastatic indication. We expect BMY to introduce price caps similar to Avastin in breast cancer.

Source: Citigroup/Baum, March 25, 2014

Oncology Indication: Skin

Keyword: Clinical Trials/Pipeline