Dendreon notches another thumbs-up for Provenge but saga continues

The Provenge saga is not over, but at least Dendreon’s investors can envision some good fortune going into the new year. An advisory panel has recommended coverage of the Seattle company’s prostate cancer vaccine, by the Centers for Medicare and Medicaid Services (CMS), for on-label use only.

A final decision by the CMS is due in June next year, and events seem to be progressing as well as could be hoped for a company that has encountered its fair share of regulatory hurdles (Event – Provenge goes another round with the regulators, September 29, 2010). The Medicare Evidence Development & Coverage Advisory Committee’s (MEDCAC) confidence rating of 3.6 out of 5 for Provenge’s survival benefit is hardly resounding backing but nonetheless is positive for Dendreon – shares rose 9% at the start of trading today, to $39.

Observers now think it increasingly likely the CMS will provide coverage for the $93,000 autologous cellular immunotherapy in the tested population of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer, as per the label. In fact a number of private insurers and Medicare’s regional divisions already provide coverage for Provenge.

The panel also recommended that off-label use in a wider prostate cancer patient base should not be covered, as there was no evidence of benefit in this setting.

Impact on national coverage plans

Interestingly, this recommendation could produce ripples for other expensive medicines tipped for coverage by the US government.

In a research note today, UBS says the situation underscores why its forecasts for Amgen’s bone metastases candidate Prolia (denosumab) are being kept conservative.

UBS noted: “We believe that limiting reimbursement for off-label use of higher-priced specialty medications may be the only way CMS can affect drug economics.”

Uncertainty with efficacy

With this in mind, the uncertainty that still surrounds Provenge’s actual efficacy means any post-marketing data that is generated could cause sales and forecasts to swing substantially.

This was stressed by the MEDCAC committee, some of whom said further efficacy studies were warranted. Indeed, whilst a 4.1-month median survival benefit over placebo provided sufficient data for FDA approval, Provenge has not actually been shown to slow tumour growth (Relief all round as Dendreon bags landmark Provenge approval, April 30, 2010).

As part of Provenge’s license, the FDA requested Dendreon conduct a post-marketing safety study in 1,500 prostate cancer patients to evaluate the incidence of cerebrovascular adverse events, flagged during phase III trials. This however will not report results until 2016.

A CMS decision mid-2011 should come around the same time Dendreon completes a ramp-up of manufacturing capabilities, which should address capacity issues (Medicare causes another waiting game for Dendreon, July 02, 2010). A thumbs-up will certainly mean Dendreon does its utmost to capitalise on a supply deal with GlaxoSmithKline, which comes into force in August.

On-label CMS coverage now looks likely; off-label endorsement was not wholly expected and analysts have not factored this into forecast models. Consensus sees nearly $3.2bn in 2016 sales, a figure which, on the back of yesterday’s news, should not dwindle. Assuming Dendreon can meet its manufacturing demands, the test for success lies with real-world efficacy.