

Dendreon scores a clear hit with Provenge data



[Lisa Urquhart](#)

It was the event that investors in Dendreon knew would be either the making of the stock or the breaking. Today, following positive topline phase III results for its prostate cancer drug, Provenge, Dendreon is on the verge of becoming the first company to successfully commercialise a cancer vaccine.

News of what chief executive, Mitchell Gold, described as a clear hit and unambiguous results in overall survival data caused shares in the company to more than double from the \$7.30 they were at on Thursday to \$20.08, their highest level since May 2007 when an FDA advisory committee recommended approval only for the FDA to reverse that decision two months later. The rise in the shares has been exacerbated by the large number of short sellers in the stock who today would have been desperately trying to unwind their positions. About 17% of Dendreon's shares are thought to be shorted.

Goal reached

But given the historical number of failures in the cancer vaccine space that have seen the likes of Cell Genesys' GVAX fall by the wayside, today's news could have gone either way ([Event - Dendreon's looming Provenge data promises to maintain excitement, March 23, 2009](#)). The group which only gave headline details of the study, saving the full read out until April 28 at the American Urological Association's annual meeting, had needed to demonstrate a 22% improvement in overall survival, which given that the last set of results only demonstrated a 20% improvement had caused some investors to doubt if this threshold would be reached.

Today, Dendreon said that the study had met the criteria and specifications outlined in its special protocol assessment agreement with the FDA

One thing that Provenge had on its side was that previous data had suggested the benefits of the drug improved over time. Dendreon said it would now be filing an amendment to its existing biologic license application in the fourth quarter of this year to gain approval of Provenge and with an expected six-month type II review the drug could be on the market by the middle of next year.

Jewel in the Crown

Provenge is the most important and most valuable drug in Dendreon's portfolio, worth \$726m to the group according to EvaluatePharma's NPV Analyzer, it is also forecast to have sales of \$255m by 2014. But now that approval could be round the corner this figure could rise as the drug is one of the few treatments for prostate cancer that come without the unpleasant side effects, and as the phase III data indicates should significantly improve a patient's life expectancy.

Dendreon expects to commercialise Provenge in the US on its own, with a specialised sales force of around 100 reps, and is currently seeking a European partner. The positive data announced today is bound to have substantially strengthened the group's negotiating power.

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