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Dendreon Got Big OK, But Still Faces Hurdles

Will 'Vaccine' Take Off?

Cancer treatment gives time, not cure; one rival may have more promise

BY PETER BENESH
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Regulatory approval of **Dendreon**'s prostate cancer treatment, Provenge, marked a huge advance for the company and perhaps for the drug industry, but there remain plenty of caveats.

For one, some observers say a different prostate cancer treatment being developed by Denmark's Bavarian-Nordic has better prospects. Also, there's much debate about the effectiveness of Provenge's method — boosting the body's own immune system to fight cancer. Finally, recent insider trading at Dendreon[DNDN] may have spooked investors.

But make no mistake, approval of Provenge is a watershed event, says Michael Becker, chief executive of biopharmaceutical consulting firm MD Becker Partners. "Despite its detractors, there is something real here," he said.

Dendreon shares skyrocketed 27% on April 29, when it finally won Food and Drug Administration approval for what will be the 18-year-old company's first product, capping a long quest.

Provenge's challenges are that it's complicated and expensive. But it's also revolutionary.

It works by boosting the patient's immune system to recognize cancer as an enemy and fight back. That puts it in the category of a therapeutic vaccine, though the term "vaccine" is misleading.

Provenge neither prevents nor cures prostate cancer. It buys time. Many experts prefer to call it an immunotherapy, and there's much debate in medical circles over whether immunotherapy is the way to go in cancer treatment.

Clinical trials showed that a third of patients on Provenge lived at least three years, compared with 20% on placebo. But the median life extension was just 4.1 months.

Mark Monane, a medical doctor and analyst with Needham & Co., points to three key issues:

Can Dendreon get Provenge to the right patient at the right time? Will doctors and patients have good experiences? And can Dendreon ramp up sales the way it hopes?

He might have added a fourth. Can Dendreon face down looming competition?

Investors have mostly answered yes. The stock is up more than 150% in the past 12 months.

Still, almost unnoticed is that on the day the FDA gave Provenge the nod, the agency also gave fast-track status to Bavarian-Nordic for Prostvac. Fast-tracking gives priority to a drug to accelerate approval. Prostvac has delivered phase-two results that some say look better than results for Provenge.

The three-year survival rate appears to be the same as Provenge, but median survival is 8.5 months.

Important to note, Becker says, is that Prostvac will be off-the-shelf, while Provenge must be custom-tailored to each patient. So it looks as if Prostvac will also be cheaper.

The FDA OK'd Prostvac's fast track because the drug has shown a potential survival benefit and excellent safety record. The target patients are the same as for Provenge — men whose prostate cancer has resisted all other treatments.

The field is getting crowded. This week, **BioSante Pharmaceuticals**[BPAX] announced that it would revive its development of its GVAX prostate cancer vaccine. The firm had discontinued GVAX in the middle of phase-three trials in 2008. If approved, its vaccine will also be off-the-shelf and not patient-specific.

Dendreon's stock, meanwhile, fell nearly 5% Tuesday on news of heavy insider selling. Monday, key Dendreon executives, including Chief Executive Mitchell Gold, reported to the SEC that they had sold shares on April 29, the day the FDA approved Provenge, and the following day. Gold sold $28 million worth but still holds more than 224,000 shares.

The sales "don't exactly instill confidence in the commercial launch or initial success of the product," Becker said.

Seattle-based Dendreon did not respond to requests for comment.

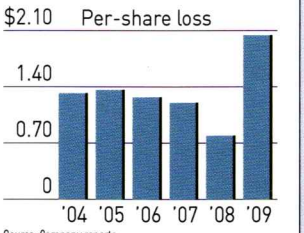
Whether Dendreon senior executives make money selling their stock is not the big question, Monane says: "The question is, can they execute their plan?"

Monane reckons that the answer is yes. His price target for Dendreon is 62; it now trades near 52. The consensus view of 12 analysts polled by Thomson Reuters is that Dendreon will be profitable by 2012.

The company plans to supply Provenge from plants in New Jersey, Atlanta and Seal Beach, Calif. Three treatments are required, at a combined cost of $93,000. Insurers haven't weighed in yet, but Medicare is covering the treatment.

Dendreon's Losses

Provenge will be the company's first commercial product, so analysts expect the firm to finally move into the black within two years



Source: Company reports

Cells are taken from patients' blood, then shipped to Dendreon. Provenge, tailored to each patient's chemistry, is added. The fortified solution goes back to the patient for infusion.

Though cumbersome and costly, it's a pioneering approach which proves that boosting the body's own immune system to fight cancer can have benefits. The hope, Monane says, is that Provenge can help fight earlier stages of prostate cancer. Trials are under way.

Becker says Provenge's approval could inspire more investment in cancer vaccine programs. Media coverage has been limited to the good news for prostate patients and for Dendreon, he said, with "little focus on what it means for the rest of the oncology industry and marketplace."

What it means is that, from now on, skeptics should stop pooh-poohing efforts to use the body's own immune system as a weapon against cancer, Becker says.

Monane agrees: "For those people who said there'll never be a cancer vaccine approved — that's so yesterday."