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Provenge Nod Bodes Well, but No Free Pass for Cancer Vaccines

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Dendreon Corp. made history last week by securing approval for Provenge (sipuleucel-T), the first therapeutic cancer vaccine ever cleared by the FDA.

The news - and Dendreon's announcement of higher-than-expected pricing - boosted the Seattle-based biotech's stock 27 percent on Thursday and another 8 percent on Friday, capping a run-up of more than 1,800 percent in just over a year. Shares (NASDAQ:DNDN) closed Friday at 54.06, up \$3.88. (See *BioWorld Today*, April 30, 2010.)

And Dendreon wasn't the only one to gain. Cancer vaccine companies basking in the reflected glow included AVAX Technologies Inc., ImmunoCellular Therapeutics Ltd., Biovest International Inc., Antigenics Inc., Celldex Therapeutics Inc., Oncothyreon Inc., Vical Inc., Cel-Sci Corp., Northwest Biotherapeutics Inc. and others - some of which saw their shares rocket up nearly 50 percent Thursday.

But what does Provenge's approval actually mean for all of those companies?

On the one hand, it proves that a therapeutic vaccine can work in cancer and establishes a regulatory precedent. Jeffrey Abbey, president and CEO of Argos Therapeutics Inc., said the approval "validates the field," and he predicted many companies in the space may benefit from the increased attention.

It certainly has been a long time coming.

The idea of using a vaccine to harness the immune system and fight cancer has captivated scientists since the early 1900s, but putting the theory into practice proved no easy task. Among the biotechs to face failure in late-stage trials were Antigenics Inc., CancerVax Corp., Cell Genesys Inc., Favril Inc., Genitope Corp., Progenics Pharmaceuticals Inc., Therion Biologics Corp. and many more. Even Dendreon missed the primary endpoint in its first two Phase III trials. The situation got so bad that the entire field re-branded itself as "active immunotherapy" because the term "cancer vaccine" had become unpalatable to both investors and partners.

The importance of Dendreon's win with Provenge cannot be overstated. President and CEO Mitchell Gold certainly was warranted in using phrases like "the dawn of an entirely new era in medicine" and "the Holy Grail of oncology."

But at the same time, Vical Inc. president and CEO Vijay Samant noted that "just because Provenge got approval doesn't mean everyone is going to get a free ride."

The fact is, while cancer vaccines get lumped into a single category, they involve a variety of technologies that are often more different than similar. And those that have failed have done so for very different reasons.

Sometimes it comes down to vaccine design. Some experts favor the autologous (personalized) approach like Provenge, while others prefer an allogeneic (off-the-shelf) product. And almost every vaccine in the clinic has its own mechanism, be it single-antigen, multiple-antigen, DNA, RNAi, whole cell, dendritic cell or something else entirely.

The choice of tumor also can impact the success or failure of a program: Patients with aggressive cancers might not live long enough to show an immune response. Trial design is important, too, and trials differ in their use of adjuvants, their administration schedule, their endpoints, their use of concomitant treatments and other factors.

All of which indicates that while Dendreon's Provenge approval is indeed a success for the entire cancer vaccine field, it is no guarantee of individual success for anyone else.

There are some, however, who may be more entitled to ride Dendreon's coattails. Argos is in a Phase IIa kidney cancer trial with cancer vaccine AGS-003, which is somewhat similar to Provenge in that it is personalized and uses dendritic cells. But CEO Abbey said that Argos has built on Dendreon's approach by using only dendritic cells rather than an antigen-presenting cell mixture. Additionally, while Dendreon uses personalized cells with an off-the-shelf antigen, Argos uses personalized cells and RNAi extracted from each patient's tumor.

Vical's Allovectin-7, on the other hand, is an off-the-shelf plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and beta-2 microglobulin, which Samant explained is designed to teach the immune system to recognize all of the antigens associated with the tumor. The approach has similarities to Merial Ltd.'s Oncept, which was approved earlier this year for melanoma in dogs.

Data from Vical's Phase III trial of Allovectin-7 are expected in the second half of 2011.

Other cancer vaccines in late-stage development include AVAX's MVax for melanoma, Bioniche Life Sciences Inc.'s Urocidin for bladder cancer, Oncothyreon and Merck KGaA's Stimuvax for lung and breast cancer, GlaxoSmithKline plc's MAGE-A3 for lung cancer, Aphera Inc.'s NeuVax for breast cancer, Transgene SA's TG4010 for lung cancer, Celldex Therapeutics Inc.'s CDX-110 for glioblastoma and GlobelImmune Inc.'s GI-4000 for pancreatic cancer.

Published May 3, 2010

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