

Manish Singh: Cancer Treatment Revolution Just Beginning

by: M. E. Garza August 11, 2011

Dr. Manish Singh, President and CEO of ImmunoCellular Therapeutics , shares his thoughts on the recent headlines which sent shockwaves through the entire biotechnology grouping on Wall Street.

Singh, a leading oncology field innovator, has positioned his own firm as one of the leaders in the cancer vaccine space-- complete with products and technologies designed to harness the power of the patient's own immune system in order to not only fight but also improve the diagnosis of cancer.

BioMedReports: *Dendreon ([DNDN](#)) shares are down more than 60% since it reported underwhelming second-quarter earnings and withdrew its 2011 revenue guidance last week. What do you make of Dendreon's recent setback and what impact does it have on the entire cancer immunotherapy space?*

Dr. Manish Singh: Analyst reports issued after last week's earnings call indicate Dendreon's setback was primarily due to slower-than-expected adoption of Provenge and the continued high cost of manufacturing. It therefore appears that Dendreon's current problems mainly relate to execution, and not to the technologies underlying its products. We know Provenge works based on data from multiple clinical trials demonstrating a clear survival benefit in treated patients. It was based on these data that the FDA approved Provenge last year, a decision that reinvigorated interest in the entire immunotherapy space. With the approval of BMS' melanoma drug Yervoy earlier this year, immunotherapy companies gained even greater momentum, which we are confident will increase even further as these companies, including ImmunoCellular Therapeutics, continue advancing novel immunotherapy products in the clinic, and ultimately to the market.

BioMedReports: *So if Provenge offers a clear survival benefit, then why has adoption been slow?*

Dr. Manish Singh: There are three issues underlying the adoption issue. First, there are reimbursement difficulties associated with its high cost and high cost density. Second, the relatively high availability of competing products has limited its use. The third issue is the marginal clinical benefit of product relative to its high price tag of \$93K a year.

BioMedReports: *If the clinical benefit of Provenge is marginal, then why is it so expensive?*

Dr. Manish Singh: The high price of Provenge reflects its high cost of manufacturing.

Provenge is not sold off the shelf; it is custom-made using the patient's own dendritic cells. Last quarter, Dendreon's cost of goods sold was around 55-60%, which means for every patient who was reimbursed \$93K, about \$50-55K went into the manufacturing cost for three shots, or roughly \$18K per shot. This is quite high by any pharmaceutical standard, and even in 2014 when analysts expect DNDN to become profitable, the expected COGS is 38% based on analyst projections.

BioMedReports: *ImmunoCellular's vaccine is also custom-made with a patient's own dendritic cells. Won't you run into the same cost issues?*

Dr. Manish Singh: Being a fast follower as opposed to be a leader has many advantages, one of them being the ability to learn from the mistakes or difficulties of the leader. Our strategy for avoiding Dendreon's cost issues is broadly to reduce the cost of making our products, and increasing their value to patients.

On the manufacturing cost side, we have designed a process that allows us to produce 20 or more shots of vaccine in a single production run, compared to one vaccine shot produced by Dendreon's process. Our cost per shot, even at these scales where we are preparing for Phase IIb, is less than \$800 per shot, compared to \$18,000 or so that Dendreon seems to be spending based on the reported COGS numbers. Also, by giving patients 10-20 shots of vaccines, we are taking out the cost density issue associated with Provenge off-the-table. So we have a huge cost advantage in producing an autologous (or patient-derived) vaccine in a way that will allow us to be profitable very quickly.

In addition to reducing manufacturing costs, we are also focused on increasing the value of our products. As we move toward a more cost-conscious and value-oriented healthcare market, it is becoming more and more important to be conscientious about providing clinical benefits that are larger than economic costs. Provenge increases survival by about 4 months, or 15%, for prostate cancer patients. Our target for our lead product candidate, ICT-107, is to improve survival by at least six months, which would be close to 40% for patients with glioblastoma, the most common and aggressive form of brain cancer. I should remind you that our goal of 6 months of improvement in phase IIb is much smaller than 24 months of survival improvement we saw in phase I study.

BioMedReports: *And how do you intend to avoid the reimbursement issues Dendreon is facing?*

Dr. Manish Singh: I think reimbursement is a critical part of a successful product launch and I do think Dendreon management has identified the correct issues with respect to cost density of Provenge and time to reimbursement, which makes small community doctors uncomfortable with prescribing products not knowing whether they will be reimbursed. I won't go into how we would have handled this, but I think this is a fixable problem that should have been identified earlier. There are some interesting solutions to this, and I am quite curious to see how Dendreon resolves this.

Our reimbursement strategy starts with ensuring larger clinical benefit, which will

influence reimbursement along with competitive pricing. If we think of Avastin as a competitive drug for glioblastoma, we are looking at possibly around \$120,000 per year, which would be justifiable if we have stellar results showing survival improvement of six months or longer. Of the patients enrolled in our Phase I study of ICT-107, 38% were still completely free of disease after 2.5 years, compared to less than 5% expected based on historical data. Additionally, the safety profile of ICT-107 is considerably better than that of Avastin. If we can continue to reproduce this data in later-stage trials, this would clearly be an extremely valuable product to patients, with very little price elasticity.

BioMedReports: *So where does the field of immunotherapy go from here? Is this just a bump on the road, or does this create a downturn?*

Dr. Manish Singh: I think we are at the beginning of immunotherapy revolution because we finally are starting to understand various aspects of tumor biology and certain nuances of immunology that were not appreciated before. There are several interesting Phase II and Phase III programs, including Oncotheyreon's MUC-1 vaccine trial for non small cell lung cancer, our Phase II trial of ICT-107 for glioblastoma. I think Dendreon's problems are truly isolated issues of a single company's failure of execution, and the rest of the field will stand on the strength of its own clinical data. In sum, I think this is a minor bump on the road and we should see next-generation products like ours to thrive, as we have already addressed a number of issues that came up with Provenge launch.

Disclosure: I have no positions in any stocks mentioned, and no plans to initiate any positions within the next 72 hours.