

# Seeking Alpha

## ImmunoCellular Therapeutics CEO Explains Economic Significance of New Vaccine Manufacturing Method

by: M. E. Garza October 13, 2010

On Wednesday morning, ImmunoCellular Therapeutics (IMUC.OB) announced that it has developed an innovative method for manufacturing the company's dendritic cell-based vaccine for the treatment of glioblastoma multiforme (GBM).

Given all the headlines that Dendreon (NASDAQ:DNDN) has made with its manufacturing problems, IMUC's lead product candidate, ICT-107, may well start making news of its own. DNDN's Provenge won FDA approval last April, but sales have been hindered by the company's limited production capacity, an issue which DNDN management has said it expects to resolve some time next year.

The method ImmunoCellular Therapeutics has announced was developed in collaboration with the Clinical Cell and Vaccine Production Facility at the University of Pennsylvania and it employs a closed-bag system designed to produce highly potent dendritic cells from white blood cells collected from patients, and for subsequently cryopreserving the dendritic cells for future vaccine treatments.

Engineering and validation runs have confirmed that this process may be used to produce 20 or more doses of ICT-107 vaccine from a single blood collection, which may be frozen and later used for vaccination and maintenance of immune response in patients until disease recurrence.

We spoke exclusively to Manish Singh, Ph.D., president and CEO of ImmunoCellular Therapeutics, about this important development:

**BioMedReports: Is it safe to say that the company has invented a whole new way to manufacture its innovative cancer treatment?**

Manish Singh: Let's start with the treatment before we talk about the process. Our product is a dendritic cell based cancer vaccine that targets cancer stem cells and multiple tumor associated antigens. Cancer stem cells are like roots of the cancers – they are resistant to chemotherapy and radiation therapy. Over the last 30 years all oncology drugs have been primarily targeting the bulk of the tumor while leaving cancer stem cells unchecked. In a phase I study involving 21 patients with glioblastoma, the most aggressive brain cancer, we have demonstrated a tripling of survival rates at 2 years (80% vs. 26% for the standard of care). What is even more impressive is almost 45% of patients are free of disease after two years which is quite unheard of in glioblastoma. Lastly, this product could be applicable for breast, ovarian and colon cancer as some of the same antigens are expressed on those tumors as well.

Going back to your question, yes, this is a new and innovative process which was originally developed at the University of Pennsylvania. We negotiated rights to this patent pending process earlier this year and have made significant improvements to it over the last six months. There are three innovative steps that are involved which have been missing in the past. Without going into

technical details, these include separation of certain type of cells which are precursors of dendritic cells, optimization of maturation of dendritic cells so that they have peak performance a few hours after they are injected, and freezing of these cells in a special solution to ensure long term stability. The net effect is we can make 20-30 doses of vaccine from a single manufacturing run and we can store them for several years, and continue to treat patients until disease recurs.

**BioMedReports: We have seen how manufacturing problems have affected other companies in the immunotherapy space, does your news today impact the sector as well as your own company?**

Manish Singh: In the past, people have taken laboratory based unscalable processes into clinical trials and once you get into a late stage clinical trial you are stuck with your process no matter how inefficient it is. We are demonstrating for the first time that one could scale-up such that the economics of making a patient specific cell therapy is not all that different from making some of the antibodies or other biologics. Our cost of making this product at this stage is expected to be less than \$1,000 per shot of vaccine. We intend to treat our patients for 2-3 years from this vaccine or until the disease recurs. Based on our reimbursement models for brain cancer using pricing information from drugs like Avastin, we think our cost of goods sold would be less than 10% which is similar to conventional biological drugs.

**BioMedReports: Can you please explain the economic significance of this news to your investors?**

Manish Singh: Cancer vaccines have been under development for the last 20 years. We all know that autologous dendritic cell based approach has demonstrated some signs of efficacy in a number of clinical trials and Provenge is a great example of a product using patients' autologous cells to elicit an immune response. The big pushback you get from large pharmaceutical companies is on the logistics and the cost of goods sold. For example, each injection of Provenge has to be made fresh and the patient has to be injected with the product within a day or so of the manufacturing of the product. It's logistically more complex and much more expensive. We have essentially cut the Gordian knot of one of the most complicated problems of autologous cancer vaccines by unbottlenecking the manufacturing process.

**BioMedReports: What are your biggest challenges going forward?**

Manish Singh: There are three risks that all biotech companies face -- execution risk, financing risk and clinical risk. I feel there is limited execution risk due to the experience of our team of developing several drugs before; by being capital efficient -- our burn for this year will be around \$4-5 million - we have reduced our dependence on raising money constantly which minimizes financing risk; so the biggest risk is really clinical risk. We have done our best to design a phase II program that has the blessings of not only some of the key opinion leaders in brain tumors but also several pharmaceutical companies. The phase II design is like a mini phase III with a double blinded, randomized, and controlled trial which takes all the biases out. The big challenge to this study is going to be to ensure a fast accrual rate of patients which we are tackling by getting a number of top notch brain tumor specialists behind this clinical trial. If the data is anything close to what we have seen so far, this product would become the new standard of care and one of the biggest changes in treatment paradigm of brain tumors.

IMUC is preparing to initiate a Phase II study of ICT-107 in GBM in the fourth quarter of this year.