

# Seeking Alpha $\alpha$

## ImmunoCellular's Promising Brain Cancer Vaccine

by: Mike Havrilla

October 28, 2009 | about: [AGEN](#) / [CLDX](#) / [EXEL](#) / [IMUC.OB](#) / [PFE](#) / [RHHBY.PK](#)

As a follow up to my [article on FDA Calendar stocks for October](#), ImmunoCellular Therapeutics (OTC: [IMUC.OB](#)) presented additional data at the Congress of Neurological Surgeons Annual Meeting in New Orleans which demonstrated that the Company's cancer stem cell therapeutic vaccine product candidate ICT-107 extends progression-free survival (PFS) by more than one year among patients with glioblastoma multiforme (GBM is the most common and aggressive form of brain cancer).

The new data presented is an update to preliminary data that was presented at ASCO 2009 in late May. It included a median PFS survival time (defined as the time between surgical tumor removal and tumor recurrence) in the 16 newly diagnosed patients enrolled in the trial of 19 months, which is over 12 months longer than the historical PFS of just 6.9 months. In addition, seven of the 16 patients continue to show no signs of tumor recurrence while three of the patients have gone more than two years without disease progression.

Since 80% of the newly diagnosed patients (13 of the 16) in the Phase 1 trial are still alive after a median time of 20 months; it is too early to determine the median overall survival (OS) for the study. As a historical comparison, typically just 26.5% patients survive two years while receiving the standard of care, which includes surgery, radiation, and Temodar (temozolomide). No safety concerns emerged in this Phase 1 clinical trial, as ICT-107 was well tolerated in the study with no significant adverse events reported.

ICT-107 is dendritic cell (DC) cancer immunotherapy and the Phase I clinical trial was initiated in May 2007 with a goal of determining the safety and immune response of patients with GBM. ICT-107 targets six glioma-specific peptides, including targets that are highly expressed on cancer stem cells. In the study, 19 patients (16 newly diagnosed and 3 recurrent) were treated and the patients received three vaccinations at two weeks apart.

Click [here for my article](#) on recent brain cancer study data reported by Antigenics (NASDAQ: [AGEN](#)) and Exelixis (NASDAQ: [EXEL](#)), which includes patients with recurrent brain cancer rather than newly diagnosed, but still provides a useful comparison for the impressive data reported by IMUC for ICT-107.

IMUC's CEO, Dr. Manish Singh, confirmed to me on the conference call today that the Company expects to close a licensing deal for ICT-107 in 2010 (indicating that such deals typically require at least 6-12 months to complete) to fund future clinical development efforts as IMUC retains its off-the-shelf, therapeutic cancer stem cell vaccine product candidate ICT-121 for in-house clinical development. In addition, IMUC is developing other cancer therapeutic / diagnostic monoclonal antibodies (mAbs) such as ICT-69, which IMUC previously entered a research and license option agreement with Roche ([RHHBY.PK](#)) for up to \$32 million in milestone and development payments for evaluation in the diagnosis and treatment of multiple myeloma and ovarian cancer.

The Phase 1 study for ICT-121 will involve 20 GMB patients receiving five treatments each with final data from the trial anticipated after about 18 months (e.g. 3Q11), since the median time to recurrence in GBM patients is only 6.9 months. ICT-121 may also be beneficial to patients with pancreatic, lung, colon, renal, melanoma, and breast cancers. Early next year (1Q10 which ends 3/31/10), IMUC expects to make an IND filing with the FDA for permission to begin human clinical trials for a Phase 1 study of its off-the-shelf cancer stem cell vaccine candidate (ICT-121). IND Filings for ICT-121 are expected for Brain Tumors in U.S. or Europe during 1Q10 while IND Filings

for ICT-121 for Pancreatic Cancer are expected in the U.S. or Europe during 3Q10.

Celldex Therapeutics (NASDAQ: [CLDX](#)) provides a useful model to estimate the value of a possible deal for ICT-107 given the impressive survival and safety data announced by IMUC for an unmet medical need for an effective brain cancer treatment. [[Click here](#) for my recent overview article on the Company including comparison information on its brain cancer vaccine study data and licensing deal terms]. Celldex received \$40 million in upfront cash and a \$10 million equity investment from Pfizer ([PFE](#)) for its therapeutic cancer vaccine CDX-110, which is also being evaluated for the treatment of GBM. In addition, Pfizer agreed to fund all development costs while Celldex is eligible to receive milestone payments exceeding \$390 million and ongoing sales royalties upon successful commercialization.

The \$50 million in total upfront cash / equity investment that Celldex received in its Pfizer deal for CDX-110 represents approximately 3X the current market cap of IMUC. It should be noted that larger, randomized clinical trials will be required to validate the promising, early-stage results for both of these promising therapeutic cancer vaccines. However, the impressive survival data and excellent safety profile reported for ICT-107 makes a transformational licensing deal (due to the expected size of the deal relative to the market cap) likely for IMUC in 2010 to advance the cancer immunotherapy through larger, late-stage trials with the benefit of the resources of a larger, more established bio-pharmaceutical company.

Some key takeaways and conclusions for ICT-107 from the presentation are outlined below.

- 1.) The Phase I study for ICT-107 demonstrated the feasibility, safety, and bioactivity of a tumor associated antigen ([TAA](#))-pulsed dendritic cell (DC) therapeutic cancer vaccine for patients with GBM
- 2.) IMUC demonstrated the ability of an active immunotherapy strategy to generate specific TAA-targeted cytotoxicity in brain tumor patients and ICT-107 offers a unique mode of action as it targets six peptides (a multi-epitope cancer vaccine) specific to brain cancer, including targets that are highly expressed on cancer stem cells (which lends itself to use in combination with Temodar and other chemotherapy drugs to target residual disease)
- 3.) IMUC believes that pulsing autologous (patient-derived), peripheral blood DC's with tumor peptides and re-injecting them into the patient should help to prime the cellular immune response to brain cancer cells and potentially generate a long-lived cytotoxic response
- 4.) The median PFS time in the 16 newly diagnosed patients enrolled in the trial was 19 months (this is 12 months longer than the historical PFS time of 6.9 months), and with 80% of newly diagnosed patients (13 of the 16) still alive at a median time of 20 months, it is still too early to determine the median OS time for this trial.

Click [here](#) to visit the IMUC News Room landing page, which includes a compilation of digital media coverage links and downloads for the Company, including a PDF for the presentation of the latest ICT-107 clinical data, which is also available at the report downloads section of BioMedReports.com under corporate presentations.

IMUC is also a component in the actively managed [HavRx ImmunoTherapy / Vaccines Index](#), which includes companies with market caps below \$5 billion at the time of index inclusion which are developing or commercializing any type of immunotherapy, gene therapy, or vaccine product that is designed to stimulate the immune system for the eradication, combination treatment, or prevention of cancer. In addition, the index will track companies which are developing or commercializing any type of vaccine product or vaccine adjuvant for all types of infectious disease such as influenza (flu) and bio-defense applications.

**Disclosure:** Long CLDX, IMUC.OB



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Mike Havrilla is a stock index developer, pharmacist, and writer with experience that includes online investing since August 1997 and writing for investors since April 2007 with a focus on the healthcare sector and medical innovation. Mike holds Doctor of Pharmacy (2003) and Bachelor of Science... [More](#)

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