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ImmunoCellular Therapeutics Poised for Growth on Presentation of Phase I Data

By: Grant Zeng June 1, 2011

ImmunoCellular Therapeutics, Ltd (IMUC.OB) will be presenting new data from the Phase I clinical trial of ICT-107, which is the company's lead cancer vaccine candidate for the treatment of glioblastoma multiforme (GBM). ICT-107 is the only cancer vaccine in clinical trials targeting cancer stem cells (CSCs).

Previously reported data

Previously, IMUC reported outstanding Phase I efficacy data and safety profile of ICT-107 for GBM.

In total of 16 newly diagnosed GBM patients, two year overall survival (OS) rates were 81% in the drug group compared with the historic median two-year survival rate of 26.5% with standard of care (SOC) alone. Median OS exceeded 30 months in the ICT-107 group compared with 14.6 months in the historical SOC group. The study's median progression-free (PFS) survival of 17.0 months also compared favorably to the historic median PFS of 6.9 months. No serious adverse events have been reported and minor side effects have been limited to fatigue, skin rash and pruritis.

Long-term data from the Phase I clinical trial showed 43.8% patients who received ICT-107 were disease-free at two years, with three of these patients (18.8%) remaining disease-free for more than three years. One of these patients remains disease-free after almost four years. No treatment-related serious adverse events have been observed to date.

New data will be presented on June 4 at ASCO

On June 4 at this year's ASCO, which will be held in Chicago from June 3 to June 7, IMUC will be reporting new data from the above Phase I study of ICT-107 in newly diagnosed GBM. The new data showed that there **isa correlation between** the immunological response that ICT-107 generated in the form of antigens and both progression-free and overall survival. These observations suggest that targeting antigens highly expressed by CSCs is a promising strategy for treating patients with glioblastoma.

ICT-107 targets six different antigens mainly targeting glioblastoma cancer stem cells. These antigens are HER-2, TRP-2, gp100, MAGE1, IL-13R α 2, and AIM-2. New data showed that all patients exhibited at least three of these antigens, and 75% exhibited all six. Correlations were observed between increased PFS and quantitative expression of MAGE1 (p=0.03), gp100 (p=0.05), AIM2 (p=0.003), and HER2 (p=0.04), the latter two of which are highly expressed by GBM CSCs.

Patients who demonstrated immunological response to vaccination with ICT-107 had longer PFS compared to non-responders. Responders also exhibited a trend toward longer OS. Patients who had recurrences after vaccination exhibited decreased levels of CD133, a biomarker of CSCs. In contrast, previous studies demonstrated an increase in CD133 expression in patients who underwent treatment with radiation and chemotherapy.

At a median analysis time of 32 months, 11 out of 16 patients in the trial were still alive (69%) and 6 out of 16 (38%) continued to be disease-free.

Our takeaways from the presentation

There are three key messages we can get from the new data:

- All patients are being targeted by ICT-107 in terms of antigens IMUC is targeting.
- There is a correlation between cancer stem cell antigen levels and survival of these patients after treatment with ICT-107 indicating these tumors may be more susceptible to T-cell killing which ICT-107 induces.
- There is a decrease in CSC population in all the patients in which CSC could be measured after disease recurrence.

The above data from ICT-107 are very impressive and are the most compelling so far for the treatment of glioblastoma. This clearly validates the mechanism of action for ICT-107 which induces a T cell response against CSC and daughter cells which results in reduction in disease progression. Six out of 16 patients continue to be disease free which is quite spectacular in this disease.

The next step

The Company initiated a **Phase II** trial of ICT-107 for the treatment of newly diagnosed GBM following resection and chemoradiation in 2011. The Phase II trial is a double-blinded, placebo-controlled, 2:1 randomized study of ICT-107 in approximately 102 patients with newly diagnosed GBM. The study will be conducted in approximately 15 clinical trial centers in the U.S. and Canada.

First patient was enrolled on January 31, 2011. The Company anticipates completing the enrollment approximately in 12 months. Interim analysis will be performed after 17 months (based on 50% events).

Patients will receive at least four intradermal injections of the ICT-107 vaccine and additional doses of vaccine during a maintenance phase until disease progression. The primary objective is to compare OS and PFS in patients when treated with ICT-107 versus control.

Based on the positive Phase I clinical trial results, we have a high confidence that the Phase II trial will be successful. Unlike the Phase I which showed a 24 month increase in OS, a six month increase in OS would be considered successful and clinically relevant for this disease as the current standard of care increases OS by 2.5 months. Upon the successful conclusion of the Phase II study, IMUC anticipates a

lucrative **partnering contract** with a major pharmaceutical or biotech company. The partnership may include a large sum of upfront payment, milestone fees and high royalties.

Great Market Opportunities for ICT-107

GBM, also called glioblastoma, is the most common and most aggressive type of primary brain tumor and accounts for approximately 50% to 60% of all primary brain tumors. It is estimated that 22,020 men and women were diagnosed with and 13,140 men and women died of cancer of the brain and other nervous system in 2010 in the US. Worldwide, approximately 176,000 new cases of brain and other CNS tumors were diagnosed in the year 2000, with an estimated mortality of 128,000.

Glioblastomas are among the most aggressively malignant human neoplasms. The median survival time from the time of diagnosis without any treatment is usually less than 1 year. Despite multimodality treatment consisting of open craniotomy with surgical resection of as much of the tumor as possible, followed by concurrent or sequential gamma knife radiotherapy, chemoradiotherapy, targeted therapy, and symptomatic care with corticosteroids, median survival is about 14 months. The overall 5-year survival is less than 10% with the standard of care today. Increasing age (> 60 years of age) carries a worse prognostic risk. Death is usually due to cerebral edema or increased intracranial pressure.

Clearly, there is an unmet medical need for the treatment of glioblastoma. Relapse of glioblastoma is attributed to the recurrence and persistence of cancer stem cells. Therefore, targeting CSCs may be an ultimate solution to treat glioblastoma more efficaciously with fewer side effects. IMUC's ICT-107 is specifically designed to target cancer stem cells of glioblastoma. So far, the data from ICT-107 are the most compelling for the treatment of glioblastoma compared to marketed products and products under development. This is encouraging although ICT-107 is at its early stages of development. The Company began to enroll patients at the end of January 2011 in a **Phase II** trial of ICT-107 for the treatment of GBM.

The glioblastoma market is a multibillion dollar business. Worldwide sales of Temodar reached \$1 billion in 2009 and about \$800 million in the first nine months of 2010. If ICT-107 ultimately reaches the market, it will command a huge market share of the GBM market due to its outstanding efficacy data and safety profile in our view. This means a lot to a small biotech company like IMUC even with a few hundred million dollars in sales. With the Phase II trial enrolling patients soon, IMUC is one step closer to achieve its long term goal.

The market potential is even greater if we consider that ICT-107 can also target other cancer indications, such as melanoma, breast cancer and ovarian cancer. If IMUC only develops ICT-107 for ovarian and GBM to be conservative, the potential market size for those two indications is huge.

We have an Outperform rating on IMUC with a twelve month price target of \$7 dollars.

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