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ImmunoCellular Therapeutics' Cancer Stem Cell Drug Garnering Much Attention

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The fight against cancer is an ongoing and ever-changing battle against a foe that is merciless and persistent. In the past, the treatment arsenal included surgery (resection), radiation, and chemotherapy. More recently, targeted therapies, such as Avastin (Roche Holdings), ([RHHBY.PK](#)) have emerged. Despite varying degrees of success with these treatments, disease still recurs without warning, even years after the cancer was thought to have been eradicated. A victory over cancer is not the proclamation that the cancer is cured but that it is in remission, testifying to the recurring nature of cancers.

The discovery of cancer stem cells (CSCs) is shedding more light on the ways cancers can recur. CSCs behave like normal stem cells, possessing the ability to self-replicate, as well as produce progenitor cells. However, CSCs are much more resistant to chemotherapy and radiation than daughter cancer cells and can often evade the killing effects traditional cancer therapies. Thus, CSCs are likely responsible for the recurrence of disease that commonly plagues patients.

Since the discovery of CSCs about 10 years ago, a number of biotech companies have been developing novel ways to target them. In 2008, GlaxoSmithKline ([GSK](#)) validated this burgeoning field by doing a \$1.5 Billion dollar deal with Oncomed, an early stage private biotech company. This validation was further sealed by Roche's acquisition of Arius Research for \$200 million to access their antibody with ability to target CSCs in breast cancer. Since then all the major pharmaceutical companies have started their own internal programs in a race to cure cancer by targeting these cells. Last week another CSC company, Verastem, filed for IPO even though its lead product is only in preclinical stages at this point. UBS Investment Bank and Leerink Swann LLC are the joint book-running managers for this demonstrating deep support for this novel space.

Among public companies there are very few companies which have been able to develop clinical stage products in this area. Immunocellular Therapeutics ([IMUC.OB](#)), a company involved in harnessing immune system to target CSCs, is gaining a lot of attention since its ASCO presentation last summer. Results from a Phase I study with ICT-107 in GBM patients were unprecedented. Median survival was extended almost two years (38.4 vs. 14.8 months) in patients treated with ICT-107 compared to patients on the current standard of care (historical comparison). The three-year survival rate was 55% for ICT-107 patients vs. 16% for historical controls. Six of the 16 patients in the Phase I trial remain free of disease recurrence over three years; one patient is approaching five years

of progression free survival. Even with incredible clinical efficacy, side-effects were minimal.

In January of 2011, IMUC [initiated a Phase II trial](#) of its dendritic cell-based cancer vaccine (ICT-107) for patients with newly diagnosed glioblastoma multiforme, a common and aggressive form of brain cancer. The double-blind, placebo-controlled, 2:1 randomized trial will enroll about 150 patients at more than 20 sites throughout the U.S. Patients will receive at least four vaccinations of ICT-107 on top of the current standard of care (surgery followed by radiation and chemotherapy with temozolomide). According to a [trial update](#) in September, enrollment should be completed by Q2 2012, and interim data analysis should be released during by Q4,2012.

In addition to ICT-107, IMUC has a number of other drugs in the pipeline. CSCs have been identified in several cancers, including brain, breast, colon, ovary, pancreas, prostate, melanoma, and multiple myeloma. IMUC is currently developing a dendritic cell vaccine that targets CSCs on ovarian cancers (ICT-140); management plans to initiate a Phase I study by Q2 2012. IMUC is also developing an “off-the-shelf” cancer vaccine for recurrent GBM (ICT-121). A Phase I study for ICT-121 should start sometime next year as well.

In early August, IMUC stock fell from approximately \$2.00 to \$1.50, dragged down by another cancer vaccine company, Dendreon ([DNDN](#)). DNDN shares plummeted from roughly \$35 down to \$12, due to poor sales and a reduced outlook for its prostate cancer drug Provenge. This “Dendreon Effect” pulled down the share price of several companies developing cancer vaccines. At first glance, the two cancer vaccine companies may appear to be similar, but a deeper analysis shows that IMUC’s technology overcomes many of the Provenge’s shortcomings. Provenge only targets one cancer protein, while ICT-107 goes after six cancer targets on both normal cancer cells, as well as CSCs. Patients treated with ICT-107 undergo only one apheresis (blood draw) procedure, which can produce as many as 20 vaccinations if not more. In contrast, Provenge patients have to submit to three apheresis procedures, which only generate three doses for vaccination. Also, ICT-107 can be stored, while Provenge has to be administered within 18-24 hours, creating logistical issues as well as additional costs. Given the optimized manufacturing process for ICT-107, the costs are competitive compared to other biologics, such as antibodies. In addition, ICT-107 is administered more quickly and conveniently via subcutaneous injection vs. IV infusion for Provenge, which benefits both patient and physician.

Investors will be keying in on the company as the Phase II trial enrollment completion nears and will be watching closely for interim data analysis, especially considering the current oversold condition of IMUC’s common stock. Additional updates on the continued data acquisition from the Phase I patients should also be forthcoming and an indicator of what lies ahead for the Phase II trial. If the Phase II data is even half as good as the Phase I data, it is almost certain the company will be acquired for significant multiples to today’s market capitalization or would receive licensing agreements affecting the stock price similarly.

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