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ImmunoCellular Therapeutics: At the forefront of targeting cancer stem cells

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ImmunoCellular Therapeutics (IMUC.OB), Targeting Cancer Stem Cells: The Root Cause of Cancer

Cancer treatment with therapeutics has made great progress in the past decade. Chemotherapy has long been the only option for oncologists to fight cancers. But the toxicities associated with chemotherapeutics have limited their use. While killing cancer cells, chemotherapeutic agents also kill healthy cells within the body making them highly toxic to humans. The situation changed when targeted therapy entered into the market a decade ago. Targeted therapeutic agents selectively kill cancer cells while leaving healthy cells unattacked. The combination of chemotherapy and targeted therapy has become the standard regime of cancer treatment currently.

However, the advent of targeted therapy has not solved the long existing, notorious problem of cancer treatment: relapse, or recurrence. The regenerative power of cancer has come to occupy the very center of cancer study. Scientists and clinicians have come to recognize that, for some cancers, this regenerative power appears to be driven by a specific cell type called **cancer stem cells (CSCs)** which is lurking within the cancer, capable of dormancy, growth and infinite regeneration. Since the groundbreaking work on cancer stem cells in1994 by John Dick from the University of Toronto, scientists and clinician have gained tremendous understanding of cancer stem cells.

Like regular stem cells in a body, cancer stem cells also possess incredible regenerative ability. But unlike a normal stem cell, a cancer stem cell could not stop regenerating, dividing and producing more cells. A cancer stem cell is also an inexhaustible reservoir of growth like a regular stem cell, but it can not stop growth. The finding of cancer stem cells may lead to a shift in cancer treatment strategy.

Key Technology Targets Cancer Stem Cells

The discovery of cancer stem cells (CSCs) in the late 1990s began a revolution in the cancer treatment paradigm. This revolution prompted groundbreaking research that gave rise to a new generation of cancer therapeutics designed to target what is widely believed to be the root cause of cancer.

Dubbed as the "evil cousin" of regular stem cells, CSCs are believed to generate tumors much in the same way that their relatives generate healthy tissue. Though CSCs appear to constitute a small portion of the overall tumor mass, their resistance to radiation and chemotherapy and ability to migrate from the original tumor site increase the chance of tumor recurrence. New treatments that effectively target and destroy these CSCs are therefore critical to ensuring long-term cancer-free survival.

ImmunoCellular's key technology is **active immunotherapy** aimed at targeting cancer stem cells. The Company is focused on developing products that harness the native immune system to attack CSCs without harming healthy tissue.

Strong pipeline Ensures Sustainable Growth

ImmunoCellular's lead product candidate is **ICT-107**. ICT-107 is an autologous, or personalized, dendritic cell-based vaccine that works by activating a patient's immune system against specific tumor-associated antigens. This is accomplished by extracting dendritic cells from a patient, loading them with the antigens, and reintroducing them to the patient's body to trigger an immune response.

The Company has finished a **Phase I** trial of ICT-107 for the treatment of glioblastoma multiforme (GBM), the most common and most aggressive type of primary brain tumor. Though at its early stage development, ICT-107 has already demonstrated outstanding efficacy data and safety profile.

In total of 16 patients, two year survival rates were 80% in the drug group compared with the historic median two-year survival rate of 26.5% with standard of care alone. The study's median progression-free (PFS) survival of 17.7 months compared especially favorably to the historic median PFS of 6.9 months. Eleven of the 16 patients continue to survive. 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 37.6% patients who received ICT-107 were disease-free after more than 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.

ImmunoCellular has contracted with Averion, a contract research organization (CRO), to conduct its planned **Phase II** trial of ICT-107 for the treatment of GBM. The planned Phase II trail will be a double-blinded, placebo-controlled, 2:1 randomized study of ICT-107 in approximately 100 patients with newly diagnosed GBM. The study will be conducted in approximately 15 clinical trial centers in the U.S. and Canada in collaboration with leading experts and opinion leaders in neuro-oncology. Enrollment of patients is expected to begin in late 2010 and is anticipated by the Company to be completed approximately 12 months after initiation.

In addition to ICT-107, ImmunoCellular Therapeutics has another active immunotherapeutic candidate ICT-121 which is an off-the-shelf, peptide-based vaccine that works by stimulating an immune response to CD-133, a protein that is over-expressed by many CSCs, but not by healthy cells. The Company plans to bring ICT-121 into clinic in the near future.

ImmunoCellular has also a series of **monoclonal antibodies** in pre-clinical studies. These antibodies are designed to target different cancer types.

The Bottom Line……

We think ImmunoCellular Therapeutics is at the forefront of fight against cancer in a totally different way than ever before. By targeting cancer stem cells, ICT-107 and its peers, may be the ultimate solution for cancer metastasis and recurrence. The Company has all the makings of a successful biotech company in our view.

The approval of Provenge, the first active immunotherapeutic agent by Dendreon, has cleared uncertainty of clinical and regulatory paths for the whole class of such drugs. With an appropriate growth strategy in place, ImmunoCellular is well positioned to deliver shareholder value.