



ImmunoCellular Therapeutics

Nov 17th 2011

ImmunoCellular: at the "forefront" of targeting cancer stem cells, says Zacks

Biotech company ImmunoCellular Therapeutics (OTC:IMUC) received earlier this week a re-iterated "outperform" rating and a 12 month price target of \$7.00 from Zacks' small cap research unit, way up from the current trading price of \$1.42.

According to Zacks analyst, Grant Zeng, CFA, the clinical stage company is at the forefront of targeting cancer stem cells, the root cause of cancer and cancer recurrence. Its main drug candidate is cancer vaccine ICT-107, which has so far been tested for its use in fighting against an aggressive type of brain tumour, glioblastoma multiforme (GMB), showing promising results in a phase one trial.

ICT-107 is a personalized, dendritic cell-based vaccine that works by activating a patient's immune system against specific tumor-associated antigens. This is done by extracting dendritic cells from a patient, loading them with the tumour-related antigens, and re-injecting them back into the patient's body to trigger an immune response against cancer cells exhibiting these antigens.

Rather than simply targeting a single tumor-specific antigen, ImmunoCellular's vaccine pursues multiple different antigens found on cancer stem cells (CSCs). Cancer stem cells are thought to be the originators of common tumor cells, and lead to cancer's re-growth after chemotherapy. It is believed that destroying the CSCs will allow for longer survival, without relapse.

ICT-107 is designed to target the antigens HER-2, TRP-2, gp100, MAGE1, IL-13R2, and AIM-2. Though the initial indication is GBM, melanoma, breast, and ovarian cancer stem cells also express many of these antigens, increasing the potential of ICT-107 considerably, said Zacks.

The phase two trial is expected to enroll between 150 to 160 newly diagnosed patients to treat a total of 102 patients, with 36 subjects enrolled already as of September. An interim analysis from the double-blind, placebo-controlled study, which will measure the safety and efficacy of the vaccine, is anticipated by the end of 2012.

To date, the company has initiated the trial in 12 centres, with plans to increase the overall number of sites to 20 or more, and has already received Institutional Review Board (IRB) approval from a total of 18 trial sites.

The phase one clinical trial saw 16 patients with newly diagnosed GMB receive three injections of ICT-107, in addition to standard treatment, which includes surgery, radiation and chemotherapy. ImmunoCellular reported a two-year overall survival rate of 80.2% from phase one trial results, compared to 26.5% with standard care alone.

At three years, 55% of patients achieved overall survival, compared to 16% with standard care alone. After three years, 38% of patients continue to show no tumour recurrence, compared to 6% without the aid of ICT-107. After four years, 19% of patients remain disease-free. Zeng said that ICT-107 holds a "high promise" for glioblastoma.

"These observations suggest that targeting antigens highly expressed by cancer stem cells (CSCs) is a promising strategy for treating patients with glioblastoma."

"Based on the positive Phase I clinical trial results, the probability of positive Phase II results is high. Unlike the Phase I

1 Year Share Price Graph



Share Information

Code: IMUC
Listing: OTCBB
Sector: Pharmaceuticals
Website: www.imuc.com

Company Synopsis:

ImmunoCellular Therapeutics, Ltd. is a development-stage company. The Company is seeking to develop and commercialize new therapeutics to fight cancer using the immune system. The product candidate portfolio includes cellular immunotherapies targeting cancer and cancer stem cell antigens, peptide based immunotherapies targeting cancer stem cells, and monoclonal antibodies to diagnose and treat different cancers.

Author:

Deborah Sterescu +44(0)1202770386
 action@proactiveinvestors.com



which showed a 24 month increase in OS [overall survival], 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."

On Tuesday, ImmunoCellular reported financial results for the third quarter, swinging to a profit of \$87,912 for the three months ending September 30, benefiting from a reduction in warrant liabilities as expenses were higher in the latest period.

As at quarter-end, the company had \$5.3 million in cash, and no long-term debt obligations. Though in the research report, Zeng said that earnings are not important for ImmunoCellular at this point, as investors should instead be focused on the company's pipeline advancement and clinical development, which in this regard, Zacks believe the oncology therapy company is making progress.

Indeed, once the phase two study for ICT-107 is concluded, ImmunoCellular anticipates a "lucrative" partnering contract with a major pharmaceutical or biotech company, which could include a large sum of upfront payment, milestone fees and high royalties, Zacks said.

"ICT-107 works the same way as Dendreon's Provenge does, but has advantages over the first-in-class cancer vaccine approved by the FDA in terms of manufacturing convenience, easy logistics, potential less side effects, cost advantages and much larger addressable markets."

In addition to ICT-107, the company also has ICT-121 in its pipeline, an off-the-shelf peptide cancer vaccine for glioblastoma and other cancer indications that works by stimulating an immune response to CD-133, a protein that is over-expressed by many cancer cells. This vaccine is still in pre-clinical studies.

ImmunoCellular also has a series of monoclonal antibodies under preclinical development for the treatment and diagnosis of various cancer indications, Zeng said, adding further potential. While the company's cancer vaccines are designed to elicit a cellular immune response, these monoclonal antibodies are designed to selectively seek and destroy cancer stem cells.

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Contact us ■ +44 (0)1202 770386 ■ action@proactiveinvestors.com

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