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ImmunoCellular Therapeutics Reports Updated Immune Monitoring Data from ICT-107 Phase 2 Trial in Newly Diagnosed Glioblastoma at the Society for Neuro-Oncology Annual Meeting 2016

Long-Term Survival Data Reported from Phase 1 ICT-107 Trial

LOS ANGELES, Nov. 21, 2016 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT:IMUC) announced the presentation of updated immune monitoring data from the phase 2 trial of ICT-107 in patients with newly diagnosed glioblastoma. Also presented were updated long-term survival data from the phase 1 trial of ICT-107. ICT-107 is a dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells. ICT-107 is currently being tested in a phase 3 registration trial in patients with newly diagnosed glioblastoma. The updated phase 1 and phase 2 data were presented in two oral sessions on Friday, November 18th, at the 21st Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology, held in Scottsdale, AZ.

The ICT-107 phase 2 trial was a randomized, double-blind, placebo-controlled phase 2 study of the safety and efficacy of ICT-107 in patients with newly diagnosed glioblastoma following resection and chemoradiation. ICT-107 is an intradermally administered autologous immunotherapy consisting of the patient's own dendritic cells pulsed with six synthetic tumor-associated antigens: AIM-2, MAGE-1, TRP-2, gp100, HER-2, IL-13Rα2. The placebo control consisted of the patient's unpulsed dendritic cells. The data from the phase 2 trial indicated a survival advantage in the ICT-107 treated group compared to the control group. The data also showed an association between immune response and survival, especially in HLA-A2 positive (HLA-A2+) patients, which is the target patient population for the ongoing phase 3 registration trial.

The updated immune response data from the phase 2 trial showed that treatment with ICT-107 resulted in the development of a measurable anti-tumor T cell response in some patients, which was associated with survival. Patients that developed the anti-tumor T cell response which was measurable by both ELISpot (to detect viable T cells capable of binding to a target antigen) and multimer testing (to detect T cell binding with higher sensitivity than ELISpot) had improved survival. The data demonstrated that immuno-monitoring can provide an early indication of patients responding to immunotherapy. In the current ongoing phase 3 registration trial of ICT-107, ImmunoCellular plans to perform immuno-monitoring to support the trial.

The data were presented at SNO by Steven J. Swanson, PhD, Senior Vice President, Research, ImmunoCellular Therapeutics, in a presentation titled, "Categorizing immune responders with fusion metrics and simulation for association to survival and progression-free survival with immune response in HLA-A2+ patients with GBM from a phase 2 trial of dendritic cell (DC) immunotherapy (ICT-107)."

Dr. Swanson commented: "ICT-107 is designed to deliver therapeutic benefit by stimulating the patient's immune system to attack tumor tissue. A first indicator that the immunotherapeutic is active is the production of tumor-specific T cells by the patient. In our SNO presentation, we described our ability to more clearly interpret the immune-monitoring data from the phase 2 trial. The ability to accurately identify negative and positive responses enabled us to better understand which of the patients in our trial generated T cells capable of attacking the tumor. We determined that patients with a T cell response measureable in both the ELIspot assay and through multimer analysis achieved longer survival as compared with patients who did not show a positive response. These data should enable us to better interpret the results of our ongoing phase 3 trial."

Andrew Gengos, ImmunoCellular Chief Executive Officer, said: "The phase 2 trial immune monitoring results indicate that patients who mount a T cell response appear to have improved survival over those without a detectable response. In designing the phase 3 trial, we have made important changes in the protocol to potentially enhance the immune response in ICT-107 treated patients with the goal of optimizing the potential survival outcomes in the trial."

Data from the phase 1 trial of ICT-107 were presented by Surasak Phuphanich, MD, Department of Neurology, Cedars-Sinai in Los Angeles, in a presentation titled "Ten-year follow up with long term remission in patients with newly diagnosed glioblastoma (GBM) treated with ICT-107 vaccine (phase 1)." The phase 1 open-label, single institution trial, which was completed in 2010, included 16 evaluable patients with newly diagnosed glioblastoma. Results of the study were initially published in 2012 (*Cancer Immunol Immunother)*.

Updated survival data presented by Dr. Phuphanich at the 2016 SNO meeting showed that 19% of patients had long-term remission of greater than 8 years, with the longest remission being 9.6 years. Also, 38% of patients demonstrated long-term survival of greater than 8 years, with the longest survivor greater than 10.2 years. Immune response data showed a correlation between survival and cancer-stem-associated expression, and a trend toward greater CD8 T cell cytokine responses in long-term survivors.

ICT-107 Phase 3 Registration Trial Underway

The ongoing phase 3 registrational trial of ICT-107 is designed as a randomized, double-blind, placebo-controlled study of HLA-A2+ subjects, which is being conducted at about 120 sites in the US, Canada and the EU, with plans to randomize at least 500 patients with newly diagnosed glioblastoma. The primary endpoint in the trial is overall survival. Secondary endpoints include progression-free survival and safety, as well as overall survival in the two pre-specified MGMT subgroups.

For patients, families and physicians seeking additional information about the ICT-107 phase 3 trial, please consult www.clinicaltrials.gov.

About ImmunoCellular Therapeutics, Ltd.

ImmunoCellular Therapeutics, Ltd. is a Los Angeles-based clinical-stage company that is developing immune-based therapies for the treatment of brain and other cancers. The phase 3 registrational trial of lead product candidate, ICT-107, a patient-specific, dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells, has been initiated. ImmunoCellular's pipeline also includes: ICT-121, a patient-specific, dendritic cell-based immunotherapy targeting the CD133 antigen on stem cells in recurrent glioblastoma; ICT-140, a patient-specific, dendritic cell-based immunotherapy targeting antigens on ovarian cancer stem cells; and the Stem-to-T-cell research program which engineers the patient's hematopoietic stem cells to generate antigen-specific cancer-killing T cells. To learn more about ImmunoCellular, please visit www.imuc.com.

Forward-Looking Statements for ImmunoCellular Therapeutics

This press release contains certain forward-looking statements, including statements regarding ImmunoCellular's intentions and current expectations concerning, among other things, timing for enrollment and randomization of patients, the activation of clinical sites, the receipt and announcement of clinical data; the development and commercialization of ICT-107; the development of our preclinical Stem-to-T-cell program and ImmunoCellular's ability to achieve its other clinical, operational and financial goals. Forward-looking statements are not guarantees of future performance and are subject to a number of risks and uncertainties, including the availability of resources to continue to develop ImmunoCellular's product candidates, the uncertain timing of completion and success of clinical trials, and the risk that ICT-107 can be further successfully developed or commercialized. Additional risks and uncertainties are described under the heading "Risk Factors" in ImmunoCellular's most recently filed quarterly report on Form 10-Q and annual report on Form 10-K. Except as required by law, ImmunoCellular undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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