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ImmunoCellular Therapeutics Treats First Patient in ICT-107 Phase 3 Registrational Trial in Newly Diagnosed Glioblastoma

LOS ANGELES, June 7, 2016 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT: IMUC) today announced that the first patient has been treated in the phase 3 registrational trial of ICT-107, the Company's lead cancer immunotherapy product candidate, in newly diagnosed glioblastoma. ICT-107 is a patient-specific, dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells. The phase 3 trial is designed as a randomized, double-blind, placebo-controlled study of 414 HLA-A2-positive subjects, which will be conducted at approximately 120 sites in the US, Canada and the EU. The primary endpoint in the trial is overall survival, which the FDA and EU regulators have identified as an appropriate endpoint for registrational clinical studies in glioblastoma. Secondary endpoints include progression-free survival and safety, as well as overall survival in the two pre-specified MGMT subgroups.

"Treating our first US patient in the phase 3 registrational trial for ICT-107 is a major milestone achievement for our Company, for patients with brain cancer and their families and for our shareholders," said Andrew Gengos, ImmunoCellular President and Chief Executive Officer. "ImmunoCellular is now one of the very few companies in the cancer immunotherapy arena that we believe to be in the final stage of clinical development. What we think differentiates our phase 3 program from any other in newly diagnosed glioblastoma is that it is based on data and insights from a placebo-controlled phase 2 trial, and it uses the overall survival primary endpoint which is the only efficacy endpoint US and EU regulatory authorities will currently accept for registration. We think we have designed into the phase 3 trial a set of protocol improvements that give ICT-107 the best probability of success. We want to express our sincere appreciation to the medical oncology community worldwide for their ongoing support of our phase 3 trial and look forward to treating our first patients in Canada and Europe in the third quarter of 2016."

The principal investigator on the trial is Prof. Dr. Michael Weller, Chairman, Department of Neurology, University Hospital Zurich, Switzerland. Dr. Weller serves as the Chairman of the German Glioma Network of the German Cancer Council, and serves as President of the European Association for Neuro-Oncology (EANO). He is also the Chairman of the Brain Tumor Group of the European Organisation for Research and Treatment of Cancer (EORTC). A world expert in glioblastoma treatment and research, Dr. Weller has provided extensive support to ImmunoCellular relative to interpretation of the phase 2 results and design of the phase 3 trial protocol, and served as the Company's clinical expert in our end of phase 2 presentation to the European Medicines Agency (EMA).

Dr. Weller commented: "Glioblastoma has remained to be one of the most difficult to treat type of cancer for decades. Conventional treatments such as radiotherapy and chemotherapy seem to have reached their limits. In contrast, there is now emerging evidence that harnessing the patient`s immune system to actively combat this deadly tumor may change this. Moreover, modern medicine increasingly tries to move away from "one-size-fits-all" approaches to more individualized approaches. ICT-107 meets these requirements in an ideal way, being an innovative design of immunotherapy taking into consideration biological characteristics of both the patients and their tumors. The phase 3 trial is well designed and will benefit from important insights from the encouraging results of the placebo controlled phase 2 trial."

ImmunoCellular has reached agreement with the US FDA on a Special Protocol Assessment (SPA) relative to the primary and secondary endpoints as well as the statistical plan for the phase 3 trial. ImmunoCellular has also been honored with a $19.9 million award from the governing Board of the California Institute for Regenerative Medicine (CIRM), California's stem cell agency, to implement the phase 3 registration trial. To support timely patient enrollment at participating sites across ten countries, ImmunoCellular has established agreements with the European Organisation for Research and Treatment of Cancer (EORTC), the Alliance for Clinical Trials in Oncology (the Alliance) in the US, and the Canadian Brain Tumor Consortium.

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 cancer 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 that are subject to a number of risks and uncertainties, including the risk that ICT-107 can be further successfully developed or commercialized, the timing for completion of the phase 3 studies, whether the results will support registration filing with the FDA or EMA and the whether the Company has sufficient resources to complete the phase 3 trial and if successful, file an NDA. Additional risks and uncertainties are described in IMUC's most recently filed quarterly report on Form 10-Q and annual report on Form 10-K. Except as permitted by law, IMUC 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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