September 17, 2014

ImmunoCellular Therapeutics Receives Positive Regulatory Feedback on ICT-107 Supporting Advancement to Registrational Phase III Testing in Newly Diagnosed Glioblastoma

ICT-107 Phase II Update Selected for Oral Presentation at Society for Neuro-Oncology Meeting in November; ICT-121 and ICT-140 Programs on Track

LOS ANGELES, Sept. 17, 2014 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT: IMUC) provides a corporate update on its plans to advance ICT-107 to a registrational phase III program in patients with newly diagnosed glioblastoma (GBM), and on its portfolio of dendritic cell-based vaccines: ICT-121 for patients with recurrent GBM; and ICT-140 for patients with ovarian cancer.

"We have now received supportive feedback from both the US FDA, and European national regulatory authorities on the phase II results of ICT-107 in GBM. Both governance bodies provided encouraging suggestions for advancing ICT-107 into phase III testing, and we are now accelerating preparations for trial initiation in 2015," said Andrew Gengos, ImmunoCellular Chief Executive Officer. "The new input from the regulatory agencies supplements the feedback we have already received from the medical and scientific community, and increases our confidence in the potential therapeutic value of ICT-107 in this deadly disease."

"As ICT-107 moves into phase III, we continue to monitor surviving patients on the Phase II trial. We look forward to presenting the next set of updated efficacy data at the upcoming Society for Neuro-Oncology (SNO) meeting in Miami, FL. We are pleased to announce that our SNO abstract has been selected for an oral presentation on Friday, November 14, 2014," added Mr. Gengos.

ICT-107: Phase III Registration Program Anticipated to Begin Mid-2015

During the second and third quarters of 2014, ImmunoCellular conducted discussions with regulatory authorities in the US and on the national level in Europe concerning the rationale, design and protocol of a phase III program for ICT-107 in newly diagnosed GBM.

IMUC held discussions with FDA representatives on the potential for future development of ICT-107 in glioblastoma in an End-of-Phase II meeting. FDA was in agreement with the proposed design of an IMUC phase III program which focuses on HLA-A2 patients. HLA-A2 represents about 50% of GBM patients in the US and Europe. Because GBM patients partition into two distinct populations based on their MGMT gene status and corresponding response to chemotherapy, the Company proposed separate phase III trials for each of these two populations. The FDA concurred with this approach and advised that the alternative approach of a single trial with patients stratified based on MGMT status also would be acceptable. The FDA indicated that positive results in either of these phase III trials demonstrating safety and efficacy, combined with data from the phase II trial, would satisfy the requirements for a Biologics License Application (BLA) submission. The FDA reiterated that overall survival is the appropriate endpoint for these registrational trials in glioblastoma. IMUC appreciated that the FDA noted the positive benefit of ICT-107 in HLA-A2 patients and commended the Company on the organized and efficient approach to the phase III program. The Company anticipates additional interactions with the FDA to finalize the phase III design and protocol, with the goal of initiating the program in mid-2015.

ImmunoCellular met with European regulatory groups from Germany, the United Kingdom and the Netherlands at a national level and received encouraging feedback on the ICT-107 program and data generated to date. Each group advised that the Company seek scientific guidance from the EMA on the program, which we subsequently requested in a submission containing similar information to our End-of-Phase II submission to FDA. In the fourth quarter, the Company anticipates receiving formal scientific advice on next clinical and regulatory steps from the Committee on Human Medicines, through the EMA, which will inform a decision on whether to include EU sites in a phase III design. ICT-107 was recently designated as an Advanced Therapy Medicinal Product by the EU Committee for Advanced Therapies, which should provide access in Phase III to valuable

services and incentives offered by the EMA, should the Company conduct the phase III program in the EU.

Oral Presentation of Updated ICT-107 Phase II Data at SNO

At the Society for Neuro-Oncology (SNO) meeting being held in Miami, FL November 13-16, the principal investigator on the ICT-107 phase II study, Patrick Y. Wen, MD, Director of the Center for Neuro-Oncology at The Dana Farber Cancer Institute and Professor of Neurology at Harvard Medical School, will present updated efficacy data from the trial. The platform presentation is scheduled for Friday, November 14th, at 3:45 pm ET.

Dr. Wen's presentation is titled "A randomized, double-blind, placebo-controlled phase 2 trial of dendritic cell (DC) vaccination with ICT-107 following standard treatment in newly diagnosed patients with GBM."

ICT-121 and ICT-140 Programs on Track; Business Development Discussions Progressing

"We are also pleased with our progress in advancing the ICT-121 and ICT-140 programs, and look forward to the prospect of having three active clinical programs underway," said Mr. Gengos. "The required operational systems and manufacturing processes are now in place to support our growing clinical portfolio, including the large ICT-107 registration program, and we are continuing to manage in a highly capital-efficient manner. On the business development front, we continue to engage in discussions concerning partnering for ICT-107. We have been active in exploring new immuno-oncology technologies that could expand and complement our dendritic cell-based platform, as well as combining our vaccines with other targeted cancer immunotherapeutics. We look forward to keeping our stakeholders apprised of our progress in the coming weeks and months."

ImmunoCellular continues to advance its other two dendritic cell vaccine programs: the ICT-121 program using cancer stem cell-antigen-primed dendritic cells in patients with recurrent GBM, and the ICT-140 program which uses a dendritic cell vaccine primed by seven ovarian cancer-associated antigens in patients who are at high risk for ovarian cancer recurrence. Additional clinical sites are being added to the ICT-121 phase I trial, and enrollment should increase shortly. The Company plans to complete enrollment of 20 patients by the second quarter of 2015. Plans are progressing well to initiate the exploratory phase II ICT-140 trial, which is designed to enroll 56 patients and utilize historical controls as the comparator in the trial.

ImmunoCellular plans to report third quarter 2014 financial results and provide a corporate update in November, 2014. The Company will host a conference call and webcast in conjunction with that report.

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. ImmunoCellular has concluded a phase II trial of its lead product candidate, ICT-107, a dendritic cell-based vaccine targeting multiple tumor-associated antigens for glioblastoma. ImmunoCellular's pipeline also includes ICT-121, a dendritic cell vaccine targeting CD133, and ICT-140, a dendritic cell vaccine targeting ovarian cancer antigens and cancer stem 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 interpretation of the meeting with the FDA and EMA, whether or not we may be in a position to start a phase III study in mid-2015, the continued progress and potential for success of ICT-121 and ICT-140 and the timing and continued enrollment of ICT-121. 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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