

November 14, 2014

ImmunoCellular Therapeutics Presents Updated ICT-107 Phase II Data at the Society for Neuro-Oncology Annual Meeting 2014

Continued Positive Trends in Overall Survival and Progression-Free Survival; Phase 3 Registration Program Anticipated to Start 1H15; Company to Host Conference Call on Tuesday, November 18th

LOS ANGELES, Nov. 14, 2014 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT:IMUC) announces the presentation today of updated efficacy data from the phase II trial of dendritic cell-based immunotherapeutic vaccine ICT-107 at the 19th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology, being held in Miami, FL. Patrick Y. Wen, MD, Director of the Center for Neuro-Oncology at Dana Farber Cancer Institute and Professor of Neurology at Harvard Medical School, and principal investigator on the trial, will present the maturing data set in patients with newly diagnosed glioblastoma multiforme (GBM) in an oral presentation.



Consistent with prior data presentations in December 2013 and June 2014, the results demonstrate a statistically significant progression-free survival (PFS) benefit, and a numeric overall survival (OS) benefit in ICT-107 treated patients compared to the control group. The ICT-107 treatment effect continues to be strongest in the pre-defined HLA-A2 subgroup of patients in which the MGMT methylated patients showed the largest treatment effect, with a significant PFS advantage over the control group, and continued potential for the OS advantage to move toward significance as more events occur. There were no differences in adverse events between the ICT-107 treated group and the control group.

"ICT-107 continues to hold promise for patients with newly diagnosed glioblastoma, as no other immunotherapy has shown statistical benefit for a clinical outcome in a controlled trial in this patient population," said Dr. Wen. "I think that the data from the phase II trial strongly support advancing to a registrational program."

"With this second update of the original trial results, we remain confident that there is a meaningful treatment benefit in HLA-A2 patients. In the per-protocol population, OS hazard ratios are in the 0.6-0.7 range for all HLA-A2 patients as a group as well as for each of the MGMT subgroups. If our upcoming phase III program generates statistically significant results in this range, ICT-107 could represent a clinically meaningful advance for GBM patients," said Andrew Gengos, ImmunoCellular's Chief Executive Officer. "The US FDA and three national European regulators have indicated support for phase III testing. We anticipate hearing shortly from the EMA, and then expect to be in position to finalize our phase III design and move into trial execution in 2015."

Updated ICT-107 Phase II OS and PFS Results

- As of October 2014, a total of 88 events (patient deaths) had been recorded from the 124 randomized patients, representing 9 additional events since these data from the phase II trial were last updated in June 2014. There were 25 active and 11 control patients alive for a total of 36 patients available for additional follow-up.
- Median PFS for the HLA-A2 methylated MGMT per-protocol (PP) population was 24.1 months for the ICT-107 treated group and 8.5 months for control, representing a statistically significant 15.6-month PFS benefit for the ICT-107 treated group (age stratified HR = 0.257 [0.095-0.697], p = 0.004).
- Median OS for the HLA-A2 methylated MGMT PP population was 23.9 months for the control group, and the median has not yet been reached for the ICT-107 treated group. At the time of the analysis, 65% of ICT-107 patients and 50% of the control patients were alive (age stratified HR = 0.631 [0.212-1.880], p = 0.404), suggesting the potential for long-term survival with ICT-107 treatment.
- Median PFS for the HLA-A2 unmethylated MGMT PP population was 10.5 months for the ICT-107 treated group and 6.0 months for the control group, representing a 4.5-month median PFS benefit for the ICT-107 treated group (age stratified HR = 0.720 [0.351-1.474], p = 0.364).
- Median OS for the HLA-A2 unmethylated MGMT PP population, was 15.8 months for ICT-107 patients, and 11.8 months for the control group, representing a 4-month median OS benefit for the ICT-107 treated group (age stratified HR =

0.652 [0.320-1.325], $p = 0.233$).

- Median PFS in the intent-to-treat (ITT) population (all phase II patients) was 11.4 months for the ICT-107 treated group and 10.1 months for the control group, representing a statistically significant benefit in the ICT-107 treated group (age stratified HR = 0.640 [0.423-0.968], $p = 0.033$).
- Median OS in the ITT population was 18.3 months for the ICT-107 treated group and 16.7 for the control group, representing a numeric, but not statistically significant, advantage for the treatment group (age stratified HR = 0.854 [0.547-1.334], $p = 0.487$).

The Company is utilizing all available information from the controlled phase II trial to design phase III testing in order to increase its probability of success, including the timing of randomization within the standard-of-care treatment these patients receive, in an attempt to limit the number of patients who are "early progressors" and unlikely to respond to therapy.

About the ICT-107 Phase II Trial

The ICT-107 phase II trial is a randomized, double-blind, placebo-controlled phase II study of the safety and efficacy of ICT-107 in patients with newly diagnosed glioblastoma multiforme following resection and chemoradiation. ICT-107 is an intradermally administered autologous vaccine 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-13R α 2. The placebo control consists of the patient's unpulsed dendritic cells.

A total of 124 patients were randomized at 25 clinical trial sites in the US. One third of the patients or 43 patients were treated with placebo, and the treatment arm included two thirds or 81 patients. All patients in the trial received standard-of-care temozolomide. The regimen is four induction doses of ICT-107 after chemoradiation, and then maintenance doses until the patient progresses. The primary endpoint of the trial is OS, defined as the time from randomization until date of death or the last date the patient is known to be alive. Secondary endpoints include PFS, defined as the time from randomization until the date of documented progressive disease or death, whichever occurs first, or the last date the patient is known to be alive and progression-free if progression or death is not observed. Other secondary endpoints include the rates of OS and PFS at six months after surgery, then assessed every three months until the end of the study. Safety and immune response are additional secondary endpoints.

Both the OS and PFS median results in the ICT-107 phase II trial were measured from the time of randomization (at the start of vaccination after standard-of-care surgery and chemoradiation). In historical studies of newly diagnosed GBM patients (e.g., Stupp, et al.), OS and PFS measurements were likely assessed from the time of surgery. In the ICT-107 phase II trial, there was an average of about 83 days from surgery to randomization.

The subgroups analyzed in the phase II trial were based on age, gender, HLA type, MGMT status, performance status and resection status.

HLA (human leukocyte antigens) are cell-surface antigen-presenting proteins. These molecules are on dendritic cells and present the tumor-associated antigens to T-cells to induce the immune response to the ICT-107 vaccine. HLA-A2 was one of two HLA types that were treated in the phase II trial. Of the two types, HLA-A2 is twice as common in the population as HLA-A1, and is the most common HLA type in North America and the EU.

HLA-A2 patients comprised about 62% of all patients randomized in the trial, meaning that these numeric and statistical outcome benefits were conveyed to a majority of treated patients.

MGMT status has been demonstrated to be predictive of response to radiation or chemotherapy. The O(6)-methylguanine-DNA methyltransferase, or MGMT, gene is responsible for a DNA repair mechanism in cells. Methylation of MGMT impedes the DNA repair mechanism in cancer cells, making them susceptible to radiation or chemotherapy, such as temozolomide. The DNA repair mechanism in cancer cells with unmethylated MGMT is intact, enabling them to survive and proliferate. GBM is the most common and aggressive primary cancer of the brain. Patients with this disease have few therapeutic options; temozolomide is currently the only FDA-approved systemic chemotherapy for newly diagnosed GBM.

For patient-related information about the ICT-107 clinical program in glioblastoma, please visit the ImmunoCellular website at www.imuc.com and access the ICT-107 "Frequently Asked Questions." The email address to contact the company directly is clintrials@imuc.com.

ImmunoCellular to Host Conference Call on Tuesday, November 18th

ImmunoCellular plans to host a conference call and webcast to discuss the ICT-107 updated data presented at SNO and other corporate matters on Tuesday, November 18, 2014, at 5:00 pm EST. The call will be hosted by Andrew Gengos, President and CEO.

LIVE CALL: (877) 853-5636 (toll-free); international dial-in: (631) 291-4544; conference code 35132957

WEBCAST: Interested parties who wish to listen to the webcast should visit the Investor Relations section of ImmunoCellular's website at www.imuc.com, under the Events and Presentations tab. A replay of the webcast will be available one hour after the conclusion of the event.

The conference call will contain forward-looking statements. The information provided on the teleconference is accurate only at the time of the conference call, and ImmunoCellular will take no responsibility for providing updated information except as required by law.

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 is conducting 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 timing and outcome of the post-phase II meeting with the FDA and EU regulatory authorities, the status of the current data and whether further analyses or later studies may confirm the successful PFS results to date, the potential for initiation and design of phase III trials and possibility of successful results from such studies. 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. In this press release, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," "future," "intend," "certain," and similar expressions intended to identify forward-looking statements.

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