

December 11, 2013

## **ImmunoCellular Therapeutics Phase II Study Demonstrates That Glioblastoma Patients Live Longer Without Disease Progression When Treated With ICT-107**

***Study Achieves Progression-free Survival Endpoint with Statistical Significance; Primary Endpoint of Overall Survival Not Statistically Significant***

***Conference Call Today at 5:00 pm ET/2:00 pm PT***

LOS ANGELES--(BUSINESS WIRE)-- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT:IMUC) announced that ICT-107, its dendritic cell-based vaccine, demonstrated a statistically significant increase in progression-free survival (PFS) in patients with newly diagnosed glioblastoma multiforme (GBM) in its randomized, placebo-controlled phase II trial. A comparison of PFS between ICT-107 and placebo showed a statistically significant difference in the Kaplan-Meier (K-M) curves favoring ICT-107 ( $p=0.014$  two-sided, hazard ratio (HR)=0.56) in the intent-to-treat population of all 124 randomized patients. The difference in the median progression-free survival times between ICT-107 and placebo favored ICT-107 and was two months in duration. For the per-protocol population (117 of 124 patients receiving at least four induction vaccinations), the K-M comparison p-value improved in treated patients to 0.0074 two-sided (HR=0.53) and the difference in median progression-free survival times increased to three months in favor of ICT-107.

The differences in the overall survival (OS) K-M curves did not reach statistical significance in the intent-to-treat population (the primary endpoint) or the per-protocol population, with p-values and HRs of  $p=0.58$  two-sided, HR=0.87, and  $p=0.40$  two-sided, HR=0.79, respectively. However, there were numerical differences in the median survivals favoring ICT-107 of two months in the intent-to-treat population and three months in the per-protocol population.

The OS analysis includes data on 67 events (patient deaths) out of a possible 124, whereas the PFS analysis includes data from 103 events. ImmunoCellular Therapeutics plans to continue following patients in this trial to collect more mature OS data. In the matured data from the open label, phase I trial, the Company observed a consistent benefit in both PFS and OS compared with historical controls, and on this basis thinks that it is possible that the primary OS benefit could be clarified as the phase II data mature.

In this phase II study, ICT-107 was generally safe and well tolerated, with no imbalance of adverse events between the active and placebo groups.

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.

Patrick Wen, MD, Director of the Center for Neuro-Oncology at The Dana Farber Cancer Institute and Professor of Neurology at Harvard Medical School, and an investigator on this trial, said, "The progression-free survival data look promising in this study. To my knowledge, this is the first time a placebo-controlled immunotherapy trial in glioblastoma has demonstrated a statistically significant improvement in a clinically relevant measure, such as progression-free survival. We await additional data to evaluate the effect on overall survival."

John Yu, MD, Founder, Chairman and Chief Scientific Officer of ImmunoCellular Therapeutics, said, "We are quite pleased to see such a strongly statistically significant result in PFS in this exploratory trial, and believe that in conjunction with the indications of a survival benefit, these results provide a strong medical rationale for continued development of ICT-107 as a potential treatment for glioblastoma. We look forward to discussing this important clinical outcome, and what next steps, including a phase III trial, might entail, with the FDA in an end-of-phase-II meeting."

Andrew Gengos, ImmunoCellular Therapeutics Chief Executive Officer, said, "Although we missed the primary OS endpoint, it is encouraging that the OS and PFS results are consistent and that most of the predefined secondary endpoints in the OS subgroups numerically favor ICT-107 over placebo, although none has reached statistical significance. These phase II results, in conjunction with the phase I results which have indicated the potential for long-term survival, support our view that ICT-107 has a biological and clinically relevant effect in GBM, and potentially may provide a long-term survival benefit. We plan to analyze the results further in the coming weeks and learn more with the goal of informing our next development and regulatory steps. We want to thank the patients who participated in this trial, and our trial site collaborators and dedicated clinical team for their high quality work."

ImmunoCellular anticipates presenting the results of the ICT-107 phase II trial at an upcoming national scientific or medical

forum.

### 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 newly diagnosed patients with glioblastoma multiforme following resection and chemoradiation. ICT-107 is an intradermally administered autologous vaccine consisting of the patient's dendritic cells pulsed with six synthetic tumor-associated antigens: AIM-2, MAGE-1, TRP-2, gp100, HER-2, IL-13R $\alpha$ 2. The 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 (their own dendritic cells not exposed to antigen), and the treatment arm included two thirds or 81 patients who received the ICT-107 vaccine. All patients in the trial received standard-of-care temozolamide. 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. The phase II trial is powered at 80% to show a nine-month overall survival benefit assessed after reaching 64 events.

Patients who have not yet progressed will continue in the trial until an appropriate termination point can be determined.

For patient related information about the ICT-107 clinical program in glioblastoma (brain cancer), please visit the ImmunoCellular website at [www.imuc.com](http://www.imuc.com) and access the ICT-107 "Frequently Asked Questions." The email address to contact the company directly is [clintrials@imuc.com](mailto:clintrials@imuc.com).

### Conference Call Today

ImmunoCellular is holding a conference call and webcast today at 5:00 pm ET to discuss the ICT-107 phase II results. The call will be hosted by Andrew Gengos, President and CEO.

LIVE CALL: (877) 853-5636 (toll-free)  
Conference code: 23984187

REPLAY: (855) 859-2056 (toll-free)  
(404) 537-3406  
Conference code: 23984187  
(Replay available from Wednesday, December 11, 2013 at 8:00 pm ET until Tuesday, December 17, 2013 at 11:59 pm ET.)

The conference call will contain forward-looking statements. Interested parties who wish to listen to the webcast should visit the Investor Relations, Events & Presentations section of ImmunoCellular's website at [www.imuc.com](http://www.imuc.com). The information provided on the teleconference and webcast 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](http://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 outcome of the post-phase II meeting with the FDA and whether further studies may confirm the successful PFS results to date. 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. 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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