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## **ImmunoCellular Therapeutics Reaches Agreement with FDA on Special Protocol Assessment (SPA) for ICT-107 Phase 3 Registrational Trial in Glioblastoma**

LOS ANGELES, Aug. 13, 2015 /PRNewswire/ -- ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT: IMUC) announced today that it has reached agreement with the US Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the phase 3 registrational trial of its cancer immunotherapy ICT-107 to treat patients with newly diagnosed glioblastoma. The phase 3 trial is designed as a randomized, double-blind, placebo-controlled study of about 400 HLA-A2 positive subjects, which will be conducted at about 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 stated is the 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. Patient enrollment is anticipated to begin in the late third quarter or early fourth quarter of 2015.



A Special Protocol Assessment is a written agreement between the sponsor company and the FDA on the design, clinical endpoints, size and statistical design of a clinical trial intended to form the primary basis of an efficacy claim in the marketing application, such as a biologic licensing application (BLA) or a new drug application (NDA). Final marketing approval depends upon the safety and efficacy results demonstrated in the phase 3 clinical program.

Andrew Gengos, ImmunoCellular's Chief Executive Officer Commented: "We are pleased to have achieved this important milestone, and think that successful completion of the SPA process adds meaningful validation to the ICT-107 phase 3 program and design, especially the use of the gold standard primary endpoint of overall survival. With this SPA in place, we think that ICT-107 is uniquely positioned in the field of immuno-oncology approaches being tested in glioblastoma. We are making significant progress toward establishing our clinical site network and obtaining the necessary institutional review board approvals. We are confident that we are on track to begin patient enrollment in the late third quarter or early fourth quarter of this year."

### 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 2 trial of its lead product candidate, ICT-107, a dendritic cell-based immunotherapy targeting multiple tumor-associated antigens on glioblastoma stem cells. ImmunoCellular's pipeline also includes: ICT-121, a dendritic cell immunotherapy targeting the CD133 antigen on stem cells in recurrent glioblastoma; ICT-140, a dendritic cell 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](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, including whether the SPA endpoints can be achieved, and even if achieved whether the FDA will deem that sufficient to approve ICT-107 and the timing of the initiation of patient enrollment for the phase 3 study in the late third quarter or early fourth quarter of this year. 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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