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Immune Initiates Bertilimumab Phase II Clinical Trial in Ulcerative Colitis Bertilimumab Targets Eotaxin-1, a Chemokine Over-Expressed in Ulcerative Colitis Patients

HERZLIYA-PITUACH, Israel and TARRYTOWN, N.Y. (February 21, 2013) – Immune Pharmaceuticals Ltd. ("Immune"), a privately held Israeli company, and EpiCept Corporation (Nasdaq OMX Stockholm Exchange and OTCQX: EPCT) announced today that Immune is initiating, following authorization from Israeli health authorities, a Phase II double-blind placebo controlled study with its lead drug, bertilimumab, in patients with moderate-to-severe ulcerative colitis. Bertilimumab is a first-in-class fully human monoclonal antibody targeting eotaxin-1, a chemokine small protein regulating eosinophilic inflammation.

The clinical trial is a randomized, double-blind, placebo-controlled parallel group study that will evaluate the safety, clinical efficacy, and pharmacokinetic profile of bertilimumab in subjects with active moderate-to-severe ulcerative colitis. 90 patients are expected to be enrolled into the study, 60 of whom will be treated with bertilimumab 7mg/kg and 30 of whom will be treated with placebo every two weeks, at days 0, 14, and 28. These patients will be evaluated for clinical response after six weeks to determine the decrease if any in the full Mayo Clinic Ulcerative Colitis Score. Secondary and exploratory end points will include clinical remission defined as symptom free, fecal calprotectin, a recognized marker of gastro-intestinal inflammation, histopathology improvement and degree of mucosal injury. Patient follow-up will continue up to day 90. Patients will be enrolled initially from up to 10 hospitals in Israel and later in other countries pending approval of local health authorities. Completion of patient enrollment and clinical results are anticipated in 2014.

Professor Eran Goldin, lead investigator for the clinical trial and Director of the Digestive Disease Institute at Shaare Tsedek Hospital in Jerusalem, Israel, stated, "Eotaxin-1 is a novel target which has been validated through extensive pre-clinical and observational clinical studies. The upcoming Phase II study with bertilimumab has been designed to assess the clinical relevance of neutralizing eotaxin-1 in patients with active moderate-to-severe ulcerative colitis."

Daniel Teper, Pharm. D., CEO of Immune and Stephane Allard, M.D., Chief Medical Officer of EpiCept and designated Chief Medical Officer of the combined company following completion of the proposed merger between EpiCept and Immune, commented, "There is a clear need for

alternative biological therapies for patients with ulcerative colitis. The established correlation between eotaxin-1 levels in tissue and the severity of the disease provides an opportunity to select patients most likely to respond to therapy."

Immune and EpiCept signed a definitive agreement to merge on November 7, 2012 and currently anticipate a closing of the transaction in the second quarter of 2013. Bertilimumab will be the lead clinical stage development drug for the combined company following completion of the proposed merger.

#### **About Bertilimumab**

Bertilimumab (also known as iCo-008 or CAT-213) is a human immunoglobulin monoclonal antibody targeting eotaxin-1, a member of the chemokine family of proteins that act as messenger molecules between the cells of the immune system. Bertilimumab has been the subject of several Phase 1 and 2 studies involving a total of 126 patients in the United Kingdom, has a good safety profile and has shown evidence of biological efficacy in single dose administration. Bertilimumab may be indicated for inflammatory disorders including inflammatory bowel disease (Crohn's Disease and ulcerative colitis), severe asthma, and orphan dermatological conditions such as bullous pemphigoid.

iCo Therapeutics (TSX: ICO) licensed the exclusive world-wide rights to bertilimumab in 2006 from Cambridge Antibody Technology Limited, now part of MedImmune, the global biologics research and development arm of AstraZeneca. iCo has retained the rights to develop the ophthalmic indications of bertilimumab including severe ocular allergies (vernal & atopic keratoconjunctivitis) and wet-age related macular degeneration.

# **About the Immune Epicept Merger**

In November 2012, Immune and EpiCept announce that they had entered into a definitive merger agreement. The transaction is currently anticipated to close during the second quarter of 2013 and is subject to satisfaction of certain customary closing conditions, including the approval of a majority of EpiCept shareholders.

#### **Additional Information**

In connection with the proposed transaction, EpiCept will file a proxy statement with the U.S. Securities and Exchange Commission (SEC) seeking appropriate stockholder approval. STOCKHOLDERS OF EPICEPT AND OTHER INVESTORS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO THE PROXY STATEMENT) REGARDING THE PROPOSED TRANSACTION WHEN IT BECOMES AVAILABLE BECAUSE IT WILL CONTAIN IMPORTANT INFORMATION. EpiCept's stockholders will be able to obtain a copy of the proxy statement, as well as other filings containing information about Immune and EpiCept, without charge, at the SEC's Internet site (<a href="https://www.sec.gov">www.sec.gov</a>). Copies of the proxy statement and the filings with the SEC that will be incorporated by reference in the proxy statement can also be obtained, without charge, by directing a request to EpiCept Corporation, 777 Old Saw Mill River Rd, Tarrytown, NY 10591, Attention: Investor Relations, Telephone: (914) 606-3500.

## **Participants in the Solicitation**

EpiCept and its directors and executive officers and Immune and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of EpiCept in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger transaction will be included in the proxy statement of EpiCept referred to above. Additional information regarding the directors and executive officers of EpiCept is also included in EpiCept's proxy statement for its 2011 Annual Meeting of Stockholders, which was filed with the SEC on April 28, 2011. Additional information regarding the directors and executive officers of EpiCept is also included in EpiCept's registration statement Post-Effective Amendment No. 1 to Form S-3 on Form S-1, which was filed with the SEC on April 6, 2012. These documents are available free of charge at the SEC's web site (<a href="https://www.sec.gov">www.sec.gov</a>) and from Investor Relations at EpiCept at the address described above.

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended (the "Act"). The securities issued in exchange for all of the outstanding shares of Immune will not be and have not been registered under the Act and may not be offered or sold in the United States absent registration or an applicable exception from registration requirements.

The merger agreement and any accompanying issuance of shares by Immune Pharmaceuticals are not, under any circumstances, to be construed as an advertisement or a public offering of securities in Israel. Any public offer or sale of securities in Israel may be made only in accordance with the Israeli Securities Act-1968 (which requires, inter alia, the filing of a prospectus in Israel or an exemption therefrom).

# About Immune Pharmaceuticals Ltd.

Immune Pharmaceuticals Ltd. is an Israel and U.S.-based biopharmaceutical company, focused on the development of next generation antibody therapeutics addressing unmet medical needs in the treatment of inflammatory diseases and cancer. Immune licensed worldwide rights for systemic indications of bertilimumab from iCo Therapeutics (TSX: ICO) in June 2011, while iCo retained rights to all ophthalmic indications. iCo originally licensed the exclusive world-wide rights to bertilimumab in 2006 from Cambridge Antibody Technology Limited, now part of MedImmune, the global biologics research and development arm of AstraZeneca. Additionally, Immune has licensed from Yissum, the technology transfer company of the Hebrew University of Jerusalem, the injectable applications of the antibody nanoparticle conjugate technology (NanomAbs®) developed by Professor Shimon Benita. For more information, visit the Immune website at: www.immunepharmaceuticals.com

### **About EpiCept Corporation**

EpiCept is focused on the development and commercialization of pharmaceutical products for the treatment of pain and cancer. The Company's pain portfolio includes AmiKet<sup>TM</sup>, a prescription topical analgesic cream in late-stage clinical development designed to provide effective long-term relief of pain associated with peripheral neuropathies. The Company's product Ceplene<sup>®</sup>, when

used concomitantly with low-dose IL-2, is intended as remission maintenance therapy in the treatment of AML for adult patients who are in their first complete remission. The Company sold all of its rights to Ceplene<sup>®</sup> in Europe and certain Pacific Rim countries and a portion of its remaining Ceplene<sup>®</sup> inventory to Meda AB in June 2012. Ceplene<sup>®</sup> is licensed to MegaPharm Ltd. to market and sell in Israel and EpiCept has retained rights to Ceplene<sup>®</sup> in all other countries, including countries in North and South America. The Company has other oncology drug candidates in clinical development that were discovered using in-house technology and have been shown to act as vascular disruption agents in a variety of solid tumors.

### **Forward-Looking Statements**

This news release and any oral statements made with respect to the information contained in this news release contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. Such forward-looking statements include statements which express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Factors that may cause actual results or developments to differ materially include: the risk that we may be unable to complete the proposed merger transaction, the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern, the risks associated with EpiCept's ability to continue to meet its obligations under its existing debt agreements, the risk that we will not be able to find a partner to help conduct the Phase III trials for AmiKet<sup>TM</sup> on attractive terms, a timely basis or at all, the risk that our product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later-stage clinical trials, the risk that we will not obtain approval to market any of our product candidates, the risks associated with dependence upon key personnel, the risks associated with reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates; the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process; our history of operating losses since our inception; the highly competitive nature of our business; risks associated with litigation; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in EpiCept's periodic reports, including reports on Forms 8-K, 10-O and 10-K and other filings with the U.S. Securities and Exchange Commission. You are urged to carefully review and consider the disclosures found in EpiCept's filings which are available at www.sec.gov or at www.epicept.com. You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors.