



## **Immune Design Announces Treatment of First Patient in Phase 1 Clinical Trial of LV305 Immuno-Oncology Agent**

### ***In vivo* T cell active immunotherapy generated from DCVex™ platform**

June 5, 2014, Seattle, WA and South San Francisco, CA – Immune Design, a clinical-stage immunotherapy company focused on the development of novel immune-based therapies for cancer and other chronic conditions, today announced treatment of the first patient in a Phase 1 clinical trial of LV305, an immuno-oncology investigational agent from the company's DCVex™ lentiviral vector platform.

The Phase 1 open label, multi-center trial ([NCT02122861](#)) is designed to evaluate the safety, tolerability and immunogenicity of LV305 in patients with locally advanced, relapsed, or metastatic breast cancer, melanoma, non-small cell lung cancer, ovarian cancer or sarcoma. The trial will enroll up to 36 patients at several clinical centers in the United States.

“The advancement of novel immuno-oncology agents such as LV305 that induce a tumor-specific *in vivo* T-cell response holds promise for the development of new and targeted approaches to cancer treatment,” said Seth M. Pollack, M.D., Principal Investigator at the Fred Hutchinson Cancer Research Center.

“LV305, which targets the NY-ESO-1 antigen expressed in a number of tumors, offers a targeted, tumor-specific *in vivo* approach to activating a T-cell immune response that we believe may provide benefit to a wide range of cancer patients,” said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer at Immune Design. “LV305 is an integral part of our prime-boost strategy that is designed to provide a superior approach to fighting cancer. Data from the trial will include immunogenicity and initial indications of efficacy, and is intended to support the combination of LV305 with a second proprietary agent, G305, into our prime-boost strategy known as CMB305. We intend to commence a Phase 1 trial for CMB by the end of 2014.”

“I am excited to see that a novel and perhaps bold idea has matured into a product candidate now being clinically evaluated, and believe that using a novel vector of this type to deliver genetic information specifically to dendritic cells opens a new avenue that holds much promise for treating cancer,” said David Baltimore, Ph.D., President Emeritus, Robert Andrews Millikan Professor of Biology, California Institute of Technology.

#### **About LV305**

LV305, generated from Immune Design's DCVex platform, is designed to activate the immune system through the *in vivo* generation of cytotoxic T cells (CTLs) initially against a specific

tumor-associated antigen, NY-ESO-1. DCVex originated from underlying discoveries made by one of Immune Design's founders and Nobel laureate, David Baltimore, Ph.D. Dr. Baltimore and his colleagues theorized that a lentiviral vector could be engineered to selectively deliver specific genetic information of a tumor antigen directly to dendritic cells to mount an immune response. LV305 is part of Immune Design's "Specific Antigen" approach, which drives the *in vivo* generation of a strong, antigen-specific CTL response against selected antigens present in a tumor. Preclinical tests have demonstrated the ability of LV305 to reduce tumor growth of NY-ESO-1-expressing tumors, increase production of antigen-specific CD8 cells, and significantly improve the survival of tumor-bearing animals. LV305 is the first step in Immune Design's novel prime-boost approach to immuno-oncology, which includes combination with G305, generated from the GLAAS™ platform, to expand CTLs and potentially generate a potent, durable immune response.

## **About Immune Design**

Immune Design is a clinical-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease. The company's technologies are engineered to activate the immune system's natural ability to create tumor-specific cytotoxic T cells to fight cancer and other chronic diseases. Immune Design's clinical programs are the product of its two synergistic discovery platforms: DCVex™ and GLAAS™. Immune Design has offices in Seattle, Washington and South San Francisco, California. For more information, visit [www.immunedesign.com](http://www.immunedesign.com).

## **Cautionary Note on Forward-Looking Statements**

This press release contains forward looking statements. Forward looking statements contained in this press release include, but are not limited to, statements about the timing and results of the Phase 1 trial of LV305, patient enrollment of that trial and the timing of commencement of clinical trials of CMB305. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward looking statements. These forward looking statements are not guarantees of future performance and involve a number of unknown risks, assumptions, uncertainties and factors that are beyond Immune Design's control. All forward looking statements are based on Immune Design's expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward looking statements. Except as required by law, Immune Design expressly disclaims any responsibility to update any forward looking statement contained herein, whether as a result of new information, future events or otherwise.

###

### **Contact:**

Julie Rathbun  
Rathbun Communications  
[julie@rathbuncomm.com](mailto:julie@rathbuncomm.com)  
206.769.9219