May 13, 2015

Immune Design Announces Positive Data from Three Phase 1 Studies at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting

Efficacy, Immunogenicity and Safety Data Across Two I-O Approaches to be Presented

SEATTLE and SOUTH SAN FRANCISCO, Calif., May 13, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ) today announced that positive clinical data from three immuno-oncology Phase 1 studies will be presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, which will take place May 29 to June 2, 2015 in Chicago.

The three trials provide first-in-human clinical data with the company's immuno-oncology cancer agents, LV305, G305, and G100, which are designed to generate anti-tumor immunity. LV305 and G305 are individually active agents that combine to form the product candidate called CMB305, the company's prime-boost approach targeting the tumor-associated antigen, NY-ESO-1. G100, in contrast, is a potent toll-like receptor-4 (TLR4) agonist that is being administered intratumorally to activate local and systemic immunity. Data from these initial Phase 1 trials to be presented at ASCO include:

-- LV305:

- Favorable safety profile with only Grade 1 or 2 adverse events observed in the twelve patients treated in this dose-escalation trial evaluating three different dose levels of LV305.
- CD4 or CD8 specific T-cell responses were observed after therapy in eight of eleven (73%) evaluable patients. Four of the six patients treated with the mid or high dose levels of LV305 developed *de novo* CD8 T-cell responses against NY-ESO-1. As expected, the therapy had no effect on anti-NY-ESO-1 antibody levels.
- Of the twelve patients with various types of soft tissue sarcoma expressing NY-ESO-1 who were enrolled and treated:
  - Four of six patients with evidence of tumor growth prior to LV305 treatment stabilized and stopped progression with the longest at 347+ days; tumor regression up to 13.8% was observed in one patient.
  - Eight of twelve (67%) patients achieved a best response of stable disease (SD) with a median duration of 208 days (range: 139-347+) and the progression-free rate (PFR) of all twelve patients at six months was at least 42%[1].
  - Although a small study and differences in the patient population exist, the observed PFR of at least 42% compares favorably to the historical PFR in the analysis of a large group of patients reported by Van Glabbeke, et al.[2], where active agents for first- and second-line treatment exhibited a PFR of > 30-56% (histology dependent) and > 14% at six months, respectively (importantly, the LV305 study consisted of patients who had all received at least one prior treatment).

-- G305:

- Favorable safety profile with only Grade 1 or 2 adverse events observed in the twelve patients treated in this dose escalation trial evaluating three different dose levels of G305 in patients with sarcoma, melanoma, urothelial or ovarian cancer.
- Nine of twelve (75%) patients had a significant humoral response to NY-ESO-1 post therapy, and five of eleven (45%) evaluable patients also had a significant CD4 T-cell response against NY-ESO-1.
- Eight of twelve (67%) patients achieved a best response of SD; median duration of SD was 245+ days (range 161 to 365+), including in one patient with ovarian cancer with a significant and sustained reduction of the CA125 biomarker.

-- G100:

- Favorable safety profile with only Grade 1 or 2 adverse events was observed in the eight patients (including two with loco-regional and six with metastatic disease) treated with single dose level of intratumoral G100 in this pilot trial of patients with Merkel cell carcinoma (MCC).
- Intratumoral G100 as a single agent resulted in a pathologic CR in 1 patient with loco-regional disease and a 28% reduction of tumor in a patient with metastases.
- The combined therapy of G100 followed by radiation and/or surgery in the eight MCC patients resulted in an objective response rate (ORR) of 50%.

The data from all three Phase 1 studies will be presented at ASCO in the Developmental Therapeutics - Immunotherapy session, which is part of the Developmental Therapeutics and Translational Research track, taking place Saturday, May 30, 2015. The data presented in the poster sessions will substantially exceed the data in the published abstracts.

CMB305

Having established the safety and individual immunologic activity of LV305 and G305, Immune Design initiated a new Phase 1B study of the product candidate CMB305 earlier this year. Based on preclinical models, the sequential combination of LV305 and G305 is expected to be synergistic and more potent as a prime-boost approach than the individual agents alone.

G100

Immune Design plans to complete the enrollment of the ongoing Phase 1 clinical trial of G100 in patients with Merkel cell carcinoma. Based on the encouraging response rate observed thus far, Immune Design also intends to expand this novel approach in a Phase 1/2 trial of G100 in non-Hodgkin's lymphoma.

Immuno-Oncology at Immune Design

All of Immune Design's product candidates are designed to work *in vivo* and activate the immune system via the induction and/or expansion of anti-tumor CD8 T cells, and are intended to be "off-the-shelf" therapies in contrast to certain other T cell approaches that require individualized, complicated *ex vivo* manipulation.

ASCO Presentation Information

Phase I, first-in-human trial of LV305 in patients with advanced or metastatic cancer expressing NY-ESO-1

Abstract #: 3021

Session Type: Poster Discussion Session
Date and Time: Saturday, May 30, 2015 3 p.m. - 4:15 p.m.
Location: S406

Session Type: Poster Session
Date and time: Saturday, May 30, 8 a.m. - 11:30 a.m.
Location: S Hall A
Poster Board: #347

Presenter: Neeta Somaiah, M.D. Department of Sarcoma Medical Oncology, The University of Texas MD Anderson Cancer Center

A first-in-human phase 1 dose-escalating trial of G305 in patients with solid tumors expressing NY-ESO-1

Abstract #: 3073

Session Type: Poster Session
Date and time: Saturday, May 30, 8 a.m. - 11:30 a.m.
Location: S Hall A
Poster Board: #399

Presenter: Amit Mahipal, M.D. Moffitt Cancer Center

Pilot study of intratumoral G100, toll-like receptor-4 (TLR4) agonist, therapy in patients with Merkel cell carcinoma (MCC)

Abstract #: 3083

Session Type: Poster Session
Date and time: Saturday, May 30, 8 a.m. - 11:30 a.m.
Location: S Hall A
Poster Board: #409

Presenter: Shailender Bhatia, MD, University of Washington/Fred Hutchinson Cancer Research Center

Immune Design Post-ASCO Clinical Research Update

Immune Design will host a post-ASCO Clinical Research Update on Wednesday, June 2, 2015 at 5:30 p.m. in New York to review the three Phase 1 data sets presented at ASCO. Participants will include Immune Design senior leadership and principal

investigators from ASCO-selected submissions, Dr. Amit Mahipal and Dr. Neeta Somaiah. The event will be webcast and available online from the investor relations section of the company website at http://ir.immunedesign.com/events.cfm.

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 generate and/or expand antigen-specific cytotoxic T cells, while also enhancing other immune effectors, to fight cancer and other chronic diseases. CMB305 and G100, the two-pronged focus of Immune Design's ongoing immuno-oncology clinical programs, are the product of its two synergistic discovery platforms, ZVex™ and GLAAS™. Immune Design has offices in Seattle and South San Francisco. For more information, visit www.immunedesign.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 based on Immune Design's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the prospects for product candidate CMB305 and potential implications of the data contained in Abstract No: 3083 to be presented at the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting for future clinical studies; the timing and results of the Phase 1B trial of CMB305; patient enrollment of the Phase 1 trial of G100 and the timing of commencement of an additional Phase 1/2 trial of G100; and clinical development of Immune Design's product candidates. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Immune Design's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Immune Design's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in more detail in Immune Design's filings with the U.S. Securities and Exchange Commission, including under the heading "Risk Factors" contained in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2015, and in subsequent filings. Except as required by law, Immune Design assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Footnote and Citation:

[1] Note that the total tumor burden in the LV305 study was restricted to < 10cm and ECOG status was < 2

[2] Van Glabbeke,et al., European Journal of Cancer,, "Progression-free rate as the principal end-point for phase II trials in soft-tissue sarcomas", 2002.

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