



## **Immune Design Reports Data Update for Lead Immunotherapy Programs: Improvement in Survival for CMB305 Monotherapy in Sarcoma and Increased Objective Responses for G100/pembrolizumab Combination in Follicular Lymphoma**

March 12, 2018

- Median overall survival of 23.7 months following CMB305 monotherapy represents approximately one-year extension of survival compared to published data in soft tissue sarcoma patient population
- Objective response rate (ORR) for follicular lymphoma patients treated with G100 and pembrolizumab combination therapy increased to 54%, with a 75% ORR in the subset of TLR4-high patients

SEATTLE and SOUTH SAN FRANCISCO, March 12, 2018 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), an immunotherapy company focused on next-generation therapies in oncology, today announced updated data from two separate trials evaluating its lead product candidates, CMB305 and G100. CMB305 is a novel prime-boost immunotherapy targeting NY-ESO-1+ cancers, and G100 is a novel synthetic TLR4 agonist for intratumoral immunotherapy. Evidence of clinical benefit continued to mature with both agents, providing not only further support for the advancement of both programs, but also supporting the view that an immunotherapy may provide additional clinical benefit with time.

### **Data Update from the CMB305 Monotherapy Trial**

Immune Design initially presented data at the American Society of Clinical Oncology 2017 Annual Meeting from 25 NY-ESO-1+ soft tissue (STS) patients, including 14 synovial sarcoma patients. The median follow up at the time was 11.4 months, in a patient population where 92% had relapsed or refractory metastatic disease, 52% had received  $\geq 2$  lines of chemotherapy, and 56% had actively progressing disease at study entry, an unfavorable prognostic factor.

As of the time of the most recent data analysis, median follow up of patients was 17.7 months. Observations are as follows:

- Median overall survival (OS) across all STS patients has been reached at 23.7 months. The median OS for the subset of synovial sarcoma patients, the targeted patient population in the company's planned Phase 3 trial, has still not yet been reached.
  - These survival data compare favorably to the reported median OS for approved second line and later agents, which are only 12.4-13.5 months for STS patients, and 11.7 months for synovial sarcoma patients specifically.
- Patients who develop an anti-NY-ESO-1 immune response on CMB305 therapy have better survival.
- CMB305 continues to be well tolerated, with only one Grade 3 adverse event.

### **Data Update from G100 and pembrolizumab Randomized Phase 2 Combination Trial**

Immune Design initially presented data at the 2017 American Society of Hematology Annual Meeting (ASH 2017) from a randomized Phase 2 trial of 26 follicular lymphoma patients, pursuant to a collaboration with Merck. Patients were randomized evenly to one of two treatment arms: G100 with fractionated, low-dose radiation (XRT) or G100+XRT with pembrolizumab combination therapy. The data have matured as of the most recent data analysis, with observations as follows:

- Additional responses have been observed in the combination arm (54% ORR, compared to a 15% ORR in the G100+XRT arm). This is an improvement from the ASH 2017 data, which showed an ORR of 39% in the combination arm.
- The patient population with high TLR4 expression in the tumor continue to receive greater benefit, with an updated 75% ORR on the combination arm (6/8 patients), an increase from the 57% ORR reported at ASH 2017.
  - These data compare favorably to pembrolizumab monotherapy presented at ASH 2017, which showed an 11% ORR in a separate follicular lymphoma study.
- 77% of patients in the combination arm experienced abscopal tumor shrinkage in un-injected tumors, compared to 54% of patients in the G100+XRT arm.
- Patients in the combination arm demonstrated a greater increase of CD8 T cells within the tumors, as compared to the G100+XRT arm.
- The safety profile continues to appear favorable when compared to recently approved therapies for patients with relapsed/recurrent disease.

"These are exciting new data that provide stronger translational and clinical benefit profiles of our CMB305 and G100 therapeutic candidates in important forms of cancer where unmet need persists," said Carlos Paya, M.D., Chief Executive Officer of Immune Design. "Armed with these findings, we look forward to beginning a Phase 3 pivotal clinical trial midyear 2018 to investigate CMB305 as a maintenance therapy in synovial sarcoma patients - an important step in our goal to provide a new treatment option to this patient population. In addition, these new G100 data give us greater confidence in the promise of this novel therapy in follicular lymphoma, and the potential to expand into other tumors."

### **Upcoming Presentation and Conference Call**

Senior management is scheduled to present at the upcoming Cowen & Company 38<sup>th</sup> Annual Health Care Conference on Monday, March 12, 2018 at 9:00 a.m. Pacific Time/12:00 p.m. Eastern Time in Boston, as well as host a webcast and conference call at 1:30 p.m. Pacific Time/4:30 p.m. Eastern Time on March 14, 2018 to discuss fourth quarter and year end 2017 financial results. A live webcast of each presentation will be available online from the investor relations page of the company's corporate website at <http://ir.immunedesign.com/events.cfm>, and an archive of each presentation will be available on the company website for at least 30 days. The March 14, 2018 live conference call may be accessed by dialing 844-266-9538 for domestic callers and 216-562-0391 for international callers. A telephone replay of the call will be available for five days by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference code: 3777048.

Immune Design may present additional detail on these data at an upcoming medical meeting.

#### **About CMB305**

CMB305 is an investigational prime-boost vaccine approach against NY-ESO-1-expressing tumors, designed to generate an integrated, anti-NY-ESO-1 immune response *in vivo* via a targeted, specific interaction with dendritic cells, a mechanism of action Immune Design believes differs from traditional cancer vaccines. CMB305 is being evaluated in soft tissue sarcoma patients in ongoing Phase 1 monotherapy and Phase 2 combination studies. Immune Design has received Orphan Drug Designation for CMB305 from the FDA for the treatment of soft tissue sarcoma, as well as from the FDA and European Commission for each of the components of CMB305 for the treatment of soft tissue sarcoma.

#### **About G100**

G100 is a product candidate from Immune Design's GLAAS discovery platform. It contains a potent, synthetic small molecule toll-like receptor-4 (TLR-4) agonist, Glucopyranosyl Lipid A (GLA), and is the lead product candidate in Immune Design's Antigen Agnostic approach. G100 activates innate and adaptive immunity in the tumor microenvironment to generate an immune response against the tumor's preexisting diverse set of antigens. A growing set of clinical and preclinical data have demonstrated the ability of G100 to activate tumor-infiltrating lymphocytes, macrophages and dendritic cells, and promote antigen-presentation and the recruitment of T cells to the tumor. The induction of local and systemic immune responses has been shown in preclinical studies to result in local and abscopal (shrinking of tumors outside the scope of the localized treatment) tumor control.

#### **About Immune Design**

Immune Design is a late-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 immune cells to fight cancer and other chronic diseases. CMB305 and G100, the leading product candidates with broad potential in oncology, are based on the company's two technology platforms that are potent stimulators of the immune system – ZVex<sup>®</sup> and GLAAS<sup>®</sup> – the fundamental technologies of which were licensed from the California Institute of technology and the Infectious Disease Research Institute (IDRI), respectively. Both ZVex and GLAAS also have potential applications in infectious disease and allergy indications, which are being developed through ongoing pharmaceutical collaborations. Immune Design has offices in Seattle and South San Francisco. For more information, please visit [www.immunedesign.com](http://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," "target," "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 that could cause Immune Design's clinical development programs, future results or performance to differ significantly from those expressed or implied by the forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, scope and results of clinical trials, the association of data with treatment outcomes, and the timing and likelihood of obtaining regulatory approval 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, the uncertainties and timing of the regulatory approval process, 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 Immune Design's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. 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.

#### **Media Contact**

Julie Rathbun  
[julie.rathbun@immunedesign.com](mailto:julie.rathbun@immunedesign.com)  
206-769-9219

#### **Investor Contact**

Sylvia Wheeler  
[sylvia.wheeler@immunedesign.com](mailto:sylvia.wheeler@immunedesign.com)  
650-392-8318

 [Primary Logo](#)

Source: Immune Design Corp.