

# Immune Design Announces New CMB305 + Checkpoint Inhibitor Topline Data from an Upcoming Presentation at the ESMO 2017 Congress

- Interim data analysis shows greater clinical benefit and immune response with CMB305+atezolizumab than with atezolizumab alone

SEATTLE and SOUTH SAN FRANCISCO, Calif., Aug. 30, 2017 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced positive topline data from its interim analysis of the ongoing, randomized Phase 2 trial evaluating CMB305 in combination with atezolizumab (TECENTRIQ®) or atezolizumab alone in 88 soft tissue sarcoma patients. The data will be presented in a poster discussion session at the European Society of Medical Oncology (ESMO) 2017 Congress, September 8-12, 2017 in Madrid, Spain.

“The two main goals of this study are (1) to determine whether combining a next-generation vaccine like CMB305 with a checkpoint inhibitor (such as an anti-PD-L1 antibody) provides improved clinical benefit compared to that of the checkpoint inhibitor alone, particularly in a PD-L1-low or -negative tumor, and (2) in a randomized setting, to determine the biological activity of CMB305,” said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. “We believe these interim data constitute the first steps towards answering both questions in a favorable manner.”

Data to be presented at ESMO build upon those data on the first 36 patients summarized in the abstract, and include a greater number of patients enrolled.

- **Clinical Benefit:** Data from the larger patient population show that patients receiving CMB305 and atezolizumab experienced greater clinical benefit in the form of Disease Control Rate (including objective responses), Progression Free Survival and Time to Next Treatment than those receiving atezolizumab alone.
- **Immune Response:** Patients who received the combination of CMB305 and atezolizumab demonstrated an increased frequency of induced immune responses to NY-ESO-1, including NY-ESO-1-specific T cells, NY-ESO-1 antibodies, and antigen spreading, in comparison to patients who received atezolizumab alone
- **Biomarkers:** In an exploratory analysis, a trend towards improved overall survival was observed in patients in the CMB305 and atezolizumab combination arm who had pre-existing and treatment-induced anti-NY-ESO-1 immunity, compared to the atezolizumab alone arm. Pre-treatment tumor biopsy analysis showed negligible levels of PD-L1 expression.
- **Safety:** No new safety signals have been observed in either arm.

The fully enrolled trial is evaluating the safety, immunogenicity and efficacy of CMB305 in combination with atezolizumab, or atezolizumab alone, in a total of 88 patients with locally advanced, relapsed, or metastatic NY-ESO-1<sup>+</sup> synovial sarcoma or myxoid/round-cell liposarcoma.

Atezolizumab is a monoclonal antibody designed to target and bind to a protein called PD-L1 (programmed death ligand-1) and is being developed by Genentech, a member of the Roche Group. The trial is being conducted pursuant to a clinical collaboration with Genentech. Immune Design intends to present survival data in 2018 once all patients have at least one year of follow up (current data are preliminary: median duration of observation <six months).

The ESMO Poster Discussion session presentation details are as follows:

**A Phase 2 Study of CMB305 and Atezolizumab in NY-ESO-1+ Soft Tissue Sarcoma: Interim Analysis of Immunogenicity, Tumor Control and Survival**

Abstract # 1480PD

Session Title: Sarcoma Poster Discussion Session

Date: Monday, Sept. 11, 2017

Time: 11 a.m. – 12:30 p.m.

Location: Bilbao Auditorium

Poster Presenter: Dr. Sant Chawla

Poster Discussant: Dr. Robert Maki

**About CMB305**

CMB305 is a 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 2 combination studies. Immune Design has received Orphan Drug Designation for CMB305 from the U.S. Food and Drug Administration (FDA) for the treatment of soft tissue sarcoma, as well as from the FDA and European Medicines Agency for each of the components of CMB305 for the treatment of soft tissue sarcoma.

**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 primary foci of Immune Design's ongoing immunoncology clinical programs, are products of its two synergistic discovery platforms, ZVex and GLAAS, the fundamental technologies of which were licensed from the California Institute of Technology and the Infectious Disease Research Institute (IDRI), respectively. Immune Design has offices in Seattle and South San Francisco. For more information, please visit [www.immunedesign.com](http://www.immunedesign.com).

TECENTRIQ® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

**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 that could cause our 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.*

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