September 8, 2017

New Randomized Data From CMB305 + Checkpoint Inhibitor Study Demonstrate Greater Clinical Benefit and Immune Response

- Phase 2 Interim Analysis Data Presented at ESMO 2017 Congress

SEATTLE and SOUTH SAN FRANCISCO, Calif., Sept. 08, 2017 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced that an interim analysis of its ongoing, randomized Phase 2 trial showed that NY-ESO-1^{+} soft tissue sarcoma (STS) patients receiving the combination of CMB305 and Genentech's checkpoint inhibitor, atezolizumab (TECENTRIQ®), experienced greater clinical benefit and immune response than those receiving atezolizumab alone. 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.

This fully enrolled trial is evaluating the safety, immunogenicity and efficacy of CMB305 in combination with atezolizumab (C+A, n=45), or atezolizumab alone (A, n=43), in a total of 88 patients with locally advanced, relapsed, or metastatic NY-ESO-1^{+} synovial sarcoma or myxoid/round-cell liposarcoma. Data to be presented at ESMO summarize patients evaluated in an interim analysis in a data cut as of July 21, 2017, with analysis divided into two groups: pre-specified interim analysis (n=36) and full study population (n=88).

Patient Characteristics:

Patients receiving CMB305 plus atezolizumab have more advanced disease than those receiving atezolizumab alone, including:

- Metastatic Disease: 98% (C+A) vs. 79% (A)
- ≥2 prior lines of systemic anti-cancer therapy: 61% (C+A) vs. 49% (A)
- ≥2 lesions at time of study entry: 96% (C+A) vs. 84% (A)
- Grade 3 disease at diagnosis: 47% (C+A) vs. 33% (A)

Greater Clinical Benefit with Combination of CMB305 and Atezolizumab:

Interim analysis data (n=36) show that patients receiving CMB305 plus atezolizumab experienced greater clinical benefit than those receiving atezolizumab alone.

- Disease Control Rate (Partial Responses (PR) + Stable Disease (SD)): 61%, including 1 PR (C+A) vs. 28% with no PRs (A)
- Median Progression Free Survival (PFS): 2.6 months (C+A) vs. 1.4 months (A)
- Time to Next Treatment (TTNT): 9 months (C+A) vs. 6.3 months (A)
- Overall survival: as of the collection date, overall survival data are immature (median duration of observation is less than six months); Immune Design intends to present survival data in 2018 once all patients approach at least one year of follow up.

In the full study population (n=88), the trend of greater clinical benefit on the combination arm remains consistent for the entire patient population:

- Disease Control Rate: 57% (3 PRs total, 1 unconfirmed) (C+A) vs. 38% (0 responses) (A)

More Robust Immune Response with Combination of CMB305 and Atezolizumab:

Patients in the full study population (n=88) who received the combination of CMB305 and atezolizumab demonstrated stronger anti-NY-ESO-1 immune responses compared to those receiving atezolizumab alone (samples evaluable from (n=60/88)), including:

- Induced anti-NY-ESO-1 T cells: 52% (C+A) vs. 17% (A)
- Induced anti-NY-ESO-1 antibodies: 52% (C+A) vs. 0% (A)
- Induced antigen spreading: 19% (C+A) vs. 0% (A)

Biomarker Analysis Shows Continued Link Between Induced Immune Response and Clinical Benefit:

In an exploratory analysis, a trend towards improved overall survival was observed in patients with an induced immune response (T cells or antibodies) who received CMB305 plus atezolizumab.

- Induced anti-NY-ESO-1 T cells: 78% reduction in mortality rate, as compared to patients without induced T cells [HR=0.22, log-rank p value=0.043]
- Induced anti-NY-ESO-1 antibodies: 87% reduction in mortality rate, as compared to patients without induced antibodies [HR=0.13, log-rank p value=0.025]
- This trend of improved overall survival in patients with induced immune response was not observed in the atezolizumab-only arm.

In addition, pretreatment tumor biopsies available from 70 patients show both an absent or very low level of PD-L1 expression and CD8 T cell infiltration, further supporting that these subtypes of STS are "cold" tumors.

Positive Safety Profile with Combination of CMB305 and Atezolizumab:

This combination was observed to be well tolerated, and there were no new safety signals in either arm.

"We believe the greater clinical benefit and more robust immune response shown in the combination study arm supports the hypothesis that the combination of an appropriately-designed, next-generation cancer vaccine such as CMB305 with a checkpoint inhibitor is important to produce clinical benefit in a cold tumor such as STS, where checkpoint inhibitors otherwise may have limited efficacy," said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. "In addition, we are pleased to observe the trend towards longer overall survival in patients with an induced anti-NY-ESO-1 immune response, further supporting the positive CMB305 monotherapy data we presented at ASCO in June."

Atezolizumab is a monoclonal antibody being developed by Genentech, a member of the Roche Group, and is designed to target and bind to a protein called PD-L1 (programmed death ligand-1). The trial is being conducted pursuant to a clinical collaboration with Genentech. TECENTRIQ® is a registered trademark of Genentech.

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 Phase 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 two leading product candidates focused in cancer immunotherapy, are the first products from Immune Design's two separate discovery platforms targeting dendritic cells *in vivo*, ZVex® and GLAAS®. Both ZVex and GLAAS also have potential applications in infectious disease and allergy as demonstrated by ongoing pharmaceutical collaborations. Immune Design has offices in Seattle and South San Francisco. For more information, please 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 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.

Media Contact
Julie Rathbun
Rathbun Communications
julie@rathbuncomm.com
206-769-9219

Investor Contact
Shari Annes
Annes Associates
sannes@annesassociates.com
650-888-0902