

IMMUNE DESIGN CORP.

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported):
September 8, 2017

IMMUNE DESIGN CORP.

(Exact name of registrant as specified in its charter)

Delaware

(state or other jurisdiction of incorporation)

001-36561

(Commission File Number)

26-2007174

(I.R.S. Employer Identification No.)

**1616 Eastlake Ave. E., Suite 310
Seattle, Washington**

(Address of principal executive offices)

98102

(Zip Code)

Registrant's telephone number, including area code: **(206) 682-0645**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On September 8, 2017, Immune Design Corp. (the “Company”) issued a press release announcing data from an interim analysis of the Company’s ongoing, randomized Phase 2 clinical trial of CMB305 in combination with atezolizumab (Tecentriq®) versus atezolizumab alone in patients with soft tissue sarcoma, which 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.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated September 8, 2017.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated September 8, 2017.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNE DESIGN CORP.

By: /s/ Carlos Paya, M.D., Ph.D.
Carlos Paya, M.D., Ph.D.
President and Chief Executive Officer

Dated: 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. 8, 2017 -- 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.

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