Immune Design Announces Positive FDA Feedback on Phase 3 Clinical Trial Design for CMB305 in Synovial Sarcoma Patients

- *CMB305 Monotherapy vs. Placebo in the Maintenance Setting*
- *PFS Analysis for Potential Full Approval as Early as 24 Months After Study Start*
- *Conference Call and Webcast Tomorrow at 5:30am PT/8:30am ET*

SEATTLE and SOUTH SAN FRANCISCO, Calif., Oct. 16, 2017 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced that based on productive discussions with the U.S. Food and Drug Administration (FDA), it plans to initiate a pivotal Phase 3 trial to support a Biologics License Application (BLA) for CMB305, a novel cancer vaccine, in patients with synovial sarcoma.

The randomized Phase 3 trial will evaluate CMB305 monotherapy vs. placebo in patients with NY-ESO-1^{+} locally advanced unresectable or metastatic synovial sarcoma, a sub type of soft tissue sarcoma, who have no evidence of progression after first-line chemotherapy. Immune Design intends to start the study in mid-2018 and enroll 248 patients aged twelve and older. Patients will be randomized 1:1 to receive either CMB305 monotherapy or placebo. The trial will have progression free survival (PFS) followed by overall survival (OS) as co-primary endpoints. If the PFS endpoint is successful, the FDA offered that it may support full approval of CMB305. Depending on the rate of events, final PFS analysis may occur as early as 24 months from the first patient dosed.

About Synovial Sarcoma

Soft tissue sarcomas are malignancies that arise from the soft tissues of the body, such as tissues that connect, support and surround other body structures including muscle, fat, blood vessels, nerves, tendons and the lining of joints. Synovial sarcoma is a sub type of soft tissue sarcoma where 70% of diagnoses occur in patients under 40 years old, is associated with a high risk of recurrence, and has been shown to have high expression of the NY-ESO-1 tumor antigen. The primary treatment for patients with locally advanced, unresectable or metastatic synovial sarcoma typically consists of an anthracycline-based chemotherapy regimen administered alone or in combination with other agents. Following disease progression after first line systemic therapy, treatment options are limited and median overall survival rates have been reported to be approximately 12 months. In connection with the planned Phase 3 study for CMB305 monotherapy, the FDA has agreed with Immune Design that synovial sarcoma patients constitute an unmet medical need.

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.

Conference Call Information

Immune Design will host a conference call and live audio webcast tomorrow, October 17, at 5:30 a.m. Pacific time / 8:30 a.m. Eastern time to discuss the CMB305 development strategy and pivotal trial design.

To participate in the conference call, please dial 844-266-9538 for domestic callers and 216-562-0391 for international callers and provide the conference ID 9299539, or access the listen-only live webcast by visiting the investor relations section of the company website at http://ir.immunedesign.com/events.cfm.

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: 9299539. An archived copy of the webcast will be available on Immune Design's website beginning approximately two hours after the conference call and will be available for at least 30 days after the conference call.

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 "safe harbor" provisions 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 design, progress, timing, scope and potential results of the pivotal Phase 3 clinical trial of CMB305 in synovial sarcoma patients, the possibility that PFS data will be sufficient to support regulatory approval and the timing of the PFS analysis. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data, clinical trial site activation or enrollment rates that are slower 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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