Immune Design Announces Launch of Web Portal for SYNOVATE Phase 3 Study of CMB305 Immunotherapy in Synovial Sarcoma

May 24, 2018

-- 1st global Phase 3 trial focused on synovial sarcoma patients

SYNOVATE

SYNOVATE is a randomized, global Phase 3 trial to evaluate CMB305 immuontherapy in synovial sarcoma patients. www.synovatestudy.com

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SEATTLE and SOUTH SAN FRANCISCO, Calif., May 24, 2018 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), an immunotherapy company focused on novel therapies in oncology, today announced the launch of the patient and healthcare provider websites for the SYNOVATE study – a pivotal trial to evaluate CMB305 immunotherapy in synovial sarcoma patients. Clinical sites will soon be open for enrollment initially in the US, with information available at www.synovatestudy.com.

“Patients with advanced synovial sarcoma often have few systemic treatment options immediately after they complete first line chemotherapy. Clinically, we often give them a break from therapy, following closely with the hope that they will not progress in the relatively short time period that is unfortunately common in this disease,” said William D. Tap, M.D., Medical Oncology and Chief, Sarcoma Medical Oncology Service, Memorial Sloan Kettering Cancer Center. “It is our hope that CMB305 may offer a new option for patients to receive a potentially beneficial therapy that will defer the need for subsequent therapy.”

SYNOVATE is a randomized, global Phase 3 clinical trial that will evaluate CMB305 monotherapy versus placebo in 248 patients 12 years of age and older with NY-ESO-1 positive, unresectable, locally-advanced or metastatic synovial sarcoma. Patients who are responding to a first-line therapy can become eligible for SYNOVATE following completion of their chemotherapy. SYNOVATE will be opened and recruiting patients in cancer centers throughout the United States, Canada, Europe, and the Asia Pacific region.

“We are very pleased to be working with high quality clinical groups around the country and internationally to launch the SYNOVATE study to explore CMB305 immunotherapy in patients with synovial sarcoma,” said Sergey Yurasov, M.D., Ph.D., Chief Medical Officer, Immune Design. “SYNOVATE is the first randomized, global Phase 3 trial of an immunotherapy focused in synovial sarcoma, and we hope it results in a new, approved therapy for these patients.”

Patient and Health Care Provider Resouces for SYNOVATE Study

Information can be found on the SYNOVATE website at www.synovatestudy.com and on the NIH clinical trial registry www.clinicaltrials.gov (Identifier: NCT03520959).

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 a prime-boost cancer vaccine targeting NY-ESO-1-expressing tumors. NY-ESO-1 is a cellular protein that is typically found only in certain cancer cells and is often frequently expressed in synovial sarcomas. CMB305 is administered to participants by injection and is designed to provide clinical benefit by generating an anti-NY-ESO-1 immune response by activating a participant’s antigen-presenting dendritic cells.

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® and GLAAS® - 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.

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 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
206-769-9219

Investor Contact
Sylvia Wheeler
sylvia.wheeler@immunedesign.com
650-392-8318

Primary Logo

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