June 5, 2017

Immune Design Updates Positive Data from Lead Cancer Immunotherapy Programs at ASCO Annual Meeting

- *Observed median overall survival for sarcoma patients treated in two separate Phase 1 studies with an NY-ESO-1 targeted novel immunotherapy meaningfully exceeds standard of care benchmarks*
- *In follicular NHL patients, intratumoral immunization with G100 induced objective responses (≥50% tumor reduction) in 44% of patients, with abscopal tumor shrinkage in 50% of patients*
- *New biomarkers associated with survival may guide patient selection in registration trials*

SEATTLE and SOUTH SAN FRANCISCO, Calif., June 05, 2017 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced updated clinical and biomarker data for its lead immuno-oncology product candidates, CMB305 and G100. The data are being presented at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting in Chicago.

CMB305 Monotherapy in Soft Tissue Sarcoma Patients: Clinical Benefit, Safety and Patient Selection

Data in an oral presentation last Friday by Neeta Somaiah, M.D., Department of Sarcoma Medical Oncology, The University of Texas MD Anderson Cancer Center, highlight the results of 25 soft tissue sarcoma (STS) patients with recurrent disease treated with CMB305:

- Patient characteristics: 92% metastatic, 56% progressing upon trial entry, and 52% with ≥2 prior lines of chemotherapy
- Survival: median overall survival (mOS) has still not yet been reached.
  • The overall survival rate at 12 and 18 months was 83% and 76%, respectively.
  • These new data compare favorably to mOS for approved second line and later sarcoma agents, which is only 12.4-13.5 months, as well as a published mOS of 11.7 months for synovial sarcoma patients specifically; the largest patient population enrolled in this trial.
- Disease control: a disease control rate (CDR) of 64% (16/25) was observed, including durable tumor growth arrest in patients who had evidence of disease progression at study entry.
- Safety: CMB305 was well tolerated, with only one related Grade 3 adverse event (AE).
- Immune response: CMB305 generated a strong and broad anti-NY-ESO-1 immune response in >50% of the patients, with 32% patients experiencing an integrated response (T cells and antibodies).
- Antigen spreading: induction of an immune response against other tumor antigens not targeted by CMB305 was detected in 33% of evaluable patients following CMB305 therapy.

In a related presentation today, Seth M. Pollack, M.D. of the Fred Hutchinson Cancer Research Institute, will present data examining the relationship between immune response against NY-ESO-1 and clinical benefit in a combined set of CMB305 and LV305 patients (n=64) with various tumor types. LV305 is the vector only, "prime" component of CMB305, and was the subject of a separate Phase 1 study:

- NY-ESO-1 specific "public" T cell receptor (pTCR): three NY-ESO-1-specific T-cell receptor sequences isolated from a patient responding to therapy were found to be shared by approximately 50% of all study patients, as well as healthy blood donors, tested. These pTCR sequences indicate a low level of pre-existing anti-NY-ESO-1 immunity which appear to be expanded by CMB305.
- Immune response: the induction of an integrated anti-NY-ESO-1 immune response (antibodies and T-cells) was observed in more than 30% of the patients who received therapy.
- Biomarker (immune response) vs. Survival: the induction of an anti-NY-ESO-1 immune response by these agents is associated with improved patient survival, particularly in patients with pre-existing anti-NY-ESO-1 immunity.
- Patient selection: these immune biomarkers, including novel bio-markers derived from pTCRs, may guide regulatory strategy via the selection of patients more likely to have survival benefit on CMB305 therapy.

G100 Monotherapy in Follicular NHL (FL) Patients: Clinical Benefit, Safety and Changes to the Tumor Microenvironment (TME)

In a poster presentation today, Christopher Flowers, M.D., Department of Hematology and Medical Oncology, Emory

University School of Medicine, will present results of 9 patients with FL treated with escalating doses of G100 monotherapy (with local radiation (XRT)).

- Patient characteristics: of the 9 FL patients enrolled, 45% were treatment-naïve and 56% were relapsed/refractory, and most had Stage III and IV disease (56% and 33%, respectively). Additionally, 55% of patients had received at least two prior therapies and 78% had progressive disease upon study entry.
- Disease control:
  • Objective responses were observed at all three dose levels tested.
  • 44% of the patients achieved a partial response (PR) based on WHO criteria (at least a 50% tumor reduction).
  • Some patients had tumor shrinkage over a prolonged period, e.g., continuing up to 8+ months, and a duration of response exceeding 4 months in some patients.
  • DCR of 100% of patients (44% PR, 56% SD).
  • 50% of evaluable patients experienced shrinkage of untreated distal (abscopal) lesion.
- Safety: G100 was well tolerated, with no related Grade 3/4 AEs in all three dose levels tested.
- Tumor microenvironment: G100 resulted in favorable tumor microenvironment changes
  • Tumor biopsies showed increased inflammatory responses and T cell infiltrates in abscopal, non-treated tumors.

"These data demonstrate that both CMB305 and G100, our lead cancer immunotherapy product candidates, are capable of activating patients' immune systems in ways that have a direct effect on patients' tumor growth, whether it is tumor-growth arrest on CMB305 therapy and subsequent survival benefit, or ORR and systemic tumor shrinkage after local therapy with G100," said Sergey Yurasov, MD, PhD, Senior Vice President and Chief Medical Officer at Immune Design. "Also, importantly, we are evaluating immune biomarkers that may identify patients who are likely to benefit the most from CMB305 therapy. We plan to present these clinical data to regulatory agencies in planning for a pivotal trial that may lead to subsequent regulatory approval, and enable us to bring these novel, safe immunotherapies to cancer patients."

ASCO Presentation Details

ORAL PRESENTATION

Immune response, safety, and survival impact from CMB305 in NY-ESO-1+ recurrent soft tissue sarcomas (STS)

Abstract # 11006
Session Title: Sarcoma
Date: Friday, June 2, 2017
Time: 3 p.m. — 6 p.m. CT (oral session)
Location: S100bc
Presenter: Neeta Somaiah, M.D., Department of Sarcoma Medical Oncology, The University of Texas MD Anderson Cancer Center

POSTER PRESENTATIONS

The Association of CMB305 or LV305-induced and baseline anti-NY-ESO-1 immunity with survival in recurrent cancer patients

Abstract # 3090
Session Title: Developmental Therapeutics—Immunotherapy
Date: Monday, June 5, 2017
Time: 8 a.m. — 11:30 a.m. CT
Location: Hall A
Presenter: Seth M. Pollack, M.D., Fred Hutchinson Cancer Research Center

Intratumoral G100 to induce systemic immune responses and abscopal tumor regression in patients with follicular lymphoma

Abstract # 7537
Session Title: Hematologic Malignancies — Lymphoma and Chronic Lymphocytic Leukemia
Date: Monday, June 5, 2017
Time: 8 a.m. — 11:30 a.m. CT
Location: Hall A
Presenter: Christopher Flowers, M.D., Department of Hematology and Medical Oncology, Emory University School of Medicine

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 STS patients in ongoing Phase 1 monotherapy and 2 combination studies with the anti-PD-L1 antibody, Tecentriq® (atezolizumab), pursuant to a collaboration with Genentech. 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 G100

G100 contains a potent synthetic small molecule toll-like receptor-4 (TLR-4) agonist, Glucopyranosyl Lipid A (GLA), and is the lead product candidate in Immune Design's Antigen Agnostic approach. It leverages the activation of both innate and adaptive immunity, including dendritic cells, in the tumor microenvironment to create an immune response against the tumor's preexisting diverse set of antigens. G100 is being evaluated as both a monotherapy (with XRT) and in combination with Merck's anti-PD-1 agent, Keytruda® (pembrolizumab), pursuant to a clinical collaboration with Merck, in a randomized Phase 1/2 trial in patients with follicular non-Hodgkin's lymphoma. The FDA has granted Orphan Drug Designation for G100 for the treatment of follicular non-Hodgkin's lymphoma.

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 its 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, 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 enrolment 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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