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Dynavax Initiates Immuno-Oncology Clinical Trial Evaluating SD-101 in Combination With Merck's Anti-PD-1 Therapy, KEYTRUDA(R) (pembrolizumab)

BERKELEY, CA -- (Marketwired) -- 10/08/15 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that it has initiated patient dosing in the company's trial evaluating the combination of two immunotherapies: Dynavax's SD-101 and Merck's (NYSE: MRK) KEYTRUDA® (pembrolizumab). The multicenter, open-label trial is enrolling patients with advanced or metastatic melanoma and will investigate the safety and potential efficacy of Dynavax's investigational toll-like receptor 9 (TLR9) agonist, SD-101, in combination with Merck's anti-PD-1 therapy, KEYTRUDA.

SD-101 and KEYTRUDA are immunotherapies designed to modulate the patient's own immune response to fight cancer. SD-101 is designed to mediate anti-tumor effects by triggering both innate and adaptive immune responses, including inducing high levels of Type 1 interferon. KEYTRUDA is a humanized monoclonal antibody that blocks the interaction between PD-1 (programmed death receptor-1) and its ligands, PD-L1 and PD-L2. Preclinical data suggest that combining SD-101 and antibodies targeting PD-1 may lead to a stronger anti-tumor immune response compared to either agent alone.

The Phase 1b dose-escalation portion of the study is enrolling up to 12 patients with advanced or metastatic melanoma. Patients will receive intratumoral administrations of SD-101 at pre-specified dose levels and intravenous doses of KEYTRUDA. Patients will be monitored for safety and tolerability while an optimal dose of SD-101 is determined. Upon completion of dose escalation, the study will be expanded into a Phase 2 study that will enroll up to 85 patients. The patients enrolled in the expansion study will either have disease that is progressing while receiving an anti-PD-1 therapy or will have baseline characteristics associated with lower rates of response to anti-PD-1 therapy.

Antoni Ribas, M.D., Ph.D., of the Jonsson Comprehensive Cancer Center at the University of California, Los Angeles, is the primary investigator on this clinical trial. More information on this clinical trial can be found at https://www.clinicaltrials.gov/ct2/show/NCT02521870?term=NCT02521870&rank=1

Dynavax expects to complete the Phase 1b dose escalation and expand into the Phase 2 portion of the clinical trial with the selected dose of SD-101 by mid-year 2016.

About SD-101

SD-101 is a proprietary, second-generation, TLR 9 agonist CpG-C class oligodeoxynucleotide. SD-101 activates multiple anti-tumor activities of innate immune cells and activates plasmacytoid dendritic cells to stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as SD-101 enhance T and B cell responses and provide potent Type 1 interferon induction and maturation of plasmacytoid dendritic cells to antigen-presenting cells. SD-101 is being evaluated in several Phase 1/2 oncology studies to assess its preliminary safety and activity.

About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B™, a Phase 3 investigational adult hepatitis B vaccine and SD-101, an investigational cancer immunotherapeutic currently in several Phase 1/2 studies. For more information, visit www.dynavax.com.

Dynavax Forward Looking Statements

This press release contains "forward-looking" statements, including expectations for the potential benefit of combining SD-101 with pembrolizumab and the enrollment in and timing of the expansion from Phase 1b into Phase 2 of the SD-101 study. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including unexpected safety or efficacy data from this or other clinical or preclinical studies, clinical trial site activation or enrollment rates that are lower than expected, the effects of competition, whether we can timely provide adequate clinical supplies, enroll a sufficient number of subjects and ultimately complete the study as well as other risks detailed in the "Risk Factors" section of our current periodic reports with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax's website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

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