Dynavax Announces Publication of Two Papers in Leading Oncology Journal Highlighting Data From Clinical Studies of Its TLR9 Agonist, SD-101

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Cancer Discovery Features Reports of Early Clinical Trials of SD-101 in Lymphoma and Advanced Melanoma

BERKELEY, Calif., Aug. 28, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced that two peer-reviewed papers reporting clinical studies of SD-101 have been published by *Cancer Discovery*, a journal publication from American Association of Cancer Research (AACR). The investigators report clinical activity and broad immune activation in the tumor microenvironment when SD-101 is administered in combination with either low dose radiation in patients with indolent lymphoma or in combination with PD-1 blockade in patients with unresectable or metastatic melanoma. Top-line results from these studies have previously been presented at major oncology conferences.

“Promising data from multiple trials studying intratumoral administration of TLR9 agonists indicate that stimulating the innate immune system through the TLR9 pathway can enhance the adaptive immune response to both injected and non-injected tumors,” said Antoni Ribas, M.D., Ph.D., Director of the Tumor Immunology Program at the Jonsson Comprehensive Cancer Center. “TLR9 agonists are showing potential as an important component of combination immuno-therapy for the treatment of cancer. With further research we hope to realize the full value that this approach can create for immuno-oncology.”

Dr. Ribas is the lead author for the paper titled *SD-101 in Combination with Pembrolizumab in Advanced Melanoma: Results of a Phase 1b, Multicenter Study*. This trial evaluated 22 patients who received intratumoral SD-101, a synthetic CpG-oligonucleotide that stimulates Toll-like receptor 9 (TLR9), in combination with a PD-1 inhibitor in patients with unresectable or metastatic malignant melanoma. The combination was well tolerated and the most common adverse events related to SD-101 were injection site reactions and transient, mild-to-moderate “flu-like” symptoms. Durable tumor responses were seen in both peripheral and visceral lesions. Among the 9 patients naïve to anti-PD-1 therapy, the overall response rate (ORR) was 78%. The estimated 12 month progression free survival (PFS) rate was 88%, and overall survival (OS) rate was 89%. Among 13 patients having prior anti-PD-1 therapy, the ORR was 15%. These clinical responses were supported by biomarker data indicating the induction of broad immune activation in the tumor microenvironment, including increased NK cells, cytotoxic cells, dendritic cells, B cells and CD8+ T cells and T cell infiltration. Increases in CD4+ and CD8+ T cells generally correlated with tumor responses. The paper can be found online here.

Ronald Levy, M.D., Robert K. and Helen K. Summy Professor in the School of Medicine at Stanford University, is the lead author of the paper titled *In situ vaccination with a TLR 9 agonist and local low dose radiation induces systemic responses in untreated indolent lymphoma*. It reports on a phase 1/2 multicenter study in which 29 patients received 4 Gy of radiation followed by five weekly intratumoral injections of SD-101 at a single tumor site. The paper can be found online here.

About SD-101
SD-101, the Company's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in several clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy, in patients with advanced melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. Dynavax maintains all commercial rights to SD-101.

About Dynavax
Dynavax is a fully-integrated biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company’s first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], was approved by the United States Food and Drug Administration in November 2017 for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit www.dynavax.com.

Forward-Looking Statements
This press release contains "forward-looking" statements, including statements regarding conduct of clinical trials of SD-101, including results from the Phase 1b/2 trials, and the potential of SD-101 in the treatment of cancer. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including initiation, enrollment and completion of clinical trials of SD-101; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials and issues arising in the regulatory process; the ability to successfully develop and commercialize SD-101; and whether or not Dynavax and parties with whom we are collaborating may reach any future agreement on further studies or a more extensive collaboration beyond the clinical trials contemplated under the existing agreements, as well as other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. 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.

Contact:
Ryan Spencer
VP, Corporate Strategy & Communications
510.665.4618


Primary Logo

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