Dynavax Announces Publication of Preclinical Study of TLR9 Agonist in Lung Cancer

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Delivery of a TLR9 Agonist Through the Airways Complements PD-1 Blockade to Generate Durable, Systemic Anti-tumor Immunity

BERKELEY, Calif., Sept. 04, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced publication of a preclinical study demonstrating that inhalation of a TLR9 agonist can stimulate effective immunity against lung tumors and complement the actions of PD-1 blockade to generate durable, systemic anti-tumor immunity. The paper titled *Inhaled TLR9 Agonist Renders Lung Tumors Permissive to PD-1 Blockade by Promoting Optimal CD4+ and CD8+ T cell Interplay,* by Dynavax scientists M.Gallotta, H. Assi, E. Degagné, S. Kannan, R.Coffman and C. Guiducci was published in the journal *Cancer Research.* The study demonstrated that combining an inhaled TLR9 agonist with systemic anti-PD-1 led to long-term survival in two different mouse lung tumor models, mediated by systemic immunity that eradicated tumors both in the lung and in distal organs. The study further delineated the distinctive mechanisms of action of these agents in the lung environment.

Administration of the TLR9 agonist SD-101 into the lungs of mice with metastatic tumors generated anti-tumor responses that controlled or eliminated tumor growth in the lungs as well as in non-treated organs, including liver. Treatment with SD-101 resulted in ~90% decrease in tumor burden in both the lung and liver. This led to a significant increase in survival time, with a majority of mice surviving beyond 90-100 days. Treatment with SD-101 and anti-PD-1 resulted in a large increase of tumor-reactive T cells, which were required for anti-tumor activity. The durable control of liver metastases shows that local administration of SD-101 to the lung generates an anti-tumor T cell response capable of controlling tumor growth beyond the lung itself.

The TLR9 agonist used in these studies was SD-101, Dynavax's lead clinical candidate currently being developed as an intratumoral agent in combination with anti-PD-1 therapy in patients with advanced melanoma and head and neck squamous cell carcinoma. Unpublished data demonstrates that another TLR9 agonist, DV281 - optimized for delivery to primary lung tumors and lung metastases - has equivalent activity in these models. These studies provide the preclinical rationale for the Phase 1b dose escalation study of inhaled DV281 currently being conducted by Dynavax in advanced non-small lung cancer patients (NCT03326752). DV281 and SD-101 stimulate potent Type 1 interferon induction along with maturation of dendritic cells into effective antigen-presenting cells. These combined actions lead to the increased numbers of cytotoxic T cells that are critical for the induction of effective systemic anti-tumor immunity.

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 preclinical studies of Dynavax's TLR9 agonist and the conduct of clinical trials of SD-101 and DV281. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including whether we can timely provide adequate clinical supplies; initiation, enrollment and completion of clinical trials of the TLR9 agonist, SD-101 and DV281; 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 these investigational compounds; 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 our 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.

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