

# Dynavax Presents Clinical Data from Lead Cancer Immunotherapy Candidate, SD-101, in Combination with Targeted Low-Dose Radiation, at ASH Annual Meeting

## **Evidence of Systemic Antitumor Activity Observed in Clinical Trial**

BERKELEY, CA -- (Marketwired) -- 12/05/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced clinical data from an ongoing Phase 1/2, two-part clinical trial evaluating intratumoral administration of SD-101 in the treatment of low-grade lymphoma. The combination of intratumoral SD-101 and low-dose irradiation resulted in tumor regression in untreated tumor sites as well as in the treated tumors. Treatment was well-tolerated and changes in T cell populations consistent with stimulation of anti-tumor immunity were observed in the treated lesions. These data were

presented in a poster session on Sunday at the 58<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in San Diego, California.

Data from the dose escalation and expansion phase of the study were reported from 28 evaluable patients. None of the patients had received prior treatment for their low-grade lymphoma. The primary endpoints of the trial are maximum tolerated dose (MTD) and evaluation of the safety of intratumoral SD-101 in combination with low dose radiotherapy. In addition, the trial is evaluating anti-tumor activity, pharmacodynamics, and duration of response. Doses ranged from 1 mg to 8 mg per injection in successive cohorts.

Key findings presented include:

- Of the 28 evaluable patients treated across all dose levels, 3 had a partial response (PR) and1 had a complete response (CR) as measured by Cheson criteria.
- Durable abscopal tumor shrinkage was observed in the majority of patients.
- Confirming observations in the dose escalation phase, the most common treatment-related treatment emergent adverse events (TEAEs) in the expansion phase were flu-like symptoms, consistent with the engagement of TLR9 and the induction of interferon-alpha.
- Increases in CD8+ cells were observed in the injected tumor, and correlated with an increased abscopal tumor shrinkage

"The clinical data emerging from our SD-101 program continues to be encouraging. We look forward to providing updates from our ongoing clinical trials," stated Eddie Gray, chief executive officer of Dynavax Technologies. "We will discuss this program and our oncology pipeline in our cancer R&D Day which will be webcast live on December 9<sup>th</sup> at 8:30 a.m. EST."

#### About SD-101

SD-101 is Dynavax's proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. SD-101 is being studied for its multiple anti-tumor activities in innate immune cells and activation of 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 safety and activity.

For information about SD-101 trials that are currently recruiting patients, please visit www.clinicaltrials.gov.

#### About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, discovers and develops novel vaccines and therapeutics in the areas of infectious diseases and oncology. Dynavax's lead product candidates are HEPLISAV-B<sup>™</sup>, 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 <u>www.dynavax.com</u>.

### Dynavax Forward Looking Statements

This press release contains "forward-looking" statements, including expectations for the conduct and timing of clinical trials of SD-101. 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, initiate one or more studies,

enroll a sufficient number of subjects and ultimately complete any study, 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 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 <a href="https://www.dynavax.com">www.dynavax.com</a> is not incorporated by reference in our current periodic reports with the SEC.

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