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Dynavax Presents Encouraging Data From Clinical Trial of Immuno-Oncology Product Candidate, SD-101

SD-101 Induces Systemic Antitumor Response in Lymphoma Patients

BERKELEY, CA -- (Marketwired) -- 04/18/16 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced encouraging additional data from Part 1 of a Phase 1/2 study (LYM-01) evaluating the company's lead immunotherapy product candidate, SD-101, in combination with low-dose radiation in lymphoma patients. The data were presented at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, Louisiana.

Clinical Findings Included:

- SD-101 was reported to be well tolerated across all dose cohorts with no dose limiting toxicities.
- The combination of direct injection of SD-101 into a tumor and low-dose radiation resulted in changes in the tumor microenvironment that potentially induced a systemic anti-tumor response.
- Tumors not directly injected with SD-101 also decreased in volume across all dose groups, and in most patients, remained stable for at least 180 to 360 days.
- No evidence of a dose response was observed, although limited numbers of patients were examined.

"This clinical trial design is unique and takes advantage of the fact that lymphoma patients have easily injectable sites of disease. The local injections are conveniently added to low dose radiotherapy, a standard treatment for low grade lymphoma," stated Ronald Levy, M.D., professor and chief of the Division of Oncology at Stanford School of Medicine and the study's lead clinical investigator. "We are pleased to have already demonstrated a safety profile, pharmacodynamics and preliminary efficacy in this study," he said.

"These additional data bolster the findings that were presented at the American Society of Hematology conference in December, demonstrating SD-101's ability to promote beneficial changes in the tumor microenvironment to induce a systemic antitumor immune response," stated Eddie Gray, chief executive officer for Dynavax.

Two additional presentations relating to SD-101 are being made at the AACR Conference -- abstract 2322 this afternoon and abstract 4985 on Wednesday morning. Both presentations contain preclinical data relating to SD-101, and all three data presentations will be available on Dynavax's website (www.dynavax.com) at the "Events and Presentations" tab under the "Investors and Media" section of the website.

About LYM-01, a Phase 1/2 Trial of SD-101 in Lymphoma

In the Phase 1/2 non-randomized, open-label, multicenter, dose-escalation and expansion study, patients had untreated low-grade B-cell lymphoma. At least two sites of measurable disease were required for participation -- one of which was treated with low dose radiation and was then injected with SD-101 on days 1, 8, 15, 22 and 29. Other lesions received no treatment.

In Part 1-- the dose escalation portion of the study -- four dose cohorts with three patients each, received SD-101 at either 1 mg, 2 mg, 4 mg, or 8 mg. The Phase 2 expansion portion of the study is ongoing and is currently enrolling two dose cohorts. 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. For more information about trial enrollment, please look for SD-101 at www.clinicaltrials.gov.

About SD-101

SD-101, the subject of AACR abstracts CT047, 2322 and 4985, is Dynavax's proprietary, second-generation, CpG-C class oligodeoxynucleotide TLR 9 agonist. SD-101 activates multiple anti-tumor mechanisms 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 induce high levels of Type I interferons and maturation of plasmacytoid dendritic cells and B 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 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.

Forward-Looking Statements

This press release contains forward-looking statements regarding clinical studies involving SD-101, Dynavax's investigational cancer immunotherapy. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including enrollment and completion of clinical trials; the results of clinical trials and the impact of those results on the initiation or continuation of subsequent trials; issues arising in the regulatory process; and other risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, 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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