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Dynavax Initiates Phase 1/2 Study of TLR-9 Agonist Immunotherapy in B-Cell Lymphoma

BERKELEY, CA -- (Marketwired) -- 10/13/14 -- Dynavax Technologies Corporation (NASDAQ: DVAX) today announced initiation of a phase 1/2 clinical trial to assess the safety and preliminary efficacy of SD-101, an investigational Toll-like receptor ("TLR") 9 agonist, in adults with untreated low-grade B-cell lymphoma. In this multicenter study (known as LYM-01), SD-101 is administered intratumorally in combination with localized low-dose radiation. The open-label, dose escalation and expansion design of LYM-01 is intended to accelerate dose optimization while simultaneously assessing the safety, tolerability and initial local and distant antitumor activity of SD-101.

"Beginning LYM-01 is an important milestone in the maturation of Dynavax's TLR-based cancer immunotherapy research and development efforts" said Eddie Gray, Dynavax CEO. "This study will provide a range of data that will be integral to our strategy for evaluating SD-101 both alone and in combination with other immuno-oncology agents, such as checkpoint inhibitors."

LYM-01 Study Design

LYM-01 is an open-label, single arm, multicenter, dose-escalation and expansion study designed to evaluate the safety and preliminary efficacy of localized low-dose radiation therapy and intratumoral SD-101 injection into a single target lesion. It will include up to 25 patients diagnosed with untreated low-grade B-cell lymphomas who do not require immediate systemic therapy and are appropriate candidates for "watch and wait." Treatment consists of local radiation given over 2 days followed by 5 weekly intratumoral injections of 1, 2, 4, or 8 mg of SD-101. The total duration of patient participation in this study is up to 2 years.

The primary objectives of LYM-01 are:

- ***To assess safety and tolerability of escalating doses of SD-101 administered with low-dose radiation;***
- ***To evaluate the pharmacodynamic profile of interferon-inducible genes in whole blood 24 hours after injection; and***
- ***To determine the maximum tolerated dose or optimal dose.***

A key secondary objective of the study is assessment of the objective response to SD-101 in untreated lesions distant from the lesion in which SD-101 and radiation were administered. All tumor responses are assessed according to the Cheson criteria.

About SD-101

SD-101 is a proprietary, second-generation, TLR 9 agonist CpG oligodeoxynucleotide (CPG ODN). SD-101 directly induces activation and maturation of plasmacytoid dendritic cells, leading to the production of type 1 interferons. Preclinical and early clinical data support the use of TLR 9 agonists in patients with solid tumors and hematologic malignancies. In preclinical studies, TLR 9 agonists have shown activity as monotherapy or in combination with various interventions, including immunotherapeutic and tumor-specific antibodies, cellular therapies, antiangiogenic agents, radiotherapy, and some chemotherapies. SD-101 has been evaluated in two Phase 1 studies to assess its preliminary safety and tolerability.

About Dynavax

Dynavax, a clinical-stage biopharmaceutical company, uses TLR biology to discover and develop novel vaccines and therapeutics in the areas of infectious and inflammatory diseases and oncology. Dynavax's lead product candidate is HEPLISAV-B, a Phase 3 investigational adult hepatitis B vaccine. For more information visit www.dynavax.com.

Forward-Looking Statements

This press release contains "forward-looking" statements, including expectations for the conduct, timing and sufficiency of LYM-01. 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 enroll a sufficient number of subjects into LYM-01 and ultimately complete the study and 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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