Dynavax Presents Phase 1b Data on Inhaled DV281 TLR9 Agonist at the 2019 AACR Annual Meeting

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- Using an investigational safety treatment regimen, inhaled DV281 in combination with systemic nivolumab was well tolerated in a population of heavily pre-treated NSCLC patients
- Target engagement was observed at all dose levels
- Evidence of anti-tumor effects was seen at all dose levels

BERKELEY, Calif., April 02, 2019 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX), a fully-integrated biopharmaceutical company focused on discovering and developing novel vaccines and immuno-oncology therapeutics, today announced results from the ongoing Phase 1b clinical study evaluating the safety of DV281, a novel toll-like receptor (TLR) 9 agonist in combination with nivolumab in patients with advanced or metastatic non-small cell lung cancer (NSCLC). The results were presented today in a poster session at the 2019 American Association for Cancer Research (AACR) Annual Meeting 2019 (Exhibit Hall B, Poster Section 17, Poster Board Number: #18, 1:00 pm. – 5:00 p.m. ET).

DV281 is Dynavax's proprietary investigational TLR9 agonist designed specifically for focused delivery to tumor-burdened lungs for the treatment of primary lung tumors and lung metastases.

“We are very encouraged by what we've seen with the TLR9 agonist DV281 in this safety study, including a favorable safety profile and evidence of target engagement,” said Edward B. Garon, MD, associate professor of medicine at the David Geffen School of Medicine at the University of California, Los Angeles, and principal investigator for the trial. “Lung cancer is the most common cause of cancer-related death, and new options are needed for this difficult disease. These preliminary results support additional evaluation of inhaled DV281 as a unique treatment option to stimulate the body’s immune system to fight lung cancer.”

The Phase 1b clinical study (NCT03326752) is ongoing. Dynavax is currently studying DV281 in this open label, multicenter study to assess the safety and pharmacodynamic activity of inhaled DV281 in combination with nivolumab in patients with advanced or metastatic NSCLC. As of March 5, 2019, 23 heavily pre-treated anti-PD-1/L1 experienced (87% of whom were PD-1/PD-L1 resistant) or naïve advanced NSCLC patients were enrolled in second-line or third-line treatment using a 3+3 design in five dose cohorts.

Key highlights from the clinical data presentation include:

- In this safety study, two doses of DV281 monotherapy followed by combination with nivolumab was well tolerated. No immune-related adverse events such as pneumonitis have been reported.
- Inhalation of DV281 leads to dose-dependent target engagement as measured by induction of IFN-regulated genes at all evaluated dose levels.
- DV281 plus nivolumab demonstrates early signs of antitumor activity in heavily pretreated patients (87% received a prior checkpoint inhibitor +/- chemotherapy.)
    - Dramatic clinical improvement and clear tumor shrinkage at day 50 in a patient treated at 25 mg who was progressing on pembrolizumab.
    - Prolonged stable disease (4 to 8 months) has been observed in all cohorts that have sufficient duration of follow-up.
    - Clear control of target lesions as measured on CT scans and slowing down of tumor growth with significantly extended tumor doubling time.
- The dose escalation phase of the study is ongoing.

“In this safety study in heavily pre-treated patients with advanced lung cancer, we were pleased to see that combination of DV281 and nivolumab was well tolerated and exhibited dose-dependent target engagement,” said Robert Janssen, M.D., chief medical officer of Dynavax. “We were further encouraged by signs of anti-tumor activity, including patients with prolonged stable disease. In addition, we were pleased to see results demonstrating that the combination slowed tumor growth and significantly extended tumor doubling time.”

Activation of dendritic cells through TLR9 in the presence of tumor antigens generates potent T cell-mediated anti-tumor immunity and can substantially improve the response to PD-1 blockade in mouse tumor models.

The combination of an inhaled TLR9 agonist with systemic PD-1 blockade can induce complete clearance of lung tumors as well as distant

metastases and provide a long-term survival benefit in mouse models of lung cancer.

The poster titled “Phase Ib, open label, multicenter study of inhaled DV281, a Toll-like receptor 9 agonist, in combination with nivolumab in patients with advanced or metastatic non-small cell lung cancer (NSCLC)” is available on Dynavax’s website at http://investors.dynavax.com/events-presentations

About DV281
DV281 is Dynavax's proprietary investigational TLR9 agonist designed specifically for focused delivery to primary lung tumors and lung metastases. DV281 is similar in biological activity and mechanism of action to Dynavax's Phase 2 immunotherapy candidate, SD-101, but has been optimized for administration as an inhaled therapy. Both SD-101 and DV281 activate plasmacytoid dendritic cells which then stimulate T cells specific for antigens released from dying tumor cells. TLR9 agonists such as DV281 and SD-101 have been shown to stimulate potent Type 1 interferon induction along with maturation of dendritic cells to effective antigen-presenting cells; both activities are important for the induction of effective 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], is approved in the U.S. 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 Dynavax compound DV281. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether early clinical study results for DV281 will support further development of the compound. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Dynavax in general, see 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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