# Dynavax Technologies and Quantum Leap Healthcare Collaborative Announce Selection of SD-101 Combined with KEYTRUDA® (pembrolizumab) in the I-SPY 2 TRIAL For Breast Cancer

October 15, 2018

BERKELEY, Calif. and SAN FRANCISCO, Oct. 15, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) and Quantum Leap Healthcare Collaborative™ (QLHC) announced today that the immunotherapy combination of Dynavax's proprietary investigational compound SD-101 and KEYTRUDA® (pembrolizumab) will be evaluated in a new randomized, investigational treatment arm for the ongoing I-SPY 2 TRIAL™ for neoadjuvant treatment of locally advanced breast cancer.

SD-101 is an intratumoral TLR9 agonist that modulates the tumor microenvironment and optimally primes T cells to generate a systemic anti-tumor response. SD-101 is expected to augment responses to anti-PD-1 therapy as has been reflected in early clinical studies of other tumor types. The combination will be added to standard of care in a new I-SPY 2 TRIAL treatment arm.

"The I-SPY TRIAL is designed to evaluate multiple emerging new agents simultaneously with the goal of getting effective and potentially less toxic treatments to patients much more quickly. We are excited to add SD-101 into I-SPY 2, and combine it with pembrolizumab with the goal of extending responses previously observed with pembrolizumab alone," stated Dr. Laura J. Esserman, MD, MBA, Principal Investigator of I-SPY 2 and Director of the Carol Franc Buck Breast Care Center at the UCSF Helen Diller Family Comprehensive Cancer Center.

"We are excited SD-101 has been chosen to be included in the I-SPY 2 trial and see this as an excellent opportunity to potentially expand its use into the emerging field of neoadjuvant immunotherapy," stated Eddie Gray, chief executive officer of Dynavax.

The I-SPY 2 TRIAL, sponsored by QLHC, is a standing phase 2 randomized, controlled, multicenter study with an innovative Bayesian adaptive design aimed to rapidly screen and identify promising new treatments in specific subgroups of women with newly-diagnosed, high-risk (high likelihood of recurrence), locally-advanced breast cancer (Stage II/III). Dynavax will provide funding and SD-101; Merck will provide pembrolizumab. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

**About the I-SPY TRIALs**
The I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis) was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The trial is a unique collaborative effort by a consortium that includes the Food and Drug Administration (FDA), industry, patient advocates, philanthropic sponsors, and clinicians from 16 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap Healthcare Collaborative is the trial sponsor and manages all study operations. For more information, visit www.ispytrials.org.

**About Quantum Leap Healthcare Collaborative**
Quantum Leap Healthcare Collaborative (QLHC) is a 501C(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco and Silicon Valley entrepreneurs. Our mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients, and researchers. Quantum Leap provides operational, financial, and regulatory oversight to I-SPY. For more information, visit www.quantumleaphealth.org.

**About SD-101**
SD-101, Dynavax's lead clinical candidate, is a proprietary, second-generation, Toll-like receptor 9 (TLR9) agonist CpG-C class oligodeoxynucleotide. Dynavax is evaluating this intratumoral TLR9 agonist in clinical studies to assess its safety and activity, including a Phase 2 study in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with advanced melanoma and in patients with head and neck squamous cell cancer, in a clinical collaboration with Merck. Dynavax maintains all commercial rights to SD-101.

**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.

**Contact:**
Ryan Spencer
VP Corporate Strategy and Communications
510.665.4618

**Media Contact:**
Rachel St. Martin
W2O
646.894.5757
rstmartin@w2ogroup.com

**Dynavax's Forward-Looking Statements**
This press release contains "forward-looking" statements, including statements regarding conduct of clinical trials of SD-101 and the potential of SD-101 in the treatment of cancer. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including initiation, enrollment and completion of clinical trials of SD-101; 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 SD-101; 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 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 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.


Source: Dynavax Technologies Corporation