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Positive Single-Season Phase 1 Data on Dynavax's AIC Ragweed Allergy Therapy Presented at AAAAI Meeting

BERKELEY, Calif., March 21 /PRNewswire-FirstCall/ -- Dynavax Technologies (Nasdaq: DVAX) announced that data from a Phase 1 clinical trial of the company's AIC ragweed allergy immunotherapy showed that AIC treatment resulted in a clinically significant improvement in symptoms (p=0.052) and a parallel reduction in medication usage during the peak ragweed season compared to placebo. The Phase 1 trial was designed to evaluate the safety and immunogenicity as well as to capture selected clinical efficacy parameters of AIC at higher doses than those used in previous studies.

AIC is currently being evaluated in a 462-patient, multi-site Phase 2/3 clinical trial. Pending the outcome of discussions with the US Food and Drug Administration (FDA) in 2005, Dynavax anticipates initiating a pivotal Phase 3 clinical program in early 2006, and plans to initiate a supportive Phase 3 trial in a pediatric indication in the first half of 2005.

"The Phase 1 safety and efficacy data underscore our enthusiasm for continued development of AIC as a treatment for ragweed allergy and add to our optimism concerning the significant therapeutic potential of this novel intervention," said Dino Dina, M.D., president and chief executive officer.

Continued Dr. Dina: "A key advantage of AIC is the ability to safely administer doses that far exceed conventional immunotherapy and to reach an effective dose in a comparatively short period of time, thus enhancing the convenience, comfort and potential for compliance on the part of the patient. This study reaffirms our previous clinical findings with AIC and provides further insight into its mechanisms of action."

The results presented at the annual meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI) showed that AIC was well-tolerated and safely administered. There were no serious local or systemic adverse events. Mechanistic findings indicated that AIC resulted in a significant rise in both anti-ragweed and anti-Amb a 1 antibody immunoglobulin (Ig) G levels compared to baseline ($p<0.05$) and compared to placebo ($p<0.05$), with no significant increase in IgE allergic antibody levels. These findings are consistent with the mechanism of action of AIC in stimulating a protective Th1 response while not triggering a harmful Th2 response. A significant decrease was observed in the AIC-treated group compared to placebo for the late-phase skin test reaction (p=0.008). This test provides a mechanistic indicator of a decrease in the cells and mediators involved in the maintenance of an allergic response.

The Phase 1 trial data indicate that treatment with AIC prior to a single ragweed season at a peak dose that substantially exceeds what can safely be used with conventional immunotherapy (30 micrograms of AIC compared to 6 micrograms of conventional immunotherapy), and in a dosing regimen that is dramatically shorter to reach peak dosing (seven weeks of AIC compared to six months of conventional immunotherapy) may have an important positive impact on efficacy endpoints of allergic symptoms and medication use.

The data were presented by Abhilash R. Vaishnav, MD and Peter S. Creticos, M.D., principal investigator of the study, from the Johns Hopkins Division of Allergy and Clinical Immunology, Baltimore, Maryland. The presentation was entitled, "Evaluation of Safety and Clinical Efficacy of Higher Dose Immunotherapy with AIC (Immunostimulatory DNA Conjugated with Amb a 1) in Patients with Ragweed-induced Seasonal Allergic Rhinitis (SAR)."

Medical management of seasonal allergic rhinitis is a multibillion-dollar global market. In the U.S. alone, approximately 40 million people suffer from allergic rhinitis. The direct costs of prescription interventions for allergic rhinitis in the US were $8 billion in 2004. Ragweed is the single most common seasonal allergen, affecting up to 75% of those with allergic rhinitis, or 30 million Americans. In addition, 20-30% of those who suffer from allergic rhinitis progress to asthma, leading to increased morbidity and disease management costs.

Phase 1 Study Design

The single-center, double-blinded, placebo-controlled Phase 1 dose-ranging safety trial included 18 ragweed allergic subjects, ages 18 to 60, randomized in a two-to-one ratio of AIC-treated to placebo-treated subjects. The study objective was to evaluate the safety and tolerability of higher starting and finishing doses of AIC as compared to those received in previous studies. The AIC treated group received seven injections over seven weeks. One AIC-treated cohort received doses escalating from 0.3 to 30 micrograms, and the other AIC-treated cohort received doses escalating from 1.2 to 30 micrograms. Both AIC-treated cohorts received the same total amount of drug. The control group was treated with histamine placebo on the same schedule. Subjects were treated December 2003 through January 2004 and evaluated throughout the 2004 ragweed season (August

through October). The primary endpoint was safety. Secondary endpoints included visual analog scores (the total assessment of allergy symptoms) and medication use. Subjects recorded their symptoms in real-time using electronic data collection devices to ensure accuracy and compliance.

About Dynavax

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative products to treat and prevent allergies, infectious diseases, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our clinical development programs are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. ISS are being developed in three initial indications: a ragweed allergy immunotherapeutic, currently in a Phase 2/3 clinical trial; a hepatitis B vaccine that is currently in a Phase 2/3 clinical trial; and an asthma immunotherapeutic that has completed a Phase 2 exploratory trial.

Dynavax cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements, including without limitation all statements related to the therapeutic and commercial potential of Dynavax' AIC treatment for ragweed allergy, the outcome of discussions with the FDA concerning timing of and plans to advance its AIC treatment into a confirmatory Phase 3 clinical trial, plans to advance its other clinical programs into additional clinical trials and demonstrate the potential of its ISS technology. Words such as "believes," "anticipates," "plans," "expects," "intend," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Dynavax that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Dynavax's business including, without limitation, risks relating to: plans and timing of initiating a pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial in children for its AIC treatment in ragweed allergy; the potential for AIC to demonstrate a therapeutic benefit lasting into a second season; the progress and timing of its clinical trials in other indications including hepatitis B and asthma; difficulties or delays in developing, testing, obtaining regulatory approval of, producing and marketing its products; the scope and validity of patent protection for its products; competition from other pharmaceutical or biotechnology companies; its ability to obtain additional financing to support its operations; its ability to maintain effective financial planning and internal controls; and other risks detailed in the "Risk Factors" section of Dynavax's Annual Report on Form 10-K filed on March 18, 2005. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Dynavax undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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CONTACT: Jane M. Green, Ph.D., Vice President, Corporate Communications, of Dynavax Technologies Corporation, +1-510-665-4630, or jgreen@dvax.com

Web site: http://www.dynavax.com
(DVAX)
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