# Dynavax Announces Rapid, Expanded Enrollment in Ragweed Allergy Pediatric Trial

**Study Designed to Support Pivotal AIC Phase 3 Trial**

BERKELEY, Calif., July 11, 2005 /PRNewswire-FirstCall via COMTEX/ -- Dynavax Technologies (Nasdaq: DVAX) announced that enrollment in the company's clinical trial of its AIC (Amb a 1 immunostimulatory conjugate) ragweed allergy immunotherapy in ragweed allergic children has exceeded expectations relative to speed of enrollment and number of study subjects. 315 subjects aged six to 15 years have been enrolled in the 19-center trial in less than two and one-half months, exceeding the original expectation of 280 subjects. The company attributes the rapid, expanded enrollment to strong investigator and subject interest in AIC due to its demonstrated tolerability and its potential to offer a more effective and convenient therapy for ragweed allergic children. This clinical trial is designed to be supportive of the company's pivotal AIC Phase 3 trial, anticipated to begin in the first half of 2006.

The primary endpoint of this clinical trial is reduction in hay fever symptoms after two seasons and a secondary endpoint is the prevention of the development of asthma symptoms over three years. It is estimated that approximately 25% of those who suffer from allergic rhinitis progress to asthma, leading to increased morbidity and disease management costs. Approximately 20 million Americans suffer from asthma and approximately nine million of those affected are children.

Dynavax is working with the Clinical Research Network (CRN), Allergy & Respiratory, LLC to conduct the trial in ragweed study coordinators whose mission is to conduct on-time, high quality clinical trials in the allergy, asthma and respiratory fields.

"Ragweed allergic children face a very high risk of developing allergic asthma, a serious medical condition that disrupts their young lives, requires long-term dependence on steroids, and for which a safe and effective preventive therapy is urgently needed," said Anjuli Seth Nayak, MD, Sneeze, Wheeze and Itch Associates, Normal, IL, principal investigator on the study and a member of CRN. "We are optimistic that AIC can provide an innovative, convenient and effective alternative to conventional immunotherapy. We believe that the two- and three-year endpoints are sensible and should provide realistic insight into the potential of AIC to reduce allergic symptoms and forestall the 'allergic march' to asthma in children."

The double-blinded, placebo-controlled trial will be conducted through three ragweed seasons, 2005 through 2007. In the 2005 season, subjects will be treated with AIC or placebo in a one-to-one randomization, and will receive six doses over six weeks prior to the start of the ragweed season. Two booster shots will be administered prior to the 2006 and the 2007 ragweed seasons on a blinded basis. The company will perform an analysis of the results based on the primary endpoint after the 2006 season. The secondary endpoint results will be evaluated following the 2007 season.

"We are gratified by the strong interest within the allergy community in evaluating AIC as a potential intervention in preventing the progression from allergy to asthma," said Dino Dina, MD, president and chief executive officer. "We are especially appreciative of the participation in this trial of the CRN and their valuable contribution to this important undertaking."

In 2004, Dynavax conducted a Phase I clinical trial of AIC in ragweed allergic children. That trial included 24 children, six to 17 years of age, 18 of whom received AIC. There were no serious or severe treatment-associated adverse events reported in that trial.

AIC is currently being evaluated in a 462-patient, multi-site Phase 2/3 clinical trial. The re-enrollment rate for the second season of this two-year trial was also extremely high -- more than 86% of the initial patient population has remained in the study. The company attributes this success to strong investigator interest in AIC, an aggressive retention program and the high level of tolerability of the therapy. Pending the results of this trial, anticipated in the first quarter of 2006, and the outcome of discussions with the FDA, Dynavax anticipates initiating a pivotal Phase 3 AIC clinical program in early 2006. If the results are positive, the pediatric AIC trial could enable Dynavax to establish efficacy in an additional target population, and could be valuable in expanding the potential labeling for the AIC therapy, should it receive marketing approval from the FDA following the completion of the pivotal Phase 3 program.

Medical management of seasonal allergic rhinitis is a multibillion-dollar global market. In the US 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.

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. Dynavax's pipeline includes: a ragweed allergy immunotherapeutic, currently in a large-scale Phase 2/3 clinical trial, and in a supportive clinical trial in ragweed allergic children; a hepatitis B vaccine that is currently in a pivotal Phase 3 clinical trial; a cancer therapy currently in a Phase 2 clinical trial; and an asthma immunotherapeutic that has shown preliminary safety and pharmacology in a Phase 2a clinical 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 in ragweed allergic children; the potential outcome of the currently ongoing Phase 2/3 clinical trial of AIC; the outcome of discussions with the FDA concerning timing of and plans to advance its AIC treatment into a pivotal 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 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" sections of Dynavax's Annual Report on Form 10-K filed on March 18, 2005 and Dynavax's quarterly report on Form 10-Q filed on May 9, 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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