



Dynavax Announces Interim Analysis From Ragweed Allergy Phase 2/3 Trial

Positive Trends Relative to Primary and Secondary Endpoints Demonstrated

BERKELEY, Calif., Dec. 20 /PRNewswire-FirstCall/ -- Dynavax Technologies (Nasdaq: DVAX) announced that the one-year interim analysis of the company's two-year Phase 2/3 clinical trial of its ragweed allergy ISS-based therapeutic (AIC, or Amb a 1 ISS conjugate) showed a clear positive trend relative to the trial's major endpoint of nasal symptom scores, as well as other secondary endpoints, following the 2004 ragweed season. The interim analysis indicated that AIC was safely administered and systemic adverse reactions were similar between the AIC and control arms.

Dynavax intends to complete the two-year clinical trial as planned, a decision that was endorsed by an independent Drug Safety Monitoring Board. Manufacturing of the Phase 3 clinical supply of AIC will also be completed. The ongoing 462-patient Phase 2/3 clinical trial, which was initiated in early 2004 and whose primary endpoint is the reduction of nasal symptom scores during the summer/fall 2005 ragweed season, will remain blinded until those data are collected and fully analyzed.

Pending the outcome of discussions with the US Food and Drug Administration (FDA) in early 2005, Dynavax will determine the design, target populations and timing of initiating a pivotal Phase 3 clinical program, now expected to begin in 2006. In addition, Dynavax will discuss with the FDA plans to initiate a supportive Phase 3 trial in a pediatric indication in 2005.

"We believe that the positive trends shown in the AIC Phase 2/3 interim analysis suggest a therapeutic benefit and we are optimistic that the benefit will last, and potentially increase, through the second season," said Dino Dina, MD, president and chief executive officer. "This promising outcome, combined with recently reported positive Phase 2/3 interim clinical results with our hepatitis B vaccine, support the clinical rationale for pursuing ISS- based approaches in other allergies such as grass, peanut and cedar, as well as in inflammatory and viral diseases. We believe that our AIC therapy has the potential to provide an important therapeutic alternative for hay fever sufferers and could become a significant commercial opportunity for Dynavax. We look forward to upcoming discussions with the FDA concerning timing and scope of a Phase 3 AIC clinical program."

In February 2004, Dynavax and UCB Pharma established a strategic partnering agreement for development and commercialization of seasonal allergy products. Dynavax understands that UCB is reviewing its commitment to the program. Should UCB Pharma opt to exercise its contractual right to return the allergy program to Dynavax, Dynavax is planning to pursue the ongoing development of AIC independently.

Design of the Phase 2/3 Clinical Trial

Over the last several years, Dynavax has generated a substantial amount of clinical data on AIC. AIC has been tested in 14 clinical trials in the U.S., France, and Canada, and more than 3,000 AIC injections have been administered to over 500 ragweed allergic people. Data from earlier trials have shown AIC to be safe and well tolerated, to provide improvements in allergy symptoms, and to reduce medication use.

The ongoing Phase 2/3 AIC clinical trial, initiated in the first quarter of 2004, is a two-year, double-blind, placebo-controlled study being conducted at 29 sites in the midwestern, southwestern and eastern US. The trial involves 462 subjects with moderate to severe ragweed allergy (hay fever). Prior to the 2004 ragweed season, which generally lasts from August through October, subjects received six weekly doses of either placebo or escalating doses of up to 30 micrograms of AIC, in a two-to-one randomization, AIC to placebo group. Prior to the 2005 ragweed season, one half of the AIC-treated subjects will receive two additional booster shots. The other half of the AIC-treated group will receive placebo injections and the original placebo-treated group will receive placebo injections. The primary endpoint of this trial is the change in the total nasal symptom score following the 2005 ragweed season. Secondary endpoints include reduction in medication usage and improvement in quality of life scores. The design of the trial should also permit comparison of the AIC- treated groups with and without the booster dose.

The blinded interim analysis was conducted following the first year ragweed season with the goal of providing a basis for determining the timing and scope of the Phase 3 clinical program. The actual design of the Phase 3 program is under review and is anticipated to include an early intervention trial in children designed to prevent allergic rhinitis and progression to asthma.

About ISS and Allergy

ISS are short synthetic DNA molecules that stimulate a Th1 immune response while suppressing Th2 immune responses. ISS

contain specific sequences that activate the innate immune system. ISS are recognized by a specialized subset of dendritic cells containing a unique receptor called Toll-Like Receptor 9, or TLR-9. The interaction of TLR-9 with ISS triggers the biological events that lead to the suppression of the Th2 immune response and the enhancement of the Th1 immune response. ISS influence helper T cell responses in a targeted and highly specific way by redirecting the response of only those T cells involved in a given disease. ISS, in conjunction with an allergen or antigen, establish populations of memory Th1 cells, allowing the immune system to respond appropriately to each future encounter with a specific pathogen or allergen, leading to long-lasting therapeutic effects.

AIC consists of 1018 ISS linked to the purified major allergen of ragweed, called Amb a 1. AIC targets the underlying cause of seasonal allergic rhinitis induced by ragweed pollen. The linking of ISS to Amb a 1 is designed to ensure that both ISS and ragweed allergen are presented simultaneously to the same immune cells, with the goal of producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy. This treatment is intended to reprogram the immune response away from the Th2 response and toward a Th1 memory response so that, upon subsequent natural exposure to the ragweed allergen, long-term immunity can be achieved.

Potential AIC Commercial Opportunity

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. Ragweed is the single most common seasonal allergen, affecting up to 75% of those with allergic rhinitis, or 30 million Americans. The direct costs of prescription and over-the-counter interventions for allergic rhinitis in the U.S. are estimated to exceed \$7 billion. In addition, 20-30% of those who suffer from allergic rhinitis progress to asthma, leading to increased morbidity and disease management costs. Dynavax believes that a significant market opportunity exists for AIC in the treatment of ragweed allergic individuals currently undergoing conventional immunotherapy or using multiple prescription or OTC medications. In addition, the product may also play a role in earlier stage disease, potentially preventing the "allergic march" from allergic rhinitis to asthma.

Dynavax will hold a conference call to discuss its AIC clinical program today at 10:00 a.m. Eastern Time. Interested parties may listen to the webcast live at <http://www.dynavax.com>. The webcast is also being distributed over CCBN's Investor Distribution Network to both institutional and individual investors. Individual investors can listen to the call through CCBN's individual investor center at <http://www.fulldisclosure.com> or by visiting any of the investor sites in CCBN's Individual Investor Network. Institutional investors can access the call via CCBN's password-protected event management site, StreetEvents, at <http://www.streetevents.com>. A telephonic replay will be available through December 28, 2004 by dialing 888-286-8010, conference identification number 54830688. International callers can dial 617-801-6888, conference identification number 54830688.

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: ragweed allergy immunotherapeutic, currently in a Phase 2/3 clinical trial; a Hepatitis B vaccine that has completed a Phase 2 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; its ability to manage its relationship with its collaboration partner; the ability of the company to ensure adequate clinical supply of AIC required to complete the Phase 3 clinical program; 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 30, 2004, and in the section titled "Additional Factors That May Affect Future Results" within Dynavax's quarterly report on Form 10-Q filed on November 8, 2004. 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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