

Dynavax Presents Positive TOLAMBA Phase 2/3 Results at AAAAI Meeting

Safety and Efficacy Endpoints Achieved Following Single, Short Course of Therapy

BERKELEY, Calif., March 6, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) presented positive results from a well-controlled, two-year, multi-center Phase 2/3 clinical trial of TOLAMBA[™], a ragweed allergy immunotherapeutic, in an oral presentation at the 2006 annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in Miami, Florida. Data showing safety and statistical significance relative to the efficacy endpoints in the study were presented by the principal investigator for the trial, Dr. William W. Busse, MD, Professor of Medicine, University of Wisconsin-Madison, Clinical Science Center and a past president of AAAAI.

"The results of the TOLAMBA Phase 2/3 clinical trial are encouraging and suggest that TOLAMBA has potential as a disease modifying agent that can reprogram the immune system and reduce the allergic response," said Dr. Busse. "The data suggest that TOLAMBA can produce a meaningful treatment effect above that which can be achieved with conventional allergy medications, that it is safe and provides a long duration of effect after only a single short course of therapy. TOLAMBA warrants continued development and has the potential to represent a new standard of care for ragweed allergics who today remain underserved by treatments that provide only temporary symptomatic relief."

Phase 2/3 Clinical Trial Results

The Phase 2/3 trial achieved its efficacy endpoint which was the change from baseline in total nasal symptom scores (TNSS) during the peak period of the 2005 ragweed season for the TOLAMBA-treated group compared to the placebo group. Secondary endpoints included: TNSS change from baseline in the first season; ocular symptoms scores; nasal/ocular symptom scores; combined hayfever symptom scores; medication use (fexofenadine and pseudoephedrine) and safety.

The TOLAMBA-treated group received a single short, six-injection/six-week course of therapy prior to the 2004 ragweed season. Prior to the 2005 season, one half of these subjects received a two injection/two week booster. TNSS is measured using four parameters (congestion, sneezing, itching and runny nose) each rated on a four-point scale (0-3).

Key results from the study, based on a final analysis of the available data to date, are the following.

-- Patients treated with a single six-week course of TOLAMBA prior to the 2004 season experienced a statistically significant reduction in total nasal symptom scores (TNSS) change from baseline during the two-week peak season compared to placebotreated patients in the first year of the trial (21.2% effect, p=0.04) and in the second year of the trial (28.5% effect, p=0.02). The treatment effect was achieved on top of a background of antihistamine and decongestant use.

-- The group receiving a single course of TOLAMBA achieved a statistically significant reduction in actual TNSS compared to placebo in both the 2004 and 2005 seasons (p=0.02 and p=0.04, respectively).

-- The group receiving a single course of TOLAMBA achieved a statistically significant reduction in major secondary endpoints such as hayfever composite score (p=0.04).

-- The group receiving a single course of TOLAMBA achieved a statistically significant reduction in antihistamine use and in decongestant use (p=0.04 and p=0.03, respectively);

-- The safety profile of TOLAMBA was favorable. Systemic side effects were indistinguishable from placebo; there were no incidents of anaphylaxis. Local injection site tenderness was minor and transient.

Booster Arm Response

In the arm of the trial in which subjects received a two-shot booster prior to the second (2005) season, statistical significance compared to placebo was not achieved relative to the primary endpoint (p=0.28; treatment effect 13.5%) or secondary endpoints (actual TNSS p=0.6; hayfever composite p=0.12; reduction in antihistamine use p=0.29; reduction in decongestant use p=0.49).

At AAAAI, Dr. Busse discussed a hypothesis for the booster group's results, suggesting that systemic boosting prior to the second season may alter lymphocyte trafficking that occurs following dosing in the first season. Boosting may redirect protective immune cells away from the nasal and ocular mucosa, to which they migrate during exposure to allergen in the first ragweed season, back to regional lymph nodes, where antigen (allergen) is being presented via systemic booster injection, thus reducing the number of potentially protective immune cells in the local environment.

As previously announced, Dynavax plans to conduct a TOLAMBA clinical trial designed to test a more intensive dosing

regimen. This trial is anticipated to start by the beginning of the second quarter 2006 to take advantage of the 2006 ragweed season.

Phase 2/3 Trial Design

The Phase 2/3 TOLAMBA clinical trial, initiated in early 2004, was a two-year, randomized, double-blind, placebo-controlled study conducted at 29 sites in the midwestern, southwestern and eastern US. The trial involved 462 subjects, aged 18 to 55 years, 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 TOLAMBA, in a two-to-one randomization, TOLAMBA to placebo group. Prior to the 2005 ragweed season, one half of the TOLAMBA-treated subjects received two additional booster shots. The other half of the TOLAMBA-treated group received placebo injections and the original placebo-treated group received placebo injections. The trial protocol permitted subjects to self-administer pseudoephedrine hydrochloride (Sudafed®, Pfizer, Inc.) and fexofenadine hydrochloride (Allegra®, sanofi-aventis), as needed.

The primary objective of the trial was to assess the treatment difference in a subject-rated 24-hour total nasal symptom score. Efficacy is measured as the change from baseline in TNSS during the peak period of the 2005 ragweed season of the TOLAMBA-treated groups compared to the placebo group. TNSS includes nasal symptoms (congestion, sneezing, itching and runny nose) rated on a four-point scale. Patients recorded their symptoms electronically on a daily basis. Results were analyzed comparing the TOLAMBA-to-TOLAMBA and TOLAMBA-to placebo groups to the placebo-to-placebo treatment group over the two-week peak period of the 2005 ragweed season.

About ISS Technology and TOLAMBA

Immunostimulatory sequences (ISS) are short synthetic DNA molecules that stimulate a Th1 immune response while suppressing Th2 immune responses. ISS contain specialized 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.

TOLAMBA consists of Dynavax's proprietary ISS molecule linked to the purified major allergen of ragweed, called Amb a 1. TOLAMBA is designed to target the underlying cause of seasonal allergic rhinitis caused by ragweed. The conjugation of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy.

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: TOLAMBA, a ragweed allergy immunotherapeutic anticipated to enter a Phase 3 pivotal trial and currently in a supportive clinical trial in ragweed-allergic children; HEPLISAV, 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 pharmacologic activity 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 forwardlooking statements, including without limitation all statements related to the positive outcome of the TOLAMBA Phase 2/3 clinical trial; plans to conduct an additional TOLAMBA clinical trial that includes an accelerated, more intensive dosing regimen and that is anticipated to start by the beginning of the second guarter of 2006; and statements related to plans to advance its clinical programs in hepatitis B and cancer and the commercial opportunities for those programs. 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: the progress and timing of its clinical trials in other indications including hepatitis B, cancer 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, Dynavax's guarterly report on Form 10-Q filed on November 14, and Dynavax's Prospectus Supplement filed on October 11, 2005. You are cautioned not to place undue reliance on these forwardlooking 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

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SOURCE Dynavax Technologies Corporation

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