



Dynavax Reports Interim, One-Year Data From Ragweed Allergy Trial at AAAAI

Clear Therapeutic Benefit Seen in Regional Analysis; New Trial Design Needed

BERKELEY, Calif., Feb 23, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Dynavax Technologies Corporation (Nasdaq: DVAX) today reported interim data from the first year of its two-year ragweed allergy trial known as DARTT, including a prespecified regional analysis of sites that clearly showed a therapeutic benefit of TOLAMBA in the Midwest. These data and the results of an in-depth analysis of 716 evaluable patients at 30 U.S. centers will be presented by Dr. Eduardo Martins, Dynavax VP, Clinical Development, on Saturday, February 24, at 2:30 p.m. PST, at the AAAAI Annual Meeting in San Diego.

As previously reported on January 8, Dynavax's analysis of total nasal symptom scores (TNSS) in the overall study population indicated that only minimal ragweed-specific allergic disease was observed, and as a result, meaningful efficacy could not be measured.

Dr. Martins explained, "A prespecified regional analysis demonstrated that sites in the Midwest -- comprising over half the study population -- did in fact include patients with more pronounced ragweed symptoms. In this group, the therapeutic benefit of TOLAMBA in reducing total nasal symptom scores was evident, as reflected in a clinically meaningful reduction of TNSS in the treated patients.

"Despite enrollment criteria that were analogous to those used in the Phase 2b trial reported at AAAAI last year as having demonstrated statistically significant efficacy, the DARTT trial was inconclusive because the enrolled subjects did not show sufficient ragweed symptoms in the peak season. We have therefore concluded that the entry requirement of a clinical history and skin test were insufficient to reproducibly select subjects with measurable disease. Unfortunately, the pediatric TOLAMBA trial suffered from the same limitation. The level of disease in the trials' study populations is so low that we believe the planned second- and third-year follow-up analyses for DARTT and the pediatric trial are unlikely to yield valuable data. We have decided to discontinue both studies.

Dr. Martins continued, "The DARTT study is not the first allergy trial to suffer from the lack of measurable disease; the results underscore the ongoing challenges of allergy trial design. However, from the regional data, we gained important insights into solutions that would minimize the risk of enrolling a large number of patients who do not have ragweed-specific disease. Importantly, the data provide a rationale for continuing to evaluate our TLR9-based approach for treating ragweed and other allergic diseases. To advance the drug toward commercialization, we will need to design new trials, define a clear regulatory path, and evaluate both the timelines and cost of completing the program."

The DARTT (Dynavax Allergic Rhinitis TOLAMBA Trial) study was a 30-center, placebo-controlled study that enrolled 738 ragweed allergic subjects, aged 18 to 55 years. The study randomized subjects into three arms: the same dosing regimen that was used in the completed Phase 2b trial; a higher total dose regimen; and placebo. Subjects received six doses of TOLAMBA over six weeks prior to the start of the 2006 ragweed season. TOLAMBA consists of Dynavax's proprietary immunostimulatory sequences (ISS) 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 linking 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 TLR9 agonist-based products to treat and prevent allergies, infectious diseases, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists 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. Our pipeline includes: HEPLISAV(TM), a hepatitis B vaccine in Phase 3; TOLAMBA (TM), a ragweed allergy immunotherapeutic; and a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1. Our preclinical asthma and COPD program is partnered with AstraZeneca. NIH partially funds our preclinical work on a vaccine for influenza; Symphony Dynamo, Inc., funds our colorectal cancer trial and our preclinical programs in hepatitis B and C therapies. While the NIH and Symphony provide program support, Dynavax has retained rights to seek strategic partners for future development and commercialization. For more information, please visit <http://www.dynavax.com>.

This press release contains forward-looking statements that are subject to a number of risks and uncertainties, including

statements about our product candidates, clinical development plans and timelines, business plans and financial position. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in our business, including the potential for further development of TLR9 approaches to the treatment of ragweed and other allergic diseases; the potential for and timing and costs of further TOLAMBA development efforts; and other risks detailed in the "Risk Factors" section of our Annual Report on Form 10-K and Quarterly Report on Form 10-Q. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

SOURCE Dynavax Technologies Corporation

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