# Dynavax Pipeline

## Clinical Development Programs

<table>
<thead>
<tr>
<th>Allergy</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>BLA</th>
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<tbody>
<tr>
<td>Ragweed Allergy</td>
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<td>HBV Vaccine</td>
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<td>Asthma</td>
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## Early-Stage Programs

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<tr>
<th>Allergy</th>
<th>Vaccines</th>
<th>Other</th>
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<tbody>
<tr>
<td>Peanut</td>
<td>Anthrax</td>
<td>Cancer</td>
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<tr>
<td>Cedar</td>
<td>Flu</td>
<td>TZP</td>
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<td>IRS</td>
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Significant healthcare dollars are spent annually on managing diseases that affect the immune system and on preventing transmission of viral disease. In the U.S., for example, the direct costs of prescription medications for allergic rhinitis are estimated to exceed $8 billion per year. These treatments provide only temporary symptomatic relief, carry the risk of side effects and require chronic administration. The spread of viral diseases such as hepatitis B (HBV), hepatitis C, flu, and more recently, avian flu, continues to increase prevention and treatment costs on a global scale. The worldwide market for HBV vaccination is approximately $1 billion. Major unmet medical needs exist in hepatitis B vaccination relative to enhanced efficacy, particularly in difficult to immunize segments, faster protection and accelerated immunization schedules to enhance compliance.

While treatment options exist for these large markets, they remain underserved. The public health need for more effective, targeted interventions designed to redress the underlying pathology of immune system disorders is significant. Dynavax’s ISS-based vaccines and immunotherapies are designed to offer more effective, convenient and durable alternatives to traditional interventions. By reprogramming the immune system’s ability to recognize and respond appropriately to allergens or antigens, ISS are designed not simply to mask symptoms, but to modify the actual disease state by stimulating the body’s innate ability to mount a protective immune response.
A Year of Growth and Achievement

In 2004, Dynavax made significant progress in advancing clinical programs into late-stage development, providing clinical validation for its ISS-based programs, and building a commercial strategy. Our initial public offering provided additional financial resources with which to advance our growing pipeline. We conducted multiple clinical trials, including two Phase 2/3 clinical programs in ragweed allergy and for a vaccine against hepatitis B, and demonstrated favorable results in the interim analyses of both. We believe that these programs represent important commercial opportunities for the company and underscore the broad applicability of our ISS-based approach to treating immune system disorders. We strengthened our organization and our management team and believe that we possess the skills needed for Dynavax to move into its commercial phase.

ISS & Allergy: Transforming the Allergen into a Drug

Dynavax’s approach to allergy chemically links ISS to the allergen so that when the combined molecules are simultaneously presented to the immune system, a strong protective or Th1 response is induced and the Th2 cells responsible for inflammation associated with the target allergy are suppressed. Upon repeated exposure to the allergen, Th1 memory cells are activated, with the potential for the treated individuals to develop a long-term protective response.

AIC consists of 1018 ISS linked to the purified ragweed allergen Amb a 1. 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. AIC is currently in the second year of a 462-patient two-year Phase 2/3 clinical trial being conducted at 29 sites in the U.S. The primary endpoint is reduction of nasal symptom scores at the end of two years, with secondary endpoints of reduction of medication use and improvement in quality of life. We conducted an interim analysis of the ongoing Phase 2/3 trial after the first (2004) season with the goal of providing a basis for implementation of a pivotal Phase 3 program. We believe the interim analysis showed clear positive trends relative to the primary endpoint of reduction of nasal symptoms as well as a positive benefit in reduction of medication use. We are pleased with this outcome, as it supports advancing to a pivotal Phase 3 program. It also strengthens our belief that our ISS-based approach can reprogram the immune system and that we can apply this approach to other allergies, such as peanut and cedar. We plan to complete the ongoing Phase 2/3 program and analyze results following the 2005 ragweed season.

We are committed to moving our AIC Phase 3 program forward expeditiously. In April 2005, we initiated a Phase 3 early intervention trial in children designed to reduce seasonal allergic rhinitis symptoms and prevent progression to asthma. The Phase 3 trial is a U.S.-based, multi-center study in up to 280 children, ages 6-15, with a primary endpoint of reduction in hay fever symptoms and a secondary endpoint of preventing progression to asthma. We will perform an analysis based on the primary endpoint after two years. Assuming a positive outcome, this supportive trial could enable us to establish efficacy in an additional target population, and be valuable in expanding the potential use of the AIC product.

Our goal is to initiate a pivotal Phase 3 clinical trial of AIC in 2006. Pending discussions with the FDA, this trial would be designed as a two-year, multi-center, U.S.-based trial with more than 800 patients. We would plan to conduct an interim analysis after one year, which, if positive, could help to support a registration filing, potentially in late 2007. Assuming a positive outcome after two years in the pediatric early intervention trial, those data could support our filing as well.

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 U.S. 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. We believe that a significant market opportunity exists for AIC in the treatment of ragweed allergic individuals. These include severely allergic people currently undergoing immunotherapy as well as people with mild to moderate allergies who try to manage symptoms with prescription and over-the-counter medications. In addition, AIC may also have utility in earlier stage disease, potentially preventing the progression from allergic rhinitis to asthma.

In early 2005, we reacquired full rights to our seasonal allergy program from UCB Farchim. The mutual decision between our companies to end our development and commercial collaboration provides Dynavax with an opportunity to commercialize products from this program independently or to establish alternative collaborations.

**Hepatitis B Vaccine: Better Protection, Faster**

In two separate clinical trials, we have demonstrated the superiority of our HBV vaccine over GlaxoSmithKline’s Engerix-B® HBV vaccine, the industry standard. Data from a comparative Phase 2 trial in Canada in 99 healthy young adults randomized to our vaccine or Engerix-B showed that our vaccine induced a protective HBV antibody response in 79% of subjects after one injection and in 100% of subjects after the second injection, given two months after the first injection. The 100% seroprotection in the ISS-treated group was sustained more than one year later. In marked contrast, subjects receiving Engerix-B had protective HBV antibody responses after the first and second injections in 12% and 64% of recipients, respectively. After the third dose given six months later, the Engerix-B treated group achieved 98% seroprotection; after one year, that level had fallen to 90%.

We conducted an interim analysis of the Phase 2/3 clinical trial comparing our HBV vaccine with Engerix-B in older, more difficult to immunize adults. Our vaccine demonstrated statistically significant superiority in protective antibody response and robustness of protective effect after two vaccinations compared to Engerix-B. The primary endpoint is seroprotection four weeks after the third injection, and we are following subjects for an additional five months to assess outcomes after a full year. We anticipate being able to discuss the primary endpoint results from this trial in the first half of 2005.

Around mid-year 2005, we plan to initiate a pivotal Phase 3 trial of our HBV vaccine in approximately 400 older adults, ages 40-70 years. This trial will compare safety, seroprotection and antibody titers in two groups, one treated with Engerix-B and one treated with our vaccine. Study centers will be located in Singapore, Taiwan, Korea and the Philippines. We plan to start a second pivotal Phase 3 trial in younger adults, ages 18-39 years, in Canada and Europe in early 2006. Assuming a positive outcome, our goal is to submit our first registration filing following the completion of the Phase 3 pivotal program, slated for 2007.

We believe the potential health benefits of our HBV vaccine – enhanced immunogenicity (particularly in difficult to immunize groups), faster protection and fewer doses – are compelling, and that strategic opportunities for a highly differentiated product exist in Canada, Europe and selected countries world-wide. Our initial commercialization activities will likely target these markets and focus on high-value, underserved populations, including pre-hemodialysis patients, HIV-positive patients, other populations with compromised immune systems, as well as professionals in healthcare and law enforcement for whom achieving seroprotection quickly is critical. We believe there may also be opportunities within the U.S. market targeting these populations.

Solidifying our commercial strategy for our HBV vaccine is a key goal for 2005. We have a long-term supply contract with Switzerland-based Berna Biotech AG that includes a commercialization option, and our companies are in the early stage of discussing this option. There may be opportunities to explore additional relationships that could be beneficial to us in target markets of interest.
Asthma: Stopping the “Allergic March”

The incidence of asthma is increasing and often occurs in response to triggering allergens. It is estimated that at least 75% of patients with asthma also have allergic symptoms and 20-30% of those with allergic rhinitis also have asthma. To treat asthma, we administer ISS alone directly to the lung, to take advantage of the allergens that are already resident in the lung to stimulate a protective immune response. We believe a key advantage of our approach is the potential to change the underlying immune disorder itself. In preclinical studies, we have shown that ISS alone can inhibit the key features of asthma, and we have demonstrated the preliminary safety and pharmacologic activity of this therapy in mild asthmatic patients in Phase 2a studies. Our goal is to continue to advance the asthma clinical program.

Valuable Assets

We have focused our efforts on advancing first-generation programs through the clinic and toward the market. Recognizing the large commercial value of novel approaches to immune system disorders, we have generated a substantial early-stage pipeline in vaccines and allergy therapeutics. We have cultivated additional novel, proprietary technologies that complement ISS and that could represent next-generation development programs. In 2004, we advanced several key preclinical programs.

We established a collaboration with the Riken Institute in Japan for development of ISS-based cedar tree allergy therapeutics. Cedar tree allergy is a serious public health challenge in Japan. The disease afflicts over fifteen million sufferers, representing approximately 12% of the country’s total population.

We presented preclinical data showing that our peanut immunotherapy (which consists of ISS linked to the peanut allergen Ara h 2) demonstrated potent inhibition of harmful allergic responses and induction of therapeutic immune responses to peanut allergen. There are currently no approved products to prevent peanut allergy. In the U.S., approximately 1.5 million people have a potentially life-threatening allergy to peanuts and the incidence is growing rapidly.

We introduced a new approach to treating autoimmune disease based upon immunoregulatory sequences or IRS, a novel class of oligonucleotides, which specifically inhibit the TLR-induced inflammatory response implicated in disease progression. We are exploring development of an IRS-based treatment for autoimmune disease, including systemic lupus erythematosus (SLE or lupus).

Our flu and anthrax vaccine programs, funded by grants from the National Institute of Allergy and Infectious Disease (NIAID), have each demonstrated enhanced potency and effectiveness over currently marketed products in preclinical studies.

Outlook for the Future

We believe that we strengthened our company’s foundation in 2004 as well as our standing as an innovator in the understanding and treatment of immune system disorders. In 2005 we will focus use of our resources on advancing our two lead programs in ragweed allergy and HBV vaccination. We anticipate completing the ongoing Phase 2/3 clinical trial of AIC for ragweed allergy and advancing our Phase 3 program. We plan to initiate the first Phase 3 clinical trial of our HBV vaccine to be followed by initiation of a second pivotal Phase 3 trial in early 2006. We plan to invest prudently in earlier-stage programs and to manage carefully our finances while seeking appropriate opportunities to fund our operations. We will focus on building the value of our key assets and advance toward establishing a commercial presence.

We are proud of our accomplishments. We have made a lot of progress in a short period of time, largely due to the dedicated efforts of our talented employees, the strength of our management team and the support of our Board of Directors. We appreciate our investors’ continued confidence and look forward to a productive 2005.

Dino Dina, M.D.
President, Chief Executive Officer and Director
Dynavax cautions you that statements included in this annual report that are not a description of historical facts are forward-looking statements, including, without limitation, all statements related to plans to advance its clinical programs 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 annual report 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; 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 and in the section titled “Additional Factors That May Affect Future Results” within Dynavax’s quarterly report on Form 10-Q. 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 annual report to reflect events or circumstances after the date hereof.