AVAX TECHNOLOGIES, INC.



Harnessing the patient's immune system for the treatment of cancer

2006 –2007 Achievements

- Phase III Registration study for MVax® cleared for launch by FDA
- Obtained SPA Agreement for Initiation of Phase III Program – Accelerated Approval
- $10M Equity Raise
- Finalizing for publication Phase I/II study in Stage III & IV melanoma
- Continue Phase I/II trial for NSCLC
- Completed cGMP facility review of Lyon facility
- $1.2M Collaboration of CTCA on OVARIAN Trial
- Expanding compassionate use in Belgium, Spain, Greece and South America

2008-2009 Objectives

- Begin enrollment of MVax Phase III Registration Trial
- Initiate Phase I/II in Ovarian
- Present clinical data from Phase I/II melanoma studies
- Complete Phase I/II in NSCLC
- Complete Phase I/II Studies in Ovarian & NSCLC
- Design Phase III studies in Second Indication

AVAX TECHNOLOGIES, INC. specializes in the development and commercialization of a universal immunotherapy for cancer. The **Autologous Cell (AC) Vaccine®** Platform Technology is a patented, therapeutic approach that stimulates the patient's own immune system to recognize, contain and eliminate cancer cells.

In November 2006 AVAX reached a significant milestone when it announced the US FDA cleared AVAX to launch its **Phase III – Registration study** for **MVax®,** the AC Vaccine Technology (AC Vaccine) for **Melanoma**. In October 2006, AVAX obtained a **Special Protocol Assessment (SPA)** agreement with the U.S. Food and Drug Administration (FDA) for its **Phase III Protocol.** The SPA allows for the start of the **Phase III Registration** clinical trial for MVax, AVAX's Autologous Cell Vaccine for the treatment of patients with metastatic melanoma. In addition, the SPA addressed AVAX's ability to use a **Surrogate Endpoint** as a basis for **Accelerated Approval.** An SPA is a written agreement between AVAX and the FDA regarding the trial design, surrogate endpoints to be used as a basis of filing for accelerated approval of MVax and the statistical analysis plan necessary to support the full regulatory approval of MVax.

MELANOMA: MVax® Melanoma is the most serious form of skin cancer and afflicts approximately 400,000 people worldwide. The American Cancer Society estimates that approximately 47,700 new cases are diagnosed each year in the U.S., with over 7,700 people dying from the disease annually.

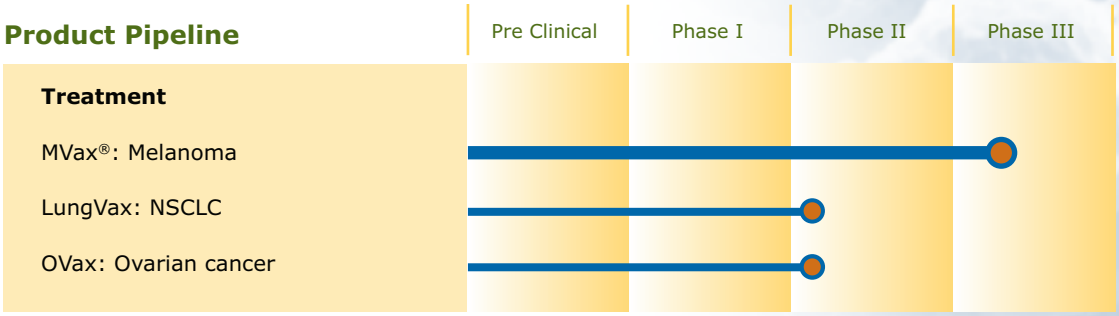
MVax is AVAX's post-surgical autologous cell vaccine for Stage III & IV melanoma. To date, over 570 patients have been treated with MVax on an outpatient basis. In February 2004 the Journal of Clinical Oncology published an article by Dr. David Berd on the treatment of 214 Stage IIIb and IIIc melanoma patients that showed a **five-year survival rate of 44%.** Comparison to published results of similar patients treated with surgery alone showed five-year survival figures of 22%. In stage IV patients MVax has demonstrated significant response rates as a monotherapy and in published reports MVax plus adjuvant IL-2 have reported **response rate of 35% (13% CR-22%PR).** This compares to published response rates in low dose IL-2 of 3%. In parallel with the Phase III program, AVAX will continue to treat patients with stage III & IV Melanoma in an ongoing Phase I/II trial. Initial data from this study were used as the basis for establishing the dose for the **Phase III Program.**

ESTABLISHED cGMP MANUFACTURING AVAX has spent considerable time and effort to develop an efficient, rapid and inexpensive manufacturing process. From its GMP manufacturing facility located in Lyon, France, AVAX supports commercial and clinical development activities worldwide. The facility has been validated for commercialization in Europe by obtaining from the French authorities the designation "Pharmaceutical Establishment" and "Cell and Gene Therapy Establishment" for the clinical and commercial production of cell and gene therapies. The US manufacturing facility located in Philadelphia Pennsylvania is being re-validated and prepared for use in the manufacture of all domestic clinical vaccines. The target start date for revalidation is Q1 2009. In implementing the commercialization of its universal vaccine platform, AVAX has optimized its manufacturing procedures to achieve significant gross margins on the commercial sale of the technology.

CLINICAL AND REGULATORY DEVELOPMENT In accordance with the **SPA Agreement,** the Phase III study for **MVax** will enroll up to 387 patients with stage IV melanoma, who will be assigned in a double-blind fashion at a 2:1 ratio to MVax or placebo vaccine. The MVax arm will consist of an initial dose of MVax (autologous DNP-modified tumor cells) followed by cyclophosphamide (CY) and then six weekly doses of MVax administered with Bacillus of Calmette and Guerin (BCG). Following vaccine administration patients will receive a specific schedule of low dose IL-2. Patients assigned to the control group will receive a treatment identical to the MVax group, except that a placebo vaccine will replace MVax. The primary endpoints of the study are best overall anti-tumor response rate and the percentage of patients surviving at least 2 years. Secondary endpoints of the study will include overall survival time, response duration, percentage complete and partial responses, progression free survival and treatment related adverse events.

The data analysis plan for the study includes an **interim analysis** of **Best Overall Response Rate** (complete and partial-RECIST) to be performed when half the patients (194 patients) have been enrolled. The comparison of the best overall response rates for the MVax and control groups will be used as the basis for an expected initial **Biologics License Application (BLA) submission under 21 CFR 601 Subpart E,** which provides for **accelerated approval** using a **surrogate endpoint** in certain life threatening diseases. The analysis of overall survival will be performed when patients have reached the two-year point.

Product Pipeline



Product pipeline: As part of its clinical development strategy, AVAX has launched its Pivotal Phase III trial in Stage IV Melanoma. In addition a Phase I/II trial in Stage III & IV melanoma has been completed. The company will continue its Phase I/II studies in non-small cell lung cancer (LungVax) and launch its Phase I/II program in ovarian cancer (OVax).

The protocol is based on published data showing that administration of **MVax** alone can induce clinically **meaningful anti-tumor responses** in patients with stage IV melanoma. Moreover, data from other clinical trials and from animal models suggest that the addition of **low dose IL2,** properly timed, can **greatly increase anti-tumor response rates.** Finally, because IL2 will be given at a low dose, AVAX expects that its use will not be limited by serious toxicity.

MVax is currently distributed commercially on a compassionate use basis in selected European countries such as Spain, Belgium, Greece and S. America. For a number of European jurisdictions AVAX has signed distribution agreements with Gruppo Ferrer S.A. ProVaccine A.G. distributes the vaccine in Switzerland. As part of its compassionate use in Belgium and Spain, AVAX is being compensated. AVAX continues to **explore and expand** development opportunities in Europe.

INVESTMENT HIGHLIGHTS

Pivotal Registration Trial AVAX has received **authorization to launch** its **Pivotal Phase III Registration** trial that is subject to an **SPA Agreement** with the FDA. Currently AVAX is recruiting sites in Israel, U.S. and Europe for participation in the study. Patient enrollment has initiated and based upon a number factors, it could reach half the patients, which is necessary for the first **planned interim data analysis** for this trial, as **early as second half of 2010.** If the data meet the primary endpoint AVAX may be able to file a BLA for approval of the treatment in accordance with the Accelerated Approval regulations.

Pipeline Application of AVAX's **Universal Vaccine Technology** will enable us to build a deep and sustainable pipeline. Moreover, AVAX anticipates that it has the potential opportunity to commence a 2nd pivotal registration trial for Non-small Cell Lung cancer within 12-18 months. (see Chart above).

Established GMP Manufacturing Facility and Optimized Manufacturing Process AVAX has an established and inspected manufacturing facility that has been approved for commercial and clinical product distribution by the French Regulatory Authorities. The facility is capable of sourcing AVAX's current planned clinical and future commercial activities.

Late-Stage Product Opportunity In Europe, in conjunction with distribution partners, AVAX has initiated commercial distribution of the vaccine on a compassionate use basis, as well as filing a BLA with the French authorities for approval. In the United States the clinical development plan is rapid in that it requires the demonstration of safety and immunological activity, as measured DTH responsiveness, for the vaccine to proceed to later stage trials.

MANAGEMENT

Dr. Francois Martelet, President & Chief Executive Officer
Dr. Martelet joined AVAX in July, 2007 on the Board of Directors and in December, 2007 as President & Chief Executive Officer. Dr. Martelet previously worked for a number of major international pharmaceutical companies, most recently working as VP, Global Franchise Head Oncology at Merck & Co.

Jean-Louis Misset, M.D., Chairman, Scientific & Advisory Board
Dr. Misset is Professor of Oncology at University Paris VII and head of the department of Medical Oncology at Saint-Louis Hospital in Paris. He is a member of the French National Council of Universities, and president of the scientific board for Positon Emission Tomography in oncology at Assistance Publique-Hopitaux de Paris. He is past-president of the French National College of Professors in Oncology, and of the Institut de Cancérologie et d'Immunogénétique, Villejuif.

Isabelle Fourthin, M.D., General Manager of Genopoietic, and Chief Medical Officer EMEA Dr. Fourthin comes to AVAX with over thirteen years of experience in the pharmaceutical/biotech industry in Europe. Genopoietic is AVAX's French subsidiary and manufacturing facility for Europe.

Henry Schea, Director, Global Quality and Regulatory Affairs
Mr. Schea has been an employee of Avax since 2002. He has over 20 years experience in research, product development, GMP manufacturing and quality control and assurance, with a focus on cell and gene therapies.

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