

TapImmune's Key Milestone

Written by Staff and Wire Reports
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After years in the lab, TapImmune (OTCBB:TPIV), the small biotechnology company developing immunotherapies, has finally announced their first FDA IND approval. Working with the Mayo Clinic, the firm will sponsor a Phase I HER-2/neu targeted therapeutic vaccine trial in HER-2/neu positive breast cancer patients. The news is expected to be the first of several key news catalysts which will finally push the company's innovative TAP technology forward.

TapImmune's Chairman and CEO, Dr Glynn Wilson, talks about this major milestone event for the company represents the first step in the development of a novel HER-2/neu vaccine that augments both CD4 T-helper cells and CD8 cytotoxic T-cells.

Question: Dr Wilson, first of all, congratulations on your IND approval from the FDA and the research agreement with Mayo Clinic. We know this been a long journey for your unprecedented platform?

Dr. Glynn Wilson, Chairman and CEO: Thank you. We are tremendously excited about our progression into the clinic with the Mayo Clinic and are delighted to be working with a top-class clinical team there led by [Dr. Keith Knutson](#) and [Dr. Amy Degnim](#).

Question: Why is this milestone important for your TapImmune platform?

Dr. Glynn Wilson, Chairman and CEO: For any biotech company the entry into clinical development represents the culmination of significant research and preclinical development work that merits testing in humans. In this particular study it represents several years of research on the HER-2/neu technology at the Mayo Clinic and on TAP by TapImmune. For TapImmune it's our first step into the clinical trial environment to test exciting product concepts and it represents a major milestone in our own corporate development and marks a new chapter for our stakeholders.

We believe deeply in the promise of our TAP technology and this HER-2/neu Mayo technology, and alone, or in combination we are very hopeful that this clinical program will result in a successful treatment and better the lives of many women and their families. The patient population for this vaccine is very broad. Broader than the current therapies and as such the opportunity to develop a vaccine that can expand the reach of treatment is very gratifying. As far as market potential, the current treatment drug had sales of over \$5Billion last year and we believe that ultimately this collaboration could significantly expand that market.

Question: Can you give us a little more specifics on this trial?

Dr. Glynn Wilson, Chairman and CEO: The FDA has approved the Investigational New Drug Application (IND) that will allow Phase I studies on a therapeutic HER-2/neu vaccine trial in HER-2/neu positive breast cancer patients.

These studies will begin shortly (Q4, 2011) and will be conducted at the Mayo Clinic, Rochester, MN, under the direction of Keith Knutson, Ph.D., and Amy Degnim, MD. In the trial, breast cancer patients that express the HER-2/neu antigen will be given the vaccine mixed with GM-CSF as an adjuvant to enhance immunity. The trial aims to evaluate the safety of this vaccine as well as immune responses.

This clinical program stems from a technology license option and sponsored research agreements between Mayo Clinic and TapImmune and is based on research on novel immunogenic peptide epitopes of the HER-2/neu antigen discovered in breast cancer patients with pre-existing immunity to HER-2/neu. The ultimate aim of further clinical trials is to test this technology in synergy with TapImmune's core TAP technology with the aim of producing a robust and long-acting immune response in a broad population of HER-2/neu positive breast cancer patients.

Question: Can you clarify how TapImmune's vaccine works and how it fits in with this trial or other possible vaccine candidates?

Dr. Glynn Wilson, Chairman and CEO: TAP, plays a key role in allowing the immune system to recognize tumor cells but in many tumors it is not functional. In preclinical studies it has been well established that restoring TAP into tumor cells and cancer-bearing animals can significantly improve the immune recognition of tumor-associated antigens. Collectively, these studies show that TAP1 gene transfer and expression of small amounts of TAP results in several critical effects:

- (1) it restores the MHC Class 1 antigen-presenting pathway
- (2) it increases the number of tumour-infiltrating cytotoxic T-cells and dendritic cells
- (3) it enhances memory T-cell subpopulations, and
- (4) it improves animal survival

As these immune effects are central to the development of a successful cancer vaccine and are applicable to many solid tumors, the potential importance of using TAP expression in the immunotherapy of cancer was recognized and has provided the catalyst for conducting clinical studies.

We realized that our TAP technology was synergistic with a wide range of tumor antigen technologies. Our search for such antigens led to our collaboration with the Mayo Clinic. In our collaboration with the Mayo Clinic on this Her-2/neu breast cancer vaccine we will ultimately be combining AdhTAP1 with a Her-2/neu antigen technology in an approach to address earlier problems in the development of HER-2/neu vaccines, namely how to get a robust and long-

acting vaccine applicable to a large population of HER2/neu positive patients.

Question: Just for a little more clarity on this type of Breast Cancer, what is Her2/neu ?

Dr. Glynn Wilson, Chairman and CEO: HER-2/neu is a cancer antigen expressed in ~20% to 30% of breast and ovarian cancers. Herceptin (trastuzumab), a monoclonal antibody that targets the HER-2/neu receptor has become standard of care for patients with breast cancer.

Annual sales of Herceptin are ~\$5 Billion, however, approximately 70% of Her-2/neu positive patients will either not respond to or lose responsiveness to this drug. Development of vaccine approaches against Her-2/neu antigens has been hampered by the inability to develop a robust cytotoxic T-cell response and a long-acting response due to stimulation of T-helper cells.

In collaboration with investigators at the Mayo Clinic, TapImmune is addressing both of these deficiencies by evaluating technologies that can stimulate both CD8 and CD4 cells as a potential vaccine that we believe will greatly increase the responsiveness of this patient population.