Peptagen, Inc.

Mucosal Nanoparticle Vaccine Platform

Business Plan

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The Company

Peptagen, Inc. (the "Company") is developing a platform of mucosally-administered cytotoxic T-lymphocyte (CTL) vaccine products for the prevention and treatment of immunologic diseases. The technology stems from the observation that a family of G-coupled protein receptors (GCPR) present in nearly all vertebrates participates in a fundamental pathway of innate and adaptive immune surveillance. As such, Peptagen's vaccine technology is solidly-based on compositions containing these novel ligands in combination with a non-infectious fragment of a normally infectious antigen for mucosal administration.

Peptagen's technology makes use of naturally occurring peptide sequences of angiotensin I which are devoid of hypertensive properties but bind the GCPR necessary for enhancing innate immune surveillance which are located on nearly all functional immune cell populations. The advantage of this vaccine composition is that a non-infectious antigen fragment may be endocytosed and cross-presented by an antigen presenting cell via the MHC Class I protein. Additionally, the vaccine composition directs the release of Th_1 cytokines, mobilization and maturation of dendritic cells, stimulation of naïve T cells, participates in TLR signaling, and up-regulates adaptive cell mediated immunity.

Peptagen's lead program involves a therapeutic mucosal vaccine for the chronic maintenance treatment of infectious diseases. A second program will co-present tumor associated antigens in the vaccine to enhance non-self recognition associated with a tumor specific pattern recognition receptor (PRR). The utility of these vaccines as a chronic treatment for minimal residual disease following traditional surgery or chemotherapy will be explored. These vaccines are intended to be administered in a nanoparticle nasal formulation. Prior to clinical studies, animal models for intranasal delivery will be completed to optimize the vaccine formulation, dose, and treatment frequency.

Peptagen Technology

The renin-angiotensin system (RAS) is best known for its regulation of blood pressure and electrolyte balance. However, the RAS has been recognized as a contributor in the regulation of host immune responses. These peptide ligands and their receptors are highly conserved in nearly every species of vertebrate. Peptagen's lead adjuvant modulates toll like receptor 4 (TLR4) with a dominant Th_1 release of the cytokines TNF-α, IL-1β, and IL-6, as well as, proliferation and activation of cytotoxic T lymphocytes (NK Cells, CD4+, CD8+, CD3, MØ, dendritic cells, and stem cells) in rodents and humans. Further, the receptor signaling activates NF-κB transcription factor nuclear translocation and inducing the expression of Th_1 chemokines. The innate activity of these ligands has been demonstrated in a number of studies of endotoxin shock as well as host resistance to peritonitis.

Nonclinical Adjuvant Results

We have completed initial proof of concept studies that utilize angiotensin ligands as adjuvants for enhancing the innate and adaptive T cell response to peptide antigens including: 1) anthrax recombinant protective antigen (rPA); and, 2) HIV peptide immunogen both combined with the natural peptide sequence Ang-(1–7). The studies evaluated the compositions ability to provide nasal adjuvant activity for the induction of serum and mucosal antigen-specific humoral and cell-mediated immune responses to include serum IgG, mucosal IgA and systemic and mucosal epitope-specific CD8 responses.

Human Studies

We have participated in studies performed under an IND to determine the safety and tolerability of the monotherapy PGN007 following intravenous injections (not as a vaccine adjuvant). When used as a hematopoietic agent, no dose limiting toxicities were observed at doses up to 100 micrograms/kg daily for 7 days. In a second study, the maximum tolerated dose was assessed to be 400 mcg/kg/day. These studies demonstrate that Ang-(1-7), as a monotherapy, may be safely used in humans when the dose is appropriately selected. These data demonstrate the human safety of the adjuvant component of the vaccine composition and allow the estimation of planned starting doses for intranasal administration.

Management

James C. Oliver, Pharm.D. President and Chief Executive Officer, Peptagen, Inc.

Dr. Oliver brings more than 28 years of clinical research experience as a principal investigator in both pre-clinical and clinical experimentation in academia and the pharmaceutical industry to his post as Chief Executive Officer and President of Peptagen Inc. Dr. Oliver received his training at Mercer University School of Pharmacy where he subsequently served in faculty roles as teacher, advisor, and mentor. His academic tenure includes head of research for a non-profit corporation, adjunct faculty collaboration with Emory University, Mercer University, and the Centers for Disease Control Epidemiology Investigations Branch. Dr. Oliver served as the President of Ockham Ventures, Vice President for Clinical Research for Maret Pharmaceuticals, and Peregrine Pharmaceuticals. In the service arena, Dr Oliver held roles as Associate Director of Medical Affairs with ClinTrials Research.

Scientific Advisory Board

Dr. Mark Davis, Ph.D.; Warren and Katharine Schlinger Professor of Chemical Engineering. California Institute of Technology

Dr. Davis is world renowned inventor and research in the field of nanotechnology. Dr. Davis is serving on Peptagen's scientific advisory board and providing guidance for development therapeutics in the field nanotechnology and chemical engineering. Dr. Davis has patented numerous nanoparticle constructs including a cyclodextrin polymer which has progressed to phase II human testing.

Dr. Jonathan Berek, M.D., MMS Professor and Chair, Department of Obstetrics and Gynecology Stanford University School of Medicine

Dr. Berek is considered one of the top key opinion leaders in surgical oncology. He attended John Hopkins Medical School and trained at the Brigham and Women's Hospital in Boston. Dr. Berek serves on Peptagen's scientific advisory board and provides guidance for development therapeutics in the field of cancer therapy.

Dr. Herman F. Staats, Ph.D., Professor of Pathology, Department of Pathology, Duke University Medical Center

Dr. Staats is an expert in the field of mucosal vaccine delivery and has authored numerous scientific articles in the field. Dr. Staats serves on the NIH vaccine advisory board and is advising Peptagen in the testing and evaluation of intra nasal administration of our vaccine in animals. He is interested in understanding the cellular and molecular mechanisms involved with the induction and regulation of mucosal immune responses as required for the development of effective mucosal vaccines.

Global Vaccine Market Opportunity

The vaccine market is one of the most active acquisition spaces in the pharmaceutical industry today. Major market players for vaccine therapies are GlaxoSmithKline, Merck, Sanofi-Aventis, Sanofi-Pasteur, Wyeth, and Novartis **(Figure 1)**.[1] Furthermore, GlaxoSmithKline, Merck and Sanofi-Aventis control approximately 60% of the global vaccine market. Worldwide revenues in the vaccine market were reported to be $23 billion in 2008 and are projected to reach $4 billion by 2012, while the cancer vaccine market is projected to exceed $8 billion **(Table 1)**. Peptagen's portfolio addresses large global markets in cancer, HIV/AIDS and other pathogenic diseases; all highly visible and extremely profitable.

Figure 1

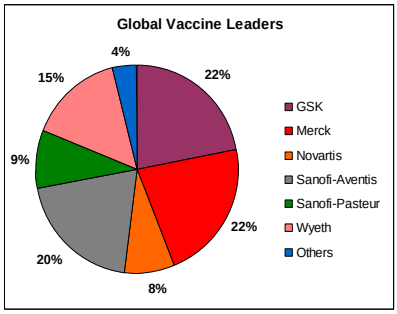

Table 1

Company	2007 Revenue ($ billion)	2008 Revenue ($ billion)
Merck	4.28	4.5
Glaxo Smith Kline	3.99	4.5
Sanofi Aventis	3.89	4.1
Pfizer (Wyeth)	2.44	3.0
Novartis	1.45	1.7
Sanofi Aventis Pasteur	1.44	1.9
Baxter	0.3	0.4

HIV

Peptagen's chronically administered HIV therapeutic vaccine represents a universal opportunity. In the United States alone, more than 22,000 Americans succumb to AIDS each year. Hospitalizations for AIDS related illness exceed 185,000 annually, representing billions of dollars in annual health care costs. While the current HAART regimens have slowed the progression of HIV to AIDS, an epidemiologic review in Western Europe (France) of

[1] Maggon K. R&D Paradigm shift. In Shayne C. Gad Ed. Handbook of Pharmaceutical Biotechnology. John Wiley, New York. May 2007.

over 100,000 HIV cases found the 5-year mortality rate from AIDS defining causes was 23% despite HAART therapy.[2] While this is a significant improvement over the pre-HAART era mortality rate of 40%; a significant need still exists for an effective immune-based therapy. Peptagen intends to initially develop a chronically administered therapeutic nanoparticle vaccine to treat the immunologic sequelae of HIV in subjects with AIDS defining illness. This treatment is anticipated to be nasally administered intermittently (every few weeks) on a chronic schedule. In addition to the treatment of acute AIDS related illness, the vaccine may be beneficial in clearing occult virus during periods of active viral budding.

Cancer

Peptagen's technology also has broad implications for the cancer market. The current treatment trend in cancer therapeutics is the use of maintenance tumoristatic agents. These drugs are administered chronically to delay the progression of tumors. As a class of oncology therapeutics, biologic angiostatic treatments for cancer exceed $15 billion annually.

Competitive Advantages

Peptagen international patent submission has been filed under PCT and represent truly novel platform of multiple compositions of matter. Peptagen patents teach the use of composition and methods for preventing and/or treating bacterial, viral, protozoan infections in man and animals. Peptagen's vaccines are projected to exhibit the following significant competitive advantages over current vaccine preparations:

- The vaccine adjuvant is an endogenous ligand in precisely controlled biologic system which elegantly regulates its own activity;
- The ability to use the same vaccine compositions and methods in man, livestock animals, and veterinarian indications;
- Provide chronic therapy administered in conjunction with anti-viral agents to induce and maintain an immune response to continued viral infection and occult infection;
- Both, the viral antigens and peptide adjuvant have been tested in humans without safety concerns;
- Can be distributed and administered intranasally without medical personnel; and,
- Demonstrate utility for a variety of infectious pathogens, immunologic disorders, or cancer.

[2] Grabar S et al. HIV Medicine 2008; 9: 246-256