

News Release

 [View printer-friendly version](#)

[<< Back](#)

PharmAthene Presents Data for Valortim(R) Anthrax Anti-Toxin and Third Generation rPA Anthrax Vaccine Programs at the Bacillus - ACT 2009 Conference

ANNAPOLIS, Md., Sept. 3 /PRNewswire-FirstCall/ -- PharmAthene, Inc. (NYSE Amex: PIP), a biodefense company developing medical countermeasures against biological and chemical threats, announced today that data from the Company's third generation recombinant protective antigen (rPA) anthrax vaccine program and its Valortim((R)) anthrax anti-toxin program were presented at the Bacillus - ACT 2009 meeting, August 30 - September 3, 2009, organized by the American Society for Microbiology.

David P. Wright, President and Chief Executive Officer of PharmAthene commented, "Preliminary data from our third generation (3G) rPA anthrax vaccine program suggest that a 3G product prototype may be able to provide a more rapid onset of immunity and enhanced immunogenicity than the currently available anthrax vaccine, suggesting the potential for a vaccine that can be given in fewer doses than is required today."

"Additionally, new data from our Valortim((R)) program were presented highlighting the potential for Valortim((R)) as a promising new therapeutic for anthrax. In the African Green Monkey (AGM) model, up to 70% of Valortim((R))-treated animals survived inhalational challenge with anthrax spores. A second poster, presented additional studies in immunodeficient mouse models, and demonstrated the unique activity of Valortim((R)) in protecting these mice from being killed by *B. anthracis*. These data suggest a potential unique mechanism of action for Valortim(TM) that will need to be substantiated in additional studies," continued Mr. Wright.

Valortim((R)), which is being co-developed by PharmAthene and Medarex, Inc., is a fully human monoclonal antibody designed to protect against and treat inhalational anthrax, the most lethal form of illness in humans caused by anthrax.

Valortim((R)) Findings Presented

Dr. Alan Cross, Professor of Medicine and Dr. Subhendu Basu, Assistant Professor of Medicine, University of Maryland School of Medicine, presented data in a poster entitled, "*Mechanisms of an anti-PA Antibody (Valortim((R))) that Mediate Protection Against B. Anthracis Infection.*" The aim of the studies was to determine if the protection against anthrax infection provided by Valortim((R)) was mediated by the immune system.

Study investigators challenged mice with an impaired innate immune system with *B.anthraxis*, with and without Valortim((R)). Their results demonstrated that Valortim((R)) conferred protection to the mice.

In a separate study, mice that lacked an adaptive immune system (devoid of T and B cells) were challenged to establish the role of the cellular immune response in Valortim((R))-mediated protection. Results showed that Valortim((R)) protected these mice at an early time point, post lethal *B. anthracis* challenge. Study results therefore showed that mice with both impaired adaptive or innate immune responses were protected by Valortim((R)) from a *B. anthracis* challenge.

Dr. Cross' team concluded that Valortim((R)) supports the ability of innate and adaptive immune responses to control *B. anthracis* infection. Previous studies have also suggested that Valortim((R)) may play a direct role in killing *B. anthracis*.

Dr. Cross remarked, "These new data, which augment results from our earlier studies, further highlight the potentially unique activity of Valortim((R)), given its ability to apparently kill *B. anthracis*, as well as support the immune system's response to anthrax infection."

The work reported by Dr. Cross is supported by the Maryland Industrial Partnerships Program (MIPS). The MIPS program was developed to accelerate the commercialization of technology in Maryland by jointly funding collaborative R&D projects between companies and University System of Maryland faculty.

Separately, Dr. Louise Pitt, Director, Center for Aerobiological Sciences, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), presented data in a poster entitled, "*Therapeutic Efficacy of Valortim((R)) an Anti-toxin Monoclonal Antibody, in the African Green Monkey Model of Inhalational Anthrax.*" Inhalational anthrax in certain primates such as African Green Monkeys (AGMs) is believed to follow a similar disease course as in humans.

In this randomized, blinded study, 48 AGMs were exposed by aerosol to Ames anthrax spores and blood samples were collected every 8 hours, beginning 24 hours post-exposure, to assess antigenemia (protective antigen 'PA' in circulation) and bacteremia. Samples were assayed for PA by a rapid electrochemiluminescence immunoassay (ECL), and bacteremia was confirmed by culture. The presence of PA in the blood of infected animals was the trigger for initiation of treatment with normal saline control, or Valortim((R)) at doses of 5, 10, 20 or 40 mg/kg.

In the study, AGMs were exposed by aerosol to Ames spores (approximately 200 LD(50)). Up to seventy percent (70%) of the Valortim((R))-treated animals survived. All AGMs were bacteremic at the time of treatment. These data suggest that Valortim((R)) may be a promising therapy for inhalational anthrax in symptomatic individuals and may have utility for use as rescue therapy.

The therapeutic efficacy study of Valortim((R)), given as a monotherapy in the AGM model, is being conducted by PharmAthene and its collaborators at USAMRIID, and has been funded in whole or in part with Federal funds from the Department of Defense through the United States Army Medical Research Institute of Infectious Diseases.

Third Generation (3G) rPA Anthrax Vaccine Findings Reported

Various government agencies, including the Institute of Medicine, have acknowledged the urgent need to stockpile next-generation anthrax vaccines employing modern vaccine technology, which offer the potential for improved safety and convenience, as well as enhanced characterization and lot-to-lot consistency. PharmAthene's portfolio includes both second and third generation rPA anthrax vaccine candidates, which incorporate significant product development and technological advancements and are designed to meet these requirements. The Company's second generation rPA anthrax vaccine, SparVax(TM), is currently under consideration for a major advanced development and procurement contract through the Biomedical Advanced Research and Development Agency.

The goal of PharmAthene's third generation (3G) rPA vaccine program is to develop a vaccine formulation which can induce a more rapid onset of protective immunity in fewer doses, and can be stored, transported and used without the need for a conventional cold chain - an important advantage for civilian biodefense deployment within the Strategic National Stockpile.

In a poster entitled, "*Faster Time to Immunity and Enhanced Immune Response to Optimized rPA Vaccine,*" Allan Watkinson, R&D Director & Principal Investigator, PharmAthene UK, presented results from a mouse model in which PharmAthene and its collaborators investigated incorporating an additional immunostimulant adjuvant into a prototype 3G product formulation.

In the study, female mice were immunized in four treatment groups of 30 and blood samples were taken on days 14, 21 and 28. When immunization of mice with the lyophilized formulation of rPA was supplemented with the immunostimulant adjuvant, a significantly enhanced ($p < 0.005$) anti-PA titre was induced, compared with the equivalent formulation lacking this adjuvant. Results showed that animals immunized with these formulations,

whether supplemented with the adjuvant or not, were fully protected against challenge with 10(3) median lethal doses of *B. anthracis* at day 21.

These preliminary data suggest that PharmAthene's 3G product prototype may be able to provide both faster time to immunity and significantly enhanced immunogenicity, indicating that the optimized formulation may be able to reduce the requirement for multiple vaccine doses, and simplify the immunization regimen for anthrax vaccines in the future.

Funding for this study was provided under a Challenge grant from the National Institutes of Health. The data from this study are intended to inform ongoing efforts in PharmAthene's 3G rPA program. In September 2008, PharmAthene was awarded a development contract from the National Institute of Allergy and Infectious Diseases (NIAID) of up to \$83.9 million for the 3G rPA vaccine program, provided the government exercises all contract options at its sole discretion.

About Anthrax

According to the Centers for Disease Control and Prevention, anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. Anthrax most commonly occurs in hooved mammals and can also infect humans. Symptoms of disease vary depending on how the disease is contracted, but usually occur within seven days after exposure. The serious forms of human anthrax are inhalation anthrax, cutaneous anthrax, and intestinal anthrax. Initial symptoms of inhalation anthrax infection may resemble a common cold. After several days, the symptoms may progress to severe breathing problems and shock. Inhalation anthrax is often fatal, even if treated by antibiotics. Currently, antibiotics are the only drugs available for therapeutic or prophylactic use for inhalation anthrax, and post-exposure prophylaxis is the only FDA-approved indication for such products. However, antibiotic therapy, while useful, is believed to be associated with a number of limitations, including: (1) lack of activity against the toxins produced by the *B. anthracis* bacteria, (2) need for long-term dosing to achieve full protection, complicated by side effects and non-compliance (3) lack of efficacy when administered late in the anthrax disease cycle, and (4) lack of effectiveness against multi-drug resistant or genetically engineered strains of anthrax.

About Bacillus - ACT 2009

Bacillus - ACT 2009 is the third joint conference representing a fusion of two conferences: the 8th International Conference on Anthrax and the 6th International Workshop on the Molecular Biology of *Bacillus cereus*, *Bacillus anthracis* and *Bacillus thuringiensis*, and is organized by the American Society for Microbiology (ASM). The major mission of the conference is to promote stimulating and fruitful interactions between investigators involved in research related to the physiology, genetics, molecular biology, and pathogenicity of these bacteria and to the prevention and treatment of diseases they cause. The conference includes scientific sessions consisting of oral or poster presentations selected from the abstract submissions.

About PharmAthene, Inc.

PharmAthene was formed to meet the critical needs of the United States and its allies by developing and commercializing medical countermeasures against biological and chemical weapons. PharmAthene's lead product development programs include:

- SparVax(TM) -- a second generation recombinant protective antigen (rPA) anthrax vaccine
- Third generation rPA anthrax vaccine
- Valortim((R))-- a fully human monoclonal antibody for the prevention and treatment of anthrax infection
- Protexia((R)) -- a novel bioscavenger for the prevention and treatment of morbidity and mortality associated with exposure to chemical nerve agents
- RypVax(TM) -- a recombinant dual antigen vaccine for plague

For more information about PharmAthene, please visit www.PharmAthene.com.

About USAMRIID

USAMRIID, located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Biological Defense Research Program, and plays a key role in national defense and in infectious disease research. The Institute conducts basic and applied research on biological threats resulting in medical solutions (such as vaccines, drugs and diagnostics) to protect the warfighter. While USAMRIID's primary mission is focused on the military, its research often has applications that benefit society as a whole. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit www.usamriid.army.mil

The information contained in this press release does not necessarily reflect the position or the policy of the Government and no official endorsement should be inferred.

Statement on Cautionary Factors

Except for the historical information presented herein, matters discussed may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to certain risks and uncertainties that could cause actual results to differ materially from any future results, performance or achievements expressed or implied by such statements. Statements that are not historical facts, including statements preceded by, followed by, or that include the words "potential"; "believe"; "anticipate"; "intend"; "plan"; "expect"; "estimate"; "could"; "may"; "should"; or similar statements are forward-looking statements. PharmAthene disclaims, however, any intent or obligation to update these forward-looking statements. Risks and uncertainties include risk associated with the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates, unexpected funding delays and/or reductions or elimination of U.S. government funding for one or more of the Company's development programs, including without limitation our bid related to SparVax ((TM)) under the HHS Request for Proposals for an Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile, the award of government contracts to our competitors, unforeseen safety issues, challenges related to the development, scale-up, and/or process validation of manufacturing processes for our product candidates, unexpected determinations that these product candidates prove not to be effective and/or capable of being marketed as products, unexpected financial obligations that could increase the rate of our cash consumption, as well as risks detailed from time to time in PharmAthene's Forms 10-K and 10-Q under the caption "Risk Factors" and in its other reports filed with the U.S. Securities and Exchange Commission (the "SEC"). In particular, significant additional non-clinical animal studies, human clinical trials, and manufacturing development work remain to be completed for both Valortim((R)) and the Company's 3G rPA anthrax vaccine candidate. At this point there can be no assurance that either of these product candidates will be shown to be safe and effective and approved by regulatory authorities for use in humans. Copies of PharmAthene's public disclosure filings are available from its investor relations department and our website under the investor relations tab at www.PharmAthene.com.

SOURCE PharmAthene, Inc.

Stacey Jurchison, PharmAthene, Inc., +1-410-269-2610,
Stacey.Jurchison@PharmAthene.com