

NEWS RELEASE

For Immediate Release

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**Anthrax Monoclonal Antibody Valortim™ Demonstrates Therapeutic Effect  
in New Primate Model of Established Anthrax Infection**

*Pilot Study Demonstrates 50% Survival in Valortim-Treated Animals*

**PRINCETON, N.J. and ANNAPOLIS, MD., March 29, 2007** - Medarex, Inc. (Nasdaq: MEDX), a leading monoclonal antibody company, and PharmAthene, Inc., a privately held biotechnology company dedicated to the development of biodefense countermeasures, today announced that Valortim™, a fully human monoclonal antibody product candidate being developed for the prevention and treatment of anthrax infection, has been shown to have a therapeutic effect in a new primate model of established inhalation anthrax infection.

The new model, which is being developed at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), seeks to improve on existing therapeutic models for anthrax by closely monitoring the disease process to establish the presence of anthrax bacteremia and determine the optimal window for therapeutic intervention. In addition, the new model uses the African Green monkey, which, based on research data, USAMRIID believes follows a similar disease course as is expected in humans exposed to aerosolized *Bacillus anthracis* spores. *B. anthracis* is the bacterium responsible for anthrax infection. This new animal model has not yet been validated under the U.S. Food and Drug Administration Animal Effectiveness Rule.

In the pilot study conducted at USAMRIID, adult African Green monkeys were exposed to aerosolized anthrax spores and blood samples were collected at regular intervals beginning 24 hours post-exposure. The samples were closely monitored for evidence of bacteremia both by culture and by use of a rapid assay designed to detect protective antigen. Protective antigen is one of the toxins produced by *B. anthracis* and its presence in the blood is being evaluated as a surrogate marker for symptomatic anthrax disease. Once bacteremia was detected by the rapid assay, animals were administered either

Valortim or saline (control) by intravenous injection. In the study, 50% of the Valortim-treated animals survived compared to none of the saline-treated animals.

“While post-exposure models of inhalation anthrax infection are relatively straight-forward, demonstrating efficacy in a therapeutic model for inhalation anthrax infection has proven somewhat challenging,” remarked Valerie Riddle, M.D., Vice President and Medical Director for PharmAthene. “In most animal species in which anthrax has been studied, the disease course and time to death is markedly shorter than that seen in humans, making it challenging to evaluate the potential therapeutic efficacy of promising products. The model being developed by USAMRIID uses a rapidly detectable surrogate marker for the development of symptomatic disease to provide a consistent window in which to determine the therapeutic efficacy of Valortim in animals confirmed to have active disease. We believe this will be an important consideration for the licensure of novel anthrax therapeutics under the Food and Drug Administration’s proposed Animal Rule.”

Dr. Riddle continued, “This is a very encouraging survival result when one considers that these animals had bacteria multiplying in their blood and were poised to manifest severe symptoms and death at the time they were treated with Valortim. We plan to continue to collaborate with USAMRIID to further refine the model and determine the optimal therapeutic dose for Valortim.”

“Previous studies in the rabbit animal model had suggested the capacity of Valortim to successfully treat symptomatic animals,” noted Israel Lowy, M.D., Ph.D., Senior Director of Infectious Disease for Medarex. “The current studies in a non-human primate model, that may be more relevant to human disease, provide additional confirmation for those results. The methodological advances of the group at USAMRIID may help to better define the therapeutic potency of Valortim and other agents in this challenging setting.”

Preclinical studies suggest that Valortim has the potential to provide significant protection against anthrax infection when administered prophylactically (prior to the emergence of symptoms of anthrax infection) and also may increase survival when administered therapeutically (once symptoms become evident). In these studies, Valortim has been shown to protect both rabbits and monkeys against the lethal effects of anthrax infection when administered at the time of exposure, at doses as low as 1.0 mg/kg. When administered to rabbits after the development of symptoms, Valortim also improved survival as late as 48 hours post-exposure as compared to controls.

“We believe that there are distinct characteristics of Valortim that make it an ideal choice for military and civilian protection against an anthrax bioterrorist attack,” commented David P. Wright, President and Chief Executive Officer of PharmAthene. “As our Phase I results have demonstrated, a single intramuscular dose of Valortim produces levels of antibodies in humans that correspond to protective levels in animal models and is well tolerated. Based on the impressive human safety and animal efficacy data collected to date, we believe that Valortim could meet the needs of the U.S. Government and could ultimately be selected for inclusion in the Strategic National Stockpile to provide protection to the American public.”

### **About Valortim**

Valortim (MDX-1303) is a fully human antibody designed to protect against anthrax infection, including inhalation anthrax, the most lethal form of illness in humans caused by the *Bacillus anthracis* bacterium. The investigational antibody is designed to target a protein component known as the anthrax protective antigen (PA) of the lethal toxin complex produced by the bacterium. The anthrax

protective antigen is believed to initiate the onset of the illness by attaching to cells in the infected person, and then is believed to facilitate the entry of additional destructive toxins into the cells. Valortim is designed to target anthrax protective antigen and protect the cells from damage by the anthrax toxins.

Findings of preclinical studies describing the activity of Valortim against anthrax infection were published in the October 2006 issue of the journal *Infection and Immunity*. An article abstract is available on the journal web site at <http://iai.asm.org/cgi/content/abstract/74/10/5840>.

In preclinical studies, Valortim both protected against infection and induced recovery and survival in animals exposed to lethal doses of inhalation anthrax spores. A study in non-human primates has demonstrated the potency of Valortim in this model using the potentially most clinically-useful intramuscular route of administration. In this study, the animals were challenged with a target aerosol dose of 200 times the median lethal dose of *B. anthracis* spores; 6 animals received no treatment, 6 animals received 1 mg/kg of Valortim intramuscularly, and 6 animals received 10 mg/kg of Valortim intramuscularly, all at the time of aerosol challenge. None of the animals were given antibiotics or other therapies. All control animals died within one week of the challenge; all treated animals in both dose groups were reported alive 60 days post-challenge. The effectiveness of doses even lower than 1.0 mg/kg may be studied in future preclinical research.

Valortim has also been administered intravenously and intramuscularly to healthy human volunteers in a completed phase I study, has been shown to be well tolerated at doses as high as 20 mg/kg (IV), and was not immunogenic. These study results were presented at the 2006 Infectious Diseases Society of America Annual Meeting. Pharmacokinetic analysis suggested that doses as low as 1 mg/kg resulted in circulating levels of antibody after a month, with a similar potency for neutralizing anthrax toxin *in vitro* as was seen with serum obtained from subjects who had been vaccinated with anthrax vaccine.

### **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 was 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 with the use of antibiotics.

### **About PharmAthene, Inc.**

PharmAthene, a privately-held biotechnology company, was formed to meet the critical needs of the United States by developing biodefense products. PharmAthene is dedicated to the rapid development of important and novel biotherapeutics to address biological pathogens and chemicals that may be used as weapons of bioterror. PharmAthene's lead programs include Valortim™ for the prevention and treatment of anthrax infection and Protexia® for the prevention and treatment of morbidity and mortality associated with exposure to chemical nerve agents. For more information on PharmAthene, please visit [www.PharmAthene.com](http://www.PharmAthene.com).

### **About Medarex, Inc.**

Medarex is a biopharmaceutical company focused on the discovery, development and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating

diseases, including cancer, inflammation, autoimmune disorders and infectious diseases. Medarex applies its UltiMAb® technology and product development and clinical manufacturing experience to generate, support and potentially commercialize a broad range of fully human antibody product candidates for itself and its partners. More than 30 of these therapeutic product candidates derived from Medarex technology are in human clinical testing or have had INDs submitted for such trials, with six of the most advanced product candidates currently in Phase III clinical trials. Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs. For more information about Medarex, visit its website at [www.medarex.com](http://www.medarex.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's mission is to conduct basic and applied research on biological threats resulting in medical solutions (such as vaccines, drugs and diagnostics) to protect the warfighter. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command.

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

### **Statement on Cautionary Factors**

For Medarex: Except for the historical information presented herein, matters discussed herein 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"; or similar statements are forward-looking statements. Medarex disclaims, however, any intent or obligation to update these forward-looking statements. Risks and uncertainties include risks associated with product discovery and development, uncertainties related to the outcome of clinical trials, slower than expected rates of study subject enrollment, uncertainties related to scheduling and completing necessary animal experiments to satisfy the FDA Animal Rule requirements in the few facilities approved to perform such experiments, unforeseen safety issues resulting from the handling of *Bacillus anthracis*, unforeseen safety issues resulting from the administration of Valortim™ (MDX-1303) in human subjects, uncertainties related to product manufacturing as well as risks detailed from time to time in Medarex's public disclosure filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the fiscal year ended December 31, 2006. There can be no assurance that such development efforts will succeed or that other developed products will receive required regulatory clearance or that, even if such regulatory clearance were received, such products would ultimately achieve commercial success. Copies of Medarex's public disclosure filings are available from its investor relations department.

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