Aeolus Pharmaceuticals Invited to Submit Full Proposal to BARDA for AEOL 10150 as a Potential Medical Countermeasure for Pulmonary Injury Associated with Acute Radiation Syndrome and Delayed Effects of Acute Radiation Exposure

MISSION VIEJO, Calif.-- Aeolus Pharmaceuticals, Inc. (OTCBB:AOLS) announced today that after review of the Company's white paper on development of AEOL-10150 as a countermeasure for the lung effects of acute radiation syndrome, the Biomedical Advanced Research and Development Authority (BARDA) Division of Chemical, Radiological and Nuclear (CBRN) Countermeasures has informed the Company that, after careful analysis and consideration, it has invited Aeolus to submit a full proposal for a contract to develop AEOL 10150 from its current level of technical readiness to FDA approval. The invitation to submit a proposal by BARDA and Aeolus' proposal are non-binding, and the selection of the Company's white paper for submission of a full proposal is not a guarantee of a contract, which will be subject to a favorable technical and scientific review and negotiation of fair and reasonable contract terms.

Aeolus submitted its white paper, "Advanced Development of AEOL 10150 as a Medical Countermeasure for Pulmonary Injury Associated with ARS and DEARE," to BARDA on August 31, 2009 consistent with the Special Instructions Amendment 4 to a Broad Agency Announcement (BAA-BARDA-09-34) for advanced research and development of medical countermeasures for chemical, biological, radiological and nuclear threats. The purpose of the special instructions amendment is to specifically solicit solutions for treating cutaneous and/or pulmonary (life-threatening pneumonitis and fibrosis) injuries resulting from exposure to ionizing radiation. BARDA is interested in advanced development and eventual licensure/approval of medical countermeasures for cutaneous and/or pulmonary injuries resulting from an acute exposure to radiation from a radiological/nuclear accident or attack, particularly injuries associated with Acute Radiation Syndrome (ARS) or Delayed Effects of Acute Radiation Exposure (DEARE).
BARDA is seeking safe and effective medical countermeasures that mitigate, treat, affect, delay, or interrupt the progression of cutaneous and/or pulmonary injury caused by ionizing radiation. Aeolus is requesting funding to further develop AEOL 10150 for the treatment and prevention of such pulmonary injuries, including pneumonitis and fibrosis. In animal studies, AEOL 10150 has demonstrated an ability to protect lung tissue against fibrosis, reduce mortality and maintain normal body weights when administered between 2 hours to 24 hours after exposure. Ongoing studies will examine how far beyond the 24 hour window the compound can be administered and still be effective. AEOL 10150 is also being tested by the National Institutes for Health, National Institute for Allergies and Immunological Disorders, Medical Countermeasures Against Radiological Threats (NIH/NIAID/MCART) as a countermeasure against radiation exposure and damage to the lungs (ARS-Lung) and Gastro-intestinal system (ARS-GI).

"We are pleased that to be moving forward to full proposal for AEOL 10150 as a potential countermeasure for BARDA's lung ARS program, and we believe that the full proposal will allow us to demonstrate to an even greater extent, the growing body of scientific evidence supporting the compound's potential as a countermeasure for radiation exposure," stated John L. McManus, President & Chief Executive Officer of Aeolus Pharmaceuticals, Inc. "We are committed to meeting BARDA's proposal deadline of February 16, 2010, and look forward to their response to our proposal. In the mean time, we anticipate results from our ongoing mice and non-human primate studies, which we hope will add further support to the positive data we have already disclosed for AEOL 10150 as a treatment against radiation exposure."

"To this end we have conducted studies of AEOL 10150 in collaboration with Duke University, the University of Maryland and a NIAID-sponsored Research Consortium focused on major organ-specific sub-syndromes of ARS and delayed effects of acute radiation exposure establishing proof of principle," stated John L. McManus, President and Chief Executive Officer of Aeolus Pharmaceuticals, Inc. "Current studies are ongoing in non-human primates and mice to both confirm efficacy and to establish optimal dosing and to expand the treatment window."

About AEOL 10150

AEOL 10150 is a small molecule that catalytically consumes reactive oxygen and nitrogen species (free radicals). The compound is a manganoporphyrin that contains a positively-charged manganese metal ion that is able to accept and give electrons to and from reactive oxygen species ("ROS") and reactive nitrogen species ("RNS"). Research has shown that ROS and RNS have important cell signaling roles, and through its interaction with RNS and ROS, AEOL 10150 appears to have multiple mechanisms of action including antioxidant, anti-inflammatory and anti-angiogenic activities. In animal studies AEOL 10150 has demonstrated reductions in the markers for tissue hypoxia, angiogenesis, inflammation and oxidative stress. Specifically, AEOL 10150 is able to down-regulate oxidative stress and severe inflammation, which is responsible for much of the tissue destruction that occurs as a result of radiation exposure.
AEOL 10150 offers several unique advantages as a countermeasure for the treatment of ARS, mustard gas and chlorine gas for civilian and military populations. These include:

-- Flexible Treatment Paradigm - AEOL 10150 is intended for the treatment of patients post-exposure, even in those who are already exhibiting symptoms, eliminating the need for immediate administration in a predefined treatment window. This approach has the added benefit of not requiring biodosimetry (a means of laboratory analysis of the blood to determine the level of radiation exposure).

-- Advanced Development Stage - AEOL 10150 has demonstrated safety in three human clinical trials, and has an extensive pre-clinical safety and toxicology package completed. The product also has an established stability profile that permits long-term storage.

-- Large scale manufacturing - Aeolus has contract capacity with a large manufacturing site to mass produce large quantities of AEOL 10150 under GMP conditions.

-- Multiple Applications - AEOL 10150 has demonstrated protective effects against radiation, chlorine gas and mustard gas exposure, and within these indications has shown the ability to treat multiple organ systems.

-- Commercial Application - Additionally, AEOL 10150 is being developed for use as an adjunct to cancer radiation therapy, and animal data suggest that the compound protects healthy normal cells from the effects of radiation without compromising the efficacy of the radiation in killing tumor cells.

Potential for AEOL 10150 as a Countermeasure Against Multiple Terrorist Threats

AEOL 10150 has shown significant protective effects against radiation, mustard gas and chlorine gas in animal models. Studies are underway or will shortly be initiated to further explore AEOL 10150’s ability to protect the lungs from damage due to exposure to radiation, mustard gas, and chlorine gas. A compound with the potential to protect against multiple threats would be of significant benefit in both the military and civilian efforts to protect citizens against potential threats. The FDA has a special "Animal Rule" under which compounds may be approved for use against chemical and nuclear threats on the strength of animal efficacy studies, which allows the potential for an accelerated approval path versus conventional pharmaceutical applications.

About Aeolus Pharmaceuticals

Aeolus is developing a variety of therapeutic agents based on its proprietary small molecule catalytic antioxidants, with AEOL 10150 being the first to enter human clinical evaluation. AEOL 10150 is a patented, small molecule catalytic antioxidant that mimics and thereby amplifies the body's natural enzymatic systems for eliminating reactive oxygen species, or free radicals. Studies funded by the National Institutes for Health are currently underway evaluating AEOL 10150 as a treatment for exposure to radiation, mustard gas
and chlorine gas.

The statements in this press release that are not purely statements of historical fact are forward-looking statements. Such statements include, but are not limited to, those relating to Aeolus’ product candidates, as well as its proprietary technologies and research programs. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aeolus’ actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Important factors that could cause results to differ include risks associated with uncertainties of progress and timing of clinical trials, scientific research and product development activities, difficulties or delays in development, testing, obtaining regulatory approval, the need to obtain funding for pre-clinical and clinical trials and operations, the scope and validity of intellectual property protection for Aeolus’ product candidates, proprietary technologies and their uses, and competition from other biopharmaceutical companies. Certain of these factors and others are more fully described in Aeolus’ filings with the Securities and Exchange Commission, including, but not limited to, Aeolus’ Annual Report on Form 10-K for the year ended September 30, 2009. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

Source: Aeolus Pharmaceuticals, Inc.