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## **Aeolus Drug Protects the Gastrointestinal Tract in Acute Radiation Syndrome Studies Sponsored by the National Institutes of Health's National Institute for Allergy and Infectious Diseases**

- AEOL 10150 effectively increases regeneration of GI stem cells and reduces the severity and duration of diarrhea
  - Drug improves survival when administered 24 hours after total body irradiation

MISSION VIEJO, CA – October 22, 2009-- Aeolus Pharmaceuticals, Inc. (OTC Bulletin Board: AOLS) announced today that recent experiments in preclinical models conducted by the National Institutes of Health's (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Radiation/Nuclear Medical Countermeasure Development program have shown that AEOL 10150 can effectively increase regeneration of gastro-intestinal (GI) stem cells, reduce the severity and duration of diarrhea and improve survival when administered at 24 hours after doses of total-body irradiation that produce the lethal GI syndrome. There are no published studies of agents that accomplish this enhanced stem cell regenerative effect while maintaining GI function and improving survival when administered post irradiation.

“The Aeolus drug AEOL 10150 passed our first phase of rigorous testing and showed definitive effects on crypt stem cells and other secondary parameters used to assess drug efficacy in ameliorating the acute GI syndrome”, stated Catherine Booth, Ph.D., Managing Director, Contract Research Services at Epistem, Ltd. “This is one of few drugs shown to affect “both” stem cell crypt regeneration and survival in a syndrome that heretofore has been resistant to mitigation with drugs administered at 24 hours post lethal exposure.”

NIAID has a contract with the University of Maryland to provide product development support services for the development of countermeasures against radiation exposure. These studies are being conducted by Epistem, a subcontractor of the University of Maryland, in compliance with criteria of the FDA that are a pre-requisite for movement of the Aeolus drug along the pathway for FDA licensure to treat lethally irradiated persons in the event of a terrorist nuclear act. Epistem operates a major contract research organization and provides services to identify novel drugs that can protect or improve the repair of the gastrointestinal (GI) tract following exposure to irradiation and performed these studies as part of its US NIH's program for the screening of a novel agents for bio-defense applications.

The NIH NIAID Radiation/Nuclear Medical Countermeasure Development program leads the U.S. effort to develop treatments for radiation sickness following a nuclear terrorist attack. GI-ARS is a massive, currently untreatable, problem following high-dose, potentially lethal radiation exposure. Agents that mitigate these effects would reduce sickness and hopefully prevent fatalities. The tests performed by NIH/NIAID are also likely to identify agents with oncology supportive care applications - agents that will reduce the severe ulceration and diarrhea (mucositis) experienced by patients during radio- and chemo-therapy. Risk of injury to the intestine is dose-limiting during abdominal and pelvic radiation therapy—interventions that limit post-irradiation intestinal dysfunction would have significant impact in large number of patients, estimated to be between 1.5 to 2 million cancer survivors with post-irradiation intestinal dysfunction. AEOL 10150 has previously demonstrated protective effects in protecting healthy normal cells from damage occurring due to cancer radiation therapy in preclinical models.

### **Radiation Damage to the GI Tract**

The intestinal epithelium, a single layer of cells lining the surface of the GI lumen, is responsible for vital functions of nutrient absorption, maintaining fluid and electrolyte balance and protection of the body from bacteria, bacterial toxins and non absorbed materials. The functional integrity of the GI system is maintained via incessant production of epithelial cells from specialized stem cells located in crypts at the base of the epithelium. High-dose, total-body irradiation can result in a lethal GI syndrome that results in significant morbidity and mortality within days consequent to killing of the crypt stem cells and loss of the protective and absorptive epithelial barrier. There are no FDA-approved drugs or biologics to treat the acute GI syndrome.

### ***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 anti-oxidant, anti-inflammatory and anti-angiogenic activities. In preclinical 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 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 preclinical 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 and mustard gas in preclinical models. Additionally, based on its mechanism, it is believed that the compound may potentially protect against exposure to chlorine gas. Studies have been initiated to further explore AEOL 10150's ability to protect the lungs from damage due to exposure to 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 rule under which compounds may be approved for use against chemical and nuclear threats on the strength of preclinical 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. Additionally, the Company has funded mouse and non-human primate studies necessary to seek approval of the compound as a treatment to protect and/or mitigate radiation-induced damage to the lungs for which there are no FDA-approved drugs. Radiation-induced pneumonitis and/or fibrosis are potentially lethal delayed effects of acute radiation exposure. The ability to control these delayed consequences will also translate into the clinic and further emphasize the dual utility of AEOL 10150.

### ***About Epistem, Ltd.***

Epistem is a biotechnology company commercializing its expertise in epithelial stem cells in the areas of oncology, gastrointestinal diseases and dermatological applications. Epistem develops innovative therapeutics and biomarkers and provides contract research services to drug development companies. The Group's expertise is focused on the regulation of adult stem cells

located in epithelial tissue, which includes the gastrointestinal tract, skin, hair follicles, breast and prostate. Epistem does not conduct research in the areas of embryonic stem cells or stem cell transplantation. Epistem operates three distinct business divisions, Contract Research Services, Novel Therapies and Biomarkers.

Epistem's Contract Research Services division provides scientific expertise and preclinical research models to the NIH's research programme on Radiation/Nuclear Medical Countermeasure Development. This research programme, funded by the National Institute of Allergy and Infectious Diseases through a contract with the University of Maryland School of Medicine, tests drugs from early screening through advanced development for the prevention and treatment of radiation sickness following exposure to high dose radiation following a nuclear terrorist attack. Epistem has developed its proprietary models to provide a unique insight into the mechanisms of intestinal damage and repair following radiation exposure. Epistem's models evaluate the efficacy, mechanism of action, optimal drug dosing and scheduling of potential new treatments. Epistem has an eight-year track record of providing testing services to over 130 international company clients in the United States, Europe, and Japan.

*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, 2008. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.*

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