Aeolus Announces Additional Data Demonstrating Efficacy of AEOL 10150 as a Medical Countermeasure Against Exposure to Nerve Agents, Sulfur Mustard Gas and Nitrogen Mustard Gas

MISSION VIEJO, CA -- (Marketwired) -- 07/01/14 -- Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS)

- **Data Presented at 8th Annual NIH Counteract Meeting in Denver**
- **Confirmatory Studies In Rats Demonstrate AEOL 10150 Significantly Improves Survival and Lung Function in Sulfur Mustard Gas Inhalation**
- **Additional Studies in Mice With Nitrogen Mustard Gas Confirm That AEOL 10150 Protects Skin From Damage**
- **Significant Progress Has Been Made Under the $4.3 Million Counteract Grant to Study AEOL 10150’s Efficacy Against Nerve Agent Exposure**

Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS) today announced the presentation of data confirming the efficacy of AEOL 10150 as a medical countermeasure sulfur mustard gas inhalation and nitrogen mustard gas skin exposure. Additionally, an update on progress under the NIH CounterACT nerve agent grant was provided. The data was presented at the National Institutes of Health ("NIH") Countermeasures Against Chemical Threats ("CounterACT") 8th Annual Conference in Denver, Colorado in June. The data presented are from studies funded by the CounterACT Program, the National Institutes of Health Office of the Director, and the National Institute of Environmental Health Sciences. Aeolus is a biotechnology company focused on developing compounds to protect against radiological and chemical threats with significant funding from the US government.

The key findings presented at the meeting were as follows:

**Sulfur Mustard Lung Program Highlights**

- Confirmatory studies were run and verified earlier reported efficacy of AEOL 10150 in rats exposed to lethal sulfur mustard gas.
  - AEOL 10150 treatment significantly (p < 0.0001) improved survival at 24 hours after sulfur mustard exposure from 42% vs. 94% and at 48hrs from 35% to 88%.
  - AEOL 10150 treatment significantly (p < 0.0001) improved lung function 25% to normal levels in sulfur mustard exposed rats which correlated with arterial
blood gas improvements in \( pO_2 \), \( pCO_2 \) and pH.

- AEOL 10150 treatment significantly \((p < 0.0001)\) improved clinical scores 60% in sulfur mustard exposed rats.
- AEOL 10150 treatment reduces airway cast formation at 24 hours \((p < .017)\) and 48 hours \((p < .0071)\)

Brian Day, PhD of National Jewish Health reported on work done to explore the impact of AEOL 10150 on sulfur mustard exposure beyond 48 and 72 hours.
Research teams led by Dr. Day and Dr. Carl White, MD at the University of Colorado evaluated the impact of AEOL 10150 treatment on survival over 28 days at a dose of sulfur mustard gas that causes 100 percent lethality by day 28 without treatment.

- Natural history studies reveal that the 1.4mg/kg sulfur mustard gas exposure is 100% lethal by 20 days. AEOL 10150 treatment increased the median sulfur mustard survival from 2.8 days to 16 days \((p < 0.05)\) with survival of AEOL 10150 treated animals past 28 days.

**Nitrogen Mustard Skin Program Highlights**

- Rajesh Agarwal, PhD of the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, provided an update on continuing research of AEOL 10150 as a countermeasure against skin mustard exposure, which builds on data recently published in the journal, "Free Radical Biology".
- 1 hour after nitrogen mustard ("NM") exposure, AEOL 10150 ameliorated NM-induced skin injury/morbidity in mice at 24 and 72 hours post-NM exposure.
- AEOL 10150 caused a reduction in NM-induced clinical lesions including edema, wounded and wrinkled skin areas. There were decreases of approximately 40% or more in NM-induced increase in skin bi-fold thickness, percent dead epidermal layer, apoptotic epidermal cell death, microvesication, and MPO activity (indicating neutrophil infiltration).
- The therapeutic effects of AEOL 10150 in reversing NM-induced inflammation and vesication could be associated with DNA damage, MMP-9 and MAPK/p38 activation, as indicated by our results.
- These studies support further investigation and assessment as well as optimization of therapeutic potential of AEOL 10150 in the sulfur mustard skin injury model.

**Nerve Agent Program Highlights**

Manisha Patel, PhD of the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences reported that her research team had accomplished the key objectives for the first year of the CounterACT grant "Neuroprotective Effects of AEOL 10150 Against Organophosphate Toxicity". Dr. Patel reported the DFP rat model developed in her lab showed significantly increased oxidative stress parameters in the brain after administration of DFP. Further, pharmacokinetic ("PK") analysis after administration of AEOL 10150 one hour after DFP exposure revealed therapeutic levels of AEOL 10150 in the plasma and the brain. The levels seen in the presence of DFP were essentially equivalent to levels seen in the absence of DFP. Work on the Soman model and the PK profile for AEOL 10150 continues. This work is funded under NIH Grant #1U01NS083422-01, a four year $4.3 million grant awarded to Dr. Patel in September 2013.
"The data presented at the CounterACT meeting further confirms the efficacy of AEOL 10150 as a countermeasure against nerve agents and mustard gas," stated John McManus, Chief Executive Officer of Aeolus. "In particular, Dr. White and Dr. Day have repeatedly shown that AEOL 10150 significantly improves survival after sulfur mustard exposure in both acute and now longer term models. We plan on presenting their data and a study design for a pivotal study in sulfur mustard gas exposure in rodents to the FDA during the second half of 2014, to get their input on the remaining steps for approval under the animal rule for this indication. We are grateful to CounterACT for their support of these studies and to Drs. Day, Patel, Agarwal, White and their teams for their research efforts."

The development of AEOL 10150 as a treatment for chemical vesicant and nerve gas exposure is funded by the National Institutes of Health's Countermeasures Against Chemical Threats ("CounterACT") program. Aeolus is also developing AEOL 10150 as a treatment for the lung syndrome of Acute Radiation Syndrome ("Lung-ARS") under a five year, cost plus contract with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services. The contract, worth up to $118.4 million, fully funds the development of AEOL 10150 through approval and licensure by the U.S. FDA. Aeolus believes that much of the chemistry, manufacturing and controls, toxicology and safety data generated under the BARDA contract will be applicable to support a potential approval of AEOL 10150 as a countermeasure against chemical threats, in addition to the Lung-ARS indication.

**About AEOL 10150**

AEOL 10150 is a broad-spectrum catalytic antioxidant specifically designed to neutralize reactive oxygen and nitrogen species. The neutralization of these species reduces oxidative stress, inflammation and subsequent tissue damage resulting from radiation exposure. The Company believes that AEOL 10150 could have a profound beneficial impact on people who are exposed to high doses of radiation.

AEOL 10150 has already performed well in animal safety studies, was well-tolerated in two human clinical trials and has demonstrated statistically significant survival efficacy in multiple studies of the lung syndrome of Acute Radiation Syndrome in multiple animal species. AEOL 10150 also currently is in development for use as both a therapeutic and prophylactic drug in cancer patients.

**About Aeolus Pharmaceuticals**

Aeolus Pharmaceuticals is developing a new class of broad-spectrum, catalytic-antioxidant compounds that protect healthy tissue from the damaging effects of radiation. Its first compound, AEOL 10150, is being developed, with funding by the US Department of Health and Human Services, as a medical countermeasure against chemical and radiological weapons, where its initial target indications are as a protective agent against the effects of acute radiation syndrome and delayed effects of acute radiation exposure. Aeolus’ strategy is to leverage the substantial investment in toxicology, manufacturing, and preclinical and clinical studies made by US Government agencies in AEOL 10150, including the contract with BARDA valued, with options, at up to $118.4 million, to efficiently develop the compound for use in oncology. For more information, please visit Aeolus’s corporate website at [www.aolsrx.com](http://www.aolsrx.com).
Forward-Looking Statements

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, the Company's initiation or potential initiation of large efficacy studies in mice and NHPs, as well as a phase 1 study in healthy volunteers, the BARDA contract, and the expected use of proceeds from the financing. 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 and 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; competition from other biopharmaceutical companies; and whether BARDA exercises one or more additional options under the its contract with Aeolus. 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, 2014. 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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