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Aeolus Initiates Phase 1 Study of AEOL 10150 in Healthy Normal Volunteers

MISSION VIEJO, CA / ACCESSWIRE / February 22, 2017 /Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS), a biotechnology company developing compounds to protect against fibrosis, inflammation, nerve damage and infection, announced today the initiation of a phase 1 study with its lead compound AEOL 10150. The phase 1 study is an open-label, single center, dose-escalation study to evaluate the safety, tolerability, and pharmacokinetics of an escalating single dose of AEOL 10150 administered by subcutaneous injection in healthy subjects.

AEOL 10150 is being developed as a treatment for the lung and delayed effects of acute radiation exposure (Lung-ARS) under a $118.4 million advanced research and development contract with the Biomedical Advanced Research and Development Authority ("BARDA"). BARDA is the division of the U.S. Department of Health and Human Services responsible for the development and purchase of medical countermeasures for chemical, biological, radiological and nuclear threats. In addition, AEOL 10150 is being developed as a treatment for idiopathic pulmonary fibrosis (IPF) and for use in conjunction with radiation therapy to treat solid tumors.

This study will expand the safety database for AEOL 10150 and will be the first set of human safety data for the new formulation of AEOL 10150 developed under the BARDA contract. The data from this study will be included in the Company's pre-Emergency Use Authorization application in Lung-ARS and will also be used to support the IPF and radiation therapy indications, as well as the use of AEOL 10150 as a medical countermeasure against lung damage from exposure to sulfur mustard gas. Prior studies with the original formulation in single and multiple dose studies of 39 patients with Amytrophic Lateral Sclerosis ("ALS"), demonstrated that AEOL 10150 was safe and well tolerated. The new formulation of AEOL 10150 is significantly cheaper than the prior formulation and is the subject of new patents pending with the US and global patent authorities. Additional toxicology work completed with Aeolus and BARDA funding has led to FDA concurrence to test the drug in healthy normal volunteers and animal efficacy data generated under the BARDA contract supports the drug's potential as a therapy for IPF. Upon completion of the phase 1 single dose study, Aeolus plans to initiate multiple dose studies in patients with IPF and cancer. Data from all of these studies will support the development of AEOL 10150 as a medical countermeasure for Lung-ARS and sulfur mustard exposure, as well as the IPF and cancer clinical indications.

"We are very pleased to have addressed the FDA's comments and received their concurrence to test AEOL 10150 in healthy subjects. The new formulation of AEOL 10150 has reduced the cost of the drug by approximately 90 percent and the additional toxicology work cleared the way for testing in healthy subjects," stated John L McManus,

President and Chief Executive Officer of Aeolus Pharmaceuticals, Inc. "This phase 1 study will give us important safety and pharmacokinetic data that will allow us to accelerate and expand the development of AEOL 10150 in both large commercial and in biodefense indications that represent major unmet medical needs. We are grateful to BARDA for their support of the program, which enabled us to achieve the improvements in the cost and consistency of manufacturing AEOL 10150 and the elimination of the toxicology concerns that had previously limited our potential clinical targets."

About AEOL 10150

AEOL 10150 protects tissue from damage and increases survival in animal models of lung damage after exposure to radiation, toxic chemicals, disease and trauma by mitigating and/or preventing cell death, inflammation and fibrosis through its action on oxidative stress and regulation of growth factors and chemokines, as well as impacting subsequent signaling pathways of reactive oxygen species production, apoptosis and fibrosis. We are developing 10150 as a MCM for national defense and for use in oncology and treating lung fibrosis.

AEOL 10150 has performed well in preclinical and non-clinical studies, demonstrating statistically significant survival efficacy in an acute radiation-induced lung injury model, and was well-tolerated in two human clinical trials. The Company believes it could have a profound beneficial impact on people who have been exposed, or are about to be exposed, to high-doses of radiation, whether from cancer therapy or a nuclear event, and potentially reduce lung damage in patients with idiopathic pulmonary fibrosis and people who inhale chemical vesicants, such as sulfur mustard gas.

About Aeolus Pharmaceuticals

Aeolus Pharmaceuticals is developing a platform of novel compounds for use in biodefense, fibrosis, oncology, infectious diseases and diseases of the central nervous system. Its most advanced 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' corporate website at 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, development strategies and research programs, including the Company's initiation or potential initiation of pre-clinical development as well as clinical trials, including a phase 1 study in pulmonary fibrosis patients. 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 imposition or continuation of clinical holds on development projects; 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, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

Contact:

John McManus
President and Chief Executive Officer
Aeolus Pharmaceuticals, Inc.
1-(949) 481-9825

SOURCE: Aeolus Pharmaceuticals, Inc.