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Aeolus Announces FDA Fast Track Designation Granted to AEOL 10150 for Treatment of Patients With Lung Acute Radiation Syndrome Following a Radiologial or Nuclear Event

MISSION VIEJO, CA -- (Marketwired) -- 06/08/17 --

Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS), a biotechnology company developing compounds to protect against fibrosis, inflammation, nerve damage and infection announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AEOL 10150 for the prevention of fatal respiratory failure among patients at risk for radiation pneumonitis following a radiological/nuclear incident sufficient to cause the Acute Radiation Syndrome ("Lung-ARS").

"We are pleased that the FDA has granted Fast Track designation to AEOL 10150 for the treatment of Lung-ARS following a radiological or nuclear event," said John McManus, President and Chief Executive Officer of Aeolus. "There are currently no approved treatments for this syndrome and we are not aware of any other compounds in advanced development for this unmet need."

The purpose of Fast Track is to get important new drugs to patients earlier. It is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical. A drug that receives *Fast Track* designation is eligible for Accelerated Approval, Priority Review and Rolling Review, as well as more frequent meetings and written communications with the FDA to discuss development plans and design of proposed clinical trials.

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 in ALS patients, and is currently being tested in a phase 1 study in healthy subjects. The Company believes that AEOL 10150 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 to efficiently develop compounds for use in commercial indications. For more information, please visit Aeolus's 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 the effects of the Notification, the Company's proprietary technologies and research programs, and the Company's initiation of a phase 1 study in healthy volunteers and/or potential initiation of a phase 1study 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 concerning BARDA and ASPR, 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 is ultimately able to exercise one or more additional options under 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.

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Source: Aeolus Pharmaceuticals