Aeolus Receives BARDA Decision Regarding Additional Options for Lung ARS Development Contract; Files Response to Assertions Made by BARDA in the Notification

MISSION VIEJO, CA -- (Marketwired) -- 03/23/17 -- Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS)

• AEOL 10150 HAS DEMONSTRATED STATISTICALLY SIGNIFICANT IMPROVEMENT IN SURVIVAL IN NHP MODEL OF THE DELAYED PULMONARY EFFECTS OF RADIATION EXPOSURE
• AEOL 10150 IS CURRENTLY BEING TESTED IN A PHASE 1 SAFETY STUDY IN HEALTHY SUBJECTS UNDER A PROTOCOL SUBMITTED TO THE FDA DIVISION OF MEDICAL IMAGING PRODUCTS UNDER THE IND FOR DELAYED PULMONARY EFFECTS OF RADIATION EXPOSURE
• AEOL 10150 IS CURRENTLY THE ONLY DRUG BEING DEVELOPED BY BARDA TO ADDRESS THE DELAYED EFFECTS OF RADIATION EXPOSURE

Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS), a biotechnology company developing compounds to protect against fibrosis, inflammation, nerve damage and infection announced today that it received a response (the "Notification") from the Assistant Secretary for Preparedness and Response ("ASPR") that the Biomedical Advanced Research and Development Authority ("BARDA") elected not to exercise additional options at this time under its contract entitled: "Advanced Development of AEOL 10150 as a Medical Countermeasure for Pulmonary Injury Associated with ARS and DEARE." The notification was sent to Aeolus in response to an "In-Process Review" ("IPR") meeting held with BARDA on February 2, 2017.

"While we are appreciative of the $30 million of tax-payer funding invested by BARDA in our drug, which has brought the government a promising treatment for the delayed effects of radiation in advanced development, we are completely stunned by the decision to discontinue development and are deeply concerned that demonstrably false reasons have been cited as the basis of the decision. We vehemently disagree with their comments about the compound's efficacy and risks of increasing doses in humans based on peer reviewed publications and existing human safety data and PK data," stated John L McManus, President and CEO of Aeolus Pharmaceuticals, Inc. "The development of AEOL 10150 for IPF and cancer will continue, but it is unfortunate that the compound will not, based on the Notification, be available to address the radiological and chemical
threats that it has shown significant efficacy against, especially as our nation's enemies have advanced their offensive nuclear efforts."

"This was not a data driven decision," stated David C. Cavalier, Chairman of the Board of Directors of Aeolus Pharmaceuticals, Inc. "We are deeply disappointed, as we have been strong advocates of the potential for public-private partnerships to bolster the funding provided by Congress to address chemical, biological and radiological threats. Whether it was a change in priorities or a flaw in the review and decision making process, the fact that this decision is based upon material falsehoods undermines predictability and adds significant risk to the prospect of developing medical countermeasures in partnership with the US Government. More importantly, it calls into significant question the integrity of the process the Government is using to make its funding decisions given that BARDA itself acknowledged to Aeolus the falsity of the letter ASPR issued to us."

**Background**

Under the contract to date, Aeolus has received $30.4 million from BARDA to deliver 65 specific milestones, including manufacturing enhancements, production of material, non-clinical toxicology to enable studies in healthy subjects, development of animal models, acceptance of those models by the FDA, dose range finding, duration of treatment, treatment window and natural history studies in murine models to inform studies in the NHP, and dose evaluation studies in the NHP to inform a potential pivotal study. Aeolus has successfully delivered 62 of 65 milestones under the contract, with one additional milestone to be delivered later this month. The two remaining milestones are final reports on drug substance and drug product stability studies to be delivered in 2018 and 2019, respectively. All deliverables and milestones have been accepted by BARDA without any notification of deficiency or non-acceptance.

At the In-Process Review meeting on February 2, 2017, AMCG/BARDA provided the decision-making body with the wrong slides for the meeting. Aeolus was forced to present its case for option exercise with a presentation that did not contain critical, up-to-date information on the program's status and accomplishments. As a result of this failure by BARDA/AMCG, the milestones achieved in the AEOL 10150 development program, the most current information on the accomplishments of the program in the animal efficacy area and the challenges faced and overcome by the program in the regulatory and human clinical areas of the development program were not accurately conveyed during the In-Process Review.

**Misstatements in Notification**

There are materially false misstatements contained in the "Notification of the In-Process Review Outcome for BARDA Contract HHSO100201100007C." To supposedly justify its decision not to exercise additional options for funding, the ASPR Office of Acquisition, Management, Contracts and Grants ("AMCG") made the following demonstrably false assertions:

1. "...A significant improvement in survival or mitigating major morbidity or clinically significant improvements in secondary markers of efficacy were not observed in studies of radiation exposure."
2. "The proposed clinical study in healthy normal volunteers was not considered because of the FDA desire for a patient population and the risk of increasing the human dosage and was not further considered under the existing contract, Contract Number HHSO100201100007C"

**Misstatements Regarding Efficacy in Notification**

The first assertion is demonstrably false and is contradicted by peer-reviewed publications and a pharmacometric analysis of animal efficacy studies conducted at BARDA's request. AEOL 10150 treatment in studies run by independent researchers in rat and mouse models of hemi-thoracic and upper half body irradiation have shown significant improvements in survival as well as secondary markers of efficacy. In murine studies designed to determine the optimal daily dose, duration of treatment and treatment window, trends for survival were determined that were then used to determine the optimal treatment protocol in the non-human primate ("NHP") studies. More specifically, in a pilot study in the NHP, treatment with AEOL 10150 after lethal whole thorax lung irradiation ("WTLI") at 11.5 Gy improved survival from 0 to 28.5 percent. In a dose evaluation study in the NHP, treatment with AEOL 10150 after 10.74 Gy WTLI improved survival from 25 to percent to 50 percent.

The pharmacometric analysis performed under the contract by a former Director of Pharmacometrics at the FDA, concluded: "Using a piecewise parametric survival model in NHP, AEOL 10150 treatment for 60 consecutive days starting at 24 hours post-exposure was found to significantly (p < 0.001) decrease mortality from acute radiation pneumonitis compared to the control arm. NHP which received 60 day treatment starting 24 hour post exposure died 40% less frequently per unit time during the pneumonitis phase compared to the untreated arm, which is comparable with the estimated hazard ratio of 0.6 from a cox-proportional hazard model."

As BARDA itself acknowledged in a teleconference following the ASPR's notification, these data, which directly contradict ASPR's letter, were published in the following peer-reviewed publications and posters that provide detailed discussions of some of the data supporting the demonstrated efficacy of AEOL 10150 in improving survival and protecting tissue after lung irradiation:

- "AEOL 10150 Mitigates Radiation-Induced Lung Injury in the Nonhuman Primate: Morbidity and Mortality are Administration Schedule-Dependent," MacVittie, et. al., Health Physics 2017 January; Volume 187.

Misstatements Regarding Safety Testing in Notification

The second assertion reflects a material misstatement of the BARDA Contract Statement of Work and knowingly fails to account for BARDA's repeated direction to Aeolus on the human safety component of the AEOL 10150 development program. In fact, until February 2016, when the clinical hold for the study in healthy subjects was lifted by the FDA Division of Medical Imaging Products ("DMIP"), BARDA insisted, over Aeolus' expressed objection, that AEOL 10150 safety testing must be done only in healthy subjects. After the clinical hold was lifted, BARDA reversed itself and informed Aeolus that it should conduct safety studies in patient populations, not healthy normal volunteers.

Aeolus initially proposed conducting human safety studies necessary for approval of AEOL 10150 under the Animal Rule in cancer patients receiving radiation therapy. At BARDA's insistence, the contract was written to conduct all human safety studies in healthy subjects. In meetings held in July 2011 and June 2012, the DMIP recommended that human safety studies be conducted in "patients that might benefit from treatment." This position was conveyed to BARDA, but Aeolus was directed to pursue studies in healthy subjects and submitted an IND in August 2014 with a protocol for a study in healthy subjects.

In September 2014, the IND was put on clinical hold and DMIP laid out a pathway for studies in healthy subjects, but again reiterated its recommendation that studies be performed in patients. In March 2015, a meeting was held with the DMIP at which the Company received guidance on its specific efforts to mitigate the clinical hold. The DMIP concurred with the approach and also laid out the path for the Company to conduct multiple dose studies in healthy normal volunteers, but again reiterated its recommendation that human safety studies be conducted in patients. Aeolus completed the work required to mitigate the DMIP concerns and submitted a full response to the clinical hold in January 2015. In February 2016, DMIP lifted the clinical hold and gave the Company permission to proceed with a single ascending dose study of AEOL 10150 in healthy normal volunteers, but again reiterated its recommendation -- strongly -- that exploration of human safety be conducted in patients that might benefit from treatment. At this point, BARDA informed Aeolus that it should propose conducting studies in patients and that BARDA would no longer require human safety studies to be done in healthy normal volunteers and that the Company should file an IND in either IPF or cancer to allow for testing in those patients.

In August 2016, Aeolus requested feedback on filing an IND and initiating a clinical study in IPF patients with the FDA Division of Pulmonary, Allergy and Rheumatology Products ("DPARP"), and in September 2016, DPARP responded with a list of concerns that were
essentially those previously raised by DMIP, and that have been addressed adequately to allow for initiation of the single dose study in healthy normal volunteers. In order to proceed to a multiple dose study, which the Company and BARDA agreed should be done in patients, a single ascending dose study would need to be performed in healthy subjects to demonstrate safety and generate human pharmacokinetic data to support multiple day dosing. After consultation with and encouragement by BARDA in January 2017, Aeolus initiated a phase 1 study in healthy subjects, at its own expense, in February 2017. This data and the demonstration to the FDA that the new formulation of AEOL 10150 -- developed under BARDA's direction -- is safe after a single dose, will meet the DMIP requirements for moving into a multiple dose study. It will also address the concerns echoed by the Division of Pulmonary, Allergy and Rheumatology Products (“DPARP”) in its initial response to Aeolus' pre-IND meeting correspondence for the Idiopathic Pulmonary Fibrosis indication, which along with cancer patients represent two groups of "patients that may benefit from treatment" that meet the DMIP's "recommendation."

In two phase 1 studies of the prior formulation, AEOL 10150 was shown to be safe and well tolerated, except for skin discoloration at the injection site and injection site reactions in one group of patients who received the drug via continuous infusion pump. Under the BARDA contract, changes were made to the final drug product formulation, which appear to have resolved this issue based on GLP non-clinical skin studies in rabbits. In the current phase 1 study, the first 6 patients have completed dosing. A total of 9 patients will receive a single injection during this study, which is scheduled to be completed during the 2nd quarter of 2017. Successful completion of this study demonstrating that AEOL 10150 was safe and well tolerated along with the pharmacokinetic data from these patients is expected to provide the data to support a multiple dose phase 1 study in either healthy subjects or in patients that might benefit from treatment.

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 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 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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