Aeolus Announces Response to FDA Clinical Hold and Plan for Clinical Development of AEOL 10150

MISSION VIEJO, CA -- (Marketwired) -- 01/08/15 -- Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS), a biotechnology company developing compounds to protect against radiological and chemical threats in partnership with the US Government, announced today that it has filed a formal mitigation response to the Division of Medical Imaging Products ("DMIP") of the U.S. Food and Drug Administration ("FDA") after consultation with its development partner, the Biomedical Advanced Research and Development Authority ("BARDA"). The response addresses the questions cited by the DMIP when it placed a clinical hold on the Investigational New Drug Application ("IND") for the testing of AEOL 10150 in healthy human volunteers in September 2014. The healthy volunteer safety studies are part of the Lung Acute Radiation Syndrome ("Lung-ARS") Medical Countermeasure ("MCM") program funded by BARDA under a five-year contract worth up to $118.4 million. BARDA is the division of the U.S. Department of Health and Human Services responsible for the advanced development of MCM for chemical, biological, radiological and nuclear threats.

Work on manufacturing, animal efficacy, toxicology and other elements of the BARDA Lung-ARS contract has continued while the response to the clinical hold was prepared and discussed with BARDA. Aeolus expects to report the results of the secondary endpoint analysis from the recently-completed non-human primate efficacy study during the first quarter of 2015. Survival results from this study showing a statistically significant doubling of survival after 60 days of treatment with AEOL 10150 were reported in September 2014. Mouse studies to determine the optimal duration of treatment and maximum delay until initiation of treatment are ongoing. In addition, studies to identify potential biomarkers and triggers to treat are underway. Results from these studies will be reported during 2015. In the manufacturing program, pilot scale batches have been produced, and the Company is finalizing process development to enable primary stability batch manufacturing in 2015. Stability studies of the bulk drug substance and final drug product have now been completed out to two years at room temperature and refrigerated conditions.

Aeolus has requested a meeting with the DMIP to discuss the action plan submitted in order to confirm that the plan adequately addresses the agency's questions. In September 2014, the DMIP notified the Company that it had placed a clinical hold on the IND for AEOL 10150 due to questions regarding: 1) the toxicology data supporting the new formulation of AEOL 10150 developed under the BARDA contract, 2) the genotoxicity data for AEOL 10150, and 3) potential for discoloration of the skin at the site of injections. The DMIP suggested several studies that Aeolus could run to address these questions, and
after consultation with BARDA, Aeolus has proposed a series of studies, including those proposed by the DMIP. Additionally, Aeolus plans to initiate phase 1 human clinical studies in cancer patients receiving radiation therapy and in a second indication that has yet to be announced that will provide further evidence of the safety of the new formulation of AEOL 10150.

AEOL 10150 has been tested previously in 39 patients with Amyotrophic Lateral Sclerosis ("ALS") with no significant adverse events reported. Some changes to the final formulation of the drug were made under the process improvement work performed under the BARDA contract, which underlies the DMIP's questions and desire for more information.

"We believe that the pre-clinical studies suggested by the DMIP and proposed by Aeolus in our response to the agency will answer the outstanding questions raised during the review of our IND for Lung-ARS," stated John L. McManus, President and Chief Executive Officer of Aeolus Pharmaceuticals, Inc. "Additionally, data from clinical studies in phase 1 studies in cancer patients should provide further support for the safety of the new formulation of AEOL 10150. We have planned to move into cancer radiation therapy patients as part of our ultimate development goal for AEOL 10150, so these studies will now provide both human data in our commercial indication and can be used to support the human safety requirements for use and ultimate approval of AEOL 10150 as an MCM for Lung-ARS."

Aeolus has also requested a meeting with the Division of Oncology Products at the FDA to discuss the phase 1 study in cancer radiation therapy patients, and plans to file an IND for that indication and initiate a phase 1 study upon completion of the IND review. The efficacy data generated under the BARDA contract has provided further evidence of the effectiveness of AEOL 10150 in protecting healthy normal tissue from radiation exposure. More than 1 million patients receive radiation therapy for cancer in the United States each year, and side effects resulting from the damage that radiation therapy does to healthy normal tissue are the dose-limiting factor for treatment with radiation. Data in the NHP, rats and mice suggests that treating cancer patients with AEOL 10150 would reduce side effects improving their quality of life and potentially improving compliance and allowing for increased levels of radiation exposure, which could improve treatment outcomes, most importantly survival. The DMIP has indicated to Aeolus in previous communications that it would accept studies in cancer patients receiving radiation therapy as evidence of safety in humans as well as being supportive of the animal efficacy required to satisfy the animal rule requirements for approval.

**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-signaling cascades resulting from radiation exposure. AEOL 10150 may have a profound beneficial impact on people who have been exposed or are about to be exposed to high doses of radiation in the treatment of oncology.

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.

About Aeolus Pharmaceuticals
Aeolus Pharmaceuticals is developing a platform of a new class of broad-spectrum, catalytic-antioxidant compounds that protect healthy tissue from the damaging effects of radiation and other inducers of reactive oxygen species. 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

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 potential initiation of human clinical studies, the BARDA Contract, and other development 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 preclinical 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, and whether BARDA exercises one or more additional options under the BARDA Contract. 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.

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

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