SolAeroMed Announces Positive Proof of Concept Data for its Lead Drug (S-1226) in Subjects with Mild Atopic Asthma

Calgary-based SolAeroMed Inc. today announced positive Phase IIa proof-of-concept results for its S-1226 lead therapeutic.

CALGARY, ALBERTA, CANADA, May 30, 2016 /EINPresswire.com/ -- Calgary, Alberta – May 30, 2016 – SolAeroMed Inc. ("SolAeroMed"), a Calgary-based biotechnology company dedicated to developing novel drugs and devices to treat respiratory diseases, today announced positive Phase IIa proof-of-concept results for its S-1226 lead therapeutic. The Phase IIa study was a placebo-controlled, randomized, double-blind, crossover single dose study to evaluate the safety, tolerability and efficacy of S-1226 (8%) administered by nebulization in subjects with mild atopic asthma.

“We are delighted to have achieved clinical proof of concept for S-1226. We are particularly pleased the trial demonstrated efficacy together with benign safety and was well tolerated by patients with mild atopic asthma. Moreover, S-1226 rapidly and effectively dilated airways in these asthmatics following an allergen-induced asthma attack.” said John Dennis, PhD, Chief Executive Officer of SolAeroMed. “Achievement of this important milestone is crucial as we believe these results have significantly de-risked the project.”

Highlights of the results include:
• In comparison with placebo, a single-dose of S-1226 was safe and well tolerated in patients with mild atopic asthma;
• Efficacy assessments showed that responder status throughout the 30 minutes after treatment were all higher in the S1226 treatment group.
• Lung function (measured by FEV1)levels were significantly increased in the S1226 treatment groups over time (P = 0.043), with higher mean estimates observed in the S-1226 group relative to placebo; and
• Statistically significant between group differences (P = 0.028) were observed for the absolute changes between pre-dose and post-dose % SpO2 levels over time. This is an important finding owing to the fact that a major challenge for treating acute asthma is the ability to quickly open constricted airways and allow delivery of O2 to the blood

SolAeroMed is exploring strategic options to accelerate technology development. These options include licensing, strategic partnerships, formation of a joint venture, a sale of the Company, or venture capital financing. “SolAeroMed will be attending the annual BIO convention in San Francisco June 6-9, 2016 to promote our Phase IIa results and explore partnership opportunities,” said Gareth Lewis, Chief Financial Officer of SolAeroMed. “We expect to secure a strategic partner in the short-term to take S-1226 through the next stages of clinical development.” The next stage of clinical

development will include a dose ranging clinical trial where the magnitude of the S1226 efficacy signal will be increased using a combination of a facemask delivery system to optimize exposure of upper respiratory tract receptors to S1226, as well as evaluating efficacy with higher doses of the %CO2 and Perflubron components.

S-1226 Technology Overview

S-1226 is SolAeroMed's lead therapy. S-1226 is formulated to rapidly reopen constricted, mucus plugged airways using a unique mechanism of action making it a first in class respiratory drug. Besides being a potent bronchodilator, it should also increase the effectiveness of delivery of other inhaled respiratory drugs. The S-1226 formulation consists of inhaled carbon dioxide (CO2) and perfluorooctyl bromide (perflubron). Inhaled delivery of S-1226 results in an immediate relaxant effect on the patient's constricted airways and enhances mucous clearing of blocked airways.
S-1226 will work to improve breathing when other drugs do not. S-1226 has a unique biophysical mechanism of action that is neither adrenergic nor cholinergic. CO2 causes temporary rapid airway dilation via epithelial receptors and vagal C-fibers while perflubron interacts with natural lung surfactant. The effect of inhaling perflubron and CO2 combination is synergistic and should result in very fast and sustained bronchodilation.

SolAeroMed completed core preclinical animal studies in both rat and sheep animal respiratory models of asthma in 2013. SolAeroMed obtained regulatory approval from Health Canada to test safety of S1226 in humans and in 2014 completed a Phase I dose escalating clinical trial for S-1226 on thirty-six (36) healthy human subjects. No significant adverse reaction were observed or reported during the S1226 Phase 1 study using 4% CO2, 8% CO2 or 12% CO2. SolAeroMed conducted Phase IIa Proof of Concept clinical trial designed to demonstrate safety and efficacy in an asthmatic patient population under the direction of Prof Richard Leigh at the University of Calgary Foothills Hospital. This Phase II Proof of Concept clinical trial has now been completed and results demonstrate both safety and results indicate S-1226 is safe and effective across all measurement metrics. Statistically significant efficacy signals were observed in both tissue oxygenation and improvement in lung function over time.

S-1226' target markets include all diseases where breathing is compromised, including acute bronchospasm (asthma), Chronic Obstructive Pulmonary Disease (COPD) and Cystic Fibrosis (CF).

About SolAeroMed

SolAeroMed Inc. is a Calgary, Canada based biotechnology company dedicated to the development of novel therapeutic strategies to treat obstructive lung diseases. SolAeroMed aims to improve the quality and longevity of patients' lives through the generation of quality biopharmaceutical technologies that are developed with "outside-the-box" thinking. SolAeroMed aims to balance ethical and effective research and development with strategic partnering and a level of investment return to attract the resources required to develop its novel therapies.

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Forward-Looking Statements

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs,

projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development and renewed focus on our therapeutic business.

We may use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate.

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