**Abstract**

- We have discovered a new short acting bronchodilator which has a different mechanism of action than current bronchodilators. The drug, S-1226™, is a novel formulation of the potent bronchodilator carbon dioxide (4-12% CO₂ enriched air) combined with a synthetic lung surfactant, perfluorocytotribromide (PFOB), delivered as a nebulized mixture of vapour and aerosol to the lungs.

- **S-1226™:**
  - **Effective:** Treats methacholine and allergen induced bronchoconstriction in sheep and rat models of asthma
  - **Safe:** Phase I clinical trial showed minimal adverse effects at all dosing levels (4%, 8%, 12% CO₂)
  - **Currently in Phase II clinical trial – allergen induced asthmatic subjects

- **S-1226™** has a unique biophysical mechanism of action
  - Neither adrenergic nor cholinergic
  - CO₂ causes temporary rapid airway dilation via epithelial receptors and vagal C-fibers
  - PFOB provides some airway dilation and interacts with natural lung surfactant
  - Synergistic effect with combination of PFOB and CO₂
  - Very fast dilation expected to last 30-60 minutes
  - The ability of the gaseous component to rapidly penetrate closed airways
  - The ability to lubricate mucus plugs enhancing mucous clearance

- S-1226™ is being developed by academic co-founders through the Canadian based biotech start-up SolAeroMed Inc.

**Medical Need for a New Asthma Treatment**

- **Asthma:**
  - Affects 300 million individuals worldwide; 400 million expected by 2025
  - 250,000 asthma deaths every year worldwide

- **Existing treatments:**
  - Short-acting β₂-agonists are the front-line emergency treatment
  - Salbutamol is the only short-acting bronchodilator available following an asthma attack
  - One-fifth to one-third of patients do not respond to this therapy

- **When treatment is ineffective:**
  - **3.7 million** asthma-related emergency department visits per year worldwide
  - Patients are treated with higher doses of same drug (Salbutamol) that failed
  - No other alternative exists
  - **$5.3 billion/year** in hospital costs

- **Major challenge** for treating acute asthma is to open occluded airways rapidly enough to re-establish ventilation and allow delivery of O₂ and conventional medication to airways

- A new treatment is required that has pharmacological properties (bronchodilation) and biophysical properties (mucous plug penetration and clearance) for a more rapid and effective therapy

**S-1226™: Novel Bronchodilator**

- **S-1226™ consists of 3mL PFOB synthetic surfactant nebulized with CO₂-enriched air (4-12% CO₂, 20% O₂, with balanced N₂)
  - Delivered as an aerosol/vapour/gas mixture
  - Short-acting bronchodilator with a novel mechanism of action
  - Both CO₂ and PFOB are well-described and safe

- Both CO₂ and PFOB have previously been approved by FDA, EMA, HC

**Pre-Clinical Studies**

- **S-1226™ has a fast and long-lasting bronchodilator effect in sheep model**

**Clinical Studies**

- **Phase I completed 2014 (publication pending)**
  - N=36 healthy patients, GLP compliant
  - Inhaled 2 minute treatment of S-1226™, dose increase from 4% CO₂, 8% CO₂ & 12% CO₂
  - No safety concerns reported

- **Phase IIa Proof of Concept (in progress; completion expected Q4 2015)**
  - Allergen induced asthma, n=12 subjects
  - Double blind crossover, GLP compliant
  - Placebo (saline & air) Vs. S1226 (8% CO₂ & PFOB)
  - Aim to evaluate safety and efficacy

**Near Term Catalysts (2015-2016)**

- **S-1226™:**
  - Rapidly dilates airways (in vivo) and enhances mucous plug clearance (in vitro) using a new mechanism of action thus rapidly opening closed airways and enhancing delivery of standard bronchodilation therapies
  - First-in-class product; pharmacological and biophysical mechanism of action
  - May be developed to treat COPD and CF exacerbations in the future

**Summary and Future Directions**

- Development of a personal rescue device to be used by patients as a first line emergency treatment following an acute asthma attack

- SolAeroMed Inc. is actively exploring licensing and partnering opportunities for our respiratory drugs and delivery device technologies

For more information, contact: 
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