**Abstract**

S-1226™ is a new bronchodilator to treat asthma via a novel mechanism of action by combining the potent bronchodilator carbon dioxide (CO₂) with a synthetic lung surfactant, perfluorocyclonobromide (PFOB) delivered as a nebulized mixture of vapour and aerosol.

- **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 III clinical trial – all dosing levels (4%, 8%, 12% CO₂)**

**Anticipated future roles for S-1226™:**
- Treat exacerbations of COPD and CF
- Combination therapy to enhance delivery and efficacy of other respiratory drugs
- A novel portable delivery device to administer S-1226™ is under development
- To be used as a personal rescue therapy following an acute respiratory attack

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

**Medical Need for a New Asthma Therapy**

- **Asthma:**
  - Affects 300 million individuals worldwide; 400 million expected by 2025
  - 250,000 asthma deaths every year worldwide
- **For 3.7 million asthma-related emergency hospital visits per year worldwide:**
  - Short-acting β₂-agonists are the front-line emergency treatment
  - Only one short acting bronchodilator is used (salmeterol)
  - One-fifth to one-third of patients do not respond to this therapy
  - Tachyphylaxis and toxicity have been demonstrated
  - In severe asthma, airways are blocked by bronchoconstriction and mucus plugs rendering personal inhalers ineffective
  - 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

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/vapor/gas mixture with a unique biophysical mechanism of action
- Both CO₂ and PFOB are well-documented, safe and approved by FDA, EMA, HC
- Rapid dilution of airways in sheep and rat models of asthma and enhancement of mucus plug clearance in vitro
- Safety demonstrated in Phase I clinical trial at all dosing levels (4%, 8%, 12% CO₂) with Phase II Proof of Concept clinical trial ongoing

**Portable rescue device to treat severe bronchoconstriction as a first line emergency treatment following an acute asthma attack**

**Expected to complement and enhance activity of other drugs, particularly when conventional drugs are ineffective**

**Components of the Device Prototype**

- Separate storage of a compressed gas cylinder and a drug-liquid ampoule within the device body
- On activation, compressed drug-gas is released through the liquid reservoir where PFOB vapor evaporates through an intermediate aerosol stage
- The combined gas and vapor mixture is then delivered to a tidally breathing patient at a controlled dosing rate and multi-minute treatment time

1. **Drug gas cartridge.** Resides within the terminal compartment. May be removed/inserted via an end cap.
2. **Mechanism to activate device releasing gas.** Compressed drug gas and puncturing drug liquid chamber allowing the drug gas and liquid to flow into the mixing chamber (4).
3. **Drug liquid holding chamber.** Capable of storing liquid in a sealed environment until device is activated.
4. **Aerosol/vapor generation and mixing chamber.** Both drug gas and drug liquid enter allowing generation of liquid vapor and aerosol.
5. **Patient interface.** Mouthpiece (with removable cap) which conducts drug mixture to patient.

**Summary and Future Directions**

- **S-1226™:**
  - Novel therapeutic bronchodilator that combines a potent bronchodilator (CO₂) with a synthetic lung surfactant (PFOB)
  - CO₂
    - Causes temporary rapid airway dilatation via epithelial receptors and vagal C-fibers
    - Rapidly penetrates closed airways
  - PFOB
    - Provides some airway dilatation and interacts with natural lung surfactant
    - Lubricates mucus plugs to enhance mucous clearance
  - First-in-class product; pharmacological and biophysical unique mechanism of action
  - May be developed to treat exacerbations of COPD and CF
  - Novel portable delivery device to be used by patients as an emergency rescue technique
  - Platform technology for delivery of other drugs in the future

- **Clinical Trials:**
  - Q4 2015 – Completion of Phase IIa proof of concept clinical trial
  - Q3 2016 – Dose-ranging Phase II clinical trial
  - Q4 2016 – Repeat dosing Phase II clinical trial
  - Q4 2016 – Non-inferiority clinical trial for S-1226™ portable delivery device

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

For further information, contact:
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