Media release

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Pharmaxis completes phase II clinical study with ASM8 in asthma patients

Pharmaxis Ltd (ASX:PXS) today announced the completion of an exploratory Phase IIa trial with ASM8 in patients with allergic asthma.

The trial was a double-blind, randomized, controlled, 3-way crossover study to evaluate the efficacy and safety of 14-day inhaled ASM8 in subjects with asthma. The primary outcome measure was the effect of ASM8 on allergen induced Late Allergic Response 3-7 hours post-allergen challenge. 16 subjects participated in the trial and each received two doses of ASM8 (3mg or 7.8mg) or control at different times, once per day in a randomized, cross over fashion.

Bronchoconstriction (as measured by change in FEV_1) during the late phase of the allergen challenge response was reduced by 44% ($p<0.05$) when dosed with3mg and by 41% ($p<0.01$) when dosed with 7.8mg ASM8, as assessed by the change in area under the curve, 3-7 hours post challenge compared to screening. This is consistent with a previously reported trial that reduced the Late Allergen Response by 59% ($p<0.005$) following 4 day dosing with 8mg ASM8. However, in the current trial, the control also reduced the Late Allergen Response by 44% ($p<0.005$), 3-7 hours post dose, meaning there was no difference between doses.

The statistically significant effect of the response when subjects were treated with vehicle is indicative of a drug carryover effect that can result in studies of a cross over design.

Dr Alan Robertson, Pharmaxis' Chief Executive Officer, commented "We remain encouraged by these new clinical data demonstrating the potential value of this approach for treating asthma. We now know that ASM8 is best dosed once per day and we know that 3mg is an appropriate dose for future trials. The statistically significant response when patients were treated with vehicle indicates that future studies with drugs of this nature should be parallel in design. The moderate to severe sector of the asthma market, which is the target of ASM8, represents a significant commercial opportunity."

ASM8 is a combination product of two RNA-silencing oligonucleotides targeted at a number of receptors for mediators of inflammation in asthma.

Paul O'Byrne, Professor of Medicine and Chair, Department of Medicine at McMaster University said: "this approach to reducing multiple inflammatory mediators may be an important clinical option for patients with severe allergic asthma and this trial indicates that additional studies are warranted."

ASM8 was shown to be safe. There were no significant differences in adverse events between the treatment groups. The full outcome of the trial including a variety of exploratory endpoints is currently being evaluated and the results will be presented at a forthcoming scientific congress.

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About the Trial

The following information is provided in accord with the draft ASX and AusBiotech Code of Best Practice for Reporting by Biotechnology, Medical Device and other Life Sciences Companies.

Name of Trial	**TPI ASM8-207**
Blinding Status	**Double blind**
Control	**Phosphate buffered 0.9% saline**
Design	**14 day treatment, 3-way crossover with 4-6 week washout between doses**
Route	**Inhalation via a nebuliser**
Frequency	**Once per day**
Dose levels	**0mg** **3mg** **7.8mg**
Number of Subjects	**16 evaluable**
Subject Selection Criteria	• **Generally good health; steroid naïve (or who have not taken inhaled/oral corticosteroid within last month) mild to moderate, stable, allergic asthma** • **History of episodic wheeze and shortness of breath** • **Forced expiratory volume in one second (FEV1) at baseline ≥ 70% of the predicted value**
Primary End Points	• **Allergen induced LAR AUC between 3-7 hours post challenge**
Exploratory End Points	• **Early and late phase reduction in FEV1 following allergen challenge.** • **Methacholine induced airway hyper-responsiveness** • **Inflammatory cell in the sputum** • **mRNA levels of CCR3 and the beta-chain IL-3, IL-5 and GMCSF** • **Plasma and sputum pharmacokinetic profile** • **Systemic biomarkers of mast cell activation** • **Safety and tolerability**
Trial Location	**Hamilton, Ontario** **Calgary, Alberta** **Vancouver, British Columbia** **Quebec City, Quebec**
Commercial partners	**None**
Sponsor	**Pharmaxis Ltd**

About Inhaled TPI ASM8

ASM8 is based on proprietary oligonucleotide technology and consists of two modified RNA-silencing oligonucleotides designed specifically to reduce the recruitment and persistence of chronic inflammatory cells and their associated release of cytokines – all key components underlying the cause of the disease. ASM8 targets two distinct cellular pathways involved in airway inflammation by inhibiting the recruitment of allergic inflammatory cells, via an effect on the CCR3 receptor, and reducing the persistence of allergic inflammatory cells via interference with the common beta sub-unit for the receptors of interleukin IL-3, IL-5 and GM-CSF. This pioneering multi-targeted approach of blocking the synthesis of specific receptors with RNA-silencing technology is expected to have advantages over current medications by providing broader, but specific, pharmacological activity with limited systemic availability, in a convenient, inhaled formulation.

About Asthma

Asthma is a chronic inflammatory disease of the airways in which many cells and cellular elements play a role—in particular, eosinophils, mast cells, and T-lymphocytes. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night and/or in the early morning. The inflammation also causes an associated increase in the airway hyperresponsiveness to a variety of stimuli. Symptoms are usually associated with widespread, but variable airflow obstruction that is at least partly reversible with treatment.

About Pharmaxis

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic respiratory and immune disorders. Its development pipeline of products includes Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and PXS4159 for asthma.

Founded in 1998, Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on +61 2 9454 7200.

Forward-Looking Statements

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Aridol and/or Bronchitol. All forward-looking statements included in this media release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We can not guarantee that any product candidate will receive regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors" section of our Statutory Annual Report available on the Pharmaxis website.