Media release

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Pharmaxis completes phase II clinical study with ASM8 in asthma patients

Pharmaxis Ltd (ASX: PXS) today announced the successful completion of a Phase IIa dose profiling study with its new anti-inflammatory agent ASM8 in patients with allergic asthma.

The study met the pre-defined primary efficacy and safety endpoints and ASM8 was found to be safe at all doses tested and particularly effective at an inhaled dose of 8mg once per day. Compared to saline control, at this dose, bronchoconstriction following allergen challenge (as assessed by change in FEV_1) was reduced by 32% (p=0.03) during the early phase of this response and by 49% (p=0.002) during the late phase of this response. In addition, inflammation as measured by sputum eosinophil count, 7 hours and 24 hours following allergen challenge was reduced by 49% (p=0.02) and by 57% (p=0.007) respectively.

Dr Alan Robertson, Pharmaxis' Chief Executive Officer, commented "We are very encouraged by these new clinical data demonstrating the potential value of this approach for treating asthma. The moderate to severe sector of the asthma market, which is the target of ASM8, represents a significant commercial opportunity, and is under-served by current therapies."

ASM8 was the leading clinical-stage asset in the portfolio of drug candidates acquired by Pharmaxis in its recent takeover of the Canadian company, Topigen Pharmaceuticals Inc.

The trial was designed to determine the efficacy and safety of ASM8 at a range of doses administered sequentially via inhalation to 12 patients with asthma followed by a controlled allergen challenge. 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, Ontario said: "Severe allergic asthma is difficult to treat and the results from this trial indicate that the approach of knocking down multiple inflammatory mediators may provide an important clinical option."

The prevalence of asthma is estimated at 60 million in the US, Europe and Japan of which approximately, three million are classified as having severe, persistent asthma.

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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 Life Sciences Companies.

Name of Trial	**TPI ASM8-206**
Blinding Status	**Open label**
Placebo Controlled	**0.9% saline used as control**
Design	**4 day treatment – sequential escalating dose design**
Route	**Inhalation via a nebuliser**
Frequency	**Once or twice per day**
Dose levels	**1mg twice per day** **2mg twice per day** **4mg twice per day** **8mg once per day**
Number of Subjects	**12 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	•**Sputum eosinophils (%) on Day 4 versus screening for each dose level. [Time Frame: 7 and 24 hrs post-allergen challenge]** •**Safety and tolerability**
Secondary End Points	• **Early and late phase reduction in FEV1 following allergen challenge.** • **Plasma and sputum pharmacokinetic profile at the two highest dose levels.**
Trial Location	**Hamilton, Ontario, Canada**
Commercial partners	**None**
Sponsor	**Pharmaxis Ltd Group**

About Inhaled TPI ASM8

ASM8 is based on Pharmaxis' 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.