



Media Release

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PHASE II TRIAL IN SUBJECTS WITH ALLERGIC ASTHMA COMPLETES ENROLMENT

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it has completed enrolment of all subjects into its Phase II clinical trial evaluating ASM8, a potential new treatment for patients with moderate to severe asthma.

Dr Alan Robertson, Pharmaxis' Chief Executive Officer, commented: "ASM8 is a new approach to asthma and operates early in the cascade of events that lead to inflammation and hyper-responsiveness in the lungs of asthmatics. We have completed enrolment into this trial smoothly and ahead of schedule. Previous studies of shorter duration have shown ASM8 to be effective in reducing the signs and symptoms of allergic asthma and this trial will give us a better understanding of the performance of the product when administered for 2 weeks."

This trial is a cross over design and its purpose is to evaluate the efficacy and safety of two doses of inhaled ASM8 compared to placebo when administered over 14 days. The Phase II trial is being conducted in four hospitals in Canada and recruited 16 asthmatic adults. The data from the trial will be available during Q2 2012 and a successful outcome will allow a dose to be selected for a longer trial in patients with uncontrolled, persistent, asthma.

ASM8 is a combination product of two RNA-silencing oligonucleotides targeted at a number of mediators of inflammation in asthma and has been developed for those patients who continue to experience moderate to severe, persistent, uncontrolled asthma despite existing medications. This market represents a significant commercial opportunity as there are few treatment options and serious consequences for the patient if disease progression is not halted.

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 ASM8-207
Blinding Status	Double-blind
Placebo Controlled	Randomised placebo-controlled
Design	14 day, 3-way crossover study
Route	Inhalation via a nebuliser
Frequency	Once per day
Dose levels	3mg once per day 7.8mg once per day
Number of Subjects	16 evaluable
Subject Selection Criteria	• Adult • Diagnosis of allergic asthma • Steroid naive
Primary End Points	• Allergen-induced late airway response (LAR) defined as the area under the curve (AUC) between 3-7 hours post-allergen challenge
Secondary End Points	• Allergen-induced late airway response • Allergen-induced early airway response • Airway hyperresponsiveness • Biomarkers • Plasma and sputum pharmacokinetic profile
Trial Location	4 sites in Canada
Expected Completion of the Trial	Q4 2011
Commercial partners	None
Sponsor	Pharmaxis Ltd

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 disorders. Its development pipeline of products includes Aridol for the assessment of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of lung fibrosis and ASM8 for asthma. 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 phone +61 2 9454 7200.

About Inhaled 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.
