# Media Release

**7 December 2010**

## PHASE II TRIAL OF ASM8 IN ASTHMA COMMENCES

Pharmaceutical company Pharmaxis (ASX: PXS) today announced it had enrolled the first subjects into a Phase II clinical trial evaluating the new asthma drug, ASM8, in patients with allergic asthma.

Dr Alan Robertson, Pharmaxis Chief Executive Officer, commented: "ASM8 represents one of the next generation drugs designed to tackle the airway inflammation that underpins asthma. We have previously shown in a short term study that ASM8 is effective in reducing the signs and symptoms of asthma. Now we will assess how effective it is over a longer treatment period. 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."

The trial is a crossover design and will 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 will recruit 16 asthmatic adults.

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

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.

#ENDS#

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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.

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|---|---|
| **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**<br>**7.8mg once per day** |
| **Number of Subjects** | **16 evaluable** |
| **Subject Selection Criteria** | • **Adult**<br>• **Diagnosis of allergic asthma**<br>• **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**<br>• **Allergen-induced early airway response**<br>• **Airway hyperresponsiveness**<br>• **Sputum eosinophils and biomarkers**<br>• **Plasma and sputum pharmacokinetic profile** |
| **Trial Location** | **4 sites in Canada** |
| **Expected Duration of the Trial** | **The trial is expected to be completed within 12 months** |
| **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 and PXS4159 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.

**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 cannot guarantee that any product candidate will receive regulatory approval or that we will seek any such approval.