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## Treatment and prevention of Asthma by Immunomodulatory Therapy (IMT) with *Streptococcus pneumoniae* (Spn)

### The University

The University of Newcastle is one of Australia's leading research Universities. Medical research at the University is of the highest quality with dedicated research facilities, buildings, Institutes and the critical mass required for rigorous experimentation and quality outputs including highly ranked education, high ranking peer reviewed publications, IP and contract research.

### The Discovery

An exciting opportunity exists for a pharmaceutical or biotechnology company to partner or license this technology in the field of asthma therapy. Researchers at the University of Newcastle have developed a novel therapy based on *Streptococcus pneumoniae* (Spn) for the prevention and treatment of allergic airways diseases (AAD) and asthma. Researchers have made significant and novel observations that provide strong evidence for the use of Spn for the prevention and treatment of asthma using a mouse model of asthma.

### The competitive edge lies in:

#### 1. The proposed IMT hits multiple molecule targets:

Unlike many non-steroidal therapies in development for treating asthma which only modulate specific molecular targets, the proposed IMT modulates a range of molecular targets which is in-line with the understanding that asthma is a multi-factorial disease.

#### 2. Similar (non asthma) products in the market:

The proposed IMT is based on components of well known and currently in-use *pneumococcal* polysaccharide vaccines. These vaccines have been widely used against diseases caused by *Spn* with well established safety profile and manufacturing processes. The identified *Spn* components are likely to induce a much better therapeutic response as compared to the whole *Spn* vaccines currently marketed, and will be administered intranasal rather than intramuscularly to achieve the desired therapeutic benefits, and are protected by our patent applications.



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**Technology**

The technology is Immunomodulatory Therapy (IMT) targeting asthma. The offering is based on the novel finding that Streptococcus Pneumonia (*Spn*) components reduce the severity of asthma symptoms in mice. Although treatment options are available they only treat the symptoms not the cause of the disease.

This novel therapy comprises of biological components derived from the bacteria Streptococcus pneumoniae (*Spn*). The IMT has been developed in mice and has demonstrated a novel mechanism of action inducing regulatory T-cells that suppress a broad range of pro-inflammatory and immune (Th2) responses, thus attenuating allergic inflammation and other hallmark features of the disease.

This technology presents a novel mechanism of action that suppresses many of the asthma causing pathways. *Spn* components have been shown to reduce the various hallmark features of asthma including suppressed TH2 cytokine production, reduced airways inflammation, prevented eosinophil and neutrophil accumulation in blood, improved lung function and reduced mucous production.

**Data**

*Spn* infection or killed *Spn* was administered before, during or after allergic sensitization of mice. An allergen challenge was performed to induce AAD. Importantly all of the hallmark features of asthma were significantly reduced with each protocol. *Spn* prevented allergic inflammation in the blood, spleen and lung, reduced mucus secretion and inhibited the reduction of lung function. The inhibition of inflammation in the blood and spleen is particularly significant as this demonstrates the suppression of systemic allergy and suggests the possibility for the long-term prevention of disease. *Spn* also induced a significant increase in regulatory cells that may be responsible for the suppression of these allergic responses. As the use of killed *Spn* had the same effect, it is the bacterial components and not the infection that has the inhibitory effects on asthma.

Researchers then investigated the use of asthma-specific IMT agents that are constructed from *Spn* components. It was shown that mixtures of *Spn* components also inhibits AAD. Therefore it has been identified that the active components of *Spn* may be used as IMTs for asthma.

Spn Infection IMT Summary							
Infection	Eos Blood	Eos BAL	Eos Tissue	IL-5	IFN-γ	MSCs	AHR
Before	↓***	↓** *	↓*	↓** *	↓*	↓** *	-
During	↓***	↓** *	↓**	↓** *	↓*	↓** *	↓*
After	↓*	↓**	-	↓** *	↓***	-	↓*

**Table 1.** The summarised above indicated that *Spn* infection suppresses all major features of AAD tested. Similar results were obtained using a natural route of sensitisation to Ova and the effects were sustained for 8 days after Ova challenge.

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## Market

Around 300 million people worldwide suffer from asthma, with 250,000 annual deaths attributed to the disease. The number of patients with asthma is increasing and is projected to reach 24 million in the USA by 2013. Similarly, in Australia, asthma remains a significant health problem, with prevalence rates of 10%, amongst the highest internationally. The global asthma therapeutics market for asthma is approximately \$15 billion with significant trending growth.

While it is difficult to estimate the potential market size and value for our IMT, such an agent should have a significant impact on the asthma market segment and current treatment strategies. It is expected to have a substantial share of the \$15 billion asthma market either as an independent treatment solution or as a component of a combination therapy. The initial target market will be for the 10% of patients who are refractory to all current treatments for asthma.

## Intellectual property position and ownership

The IP for the IMT incorporates the components likely to be critical active ingredients in the final composition of the therapy and is the subject of the patent application; "Vaccine compositions", publication No: WO/2009/094730; international application No: PCT/AU2009/000120, with a priority date of 01/02/2008. The patent application is shortly due to enter national phase examinations and will be lodged in the USA and Europe. This patent is a selection patent and is the core of the current application that is based on an earlier patent application titled "Treatment and prevention of allergic airways diseases", publication No: WO/2008/014570; international application No: PCT/AU2007/001098, with a priority date of 03/08/2006.

## Publications

1. Thorburn AN, **Hansbro PM, Gibson PG**. *Pneumococcal Vaccines for Allergic Airways Diseases. Expert Opinion on Biological Therapy*, 2009;9(5):621-9 (IF = 3.215, ERA = B).
2. Thorburn AN, **Hansbro PM**. *Harnessing regulatory T cells to suppress asthma: From potential to therapy. Accepted American Journal of Respiratory Cell and Molecular Biology* 24.12.09. (IF = 4.319, ERA = A).
3. Preston JA\*, Thorburn AN\*, Starkey MR, Beckett EL, Wade MA, Horvat JC, O'Sullivan BJ, Thomas R, Beagley KW, **Gibson PG, Foster PS, Hansbro PM**. *Respiratory Streptococcus pneumoniae infection suppresses allergic airways disease through the induction of regulatory T cells. Accepted European Respiratory Journal* 1.5.10. (IF = 5.527, ERA = A).
4. Preston JA, Essilfie AT, Horvat JC, Wade MA, Beagley KW, **Gibson PG, Foster PS, Hansbro PM**. *Inhibition of allergic airways disease by immunomodulatory therapy with whole killed Streptococcus pneumoniae. Vaccine* 2007;25(48):8154-62 (IF = 3.616, ERA = A).
5. Thorburn AN, O'Sullivan BJ, Thomas R, Kumar RK, Foster PS, **Gibson PG, Hansbro PM**. *Pneumococcal conjugate vaccine-induced T regulatory cells protect against allergic airways disease. Accepted Thorax* 19.8.10. (IF = 7.041, ERA = A\*).



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