

**Investment Brief for
A Therapeutic Antibody to Treat Chronic
Inflammatory and Autoimmune Diseases**

**NSW
AREA HEALTH
SERVICES**

Office of Commercialisation

**For further information under a Confidential Disclosure
Agreement, please contact the following OoC team member**

**Ms Sandra See MBA
Northern Sydney Central Coast Area Health Service – Office of
Commercialisation
Ph: +61 2 9926 7523
e-mail: ssee@officeofcommercialisation.com
Level 4 Vindin House Royal North Shore Hospital St Leonards
(Sydney) NSW 2065 Australia**

A Therapeutic Antibody to Treat Chronic Inflammatory and Autoimmune Diseases

Summary

Chronic inflammatory and autoimmune diseases are caused by inappropriate amplification and overproduction of T-helper cell type-1 (Th1) and IL-17 cytokines by human immune cells. These events and the pathological progression of a wide range of autoimmune diseases and inflammatory conditions are controlled by a transcription factor which has been proven to play an important role in both animal and clinical studies. We have identified and demonstrated that an antibody, specific to a surface-membrane antigen, can down-regulate the expression of this transcription factor and other inflammatory cytokine production in human immune cells. We have demonstrated and confirmed that the antibody is highly effective in suppressing joint inflammation in collagen-induced arthritis – a well-established ***in vivo*** mouse model of the human auto-immune disorder of rheumatoid arthritis.

Potential Markets

Due to the mechanism of actions of the antibody in the pathological process, our treatment targets a wide range of autoimmune diseases (including rheumatoid arthritis, multiple sclerosis, type-1 diabetes mellitus, lupus nephritis, inflammatory bowel disease and psoriasis) and other inflammatory conditions (allograft transplantation rejection, graft versus host diseases, recurrent spontaneous abortion, failure of IVF implantation).

The market for these diseases is enormous considering that these are some of the most common conditions worldwide and their incidences are increasing. Rheumatoid arthritis affects 13 million people in America alone. Around 3 million people suffer from multiple sclerosis and nearly 5 million people have type-1 diabetes worldwide. Allograft rejection and graft versus host diseases are common problems in transplantation, while recurrent spontaneous abortion occurs in 10-15% of all pregnancies. The current annual global cost for the drug treatment of these diseases is in excess of US\$10 billion.

Benefits

Currently there is no universally effective treatment for these diseases and most treatments only target symptoms rather than the pathology of the disease. Drugs like corticosteroids, cyclosporine and methotrexate are effective immunosuppressive drugs but all have severe side-effects. Furthermore, they are not suitable for use during pregnancy in the treatment of gestational diabetes or recurrent miscarriage because of their potentially toxic effects on the fetus. The antibody used in our treatment provides high specificity for the target, and being a natural biological agent, it has less risk of side-effects, liver or renal toxicity. It is suitable for use in pregnancy because it does not cross the placental barrier or affect maternal hormonal status. Of equal importance, a major difference from other general

immunosuppressive drugs (which suppress the immune response in a broad and non-specific manner that increases the risk of opportunistic infections), is that our therapeutic antibody specifically targets the amplification of pro-inflammatory cytokine production responsible for the disease without compromising immune competence by shutting down the immune response completely.

Status of Intellectual Property

The invention has been protected by an International (PCT) Patent application which is owned by Northern Sydney and Central Coast Area Health Service (NSCCH) and the University of Sydney. We are seeking to license the technology to a commercial partner able to humanize the antibody and take it through to human clinical trials in one or more disease indications.