Neuren research shows cancer regression in preclinical model

Key points:

- Two Trefoil Factors (TFFs) have been identified as critical for cancer cell survival
- Inhibition of TFFs using antibodies resulted in almost complete regression of breast cancer in animal models
- Inhibition of TFFs has applicability to a range of cancers including colon, lung and prostate cancer
- Patent applications filed

Friday, 20 October 2006: Neuren Pharmaceuticals Ltd (ASX:NEU) announced today exciting progress in its preclinical cancer program. Neuren has discovered and applied for patents covering a novel method of treatment for a number of cancers, including breast cancer.

Key research findings that the growth hormone (GH) inside breast cancer cells (i.e. autocrine GH) plays a major role in the growth and spread of this cancer have already been published by Professor Peter Lobie, the head of the Neuren cancer project. New experiments have revealed that these effects of autocrine GH are caused by two extra-cellular proteins called Trefoil Factors (TFFs) 1 and 3. Because the TFFs operate downstream from a range of other cancer causing agents, they affect a number of other cancers as well.

New experiments have shown that these TFFs are critical for cancer cell survival and that their inhibition is the basis of a new therapeutic opportunity for Neuren. The rate of growth and spread of breast cancer and other common cancers, including colon, lung and prostate cancer, have been significantly reduced in-vitro using antibody fragments directed against TFFs.

Neuren has also shown for the first time that the inhibition of TFFs in animal models causes almost complete regression of human breast cancers. The targeting of the TFFs also overcame Tamoxifen resistance which is a clinical problem for many patients undergoing this standard treatment for breast cancer.

Professor Peter Lobie said “I am particularly excited by the therapeutic opportunities offered by using TFF inhibition to produce the regression of various cancers by increasing tumour cell death (apoptosis)”.

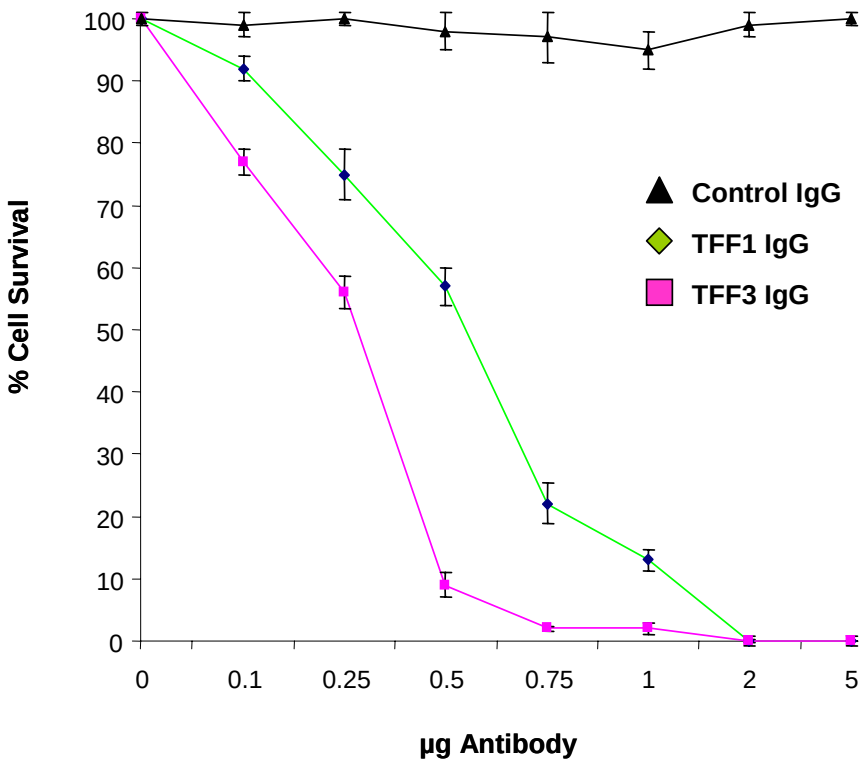
Neuren’s own observations are supported by third party clinical studies of cancer patients which show a strong correlation between TFF levels, the existence of cancer and the response to therapy and survival of cancer patients. This significant association between experimental results and clinically relevant outcomes supports Neuren’s decision to develop anti-cancer therapies based on its discoveries and using human antibodies. The use of antibodies targeted towards cancer proteins is a well accepted approach and has resulted in a number of successful products such as Herceptin. Herceptin sales for the 2005 year were US$750 million and growing at 50% per annum.

Professor Edison Liu, executive director of the Genome Institute of Singapore and former Scientific Director at the National Cancer Institute, USA said "This is an exciting breakthrough for breast cancer research. If successfully translated into clinical practice, these findings could be expected to significantly impact on cancer treatment".

Mr David Clarke, Chief Executive Officer of Neuren stated, “The opportunity to create therapies in the cancer field adds significant value to Neuren’s development pipeline in a new and commercially profitable area complementing our commitment to our CNS clinical programme.”

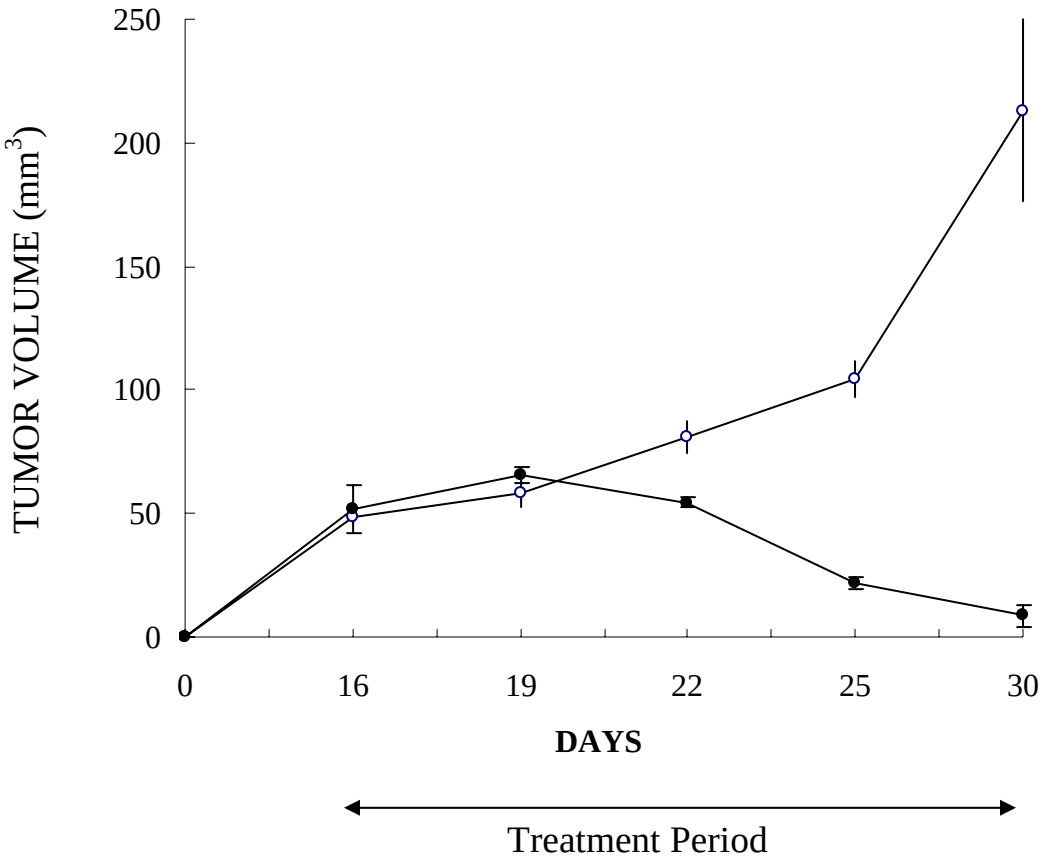
Appendix

TFF-1 and TFF-3 antibodies inhibit mammary carcinoma (MCF-7) cell survival.



To determine cell survival, a colorimetric assay was used to determine the number of viable cells. Cells were treated with different concentrations of TFF1 and TFF3 antibodies and a control IgG for control and comparison purposes. This assay was repeated three times and each point was performed in triplicate for each assay. Results are presented as mean plus standard error of mean for each concentration of antibody. In all cases results are significant with $p<0.001$.

TFF-1 antibody produces regression of human mammary tumour in a xenograft model



Human mammary tumours were grown by injection of $5x10^6$ MCF-7 cells mixed with matrigel in the mammary fat pad of female immunodeficient mice supplemented with a 60-day release pellet containing 0.72 mg of Estradiol. Once tumours had formed the mice were treated either with TFF1 antibody (dark circle) or control IgG (open circle). TFF1 antibody (10 µg/ g mouse) was delivered by *i.p*. injection every day for 2 weeks. Tumour volume was measured in two dimensions with a Vernier caliper and calculated using the formula $V= L/_2 \times W^2$ where L is Length and W is width. Results are presented as mean ± standard deviation. n = 6 for each group and results were significant between control and TFF1 treated group at 30 days; $p<0.001$.

About Neuren Pharmaceuticals:

Neuren Pharmaceuticals (ASX: NEU) is a biopharmaceutical company developing novel therapeutics in the fields of brain injury and diseases and metabolic disorders. The Neuren portfolio consists of six product families, targeting markets with large unmet needs and limited competition. Neuren has three lead candidates, Glypromate® and NNZ-2566, presently in clinical trials to treat a range of acute neurological conditions, and NNZ-2591 in preclinical development for Parkinson's and other chronic conditions. Neuren has commercial and development partnerships, including with the US Army Walter Reed Army Institute of Research, Metabolic Pharmaceuticals, UCLA Medical Center and the National Trauma Research Institute in Melbourne.

For more information, please visit Neuren's website at www.neurenpharma.com

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