



31 May 2011
Announcement # 419

ASX Code: VHL

VIRAX HOLDINGS LIMITED
SHAREHOLDER OVERVIEW OF TG1042 SKIN CANCER IMMUNOTHERAPY PRODUCT

Please find attached a Shareholder overview of the Virax TG1042 skin cancer immunotherapy product.

TG1042 - CLINICAL PROGRAM – SKIN CANCER

In February 2011 the company executed an exclusive global licence from Transgene to further develop TG1042 – a therapeutic vaccine for skin cancer. This licence permits the company to build on the existing clinical data obtained by Transgene in a rare form of skin cancer (cutaneous lymphoma) that demonstrated the vaccine to be safe, well tolerated and efficacious. The licence for this “clinic ready” program will permit the Company to commence clinical trials upon receipt of the TGA approval - anticipated to be during this year. The initial focus will be nodular basal cell carcinoma (BCC), however the licence is broad in its scope and could be focused on other skin cancer indications, which may include melanoma, should such clinical development be commercially justified.

About Virax Holdings

Virax is an Australian biopharmaceutical company engaged in the discovery and development of novel immunotherapeutic products for the treatment of chronic infectious diseases and cancer.

Virax has a Licence Agreement with major French biotechnology company Transgene for access to Virax's Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are; TG4001 – a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to cervical cancer, and TG4010 – a treatment for non-small cell lung cancer (NSCLC).

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TG1042 Skin Cancer Immunotherapy Product Shareholder Overview

- Virax has an exclusive Licensing Agreement for TG1042 skin cancer treatment product
- Licensing Agreement is a major opportunity in the Australian and global skin cancer treatment market
- Virax plans to move rapidly to clinical trials in 2011
- Trials to be conducted in Australia to take advantage of world-leading skin cancer trial resources

Summary

In February 2011 Virax Holdings signed an exclusive worldwide License Agreement with leading French biopharmaceutical company Transgene (Eurolist Paris: FR0005175080) to develop TG1042, a clinical-stage skin cancer immunotherapy product.

The licence covers the use of TG1042 in all skin cancer applications.

Transgene has invested significant resources in developing TG1042, including the development of a commercially scalable manufacturing process, an extensive pre-clinical package and Phase 1 and Phase II trials.

These TG1042 trials were conducted in Europe in patients with cutaneous lymphoma (CTL), a rare form of skin cancer. Data from these trials showed TG1042 to be safe and well-tolerated and also showed very promising anti-tumor activity with clinical benefit to patients.

Virax plans to move rapidly into its own clinical trials for TG1042 and will target the much-larger Basal Cell Carcinoma (BCC) market. The company believes the safety data and positive responses from the trials conducted by Transgene increase the likelihood of success in the planned BCC trials and thereby reduces risk.

The availability of clinical data for this in-licensed product also facilitates the near-term initiation of trials in Australia, planned for Q3 2011.

Virax Holdings Limited

ASX: VHL

Virax Holdings is an emerging Australian biotechnology company, which is focused on the development of immunotherapy products to treat major serious disease and illness.

Its core product is the TG1042 skin cancer immunotherapy treatment product. Virax plans to move rapidly into clinical trials on the product this year.

Capital Structure

(20 May 2011)

Share Price: \$0.027

Market Cap: \$4.9M

Shares on Issue: 181.5 million

Board and Management

Michael Humphris, Chairman

Dr Larry Ward, CEO

Timothy Cooper, Non-Executive Director

Ian Pyman, Non-Executive Director

John Morrison, Company Secretary

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VIRAX TG1042

A GLOBAL SKIN CANCER OPPORTUNITY

Skin Cancer Facts

Facts and Figures

- There are currently 2-3 million skin cancers occurring annually worldwide (Skin Cancer Foundation)
- One in every five Americans will develop skin cancer during their lifetime (Skin Cancer Foundation)
- Two of every three Australians will be diagnosed with skin cancer by age 70 (www.cancer.org.au)
- Incidence of skin cancer in North America, Europe and Australia is increasing 3-6% annually
- Skin cancer can be considered a chronic disease with two thirds of patients treated for primary BCCs developing new lesions within 5 years.

Global incidence of non-melanoma Skin Cancer estimated at 3.77 million in 2018



TG1042: a new way to treat skin cancer

MARKET POSITIONING

The TG1042 Opportunity

Skin cancer is the most prevalent form of cancer worldwide.

There are many forms of skin cancer but the most common is Basal Cell Carcinoma (BCC). BCC accounts for an estimated 75% of non-melanoma skin cancers, with nodular BCC (nBCC) being the most prevalent form (Skin Cancer, 2008, K Nouri, McGraw Hill). A recent review article reported that nBCC accounted for 62-70% of all BCC diagnoses (Scrivener et al. Brit J Dermatol. 2002; 147:41-47). 80% of nBCC lesions occur in the face, neck and head, which complicate the process of surgical excision due to either location or concerns of cosmetic outcome from the surgery.

A variety of treatment modalities have been developed to treat BCCs including electro desiccation and curettage, cryosurgery, radiation, topical imiquimod and 5-fluorouracil. While these treatment modalities are suitable for some histological subtypes of BCC such as superficial BCC (sBCC) they are not highly effective for nBCC, for which surgical excision remains the gold standard.

It is estimated that for surgical excision of nBCCs, about one quarter can be classified as difficult surgeries, due to their size or anatomical location (e.g. close to eyelids). Surgery on the face may also produce a scar that is cosmetically disfiguring. In addition, successful surgical treatment requires leaving a clean margin, histologically clear of cancer cells. For a significant number of patients with nBCC in the face and head, surgical excision is problematic. A conservative approach that spares the excision margin around the lesion often leads to higher relapse rates for nBCCs located on the face.

Difficult surgery is a target application for TG1042 as a viable treatment alternative



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VIRAX TG1042

A GLOBAL SKIN CANCER OPPORTUNITY

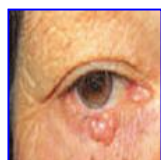
TG1042 – A new way to treat Skin Cancer

About TG1042

TG1042 is based on an antigen-independent immunotherapy platform utilising a replication deficient adenovirus type 5 (Ad5) carrying the human IFN- γ gene. It is designed for direct intra-tumoral injection. The mechanism of action relies on gene transfer-mediated antigen independent immunotherapy by intralesional delivery of the active agent. The pleiotropic effects of both the adenovirus vector and the expressed IFN contribute to the anti-tumor effects of the drug. Intratumoral administration of TG1042 has been shown to effect sustained intratumoral production of cytokine. This is important as detection of IFN transcripts have been shown to correspond to therapeutic response in patients.

IFN- γ belongs to a family of proteins called interferons consisting of Type 1 (IFN- α and IFN- β) and type 2 interferons (IFN- γ). Interferons are central coordinators of tumor-immune system interactions.

In prior clinical studies of TG1042 in cutaneous lymphoma (see section below) it was shown that the observed clinical response of the treated lesions related to both induction of Type 1 and Type 2 interferon responses. TG1042 induces this dual interferon response by; Type 1 interferons being produced upon infection of the tumor cells by the adenovirus vector and direct expression by TG1042 of the Type 2 interferon, IFN- γ .



TG1042 aims to provide an alternative to difficult BCC surgery, such as these

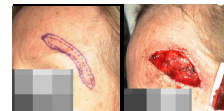


TG1042 to treat Basal Cell Carcinoma

A review of 15 clinical trials in 858 patients indicates that multiple intralesional injections of protein forms IFN α , IFN β or IFN γ are effective treatment of BCC. Multiple intralesional injections of IFN α 2 protein induces overall remission rates of 70-100% in BCC patients, making it comparable to surgical excision. In addition IFN- γ has also shown efficacy in BCC. Long term follow up (minimum 10 years, average 13.5 years) of BCCs treated with perilesional IFN α 2b showed a cure rate of 96% (Tucker, 2006) which compares to most methods of BCC eradication.

Despite recombinant protein forms of IFNs having previously been used with good effect for the treatment of BCC their widespread use has been discontinued as multiple injections by the doctor into the tumor (up to 9 times over a three week period) is required, which was not practical. The use of the viral vector delivery approach utilized by TG1042 circumvents this problem as expression of IFN- γ by the virus lasts 1-2 weeks. The synergistic production of both Type 1 and Type 2 Interferons by TG1042 has the potential to further increase the potency of this approach.

MARKET POTENTIAL



- BCC is the most common skin cancer and accounts for about 75% of all skin cancer diagnoses. Based on worldwide skin cancer figures (from market research firm Frost & Sullivan) there will be a total BCC patient pool of 2.75 million in 2018.
- Using the reported rates of nBCC as a percentage of BCC from the British Journal of Dermatology, a nBCC patient pool of 1.7-1.9 million will exist in 2018.
- Assuming a market penetration of 25% for TG1042, a market of 425,000-500,000 patients exists.
- Based on estimates of current therapeutic costs and projected future clinical development costs, Virax projects a future price per treatment for TG1042 of \$750-\$1000.
- Using these estimates, a peak annual market potential of up to US\$500 million can be estimated.

If data from future, larger clinical trials shows TG1042 has an equivalent efficacy to surgery in clearing nBCC, it may create an even larger potential market than the indicative 25% of difficult surgeries. The availability of an equivalent non-surgical approach for nBCC lesions on the face and neck is likely to have a strong appeal to patients. Virax bases these observations on literature review and discussions with dermatologic surgeons. Subject to supporting clinical data, the increase in potential market could be a further 25-50%.

Development plans for TG1042

Manufacturing

A commercially scalable manufacturing process using current Good Manufacturing Practice (cGMP) has been developed for TG1042. Under the License Agreement between Virax and Transgene, Transgene will provide an appropriate amount of clinical grade TG1042 for clinical trials up to Phase II. This is an important feature of the License Agreement and will enable Virax to pursue its aggressive clinical development plan for TG1042.

TG1042 is produced as a viral suspension and is formulated in sterile fill glass ampoules for injection. Ampoules are stored at -70 C with stability trials ongoing.

Virax is currently in discussions with potential contract manufacturers to produce TG1042 in larger quantities for future large scale Phase III clinical trials and eventual commercial scale production.

Pre-Clinical testing

Extensive pre-clinical pharmacological and toxicological studies of TG1042 have been completed, demonstrating the efficacy of the direct intratumoral injection as well as the safety of the approach. The pre-clinical package detailing these studies is extensive and has supported the prior approval for human clinical testing of TG1042 as adjudged by the US regulatory authorities as well as various European authorities. The availability of this package should also facilitate rapid clinical testing of TG1042 in Australia in the area of BCC.

Prior Clinical Testing

TG1042 has been tested previously in humans in skin cancer indications for the treatment of cutaneous lymphomas (via intratumoral injection), where it has shown highly promising results in Phase I and Phase II Clinical Trials. It has also been shown to be safe and well tolerated up to a dose level of 3×10^{11} virus particles.

In Phase I Trials with patients with advanced cutaneous T-cell lymphoma (CTCL) and multi-lesional cutaneous B-cell lymphoma (CBCL), treatment with TG1042 induced a high overall response rate of local clinical responses.

In Phase II Clinical Trial of Intra-lesional administration of TG1042 (Adenovirus-interferon-gamma), patients with relapsing primary cutaneous B-cell lymphomas, the primary endpoint was met in the first step of the Phase II trial as measured by overall objective response rate of 83%. These studies suggest that local administration of Ad-IFN- γ is both safe and demonstrates anti-tumor activity with clinical benefit

This treatment was highly promising and on this basis was awarded Orphan Drug status by the European medical regulatory body, European Medicines Agency (EMA) for the treatment of Cutaneous T cell Lymphomas. This prior human testing of the product has significantly lowered the technical risk of the project in nodular BCC.

Future clinical development

Virax plans to now move rapidly into Phase I/IIa Clinical Trials for TG1042 in 2011 (subject to receiving the necessary regulatory approvals). The trials will be conducted in Australia in order to take advantage of the country's world-leading skin cancer trial resources. The initial focus will be in nodular basal cell carcinoma. The major efficacy outputs of the trial will be clinical response (measures of effect on lesion size) and histological response.

Virax is in communication with the TGA to discuss the trial design prior to submission of a CTX soon thereafter. The commencement of the trial is planned for Q3, 2011.

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