

ASX & Media Release

Royal Adelaide Hospital Approves Commencement of Patrys Melanoma Human Trial

- Approval granted for human clinical trial to evaluate PAT-SM6 as a treatment for melanoma
- Trial to be conducted in Australia where melanoma rate is highest in the world
- Patient recruitment will commence immediately; first data expected during the 2HCY2010

Melbourne, Australia; 2 August, 2010: Patrys Limited (ASX: PAB), a biopharmaceutical company focused on the development of natural human antibody based therapies for deadly cancers, announced today the approval of a human clinical trial to evaluate PAT-SM6 as a treatment for melanoma.

Approval to commence the trial came from the Human Research Ethics Committee at the Royal Adelaide Hospital.

PAT-SM6 is a natural human antibody that has shown great promise in laboratory and animal testing as a potential treatment for multiple types of cancer, with a particularly strong potency against melanoma.

Melanoma is a very serious global medical problem, with an expected doubling of incidence every 15 years. Australia has the highest rate of skin cancer in the world, where nearly 10,000 cases are diagnosed each year. Current treatments for metastatic melanoma are largely ineffective, resulting in a five year survival rate of just 16%.

This will be the first trial globally to target Glucose-Regulated Protein 78 (GRP78) as a treatment for melanoma. GRP78 is a protein over-expressed on the surface of cancer cells that plays a role in the aggressiveness of the disease. In contrast, GRP78 is not present on the surface of normal cells. PAT-SM6 is thus a novel treatment with a potentially potent yet safe profile.

Patrys CEO, Dan Devine, commented: "This is exciting on a number of levels. First, PAT-SM6 offers a potentially new treatment for melanoma, where current therapies are largely ineffective."

"In addition, this is the first trial of a product produced using Patrys' proprietary manufacturing platform for natural human antibodies – which is groundbreaking and which sets a precedent for advancing other clinical candidates from our pipeline."

The clinical trial will be conducted at the Royal Adelaide Hospital in Australia and enrol approximately 10 patients. The primary endpoint for the trial is to measure the safety of PAT-SM6. Multiple secondary endpoints are aimed at measuring the anti-tumour activity of PAT-SM6.

First patient data from the trial is expected to be available in the 2HCY2010. The trial is expected to take approximately twelve months to complete.

Should PAT-SM6 prove safe and well tolerated in this first human study, Patrys anticipates the immediate start of a second clinical trial for PAT-SM6 that will target up to 25 patients with metastatic melanoma and additional types of cancer. The production process for this larger trial has commenced.

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About Patrys Limited:

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibody therapies for cancer. Patrys has a deep pipeline of internal development candidates and additional products that are the subject of a collaboration agreement with a larger industry partner. More information can be found at www.patrys.com.

About PAT-SM6:

The natural human antibody PAT-SM6 has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has now screened PAT-SM6 against more than 200 tumours from individual patients with various cancers, and the product binds to over 90% of the tumours screened regardless of cancer type, age, gender or disease stage. With respect to melanoma, PAT-SM6 has shown particularly strong promise. In a broad panel of experiments, PAT-SM6 has shown a potent ability to kill melanoma cells. In addition, PAT-SM6 has been shown to bind to 100% of different malignant melanoma patient tumours screened, an attribute that not only opens up commercial opportunities, but also greatly facilitates clinical development because all patients with metastatic disease can be included in the respective clinical trials. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. A human clinical trial evaluating PAT-SM6 as a treatment for melanoma commenced in August of 2010.

About GRP78:

Patrys clinical candidate PAT-SM6 binds to a form of Glucose-regulated protein 78 (GRP78), which is expressed on the surface of cancer cells but not detected on the surface of healthy cells. Once bound, the PAT-SM6/GRP78 complex is then internalised into malignant/cancer cells inducing apoptosis and cell death. The potential of GRP78 as a target for cancer therapy is supported by extensive third party literature that has reported several roles played by GRP78 with respect to promoting tumour proliferation, tumour survival, metastases and resistance to a wide variety of existing anti-cancer therapies. As a result, GRP78 expression has been correlated with an adverse prognosis in melanoma, breast, lung, gastric, hepatocellular and prostate cancer, and drug resistance in breast cancer. Given GRP78's reported roles with respect to several cancers, a molecule such as PAT-SM6 presents a promising anti-cancer treatment to the extent it interferes with the function of GRP78 in cancer.

Appendix: PAT-SM6 Human Clinical Trial - Melanoma

Approval: Approval for this trial was granted by the Human Ethics Committee of the Royal Adelaide Hospital on 30 July 2010 and notification given to the Australian regulatory body, the Drug and Safety Evaluation Branch of the Therapeutic Goods Administration (TGA). The trial will be conducted under the TGA's Clinical Trial Notification (CTN) scheme.

Global Standards: The trial will be conducted in accordance with the principles of the International Conference on Harmonization (ICH), which incorporate standards of conduct for clinical trials that are essentially uniform for all the major regulatory agencies world-wide, including the United States FDA and Australia's TGA.

Trial Title: A Single Dose, Dose Escalating, Phase I Clinical Trial of PAT-SM6 Monoclonal Antibody in Patients with Recurrent In-Transit Cutaneous Melanoma

Primary Objectives: Establish the safety profile of a single dose of the anti-GRP78 monoclonal antibody PAT-SM6 in patients with recurrent in-transit cutaneous melanoma

Major Secondary Objectives:

- Describe the pharmacokinetics of PAT-SM6
- Screen for the development of patient antibodies against PAT-SM6 (immunogenicity)
- Explore the anti-tumour activity of PAT-SM6
- Assess the pharmacodynamic effect(s) of PAT-SM6 in patient tumour samples
- Identify potential predictors (biomarkers) of therapeutic efficacy and/or safety

Method: This trial is a multicentre, open-label, dose-escalation, Phase I study. Patients will receive a single dose of PAT-SM6 intravenously, followed 96 hours later by collection of cutaneous tumour tissue.