

Patrys Announces Successful Phase I Clinical Trial for PAT-SM6

Key points

- **Final trial data analysis confirms all dose levels administered were safely received**
- **No significant adverse immune reactions observed in any patients**
- **PAT-SM6 found in patient tumours to cause cell death**
- **Additional multi-dose animal toxicology work completed successfully**

Melbourne, Australia; 20 March, 2012: Patrys Limited (ASX: PAB; “the Company”), a clinical stage biopharmaceutical company, is pleased to advise that final data is now available from its recently completed Phase I clinical trial. This trial was conducted in patients with melanoma, who were dosed with the Company’s anti-tumour antibody PAT-SM6. The data provides uniform evidence for PAT-SM6’s safety, and initial data supporting its ability to specifically target melanoma tumours.

The primary trial objective was to establish safety and tolerability. No significant safety issues were observed or reported for any patients treated with PAT-SM6 during infusion, immediately following dosing, or during the month-long follow up period. All patients completed the trial without incident and were eligible for assessment.

There were a number of additional secondary objectives. Analysis of blood samples collected during the trial confirmed that no patient generated a significant adverse immune response to PAT-SM6. This is an important finding as adverse immune reactions to existing marketed antibodies is known to limit the effectiveness of these treatments. This result provides additional support for the Company’s decision to ensure the natural human properties of the antibodies are preserved throughout development, by advancing production through the manufacturing human cell line PER.C6®.

Additional blood samples were assessed for pharmacokinetic parameters (such as drug half-life) to provide valuable information which will aid in the design of dosing regimens for the next PAT-SM6 trial currently in planning, with patients suffering from multiple myeloma, a serious blood cancer.

Pre-dose and post-dose melanoma tumour samples from the final cohort were also examined. Despite the low dose of PAT-SM6 relative to expected therapeutic dose levels, an increased level of cancer cell death (apoptosis) was observed to be widespread in one of the patient’s post-treatment samples, compared to the same patient’s pre-treatment specimen.

“This data is very exciting and provides a glimpse into the promise of Patrys’ unique pipeline which is based on natural human antibodies like PAT-SM6. The safety of PAT-SM6 as demonstrated in this trial and the additional information we have gathered lays the groundwork for our upcoming multidose study in patients with multiple myeloma,” said Dr Marie Roskrow, Patrys’ Chief Executive Officer.

“These data represent a significant milestone for Patrys and strengthens our position as a clinical stage cancer development company.”

In addition to the completion of the clinical trial, Patrys has recently completed an additional multi-dose animal toxicology study in order to further support human trials and the pool of data surrounding PAT-SM6. No adverse effects were observed in the test animals despite the very high doses administered. These doses were many times the expected maximum therapeutic dose that would be used to treat humans, and therefore create a significant safety margin for dosing in future trials.

PAT-SM6 is a natural human antibody that has shown promise as a potential treatment for multiple types of cancer including solid tumours (e.g. melanoma), and multiple myeloma. It is the first reported clinical product to target an important protein on the surface of cancer cells called GRP78 that plays a number of key roles in cancer cell survival, growth and metastasis.

- Ends -

For further information, please contact:

Patrys Limited:

Dr. Marie Roskrow
Chief Executive Officer
P: +61 3 9670 3273
info@patrys.com

Patrys IR:

Rebecca Wilson
Buchan Consulting
P: 0417 382 391
rwilson@buchanwe.com.au

Patrys Media:

Tom Donovan
Buchan Consulting
P: +61 3 9866 4722
tdonovan@buchanwe.com.au

About Patrys Limited:

Based in Melbourne, Australia, Patrys (ASX: PAB) a clinical stage company, is focused on the development of natural human antibody therapies for cancer. 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 or patient age, gender or disease stage. With respect to melanoma, PAT-SM6 has shown particularly strong promise. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. In October 2010, Patrys initiated a human clinical trial to evaluate PAT-SM6 as a therapy for melanoma. This trial concluded in February 2012. The clinical trial took place at the Royal Adelaide Hospital Cancer Centre and associated Pain and Anaesthesia Research Clinic and the Princess Alexandra Hospital in Queensland.

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 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.