



ASX & Media Release

## Shareholder Update

- **PAT-SM6 Multiple Myeloma Phase I/IIa clinical trial hits primary endpoint**
- **Manufacturing and planning underway for combination study with Patrys' PAT-SM6 and Onyx Pharmaceuticals' Carfilzomib**
- **PAT-LM1 preclinical programme enters scale-up manufacturing**
- **PAT-SC1 gastric cancer survival data published in Oncology Reports**
- **Strong reported cash position of \$10.3 million**

**Melbourne, Australia; 23 January, 2014:** Patrys Limited (**ASX: PAB**), a clinical stage biotechnology company is pleased to provide a Company update for its shareholders and the broader market.

### **Lead Programme PAT-SM6:**

The recently completed PAT-SM6 Phase I/IIa clinical trial, in patients with refractory or relapsed multiple myeloma (MM), has successfully achieved the primary endpoint of safety and tolerability. All twelve patients, including those treated at the highest dose level (6mg/kg/dose), tolerated PAT-SM6 very well. There were no drug-related serious adverse events and no dose-limiting toxicities. These data have been reviewed and approved by the Data and Safety Monitoring Board (DSMB).

Of the twelve treated patients (10 male and 2 female, median age 71 years all of whom had failed their current therapeutic regimes) four of them (33%) with end-stage, multi-resistant MM showed evidence of stable disease according to the International Myeloma Working Group criteria. Two of these patients were stable for more than 100 days.

Patients treated with PAT-SM6 also had a mean time to next therapy of 47 days which is clinically significant. A full and detailed analysis of the complete laboratory data is ongoing and will be released before the end of March 2014, as previously stated.

On the basis of these results and the strong preclinical package, Patrys is now preparing for the next clinical trial, a combination study of PAT-SM6 and Carfilzomib, which is to be sponsored by Onyx Pharmaceuticals, a subsidiary of Amgen.

A strong cash position has enabled Patrys to commit to completing the large-scale manufacturing of PAT-SM6 which is required for this planned combination study. This process is expected to cost approximately AU\$4 million and to be completed by the middle of 2014. Thereafter, the Company will seek approval, from the Paul-Ehrlich Institute in Germany, to conduct the clinical study at the University of Würzburg under the direction of Professor Dr. Hermann Einsele. Further details on this planned trial will be available later this year.

In addition, Patrys continues to collaborate with a number of international groups on a variety of preclinical projects involving PAT-SM6 and we anticipate 2-3 publications on this work during 2014.

Patrys retains worldwide rights to PAT-SM6 and, on conclusion of the planned combination study, we anticipate partnering this asset with a major pharmaceutical/biotechnology company.



**PAT-LM1:**

Patrys' second programme, PAT-LM1, has now entered the scale-up manufacturing process in preparation for a future clinical trial. In addition to production, Patrys will conduct multi-species toxicology studies before embarking on a clinical programme. We anticipate spending approximately AU\$2 million on PAT-LM1 in 2014 and approximately a further AU\$2 million in 2015.

Patrys continues to explore the best clinical indication for this antibody and currently, it is anticipated that a type of blood cancer will be chosen. We intend to publish some preclinical data later this year.

**PAT-SC1:**

As announced to the market, survival data from the first clinical trial using PAT-SC1 in patients with gastric cancer have been published in Oncology Reports.

A commercial partner is being sought for this antibody and discussions are currently ongoing.

**Early preclinical antibodies:**

In 2014 the Company anticipates securing new research collaborations with international groups to escalate the rate and quality of data generation. Discussions are currently ongoing and further details will be provided later in 2014. We anticipate spending approximately AU\$500k on these early-stage programmes in 2014.

Patrys' CEO, Dr. Marie Roskrow, said: "After a very successful 2013, in which we hit all of our programme milestones and raised a significant amount of new capital, we are now looking forward to an even better 2014."

"Our lead asset, PAT-SM6, performed excellently in the recently-completed clinical trial and 2014 will see this programme move forward significantly, creating value for our shareholders. This year we are in a position to also advance PAT-LM1 and a couple of other earlier-stage assets. Moving multiple programmes forward in parallel is critical for us both to create shareholder value and to diversify risk."

"The data coming out of these programmes look very exciting and we look forward to reporting more as we progress through the year. Presentation and publication of data is very important and we will be focussing considerable effort in this area this year. Finally, I would like to take this opportunity to thank our shareholders for their continued support and we look forward to a very successful 2014".

**-Ends-**

**For further information, please contact:**

**Patrys Limited:**

Dr. Marie Roskrow  
Chief Executive Officer  
P: +61 3 9670 3273  
[info@patrys.com](mailto:info@patrys.com)

**Patrys IR:**

Rebecca Wilson  
Buchan Consulting  
P: 0417 382 391  
[rwilson@buchanwe.com.au](mailto:rwilson@buchanwe.com.au)

**Patrys Media:**

Kellie Hanrick  
Buchan Consulting  
P: +61 3 9866 4722  
[khanrick@buchanwe.com.au](mailto:khanrick@buchanwe.com.au)

**About Patrys Limited:**

Based in Melbourne, Australia, Patrys (ASX: PAB) is focused on the development of natural human antibodies as therapies for cancer and other major diseases. Patrys has a deep pipeline of anti-cancer natural human antibodies that enable both internal development and partnering opportunities. More information can be found at [www.patrys.com](http://www.patrys.com).

**About PAT-SM6:**

PAT-SM6 is a natural human IgM antibody which has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. More specifically, Patrys has 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. Patrys has filed patent applications to cover the PAT-SM6 antibody molecule, disease target, and the mechanism of action. Patrys' PAT-SM6 has shown convincing evidence of potential therapeutic benefit in the recently completed Phase I/IIa clinical trial in patients with relapsed and refractory multiple myeloma. PAT-SM6 has been granted orphan drug status in Europe and the USA for multiple myeloma. Patrys has also successfully completed a Phase I clinical trial to evaluate PAT-SM6 as a therapy for melanoma. Patrys is now preparing for the next clinical trial (a combination study of PAT-SM6 and Carfilzomib) which is to be sponsored by Onyx Pharmaceuticals, a subsidiary of Amgen.

**About PAT-LM1:**

PAT-LM1 is a natural human IgM antibody that binds to a proprietary disease target NONO that is expressed on the surface of cancer cells, but not on the surface of the healthy tissues. Binding of PAT-LM1 to NONO causes cell death through interference with the gene regulation mechanisms inside the cells. PAT-LM1 has been shown to have potent anti-cancer properties in a large number of laboratory and animal studies. With over 200 individual patient tumours screened, covering several different cancers, PAT-LM1 binds to nearly 98% of those tumours regardless of cancer type, age, gender or disease stage. PAT-LM1 has now entered the scale-up manufacturing process in preparation for a future clinical trial. The clinical indication for PAT-LM1 is yet to be determined. Patrys has patents granted that cover the PAT-LM1 molecule and its method of treatment.

**About PAT-SC1:**

PAT-SC1 is a natural human IgM antibody that acts by binding to a specific form of a protein, called CD55 that appears on the surface of cancer cells (including gastric, lung, cervical and colon), but not on healthy cells. Binding of PAT-SC1 antibody to its CD55 target on the cell surface results in cross linking and signalling of internal proteins ultimately leading to the killing of the cancer cell. PAT-SC1 has been evaluated in an investigator led human clinical trial, at the University of Würzburg (Germany) Surgical Clinic, under which treated patients were dosed with PAT-SC1 48 hours prior to a surgical procedure that involved the removal of the primary tumour (standard treatment for gastric cancer patients). Follow up 10-year survival data has shown that 55% of these patients are still alive whilst only 30% of the control group have survived, indicating that the treatment of gastric cancer patients with PAT-SC1 confers a significant survival benefit. PAT-SC1 is currently the focus of an out-licensing programme.