

ASX & Media Release

## Gastric Cancer Antibody Exceeds Manufacturing Yield Expectations; Disease Target of Industry Interest

- PAT-SC1 successfully transferred to Patrys' proprietary, large scale manufacturing technology
- Achievement of highest yields to date for any Patrys program, exceeding 4 grams/litre titres
- Expect production cell line to be ready for GMP clinical trial production by July 2011
- Independent research reports on key role in cancer for PAT-SC1's disease target, CD55

**Melbourne, Australia; 9 March 2011:** Patrys Limited (ASX: PAB), which is developing a new class of antibody molecules for the treatment of cancer, is pleased to announce success in obtaining commercial production yields for natural human antibody PAT-SC1, facilitating the advancement of this promising product toward a second human clinical trial for the treatment of cancer.

Prior to being acquired by Patrys, PAT-SC1 was evaluated for safety and efficacy in a human clinical trial involving gastric cancer patients. The results were encouraging, as patients treated with PAT-SC1 experienced a significant survival benefit compared to a historical control set of patients that received similar treatment but for the PAT-SC1 antibody. When acquired, the product was produced using outdated and low-yielding technology, necessitating a move to Patrys' newly developed proprietary manufacturing technology for natural human antibodies.

That transfer has now occurred, with yields achieved of 4 grams/litre, which far exceeds the commonly cited industry standard for production of an antibody in Phase I/II clinical trials of 1 gram/litre.

The manufacturing program is conducted at Percivia, a U.S. based joint venture between global biopharmaceutical company Crucell N.V., a subsidiary of Johnson & Johnson, and leading manufacturing firm DSM Biologics. All data on PAT-SC1 yields was generated by Percivia.

"While we were confident Percivia would succeed in achieving targeted yields, this now confirms that PAT-SC1 can be produced in sufficient quantities to support advanced clinical development. We will now focus our efforts on how best to achieve that aim – whether as an internal or partnered program," commented Patrys Chief Executive Officer, Dan Devine.

In addition to manufacturing advances, over recent months several researchers from independent laboratories have reported new data pointing to an expanded and critical role of CD55 in cancer, the disease target for PAT-SC1. Among other findings, over the past several months international researchers reported the following (complete citations available below):

- Cancer cells expressing CD55 are resistant to multi-billion dollar antibody rituximab (*Cancer Research*).

- Inhibition of CD55 clearly sensitises breast, prostate and leukaemia cancer cells to complement attack and therefore could be useful as possible adjuvant to improve antibody-based cancer immunotherapy (*Current Cancer Drug Targets*).
- Expressions of CD55 in rectal tumour tissues significantly higher than in normal colorectal tissues, and expression of CD55 correlates with tumour recurrence and metastasis. (*International Journal Colorectal Disease*).
- Expression of CD55 significantly increased in human cervical cancer tissues; inhibition of CD55 enhanced cell death and helped control cancer cell migration (*Journal of Cancer Research Clinical Oncology*).

Late last year PAT-SC1 was confirmed orphan drug status by the United States Food and Drug Administration (FDA), allowing the product to benefit from the potential for fast track development in the United States. This can in turn be leveraged globally where the market is more commercially significant with over 1,000,000 new cases diagnosed each year.

Looking forward, Percivia will now turn to optimising upstream processes for PAT-SC1. The program is expected to be complete by July 2011, at which time PAT-SC1 will be ready for a clinical trial production program.

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**For further information, please contact:**

*Patrys Limited:*

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

*Patrys Media and Investors:*

Rebecca Wilson  
Buchan Consulting  
P: +61 3 9866 4722  
[rwilson@bcg.com.au](mailto:rwilson@bcg.com.au)

**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](http://www.patrys.com).

**About PAT-SC1:**

PAT-SC1 is a natural human antibody that acts by binding to a special form of a protein, called CD55 that appears on the surface of gastric cancer cells but not on the surface of healthy cells, thereby permitting PAT-SC1 to kill the cancer cells while sparing the healthy cells. PAT-SC1 was evaluated in an investigator led human clinical trial, under which treated patients were dosed with PAT-SC1 48 hours prior to a surgical procedure that involved the removal of the primary tumour (surgical removal of the tumour is currently the standard treatment). Thirty-five PAT-SC1 treated gastric cancer patients showed a statistically significant increased survival benefit compared to a historic control group of 53 patients that received the same surgical treatment but who did not receive PAT-SC1. Additional published data shows that PAT-SC1 at this dose level was very safe and well tolerated by patients receiving the treatment. The referenced clinical results were compiled by an independent research firm.

**About Gastric Cancer:**

Gastric cancer can develop in any part of the stomach and may spread throughout the stomach and to other organs; particularly the esophagus, lungs, lymph nodes, and the liver. Stomach cancer causes about 800,000 deaths worldwide per year. Gastric cancer shows a male predominance in its incidence as up to three males are affected for every female. Surgery is the most common treatment and is often the only hope of cure for stomach cancer. The surgeon removes part or all of the stomach, as



well as the surrounding lymph nodes, with the basic goal of removing all cancer and a margin of normal tissue. Depending on the extent of invasion and the location of the tumor, surgery may also include removal of part of the intestine or pancreas.

**Literature Citations:**

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Han SL, Xu C, Wu XL, Li JL, Liu Z, Zeng QQ. The impact of expressions of CD97 and its ligand CD55 at the invasion front on prognosis of rectal adenocarcinoma. **International Journal Colorectal Disease**, 2010, 25(6): 695-702.

Gao LJ, Ding L, Guo SY, Cai YQ, Su YJ, Gong H, Liu Y, Chen C, Gu PQ. Role of decay-accelerating factor in regulating survival of human cervical cancer cells. **Journal Cancer Research Clinical Oncology**, 2011, 137(1): 81-7.