



ASX & Media Release

## Further Manufacturing Update– Clinical Trial Remains on Hold

**Melbourne, Australia; 11 June, 2015:** Patrys Limited (ASX: PAB, “the Company”) has today provided an update on the status of the manufacturing and proposed clinical trial of its lead anti-cancer drug candidate, PAT-SM6.

The Company reports that the current production run of PAT-SM6 IgM has not produced an adequate mass of antibody that meets release specifications. As the variability in the yield and consistency of the end product is unresolved, the initiation of the proposed combination trial of PAT-SM6 in refractory multiple myeloma patients remains on hold.

In November 2014, the Company announced complications in manufacturing which would delay the commencement of its planned clinical trial. These complications, which involved purification yields, were overcome by changing the protein separation system used.

In February 2015, the Company announced that the bulk finished antibody product had not met release specifications. Based on the advice of external experts the Company believed at the time and still believes, that the observed variations in product quality are likely the result of this change in the protein separation system.

As a result, individual batches of product do not meet the pre-identified specifications of acceptable product, and there is batch-to-batch variation of specifications, meaning that individual batches cannot be pooled as a single stock of IgM for clinical trials.

The Company’s independent advice is that the release specifications are too rigid for a product at this stage of development given the batch-to-batch variability.

As the batches did not meet specification, the manufacturer has informed Patrys that it will not release these batches of antibody for human use. The Company intends to approach the scientific advisory board of the German regulator, the Paul Ehrlich Institut (“PEI”) with data that has been collected over the past months in an effort to obtain its advice regarding product quality. Based on advice from its CMC consultant, the Company believes this approach will have a low probability of success in getting approval to use the material in a clinical trial.

“We understand the frustration felt by shareholders of Patrys with this latest setback,” said Dr. James Campbell, CEO and Managing Director. “The production and development of antibodies is a complex, costly and lengthy process, and whilst these types of issues are not unusual it is nevertheless disappointing.”

“Given the therapeutic responses observed in patients treated with PAT-SM6 and PAT-SC1, in the clinic, Patrys remains committed to realising the potential of IgMs. The Company will be reviewing its strategy moving forward in regard to IgMs, including the potential for process improvements based on lessons learned from this latest manufacturing set back. The Company also continues to evaluate strategic collaborations and other complementary assets with a view to maximising value creation and investor return.”

The Company will provide further updates as information becomes available.

### **Investor Conference Call – Friday 12 June, 9.30am AEST**

Patrys' CEO and Managing Director, Dr. James Campbell will host a 30 minute conference call for shareholders commencing at 9.30am AEST tomorrow, Friday June 12<sup>th</sup>, with the following dial in details:

**Conference ID: 6481 7684**

#### Australian Participant Dial-in Numbers

**Toll:** +61 2 8038 5221 (this number can be used if dialing from an international location)

**Toll Free:** 1800 123 296

#### International Participant Dial-in Numbers

Toll-free dial-in numbers for each country are listed below. For countries not listed below, the Australian Toll number provided above may be used.

New Zealand	0800 452 782
China	4001 203 085
Canada	1855 5616 766
Hong Kong	800 908 865
India	1800 3010 6141
Japan	0120 985 190
Singapore	800 616 2288
United Kingdom	0808 234 0757
United States	1855 293 1544

A recording of the call will be available at <http://www.openbriefing.com/OB/1812.aspx> shortly after the completion of the teleconference. The audio file will also be available on the Patrys website, late morning: <http://www.patrys.net.au/patrys-news-room/media-centre-audio>.

**-Ends-**

#### **For further information, please contact:**

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#### **About Patrys Limited:**

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