

## ASX & Media Release

### PAT-DX1 Suppresses Breast Cancer Brain Metastases and Enhances Low Dose Radiation Therapy

**Melbourne, Australia; 30 May 2019:** Patrys Limited (ASX: PAB, “Patrys” or the Company), a therapeutic antibody development company, is pleased to announce new pre-clinical animal data for its lead candidate, PAT-DX1. Results of the study provide further support that PAT-DX1 could suppress tumor growth in patients with triple-negative breast cancer (TNBC) brain metastases.

#### Key highlights

- Yale School of Medicine completed a new pre-clinical study demonstrating that Patrys’ lead agent, PAT-DX1 significantly suppresses brain metastases even with a shortened dosing regimen
- The study broadens understanding of the dosing and impact of PAT-DX1 on TNBC brain metastases
  - **PAT-DX1 was able to cross the blood brain barrier and no toxicity was observed**
  - **PAT-DX1 as a single agent caused similar tumor growth suppression to that of low dose radiation treatment**
  - **Combination of PAT-DX1 and radiation treatment resulted in significantly more tumor suppression than either treatment alone**
- The precursor animal study (announced 20-Dec-18<sup>1</sup>) demonstrated that PAT-DX1 administered systemically, significantly reduced TNBC brain metastasis proliferation and improved survival
- Patrys and the Yale School of Medicine will now further explore the interactions between different radiation and PAT-DX1 dosing regimens that will inform and guide clinical development of PAT-DX1

**Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said:** “We are delighted to be able to report the confirmation that PAT-DX1 crosses that blood brain barrier and shows single agent efficacy in a sophisticated animal model of TNBC brain metastases. We are not aware of any other antibody that brings together these transformative attributes. We are particularly excited to report that a limited dose of PAT-DX1 enhanced the efficacy of low dose radiation therapy. This study represents another substantial advance in our understanding of the dosing and the possible clinical applications for PAT-DX1. The Company is excited by the prospects that our lead candidate may have in improving patient outcomes where there remains a large unmet medical need for TNBC brain metastases.”

#### Study overview and results

The pre-clinical study was conducted to compare the effects of:

<sup>1</sup> Refer to ASX release dated 20 December 2018, “PAT-DX1 Supresses Breast Cancer Brain Metastases and Increases Survival”

<https://www.asx.com.au/asxpdf/20181220/pdf/441d7bwj4phsr.pdf>

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- PAT-DX1 alone
- Low dose radiation alone
- PAT-DX1 in combination with low dose radiation

The study employed a relatively short dosing regime, where PAT-DX1 was administered for just one weekly cycle of 3 doses (all 3 doses in one week) relative to the precursor study with four weekly cycles (thus 12 doses in total).

Results of the study showed that even with the reduced and shortened dosing regimen, PAT-DX1 was able to significantly suppress TNBC brain metastases after just one week of treatment, with responses maintained for several weeks after the drug administration was discontinued. A combination of both PAT-DX1 and low dose radiation therapy resulted in significantly increased tumor suppression. No toxicity associated with PAT-DX1 treatment was observed.

The study was conducted by Drs. James Hansen and Jiangbing Zhou of the Yale School of Medicine and builds on the findings of a precursor study conducted last year (refer to ASX release dated 20 December 2018<sup>1</sup>, “PAT-DX1 Supresses Breast Cancer Brain Metastases and Increases Survival”). The precursor study demonstrated that PAT-DX1 administered systemically, significantly reduced TNBC brain metastasis proliferation and improved survival.

The new study forms part of the Company’s broader program to identify and optimize dosing regimens for future studies. Patrys and the Yale School of Medicine are now planning additional studies to explore the interactions between different radiation and PAT-DX1 dosing regimens that will inform and guide the clinical development of PAT-DX1.

## **Metastatic triple-negative breast cancer (TNBC) overview**

Breast cancer is a leading cause of cancer death in women, and approximately 1.67 million<sup>2</sup> new cases are diagnosed worldwide each year. Subtypes of breast cancer are stratified in accordance with their expression of estrogen, progesterone, and HER2 receptors. Tumors that lack all three receptors are referred to as “triple negative breast cancer (TNBC)”, and this subtype makes up 15-20% of all breast cancer cases and is the most aggressive and difficult to treat. The global market for TNBC was US\$296m in 2015, and is expected to increase to US\$1.59bn by 2025<sup>3</sup>.

Metastatic TNBC is a challenging disease, with up to 50% of patients developing brain metastases that have devastating effects on overall quality of life and survival. There remains a large unmet medical need for new therapeutic approaches to target and treat TNBC brain metastases<sup>4</sup> and an inability to cross the blood brain barrier has created an obstacle for many potential therapeutics.

**-Ends-**

<sup>2</sup> <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/global-cancer-facts-and-figures/global-cancer-facts-and-figures-3rd-edition.pdf>

<sup>3</sup> GlobalData Her2-/Her2+ and Triple Negative Breast Cancer- GlobalDrug Forecast and Market Analysis to 2025

<sup>4</sup> Anders, C. K. (2016) Management of Brain Metastases in Breast Cancer. Clinical Advances in Hematology & Oncology, August 2016 - Volume 14, Issue 9.



To learn more please visit: [www.patrys.com](http://www.patrys.com).

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**About Patrys' Deoxymab 3E10 platform – lead candidates PAT-DX1 and PAT-DX1-NP:**

Deoxymab 3E10 is a DNA damage-repair (DDR) antibody that was first identified in lupus as an autoantibody that bound to normal cells. Of particular interest is that whilst most antibodies bind to cell surface markers, Deoxymab 3E10 penetrates into the cell nuclei and binds directly to DNA where it inhibits DNA repair processes and kills cells that have mutations or deficiencies in DNA repair mechanisms as found in various cancer cells. Deoxymab 3E10 has single agent therapeutic potential and has been shown to significantly enhance the efficacy of both chemo- and radiotherapies. Further, Deoxymab 3E10 can be conjugated to nanoparticles to target delivery of chemotherapeutics and imaging agents to tumors.

Patrys has developed a humanized form of Deoxymab 3E10, PAT-DX1 with improved activity over the original version of 3E10, and is progressing this, and a nanoparticle-conjugated form (PAT-DX1-NP) towards the clinic. In a range of pre-clinical cancer models PAT-DX1 has shown significant ability to kill cancer cells in cell models, human tumor explants, xenograft and orthotopic models. Treatment with PAT-DX1 has been shown to significantly improve survival in orthotopic models of both triple negative breast cancer brain metastases and glioblastoma. PAT-DX1 has also been shown to work synergistically with the approved PARP inhibitor, olaparib. Patrys believes that PAT-DX1 may have application across a wide range of malignancies such as gliomas, melanomas, prostate, breast, pancreatic and ovarian cancers.

Patrys' rights to Deoxymab 3E10 are part of a worldwide license to develop and commercialize as anti-cancer and diagnostic agents a portfolio of novel anti-DNA antibodies and antibody fragments, variants and conjugates discovered at Yale University.