



ASX & Media Release

## **PAT-DX1 significantly improves survival in an animal model of highly aggressive glioblastoma brain tumours**

**Melbourne, Australia; 22 July 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 additional data in support of the potential for PAT-DX1 to improve patient outcomes in glioblastoma (GBM).

### **Key highlights**

- **Yale School of Medicine completed a new animal study, further highlighting that PAT-DX1 may have the potential to improve radiation therapy, a common standard of care treatment for GBM patients**
- **As a single agent, PAT-DX1 increased tumour suppression in a highly aggressive human GBM tumour explant, improving survival with no toxicity observed**
- **In combination with low dose radiation, PAT-DX1 treatment resulted in significantly more tumour suppression and prolonged survival compared to low dose radiation alone**
- **Results support the biologic rationale to study PAT-DX1 in clinical trials and reinforce previous findings from a precursor animal study**
- **Ongoing studies will further explore several radiation and PAT-DX1 dosing regimens to inform and guide clinical trial design**

**Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said:** *"Radiation therapy plays an important role in treating GBM. However, radiation therapy often results in significant morbidity and severe side effects, particularly in elderly populations. The ability to improve clinical outcomes by reducing the dose of radiation required, could be an important advancement in the treatment of GBM.*

*This data supports that PAT-DX1 enhances the efficacy of low dose radiation, potentially improving the standard of care, while reducing side effects. We would like to thank our collaborators at Yale School of Medicine for their outstanding work to advance our understanding of the possible clinical applications for PAT-DX1."*

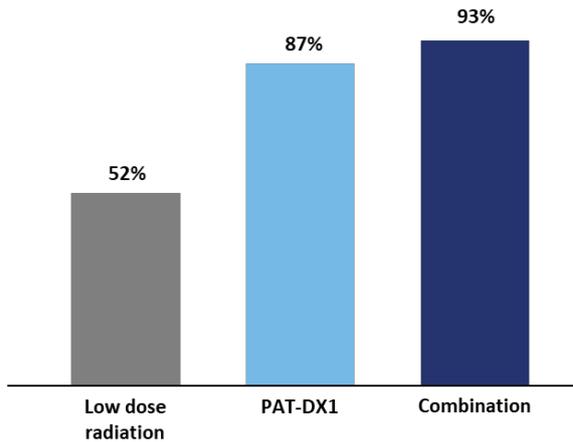
### **Study overview and results**

Yale School of Medicine used a highly aggressive human GBM tumour explant to generate brain tumours in mice. The study then tested the effects of PAT-DX1 and low dose radiation on tumour growth and mouse survival across four different treatment regimens:

- **Control:** Control vehicle delivered three times a week
- **Low dose radiation:** Control + a single low dose radiation treatment
- **PAT-DX1:** PAT-DX1 alone delivered three times a week
- **Combination:** PAT-DX1 + a single low dose radiation treatment

A GBM tumour explant was used to inoculate the brains of mice and the tumour was imaged weekly. Figure 1 shows that as a single agent, PAT-DX1 outperformed low dose radiation in tumour suppression and extended survival. Further, when PAT-DX1 was used in combination with low dose radiation, an even greater reduction in tumour size and survival was achieved.

**Figure 1: Reduction in tumour size relative to control (week 2)**



**Figure 2: Survival benefit due to treatment**

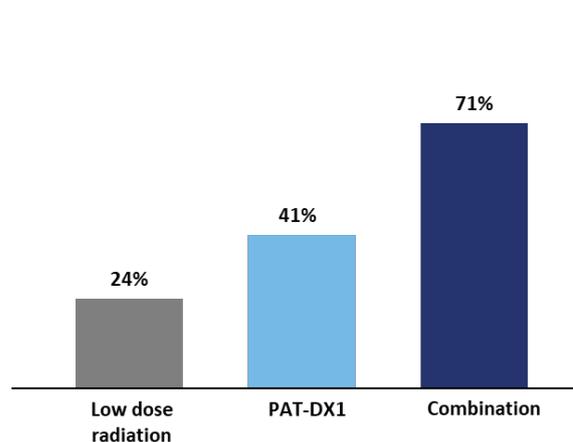


Figure 1 shows that two weeks after initiation of treatment, low dose radiation, PAT-DX1, and the combination reduced tumour size by 52%, 87%, and 93% compared to control, respectively.

Figure 2 shows that low dose radiation alone extended mouse survival by 24% ( $P=0.04$ ), as a single agent, PAT-DX1 extended survival by 41% ( $P=0.01$ ), and PAT-DX1 used in combination with low dose radiation extended survival by 71% ( $P=0.002$ ). No toxicity associated with PAT-DX1 treatment was observed.

The study was conducted by Dr. James Hansen and Dr. Jiangbing Zhou of the Yale School of Medicine and builds on the findings of a precursor study from last year. The precursor study, in a different human GBM tumour model, demonstrated that PAT-DX1 administered systemically crossed the blood-brain barrier (refer to 28 February 2018 ASX release), suppressed GBM tumour growth and improved survival (refer to 19 March 2018 ASX release).

The new study forms part of the Company's broader program to identify and optimise dosing regimens for future studies. Upcoming additional studies will be conducted to explore the interactions between different radiation and PAT-DX1 dosing regimens and this data will inform and guide the design of clinical trials to test PAT-DX1 against GBM in human patients.

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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.

**About Glioblastoma (GBM)**

Glioblastoma is a particularly aggressive, highly malignant form of brain cancer characterized by very fast cellular reproduction. Glioblastomas constitute approximately 17% of all primary brain cancers, with almost 12,000 new cases diagnosed in the U.S. each year<sup>1</sup>. The current standard of care for glioblastoma is surgical resection followed by radiation and chemotherapy (temozolomide, trade name TEMODAR<sup>®</sup>), with a median survival period of 15 months<sup>2</sup>, depending on disease severity.

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<sup>1</sup> American Association of Neurological Surgeons (AANS), Glioblastoma Multiforme

<sup>2</sup> Davis ME. Glioblastoma: Overview of Disease and Treatment. Clin J Oncol Nurs. 2016;20(5 Suppl):S2–S8. doi:10.1188/16.CJON.S1.2-8