



ASX & Media Release

Market Update

PAT-DX1 Clinical Trial Preparation

Melbourne, Australia; 3 August 2021: Patrys Limited (ASX: PAB, “Patrys” or the “Company”), a therapeutic antibody development company, provides this interim update on its PAT-DX1 clinical trial program.

As announced in February 2021, Patrys has selected a stable, high-yielding cell line suitable for the commercial production of clinical-grade PAT-DX1. Using this cell line, Patrys’ commercial contract manufacturer has prepared production and purification processes for PAT-DX1 at its facility. Planning for this campaign commenced over 12 months ago and included ordering the required materials 6 months in advance of use.

Patrys has now been advised by its manufacturer that there are anticipated delays in procuring certain key components required for the fermentation media used for PAT-DX1 production. These pending delays are entirely due to the impact of the COVID-19 pandemic on global reagent production and supply chains and are outside the control of either Patrys or its contract manufacturer. The proprietary nature of these key reagents means that the Company is not able to source materials from alternative suppliers. As a result, the engineering run for PAT-DX1 is now anticipated to be delayed until Q4 2021.

The anticipated deferred commencement of the engineering run for PAT-DX1 means the start of the GMP toxicology studies for PAT-DX1 has been rescheduled to Q1 CY2022, pending the availability of GMP grade PAT-DX1. On this revised timeline, Patrys expects it will now submit a Human Research Ethics Application (HREA) for the phase 1 clinical trial in H2 CY2022.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “The anticipated delay to the start of our planned PAT-DX1 phase 1 clinical trial by up to six months is disappointing for the Patrys team and our loyal shareholders. This delay is based solely on global supply chains, not technical obstacles, and highlights the many ways that the COVID-19 pandemic is impacting on our lives, including disrupting the production of critical medical products and services. Even so, the recent data from ongoing pre-clinical studies has been extremely positive and has highlighted the many ways our deoxymabs may be able to improve the health of patients with a range of difficult to treat cancers. We continue to work with our global suppliers to prepare for and initiate the first PAT-DX1 clinical trial in late 2022. In addition, we will continue to pursue a range of unique development opportunities for both PAT-DX1 and PAT-DX3.”

-Ends-

This announcement is authorised for release by the Board of Directors of Patrys Limited.



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About Patrys Limited

Based in Melbourne, Australia, Patrys (ASX:PAB) is focused on the development of its deoxymab platform of cell-penetrating antibodies as therapies for a range of different cancers. More information can be found at www.patrys.com.

About Patrys' deoxymab platform:

Patrys' deoxymab platform is based on the deoxymab antibody that was first identified as an autoantibody in a mouse model of the human disease systemic lupus erythematosus (SLE). While most antibodies bind to cell surface markers, deoxymab penetrates into the cell nuclei and binds directly to DNA where it inhibits DNA repair processes. Cancer cells often have high levels of mutations and underlying deficiencies in the DNA repair mechanisms. For these reasons, the additional inhibition of the DNA repair processes by deoxymab can kill cancer cells, but appears to have little impact on normal cells. As a single agent, deoxymab has been shown to significantly enhance the efficacy of both chemo- and radiotherapies. Further, deoxymabs can be conjugated to nanoparticles to target delivery of chemotherapeutics and imaging agents to tumours.

Patrys has developed two humanised forms of deoxymab, both which have improved activity over the original deoxymab antibody. PAT-DX1 is a dimer (two joined subunits) of the short chain from the binding domain of deoxymab, while PAT-DX3 is a full-sized IgG antibody. In a range of pre-clinical studies, PAT-DX1 has shown significant ability to kill cancer cells in cell models, human tumour explants, xenograft, and orthotopic models. PAT-DX1 has been shown to cross the blood brain barrier, reduce tumour size, and increase survival in multiple animal models of brain cancer, other cancers, and cancer metastases. PAT-DX1 is tumour-agnostic, meaning that it can target many different tumour types in the body, regardless of specific tumour antigens. Patrys believes that PAT-DX1 may have application across a wide range of cancers including gliomas, melanomas, prostate, breast, pancreatic, and ovarian cancers.



Deoxymabs, such as PAT-DX1 and PAT-DX3, can be used to target nanoparticles carrying a payload of anti-cancer drugs specifically to tumours. This allows specific delivery of cancer drugs to multiple types of cancer while having minimal impact on normal, healthy cells.

Patrys' rights to deoxymab are part of a worldwide license to develop and commercialise a portfolio of novel anti-DNA antibodies and antibody fragments, variants and conjugates discovered at Yale University as anti-cancer and diagnostic agents. Six patents covering the unconjugated form of deoxymab (and derivatives thereof) have already been granted (Europe, Japan, China, and 3 in the USA), and one patent covering nanoparticle conjugation has been granted (Australia).