



ASX & Media Release

PAT-DX1 Engineering Run Successfully Completed

Melbourne, Australia; 4 July 2022: Patrys Limited (ASX: PAB, “Patrys” or the “Company”), a therapeutic antibody development company, is pleased to announce that its Contract Development Manufacturing Organisation (CDMO) has successfully completed a second engineering run which used an updated purification process to produce large scale quantities of clinical grade PAT-DX1. Subject to meeting specification, the manufactured PAT-DX1 antibody from this engineering run will provide sufficient PAT-DX1 for Patrys to complete the remaining pre-clinical toxicology studies in preparation for a proposed phase 1 clinical trial of PAT-DX1 in H2 CY2023.

The engineering run consisted of two phases; a fermentation phase, in which cells were grown in culture to produce PAT-DX1, followed by a purification phase, in which the PAT-DX1 produced during the fermentation process was isolated and purified. As announced by Patrys on 24 January 2022, the first engineering run for PAT-DX1 was unsuccessful due to low recoveries of drug product during the purification phase. Patrys and its CDMO subsequently developed a modified purification process that was used in this second engineering run. The initial yield from this commercial scale run exceeds what the Company was expecting based on previous, smaller-scale pilot runs.

In the coming weeks, the PAT-DX1 antibody product from this engineering run will be tested to ensure that it meets specification. As PAT-DX1 from all prior manufacturing runs to date has met specification, Patrys expects to complete pre-clinical GLP toxicology studies as planned from Q4 CY2022 to Q2 CY2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “This is an outstanding result, and a tribute to the close working relationship between Patrys and our CDMO. The commercial-scale manufacture of antibodies is a complex, multi-dimensional process. The efforts made to understand and remediate the issues with the first engineering run have been both extensive and exhaustive. We are delighted that this has delivered such a successful outcome, both addressing the issue with the original purification process and improving the overall yield. We are now in a position to proceed with our plan to initiate the final GLP toxicology studies by the end of the year, to support our target of initiating a phase 1 clinical study of PAT-DX1 in H2 CY2023.”

-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 3E10 platform:

Patrys' deoxymab platform is based on the deoxymab 3E10 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 3E10 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 3E10 can kill cancer cells, but appears to have little impact on normal cells. As a single agent, deoxymab 3E10 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 tumours.

Patrys has developed two humanised forms of deoxymab 3E10, both which have improved activity over the original deoxymab 3E10 antibody. PAT-DX1 is a dimer (two joined subunits) of the short chain from the binding domain of deoxymab 3E10, 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.

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Patrys' rights to deoxymab 3E10 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. Overall, eight patents in the portfolio have been granted with six patents covering the unconjugated form of deoxymab 3E10 (and derivatives thereof) have already been granted (Europe, Japan, China, and 3 in the USA), and two patents covering nanoparticle conjugation (Australia and India).

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