



ASX & Media Release

PAT-DX1 Engineering Run Product Meets all Specification Tests

- Batch specification testing for GMP PAT-DX1 material successfully completed
- Provides drug material for GLP toxicology studies to support of Phase 1 clinical trial in H2 CY2023

Melbourne, Australia; 30 August 2022: Patrys Limited (ASX: PAB, “Patrys” or the “Company”), a therapeutic antibody development company, is pleased to announce its Contract Development Manufacturing Organization (CDMO) has successfully completed specification testing of PAT-DX1 drug substance produced in the recently-completed engineering run. As anticipated, the GMP material produced has passed all specification requirements and can now be used to complete remaining pre-clinical toxicology studies in preparation for a phase 1 clinical trial of PAT-DX1 that is planned to commence in H2 CY2023.

Specification, or batch release, testing is a necessary requirement to ensure high quality pharmaceuticals are used in GMP and clinical studies. A wide range of analytical tests are conducted to analyse the physical characteristics of the drug substance and to ensure that the activity and purity of the drug material fall within pre-defined tolerance levels. The PAT-DX1 drug material has also undergone microbiological and chemical testing to verify the absence of contaminants.

This GMP PAT-DX1 drug material will be used to complete the two remaining animal toxicology studies that are required before first-in-man studies can be initiated. Patrys has already successfully completed animal toxicology studies using non-GLP PAT-DX1 drug material and these showed that it is safe and well-tolerated. No mortalities or antibody-related changes in body weight, hematology or clinical chemistry were observed in these studies which were conducted in two different animal species (rodents and primates). These data have been used to inform the design of GLP toxicology studies for PAT-DX1 which are scheduled to commence in Q4 CY2022.

Patrys’ Vice President of Research and Development, Ms Valentina Dubljevic said: “Our CDMO has worked tirelessly throughout this process to ensure a successful outcome. This has been the result of an effective a collaborative process with our specialist manufacturing consultant and in-house team.”

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “We are very pleased to have developed and refined a manufacturing process for PAT-DX1 that puts us on a solid trajectory to initiate the planned Phase 1 clinical trial in H2 CY2023. We are delighted that this improved process has provided us with both GMP-quality material that has met specification and has also improved the yield. Given the positive safety and tolerability profile we have seen with PAT-DX1 to date, we remain confident that the remaining animal toxicology studies will support the advancement of PAT-DX1 into the clinic next year.”

-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. While most antibodies bind to cell surface markers, deoxymab 3E10 penetrates into the cell nuclei and binds directly to DNA where it inhibits the 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 while having little impact on normal cells. As a single agent, deoxymab 3E10 has been shown to significantly enhance the efficacy of both chemo- and radiotherapies in animal models of human cancer.

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 numerous pre-clinical studies, PAT-DX1 has shown significant ability to kill cancer cells in cell-based experimental systems, 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, non-brain cancers, and metastatic disease. PAT-DX1 is tumour-agnostic, meaning that it can target many different tumour types in the body, regardless of pathology-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. PAT-DX3, being a full-sized IgG molecule, also has potential for antibody drug conjugate (ADC) and antibody oligonucleoside

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conjugation (AOC) programs. A PAT-DX3 based ADC showed significant tumor targeting and survival benefit in proof-of-principle studies.

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, nine patents in the portfolio have been granted with six patents covering the unconjugated form of deoxymab 3E10 (and derivatives thereof) granted (Europe, Japan, China, and 3 in the USA), and three patents covering nanoparticle conjugation (Australia, India and Canada).

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