



ASX & Media Release

Updated guidance for PAT-DX1 phase 1 clinical study

Melbourne, Australia; 31 March 2023: Patrys Limited (ASX: PAB, “Patrys” or the “Company”), a therapeutic antibody development company, advises that, based on recent updates from its Contract Development Manufacturing Organisation (CDMO) regarding the timing of availability of clinical-grade PAT-DX1, it now expects to initiate the Phase 1 clinical trial of PAT-DX1 in calendar year 2024.

Preparations for the study are well underway and the Company remains clearly focused on advancing PAT-DX1 to the clinic. However, despite prior successful manufacturing test runs, Patrys’ CDMO has reported a sporadic issue relating to the cell line used to produce Good Manufacturing Practice (GMP) PAT-DX1. While this issue is actively being investigated and resolved, it will result in a delay in the availability of investigational drug material to be used for Patrys’ Phase 1 clinical trial of PAT-DX1. In the meantime, the final, non-clinical GLP toxicology studies of PAT-DX1 remain on-track with initial results expected in May 2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell, said: “We are disappointed that the delay in availability of clinical grade material is going to push our Phase 1 clinical trial of PAT-DX1 into calendar year 2024. Once the sporadic issue affecting GMP production is resolved, we are confident the manufacturing and purification process developed and tested for PAT-DX1 can provide the material required to initiate the first human clinical trial of a deoxymab antibody. In the meantime, we look forward to completing the remaining, non-clinical GLP toxicology studies of PAT-DX1 in May as scheduled. Furthermore, work on our full-sized IgG deoxymab, PAT-DX3, is progressing well and we expect to provide an update on this program in coming weeks.”

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

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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.

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).