



ASX & Media Release

PAT-DX1 engineering update

Melbourne, Australia; 24 January 2022: Patrys Limited (ASX: PAB, “Patrys” or the “Company”), a therapeutic antibody development company, has completed the first engineering run of its lead asset PAT-DX1.

The product yield from the fermentation process for PAT-DX1 was consistent with the small scale pilot production run conducted previously. However the purification of PAT-DX1 from the cell harvest resulted in lower drug product recoveries than expected. In view of this, Patrys is currently working with its Contract Development Manufacturing Organisation (CDMO) to implement improvements for the large-scale purification process. It is anticipated that a further engineering run for PAT-DX1 using an improved large-scale purification process will commence in Q2, 2022.

Using available drug product, the non-GLP toxicology studies in non-human primates will progress as planned in Q1/Q2 2022. The lower yield from the first engineering run will impact the timing of the subsequent GLP (Good Laboratory Practice) toxicology studies, which, in turn, will impact on the initiation of the planned first human study of PAT-DX1. It is a requirement that these GLP toxicology studies are conducted using drug product generated by the same manufacturing process that will be used for the planned Phase 1 clinical trial. Accordingly, Patrys is currently working with its toxicology service provider with the aim of rescheduling the GLP rodent and GLP non-human primate toxicology studies to commence in Q3 2022.

This six month delay will impact the timing of the first in human study of PAT-DX1, which is now planned for mid-2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “While we were very happy with the yield from the fermentation process in our first engineering run, we are clearly frustrated that the purification process did not perform as well as expected. We have worked closely with our CDMO to identify and resolve the purification issues and are confident that the changes being implemented will improve the yield from this step. This set-back to the timing of our PAT-DX1 program is material, but is offset by the significant advances being made with the PAT-DX3 manufacturing program and a range of business development activities.”

-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.



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About Patrys' deoxymab 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 payloads including small molecules, nanoparticles and imaging agents to target delivery to tumours.

Patrys has developed two humanised forms of deoxymab, 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, 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 and cancer metastases. PAT-DX1 has also been shown to reduce tumour size and increase survival in non-brain cancers such as triple negative breast cancer and pancreatic cancer. PAT-DX3 can cross the blood brain barrier to target cancers of the brain. Both PAT-DX1 and PAT-DX3 are tumour-agnostic, meaning that they can target many different tumour types in the body, regardless of specific tumour antigens. Patrys believes that PAT-DX1 and PAT-DX3 may have application across a wide range of cancers including gliomas, melanomas, prostate, breast, pancreatic, and ovarian cancers.

Patrys has completed proof of concept studies showing that it is possible to conjugate small molecule payloads to PAT-DX3, and is advancing antibody drug conjugate (ADC) efforts using deoxymabs. In addition, 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. To date, seven patents have been granted across the deoxymab portfolio. Six patents protecting deoxymabs (and derivatives thereof) have already been granted (Europe, Japan, China, and 3 in the USA), and one patent covering nanoparticle conjugation to deoxymabs has been granted (Australia).