ASX & Media Release

PAT-DX1 clinical development update

Melbourne, Australia; 2 October 2024: Patrys Limited (ASX: PAB, "Patrys" or the "Company"), a therapeutic antibody development company, provides the following update with respect to its planned activities for the initiation of clinical development for its deoxymab technology.

The Company will be hosting a webinar to discuss this announcement and to provide investors with an opportunity to ask questions at 10:30am today, Wednesday 2 October 2024. Details for how to register for this webinar are provided at the end of this release.

Patrys' Contract Development and Manufacturing Organisation (CDMO) has advised that the purified drug material from the recent good manufacturing practice (GMP) production run for its antibody fragment, PAT-DX1, has met the target product characterisation and specification testing requirements. However, a number of parameters have achieved the threshold levels of acceptance with a narrower margin than has been observed in the past. Given Patrys' experience with potential product deterioration under long-term storage of PAT-DX1, the Company believes that the risk of potential safety issues from using this batch of PAT-DX1 is not acceptable. In light of this, Patrys has decided it is not appropriate to use this material to initiate a first-in-human Phase 1 clinical trial of PAT-DX1 in cancer patients as had been planned.

Further, given the ongoing challenges Patrys has experienced over multiple GMP production runs of PAT-DX1, the Company is planning to prioritize the development of therapeutic opportunities available for PAT-DX3 for its future R&D activities for the deoxymab platform. In view of this, Patrys intends to use the existing data and available drug material to establish co-development and licensing opportunities for PAT-DX1 with partners who have the requisite expertise and resources to optimise a robust manufacturing process for this challenging molecule.

PAT-DX3 is a full-sized, humanised IgG antibody — similar in structure to the majority of successful therapeutic antibodies — and has several advantages over PAT-DX1 including yield, stability and potential to be used as a scaffold for antibody drug conjugates. Patrys has already produced a stable cell line and master cell bank for PAT-DX3, has finalised a production protocol (both upstream fermentation and downstream purification), and is ready for commercial scale production in an engineering run.

Positive discussions with clinicians and industry experts on the Company's data to date suggest that deoxymabs may have clinical application in a range of inflammatory conditions involving NETosis where there is high unmet need for disease modifying treatments. It is envisaged that additional preclinical studies in the area of inflammation along with cancer, will help identify the most appropriate path for deoxymabs and provide the greatest optionality for their future development and partnering activities.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell, said: "While we continue to believe PAT-DX1 has great potential for a number of therapeutic applications, the specialised product optimisation that has become apparent and which is required to reliably manufacture this unique molecule is better aligned with the resources of larger industry players. This is a disappointment to both shareholders, the Board and management of Patrys. However, PAT-DX1 has proven to be a challenging molecule to produce and purify over multiple production runs. We believe it is in the best interest of the Company and its shareholders to focus our future development activities and investment on PAT-DX3 rather than PAT-DX1, as we further evaluate other opportunities to advance our deoxymab technology."

Patrys invites shareholders and investors to a Zoom investor briefing (webinar):

When: *Oct 2, 2024 10:30 AM AEST*
Topic: *Patrys clinical development update*

Register in advance for this webinar using the link below:
https://us02web.zoom.us/webinar/register/WN_mNaRYiW1R3aK__yOKI7dEg

After registering, you will receive a confirmation email containing information about joining the webinar.

Attendees will be able to submit questions to Patrys CEO and MD, Dr James Campbell using the Q&A function on Zoom once the webinar has commenced.

-Ends-

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

For further information, please contact:

General enquiries
James Campbell
Chief Executive Officer
P: +61 3 96703273
info@patrys.com

Media enquiries:
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

Registered Office Address
Level 4, 100 Albert Road
South Melbourne VIC 3205

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. 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 five patents covering nanoparticle conjugation has been granted (Australia, Canada, China, India and the USA).