INVION RECEIVES ETHICS APPROVAL FOR ITS PHASE I/II NON-MELANOMA SKIN CANCER TRIAL

Highlights:

- **Invion has been granted Human Research Ethics Committee (HREC) approval for its open label Phase I/II trial on patients with non-melanoma skin cancers (NMSC) using topical INV043.**
- **As part of standard procedure, Invion has notified the TGA on the trial via the Clinical Trial Notification (CTN) process.**
- **Invion has secured all the necessary regulatory approvals for patient screening, treatment and follow-up, which are expected to commence from next month.**
- **The study will be performed at Veracity Clinical Research's trial facilities, based in Queensland Australia.**
- **Skin cancer is one of the world's most common cancers and NMSC constitutes >98% of all skin cancers.**
- **Preclinical studies indicate INV043 may have distinct advantages over current non-melanoma skin cancer treatments, such as efficacy without scarring or pain.**

MELBOURNE (AUSTRALIA) 11 September 2024: Invion Limited (ASX: IVX) ("**Invion**" or the "**Company**") is pleased to announce that it has received ethical approval from the St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC) to commence the Phase I/II non-melanoma skin cancer (**NMSC**) trial for its lead drug candidate INV043, a novel photosensitiser developed in Australia for use in Photodynamic Therapy (**PDT**).

As part of the standard procedure following HREC approval, Invion has notified the Therapeutics Goods Administration (**TGA**) on the trial via its Clinical Trial Notification (**CTN**) submission.

Invion has now completed all necessary regulatory processes to undertake its skin cancer trial and patient screening, treatment and follow-up are expected to commence from October 2024. The trial will be conducted at Veracity Clinical Research (**Veracity**) in Brisbane, Queensland, a leading dermatology clinical research site in Australia, and the principal investigator is Dr Lynda Spelman (from Veracity).

Skin cancer is one of the world's most common cancers and NMSC makes up over 98% of all skin cancers[1] with the global treatment market to hit US$21.1 billion by 2032[2].

The primary endpoints of this open label trial focus on safety and secondary / exploratory endpoints include dose optimisation and efficacy signals.

As an adaptive trial design, additional cohorts of patients may be added to evaluate other safety aspects of the treatment if required, as well as dose optimisation and efficacy endpoints. As such, the total number of patients can range between 18 and 174, and the number of treatment cycles and the length of the study can vary because of this.

[1] https://www.cancercouncil.com.au/skin-cancer/about-skin-cancer/
[2] https://www.fortunebusinessinsights.com/skin-cancer-treatment-market-102806

Veracity will select male and female patients over the age of 18 with non-metastatic cutaneous squamous cell carcinoma (**SCC**) and basal cell carcinoma (**BCC**), although other NMSCs may be approved on a case-by-case basis. Other screening criteria include size and location of the lesion.

The Executive Chair and Chief Executive Officer of Invion, Thian Chew, said:

> *"We are excited to reach this major milestone in our non-melanoma skin cancer clinical trial and look forward to starting patient screening, treatment and follow up starting next month.*
>
> *"Our next-generation PDT has the potential to become an important alternative treatment for this and other cancers as it overcomes many key shortcomings of current standard of care. Preclinical studies have shown INV043 to have a solid safety profile and strong efficacy against multiple cancers without scarring."*

The trial will be conducted under International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) good clinical practice (GCP) and ISO 14155 standards.

Once the trial results have been analysed, in addition to progressing the NMSC program, Invion plans to leverage this data into a Phase II anogenital cancer trial using topical INV043, and potentially including the use of immune checkpoint inhibitors (ICI) on the back of solid *in vivo* data from the Peter MacCallum Cancer Centre that showed 80% completed pathological control of anogenital squamous skin cancers versus a 12% response rate on ICI treatments on a standalone basis.

This announcement was approved for release by the Board of Directors.

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About Invion

Invion is a life-science company that is leading the global research and development of the Photosoft™ technology for the treatment of a range of cancers, atherosclerosis and infectious diseases. Invion holds the exclusive Australia and New Zealand license rights and exclusive distribution rights to Hong Kong and the rest of Asia Pacific, excluding China, Macau, Taiwan and Japan, to the Photosoft technology for all cancer indications. It also holds the exclusive rights to the technology in Asia and Oceania, excluding China, Hong Kong, Taiwan, Macau, the Middle East and Russia for atherosclerosis and infectious diseases, and subsequently acquired the rights to the United States, Canada and Hong Kong for infectious diseases.

Research and clinical cancer trials are funded by the technology licensor, RMW Cho Group Limited. Invion is listed on the ASX (ASX: IVX).

About Photodynamic Therapy (PDT)

Invion is developing Photosoft™ technology as a novel next generation Photodynamic Therapy (PDT). PDT uses non-toxic photosensitisers and light to selectively kill cancer cells and promote an anti-cancer immune response. Less invasive than surgery and with minimal side effects, PDT offers an alternative treatment option aimed at achieving complete tumour regression and long-lasting remission. PDT has also demonstrated broad-spectrum activity across multiple infectious diseases, including bacteria, fungi and viruses. Photosoft has the potential to address the global challenge of antibiotic-resistant "superbugs".