INVION DOSES FIRST PATIENT IN PHASE I/II NON-MELANOMA SKIN CANCER TRIAL

Highlights:

- **First patient has been dosed in Invion's open label Phase I/II non-melanoma skin cancer (NMSC) trial using topical INV043.**
- **The study is being conducted at Veracity Clinical Research's facilities, based in Queensland Australia.**
- **Skin cancer is one of the world's most common cancers and NMSC constitutes >98% of all skin cancers[1] with the global treatment market to hit US$21.1 billion by 2032[2].**
- **Preclinical studies indicate INV043 may have distinct advantages over current NMSC treatments, such as efficacy without scarring and with minimal pain.**
- **The NMSC trial follows the release of promising Phase II prostate cancer trial results using INV043, and Invion plans to leverage the NMSC data into a planned Phase II anogenital cancer trial**

MELBOURNE (AUSTRALIA) 03 December 2024: Invion Limited (ASX: IVX) ("**Invion**" or the "**Company**") is pleased to announce the dosing of the first patient in its Phase I/II non-melanoma skin cancer (**NMSC**) trial conducted at Veracity Clinical Research (**Veracity**) in Brisbane.

The trial marks a significant milestone for Invion and is designed to evaluate the safety and efficacy of its lead drug candidate INV043, a novel photosensitiser developed in Australia for use in Photodynamic Therapy (**PDT**) for the treatment of multiple cancers.

Trial Design and Objectives

This open-label, adaptive trial provides flexibility to go beyond the testing and collection of human safety data of the topical formulation of INV043.

The initial part of the study aims to assess the safety profile of the topically applied INV043 in non-metastatic cutaneous Squamous Cell Carcinoma (**cSCC**). Subsequent parts aim to address dose optimisation (dose-light interval and light intensity) and the identification of efficacy signals. Part 3 will expand testing to include superficial Basal Cell Carcinoma (**sBCC**)

The adaptive design allows for modifications to the trial procedures based on interim results, enhancing the efficiency and effectiveness of the study. As such, the trial will enrol a minimum of 18 patients, which can be increased depending on the results.

Veracity will select male and female patients over the age of 18 with non-metastatic cSCC and sBCC, although other NMSCs may be approved on a case-by-case basis. Other screening criteria include size and location of the lesion.

Significance of NMSC

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 prevalence

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

of the disease highlights the urgent need for effective and affordable treatments with minimal side effects.

Currently, the mainstream treatment for SCC and BCC is surgery, which can lead to permanent scarring. Preclinical studies undertaken at the Hudson Institute of Medical Research showed the potential for INV043 to regress cancers without scarring and with minimal pain.

Next Steps

The NMSC trial follows the release of promising results from a Phase II prostate cancer trial using the same active pharmaceutical ingredient, INV043. Once the trial results have been analysed, in addition to progressing the NMSC program, Invion plans to leverage this data into a planned Phase II anogenital cancer trial using topical INV043, and potentially including the use of immune checkpoint inhibitors (**ICIs**) on the back of solid *in vivo* data from the Peter MacCallum Cancer Centre.

This study showed 80% complete pathological control of anal squamous skin cancers versus a 12% response rate on ICI treatments on a standalone basis.

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

> *"Having the first patient dosed in our NMSC trial is a significant milestone for Invion in demonstrating the potential for the Photosoft technology to address limitations and undesirable side effects of current standard of care for NMSCs, including scarring and pain."*
>
> *"On the back of the recently announced prostate cancer results, this trial can also provide clinical evidence that INV043 can be safely used in more than one formulation to treat multiple cancers. This can then open up the potential for our next-generation PDT to become an important alternative modality for treating cancers."*

The NMSC 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.

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

***Sign up at Invion's Investor Hub to receive regular updates, provide feedback and participate in discussions**: https://investors.inviongroup.com/*

Investor and Media enquiries:

Thian Chew (Chairman & CEO)
T: +61 3 9692 7222
E: investor@inviongroup.com

Brendon Lau (Investor & Media Relations)
M: +61 409 341 613
E: brendon.lau@inviongroup.com

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".