

## ENCOURAGING SAFETY REVIEW COMMITTEE FINDINGS ON SKIN CANCER TRIAL FOR INITIAL PATIENT GROUP

### Highlights:

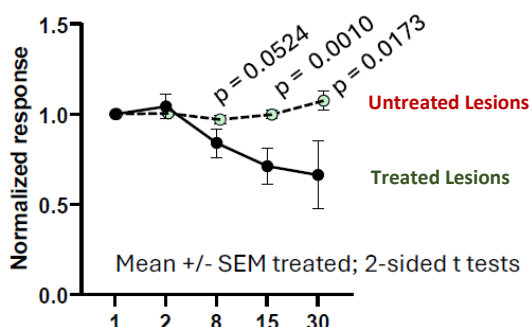
- No adverse events identified by the Safety Review Committee (SRC) following the treatment of the first six patients in Invion's Phase I/II non-melanoma skin cancer (NMSC) trial
- Early indications show an observable reduction in the NMSC lesion size after a single treatment cycle
- Clinician feedback indicated that patients did not experience any pain during the treatment, which compares favourably to currently approved PDT treatments
- The early results also highlighted INV043's potential as a diagnostic with suspected cancers fluorescing under violet light
- Proceeding to Part 2 of the adaptive trial that will enable further dose optimisation permitted under the protocol
- The safety data is also an important input into the upcoming Ph I/II anogenital trial done in partnership with the Peter MacCallum Cancer Centre

**MELBOURNE (AUSTRALIA) 29 May 2025:** Invion Limited (ASX: IVX) ("Invion" or the "Company") is pleased to announce the conclusions from the Safety Review Committee (SRC) after the treatment of the first six patients in its Phase I/II non-melanoma skin cancer (NMSC) trial in Queensland.

The SRC did not identify any adverse events associated with the application and use of INV043 (Invion's lead drug candidate for the treatment of cancers) in ointment form. All data suggests that the treatment was well tolerated and feedback from clinicians indicated there were no signs of pain associated with the treatment, which is a significant benefit over other Photodynamic Therapy (PDT) treatments for NMSC.

Further, there were early indications of patients responding positively to the treatment with an observable reduction in the NMSC lesion size after a single treatment cycle at 15- and 30- days post treatment, while on average, untreated patient-matched lesions increased slightly in diameter over the same corresponding periods post treatment.

### Change in size of NMSC lesions – treated and untreated lesions\*



SEM = Standard Error of the Mean

*\*Based on SRC review of available data to date. Further analysis will be conducted at the next stage of the trial.*

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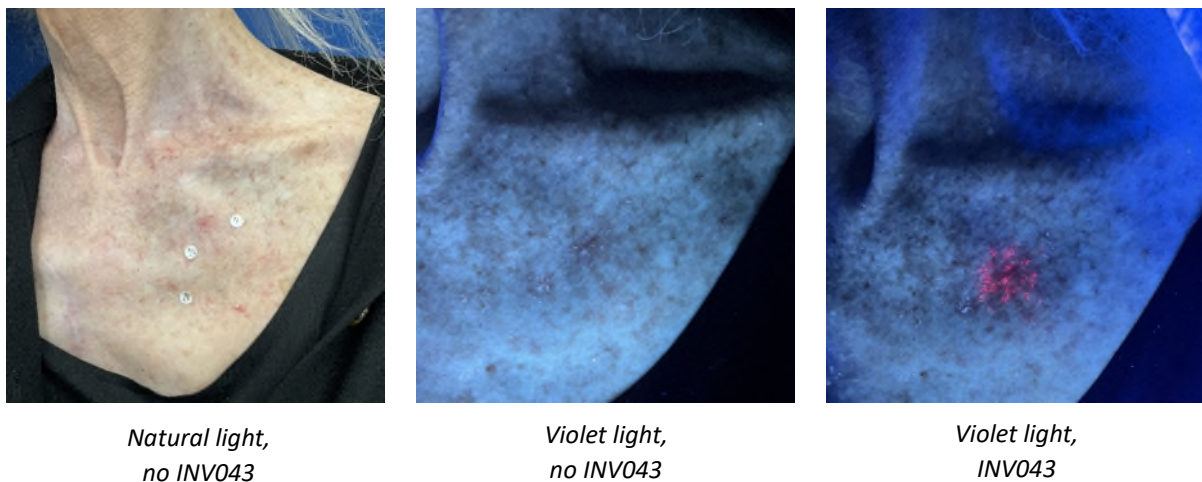
Preliminary data analysis indicates a trend towards reduced lesion diameter following one round of INV-043 treatment.

### **INV043's Potential as a Theragnostic (Therapy and Diagnostic)**

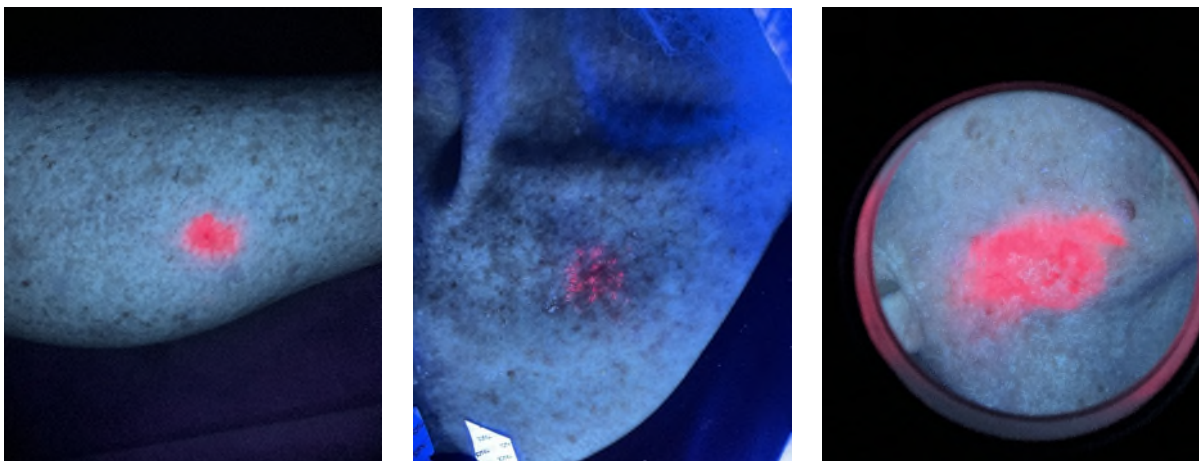
Additionally, the potential to use INV043 as a diagnostic tool was further demonstrated during trial. While red light of 660nm would activate INV043 to generate Reactive Oxygen Species (ROS) to kill the cancer, violet light of 405nm causes cancer cells to fluoresce.

Having an effective diagnostic tool may help surgeons more accurately identify and remove cancers to minimise the risk of either missing some of the cancer margin or cutting too much of the healthy tissue.

**Fig 1: Patient 101-002 at Day 1 of the treatment (INV043 ointment)**



**Fig 2: Photos from three different patients in the trial**



*INV043 appears to localise in the lesion site, which is consistent with preclinical data that showed accumulation in the tumour cells.*

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### Next Steps

The Phase I/II NMSC trial is an adaptive trial, which provides flexibility to adjust the treatment protocol to optimise outcomes. Following the SRC meeting, it was determined that the maximum light dose allowed under the protocol would be used, and that the trial would progress to Part 2 of the study, which will include adjusting dose-light interval (time between the topical application of INV043 to the lesion and subsequent activation by light). The adaptive trial also enables other dose optimisation dimensions allowed under the protocol.

The safety data is also an important input into the upcoming Phase I/II anogenital trial that Invion will undertake in partnership with the Peter MacCallum Cancer Centre (**Peter Mac**). The anogenital trial aims to include a study on the impact of INV043 when used in combination with immune checkpoint inhibitors (**ICIs**), such as PD-1.

Preclinical studies undertaken at Peter Mac and Hudson Institute of Medical Research have shown INV043's potential to significantly improve the efficacy of ICIs.

The Executive Chair and CEO of Invion, Prof Thian Chew, said:

*"We are very pleased with the safety profile of INV043 and look forward to exploring other elements that may help optimise the dose regime. It is also exciting to see how clearly and easily INV043 can 'illuminate' the cancers.*

*"The results set us up for the next stages of our clinical program, including the planned Phase I/II anogenital trial as well as the next part of the NMNC trial, where we are seeking to further demonstrate the safety of INV043 and to better optimise the treatment regime in the next group of patients."*

Skin cancer is one of the world's most common cancers and NMSC makes up over 98% of all skin cancers<sup>1</sup> with the global treatment market to hit US\$21.1 billion by 2032<sup>2</sup>. The prevalence of the disease highlights the urgent need for effective and affordable treatments with minimal side effects.

Currently, the mainstream treatment for SCC and BCC includes 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.

More details on the Phase I/II NMSC trial design can be found at:

<https://investors.inviongroup.com/announcements/6690510>.

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

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<sup>1</sup> <https://www.cancercouncil.com.au/skin-cancer/about-skin-cancer/>

<sup>2</sup> <https://www.fortunebusinessinsights.com/skin-cancer-treatment-market-102806>

## **ASX ANNOUNCEMENT**

### **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".