ORPHAN DRUG DESIGNATION GRANTED BY US FDA FOR ANAL CANCER (INV043)

Highlights:

- **US FDA grants Orphan Drug Designation to INV043 (Invion's lead cancer drug candidate) for anal cancer**
- **Orphan Drug Designation benefits include:**
  - **Seven-year exclusive marketing rights in the US post drug approval**
  - **Various financial incentives, such as potential tax credits for clinical trials, fee waivers, etc.**
  - **Potentially faster path to market compared to non-orphan drugs with fast tracked approvals and shorter/smaller trials**
- **INV043 shows pre-clinical efficacy, achieving ~80% tumour control in mice when used in combination with immune checkpoint inhibitors**
- **Invion and the Peter MacCallum Cancer Centre are planning to undertake an anogenital cancer clinical trial**

MELBOURNE (AUSTRALIA) 20 August 2025: Invion Limited (ASX: IVX) ("**Invion**" or the "**Company**") is pleased to announce that the United States Food and Drug Administration (**FDA**) has granted Orphan Drug Designation to INV043 for the treatment of anal cancer.

This is a significant development for Invion as the FDA orphan drug designation is a special status granted to drugs intended to treat rare diseases, providing various incentives to encourage their development.

Benefits of Orphan Drug Designation

The designation aims to help solve the shortage of treatments for rare conditions by offering incentives to biomedical organisations and researchers.

Some of the benefits include seven years of exclusive marketing rights in the US (after treatments have been approved), various potential financial incentives, such as tax credits for clinical trial costs, waiver of certain fees, etc., and a faster path to market due to a variety of factors, including fast tracked approvals and shorter/smaller clinical trials.

Impact on Invion's Clinical Program

This milestone complements the promising preclinical data from the Peter MacCallum Cancer Centre (**Peter Mac**) demonstrating INV043's effectiveness in treating anal cancer, notably:

- *In vitro* studies showing efficacy against six squamous cell carcinoma (**SCC**) cell lines that represent a full range of anal cancers,
- *In vivo* preclinical studies, including combination therapy with immune checkpoint inhibitors (ICIs), achieving approximately 80% tumour control in mouse models of anal

squamous cell carcinoma (vs. ~12% with ICI alone[1]) with no negative side effects noted.

Invion is working with Peter Mac to undertake an anogenital cancer clinical trial using INV043 in combination with ICIs. Anogenital cancers include anal, vulvar and penile cancers. These are typically challenging to treat, and mainstream treatments, such as surgery, can have severe side effects.

Prof Thian Chew, Invion's Executive Chairman and CEO, commented:

"This regulatory milestone enhances our ability to bring INV043 forward more quickly and cost-efficiently, with meaningful benefits for patients suffering from this challenging disease.

"Over the next five years, the pharmaceutical industry is facing its biggest patent cliff since 2010 as several blockbuster drugs, including ICIs, are expected to lose their patent protection[2]. The Orphan Drug Designation may increase our appeal to strategic partners because of the potentially accelerated pathway to leverage intellectual property that combines their ICIs with our complementary technology."

INV043 shows promise for treating multiple cancers. Early results from Invion's ongoing Phase I/II non-melanoma skin cancer trial indicate that the topical application of INV043 is well tolerated in patients and shows encouraging signs of efficacy[3], while a Phase II prostate cancer trial demonstrated a positive response rate of 40-44%, with no significant adverse events[4].

This announcement was approved for release by Invion's 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

[1] https://announcements.asx.com.au/asxpdf/20240304/pdf/0614byrl2c4ww0.pdf
[2] Blockbuster Drugs on Patent Cliffs: Strategic Intelligence - Market Research Reports & Consulting | GlobalData UK Ltd.
[3] https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02951443-2A1598901&v=4a466cc3f899e00730cfbfcd5ab8940c41f474b6
[4] https://announcements.asx.com.au/asxpdf/20240918/pdf/0680l22d3wlz2j.pdf

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".