

## INVESTOR PRESENTATION

**MELBOURNE (AUSTRALIA) 19 September 2024:** Invion Limited (ASX: IVX) ("Invion" or the "Company") wishes to release the attached presentation, which will be used by the Company's Executive Chair and Chief Executive Officer, Thian Chew, at various investor meetings and seminars.

This announcement was approved for release by Thian Chew, Chairman of the Board.

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

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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".

# CORPORATE PRESENTATION

September 2024

**INVION**<sup>™</sup>

ASX: IVX

**Next Generation Photodynamic Therapy (PDT)  
for Cancers and Infectious Diseases**



# DISCLAIMER

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# COMPANY HIGHLIGHTS

## INVION AT CLINICAL INFLECTION POINT



**Clinical-stage** life sciences company **listed on the ASX** that is developing Photosoft™



**Patent-protected** Photosoft™ is the Next-Gen **Photodynamic Therapy (PDT)**



**Positive Ph II prostate cancer results**, ongoing **Phase I/II skin cancer** with other trials planned



Focus on unmet medical needs (**cancers & infectious diseases**), including Asian-centric indications



**Collaboration with world-leading research institutes** (e.g. Peter Mac, Hudson Institute)



Targeted research programs **funded by partners** (i.e. Hanlim Pharma, Dr.inB)

# THE PHOTOSOFT™ ADVANTAGE

## NEXT GENERATION IMPROVEMENT ON APPROVED PDTs



There are several approved PDT treatments on the market, but Photosoft™ is a ground-breaking technology that overcomes many of their significant shortcomings & side effects



Photosoft™ is a minimally invasive modality for treating cancer that specifically identifies and destroys cancer cells whilst leaving the rest of the body's normal cells unharmed

**Photodynamic Therapy (PDT)** consists of three elements:

1

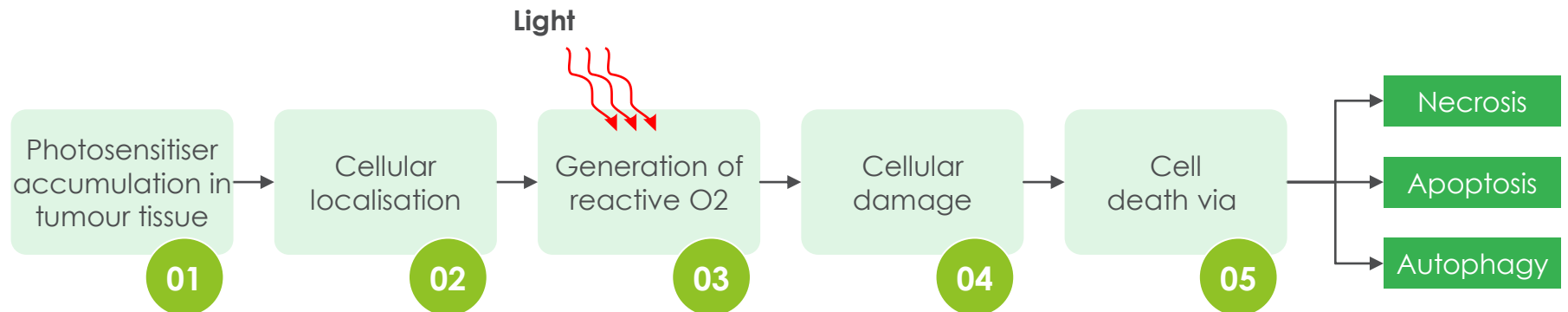
Combines photosensitiser compound with light-induced activation

2

Generates reactive oxygen species ("ROS") causing damage to only targeted cells

3

Direct cell death along with activation of immune response





# TARGET DISEASES AND INDICATIONS

## PDT FOR TREATMENT OF CANCERS AND INFECTIOUS DISEASES

### PRIMARY FOCUS: CANCER (INV043)

- Multiple cancer indications
- Ablation and activation of immune response
- Improved efficacy of immune checkpoint inhibitor (ICI) treatments when in combination
- Topical and systemic formulations
- Strong therapeutic profile

#### ○ Target Indications

- Non-melanoma skin cancer (topical)
- Prostate cancer (sublingual)
- Anogenital cancer (topical)
- Glioblastoma (GBM): studies undertaken and **funded by Hanlim Pharma**
- Solid tumour cancer TBD (IV)

### INFECTIOUS DISEASES

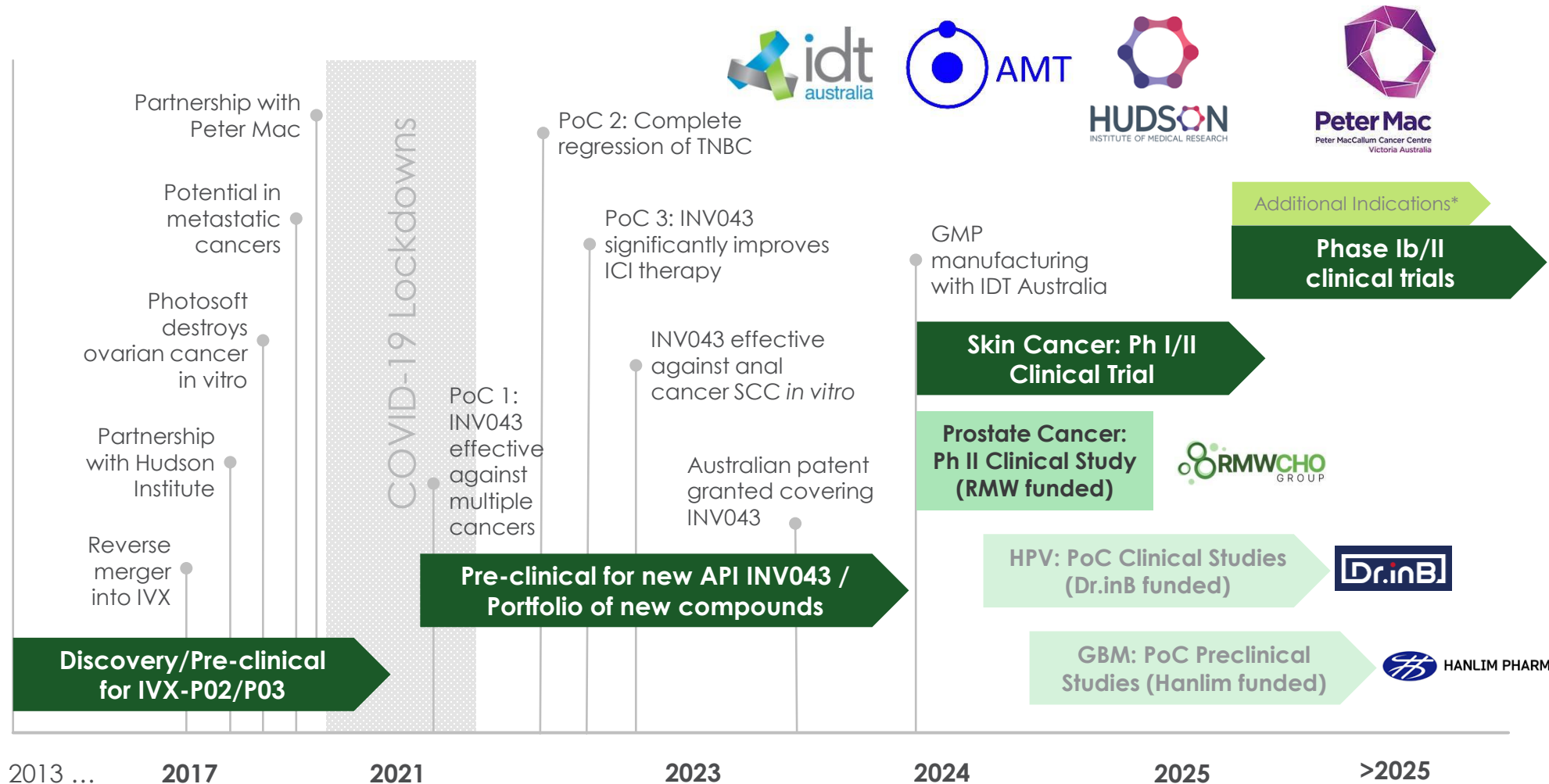
- Broad spectrum antimicrobial activity against viruses, bacteria and fungi
- No known drug resistance (to address AMR)
- Commercially viable focus

#### ○ Target Indications

- Human Papilloma Virus (HPV): studies undertaken and **funded by Dr.inB**
- Oral antimicrobial: peri-implant mucositis
- Additional TBD

# BACKGROUND AND DEVELOPMENT PATHWAY

## LAYING GROUNDWORK FOR MULTIPLE CLINICAL TRIALS



\*Indicative timelines

**INVION**

# LEAD CANCER DRUG CANDIDATE INV043

## MULTIPLE CANCERS, ATTRACTIVE THERAPEUTIC PROFILE



### Photosoft™

**Photosoft™ is a portfolio of photosensitisers protected by over ten patent families.**

INV043 is one of the photosensitisers described in a patent first granted in 2023 (Australia) with IP protection extending until at least 2041

### IVX Photosensitiser for Cancer: INV043



Effective in regressing multiple types of cancer *in vivo*<sup>1</sup>



~600x greater phototoxicity than Talaporfin (widely used photosensitiser)



Selectively absorbed by cancer cells and not healthy tissue



Stimulate the body's natural immune response



Work additively with blockbuster ICI<sup>2</sup> drugs



Non-toxic, safe and limited side effects at up to 100x therapeutic dose





# RESULTS AND FINDINGS: CANCER

Clinical & Preclinical Data

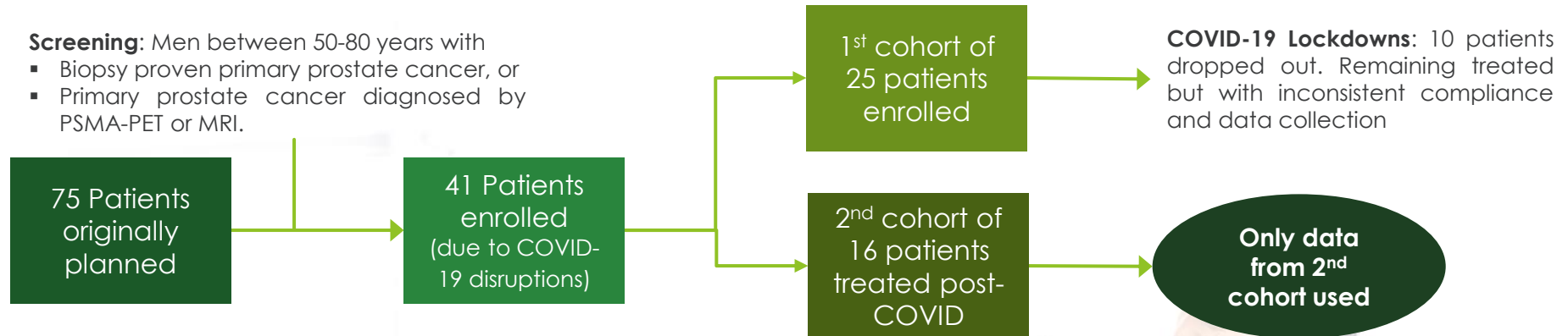
**INVION**<sup>™</sup>

# PHASE II PROSTATE CANCER CLINICAL TRIAL USING INV043

## PHASE II INVESTIGATOR-LED PROSTATE CANCER STUDY\*

**Screening:** Men between 50-80 years with

- Biopsy proven primary prostate cancer, or
- Primary prostate cancer diagnosed by PSMA-PET or MRI.



### PRIMARY ENDPOINT

To assess INV043 PDT treatment effectiveness using Response Evaluation Criteria in Solid Tumours (RECIST 1.1)

### SECONDARY ENDPOINTS

To assess safety and tolerability as well as further assessments on effectiveness using standard outcome measures

### TREATMENT PROTOCOL

Clinical trial participants underwent a total of 6 cycles of PDT treatment (monotherapy) over 9 weeks (3 rounds of 2 consecutive PDT cycles with 4-week interval before rounds). Each PDT cycle consisted of 2 steps.

**Step 1:** Sublingual administration of photosensitiser

**Step 2:** ~15-20 hours after dosing, 25 min of 660 nm laser administered

The treatment schedule consisted of two laser therapy cycles conducted over 2 consecutive days (e.g. Mon, Tue), followed by a four-week interval.

# PHASE II PROSTATE STUDY RESULTS: SOLID SAFETY DATA

## NO SERIOUS ADVERSE EVENTS, ONLY MILD SIDE EFFECTS OBSERVED

### INV043: Safe and Well Tolerated

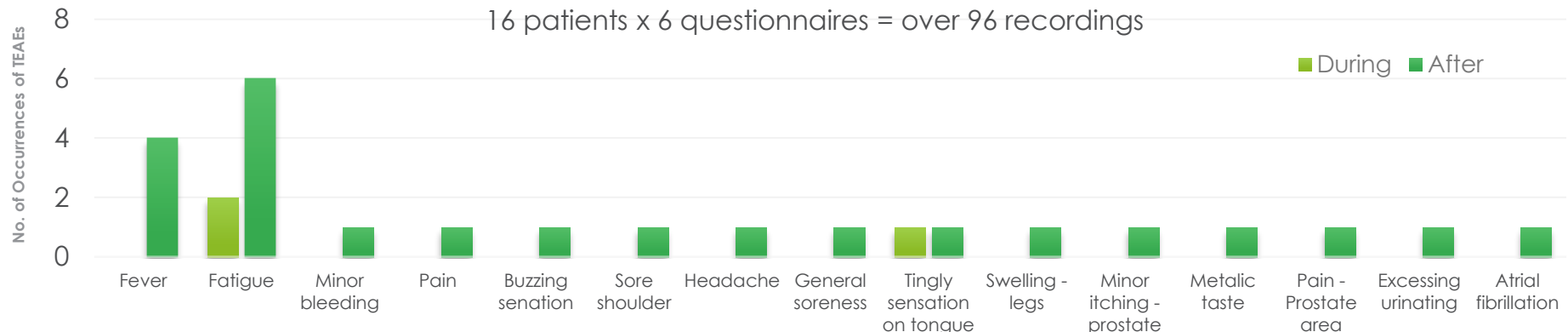
INV043 appeared to be safe and well-tolerated when administered sublingually to patients over the 6 cycles of PDT treatments (based on findings from 2<sup>nd</sup> cohort of 16 treated participants):

- No serious adverse events, life-threatening treatment or emergent adverse events (TEAEs)
- No clinically significant changes in vital signs, ECGs, or clinical laboratory parameters reported on study
- **All adverse events reported were mild**

**In contrast, current treatment options (eg, radiotherapy, chemotherapy and surgery) carry risks of significant side effects such as incontinence, bowel dysfunction, erectile dysfunction and/or infertility<sup>1</sup>**

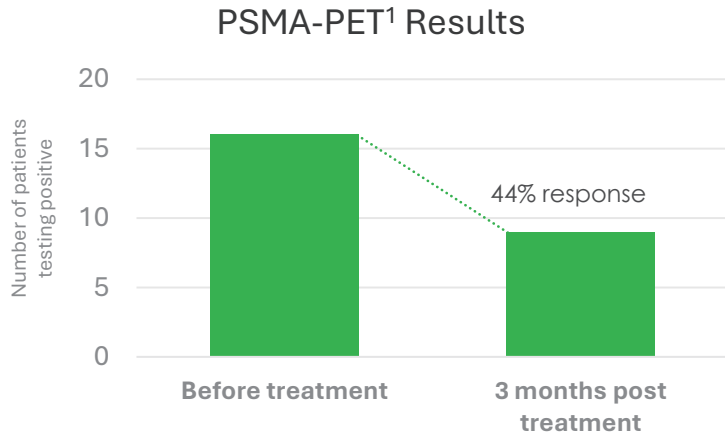
### Recorded Adverse Events

16 patients x 6 questionnaires = over 96 recordings



# PHASE II PROSTATE STUDY RESULTS: PROMISING EFFICACY SIGNALS

## 40-44% RESPONSE RATE TO STANDALONE TREATMENT



### INV043 Results 3 Months Post Treatment

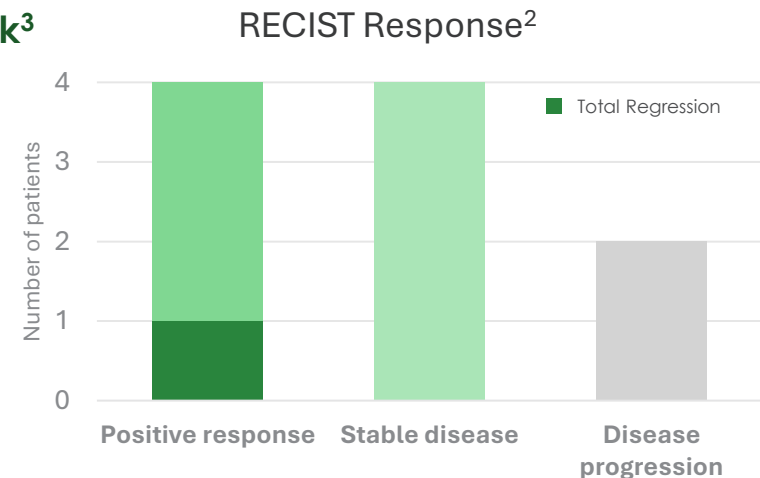
Patients (Cohort 2, n=16) evaluated using PSMA-PET scan to detect prostate cancer:

- **BEFORE: All 16 patients were positive before treatment.**
- **AFTER: 7 patients negative 3 months after treatment (~44% response), 9 patients were positive**

### RECIST (Response Evaluation Criteria in Solid Tumours) Framework<sup>3</sup>

Where possible, MRI scans taken pre and post treatment to measure lesion size in prostate<sup>2</sup>

- **40% patients showed a positive response 3 months post treatment**
  - 1 showed complete regression (no detectable lesion)
  - 3 showed partial regression (>30% reduction in lesion size)
- **4 patients showed stable disease**
- **2 patients showed disease progression (>30% increase in lesion size)**



<sup>1</sup> PSMA PET-CT now routinely used in evaluation of prostate cancer in context of primary staging and suspected tumour recurrence (Combes AD, 2022). It employs a radioactive substance that targets a protein called PSMA (prostate-specific membrane antigen) which is expressed by prostate cancer cells.

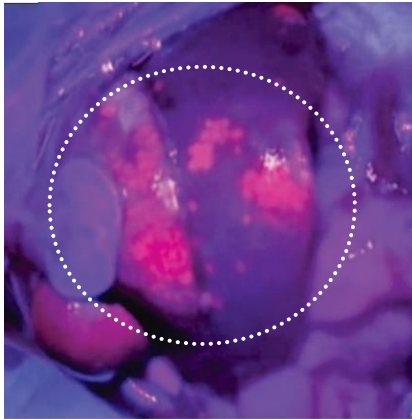
<sup>2</sup> Two had received a prostatectomy prior to the photodynamic treatment and were excluded. Four patients did not have MRI scans for various reasons (such as the presence of implants) and were excluded from the assessment.

<sup>3</sup> <https://recist.eortc.org>

# THERAGNOSTIC POTENTIAL

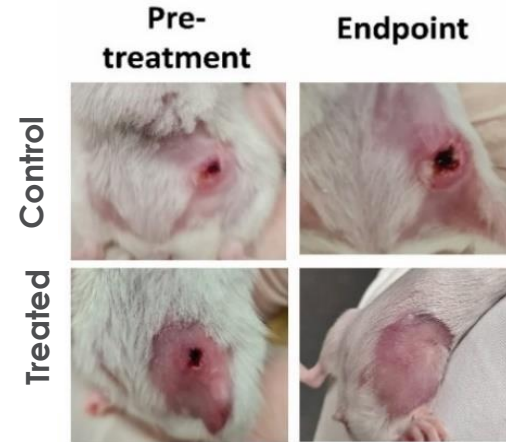
## MULTIPLE CANCERS, PRECISION CANCER TARGETING, PROTECTIVE IMMUNITY

### SELECTIVE TARGETING



- INV043 **selectively retained** in malignant but not healthy tissue, **across multiple cancers** (incl. pancreatic, triple-negative breast, T-cell lymphoma *in vivo*)
- **Minimises collateral damage** to healthy organ tissues with no notable toxicity issues
- INV043 has both **fluorescence** as well as **ablation** characteristics (under different wavelengths of light)
- Applications in both diagnostic (405nm) and therapeutic use (660nm) – **theragnostic potential**

### PROTECTIVE IMMUNITY



<https://inviongroup.com/videos-reports/>

- Triple Negative Breast Cancer (TNBC) is a hard-to-treat cancer resistant to most chemotherapies
- Hudson Institute proof-of-concept (PoC) pilot showed **complete regression of TNBC** *in vivo* following INV043 treatment
- Tumour mass undetectable two weeks after initial treatment and no scarring evident
- No recurrence of disease, re-challenge with TNBC implant could not re-establish new tumours, suggesting development of **protective immunity**

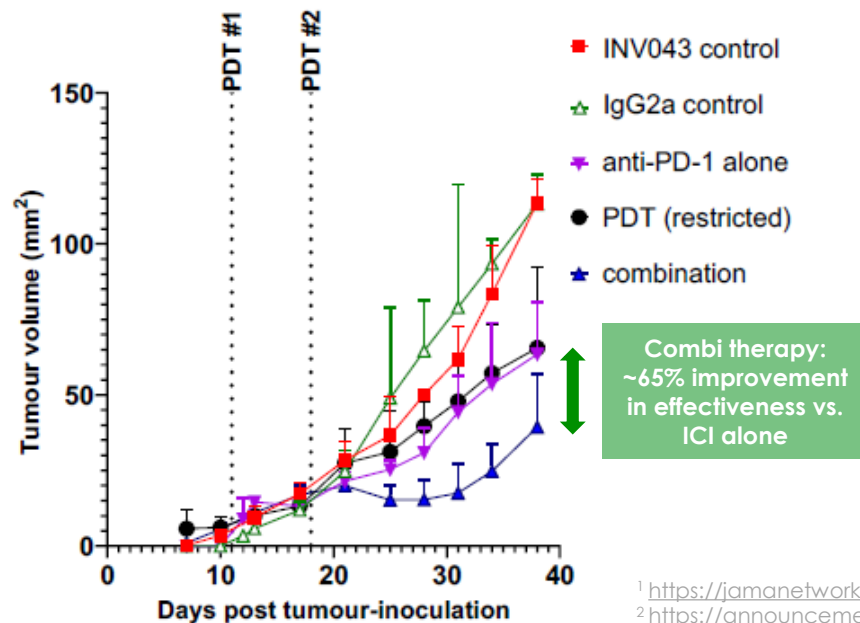
# COMBINATION WITH IMMUNE CHECKPOINT INHIBITORS (ICI)

## IMPROVING IMMUNOTHERAPY OUTCOMES, PARTNERSHIP POTENTIAL

- Immune checkpoint inhibitors (ICI), a type of immunotherapy, is standard of care in treatment of several cancers
- Despite widespread use of ICIs, the patient response rate can be as low as 12.5%<sup>1</sup>**
- Independent *in vivo* studies showed **combined INV043 and anti-PD-1** therapies achieved 80% tumour elimination

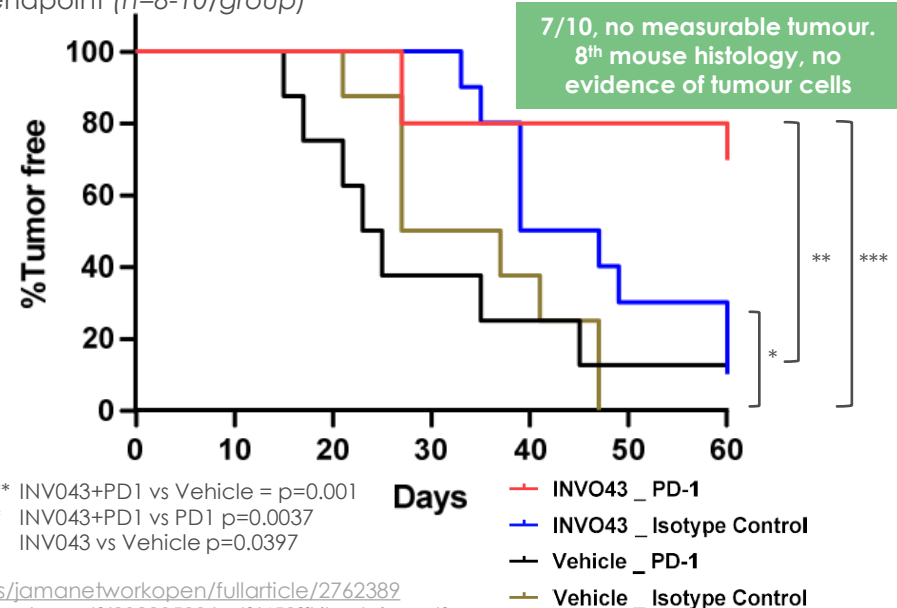
### HUDSON INSTITUTE: ~65% IMPROVEMENT IN TUMOUR VOLUME (TRIPLE NEGATIVE BREAST CANCER, INTRATUMORAL)<sup>2</sup>

- 4T1 breast tumours treated using a restricted INV043 PDT protocol (intratumoural) and / or anti PD-1 antibody (intratumoural)
- Monotherapies restricted tumour growth vs untreated controls
- Combination therapy regressed and stabilized tumours and achieved a ~65% reduction in tumour size at endpoint ( $n=4/\text{group}$ )



### PETER MAC: ~80% RESPONSE RATE (ANAL SCC CANCER, TOPICAL)<sup>3</sup>

- Anal Squamous Cell Carcinoma (ASCC) tumours treated using a restricted INV043 PDT protocol (topical) and / or anti PD-1 antibody
- Monotherapies restricted tumour growth vs untreated controls, with standalone INV043 showing lower tumour volume vs ICI alone
- Combination therapy resulted in 80% tumour-free subjects at endpoint ( $n=8-10/\text{group}$ )

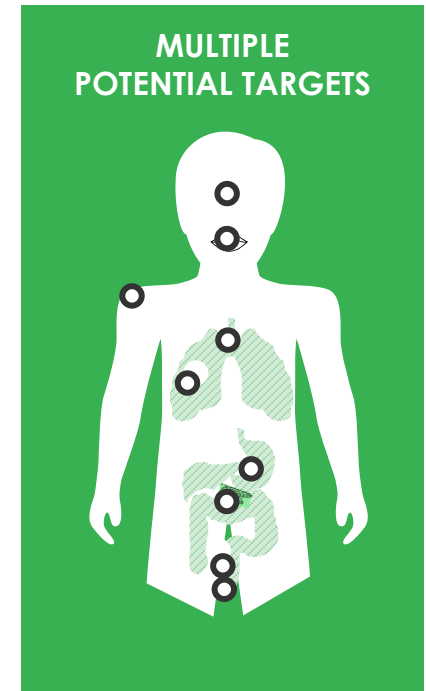
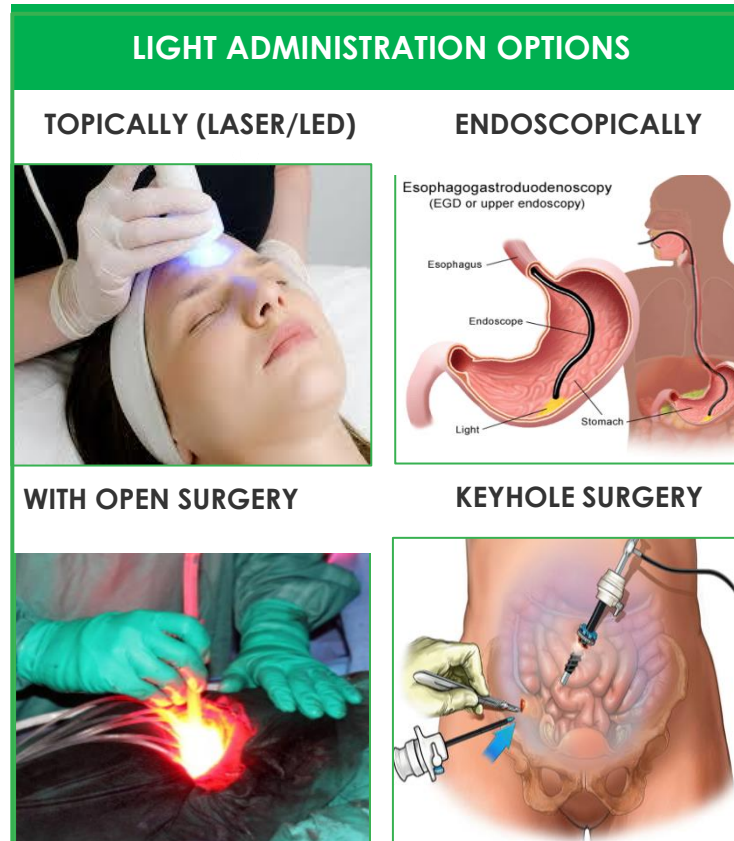




# TREATMENT OPTIONS: FLEXIBILITY FOR CLINICIANS

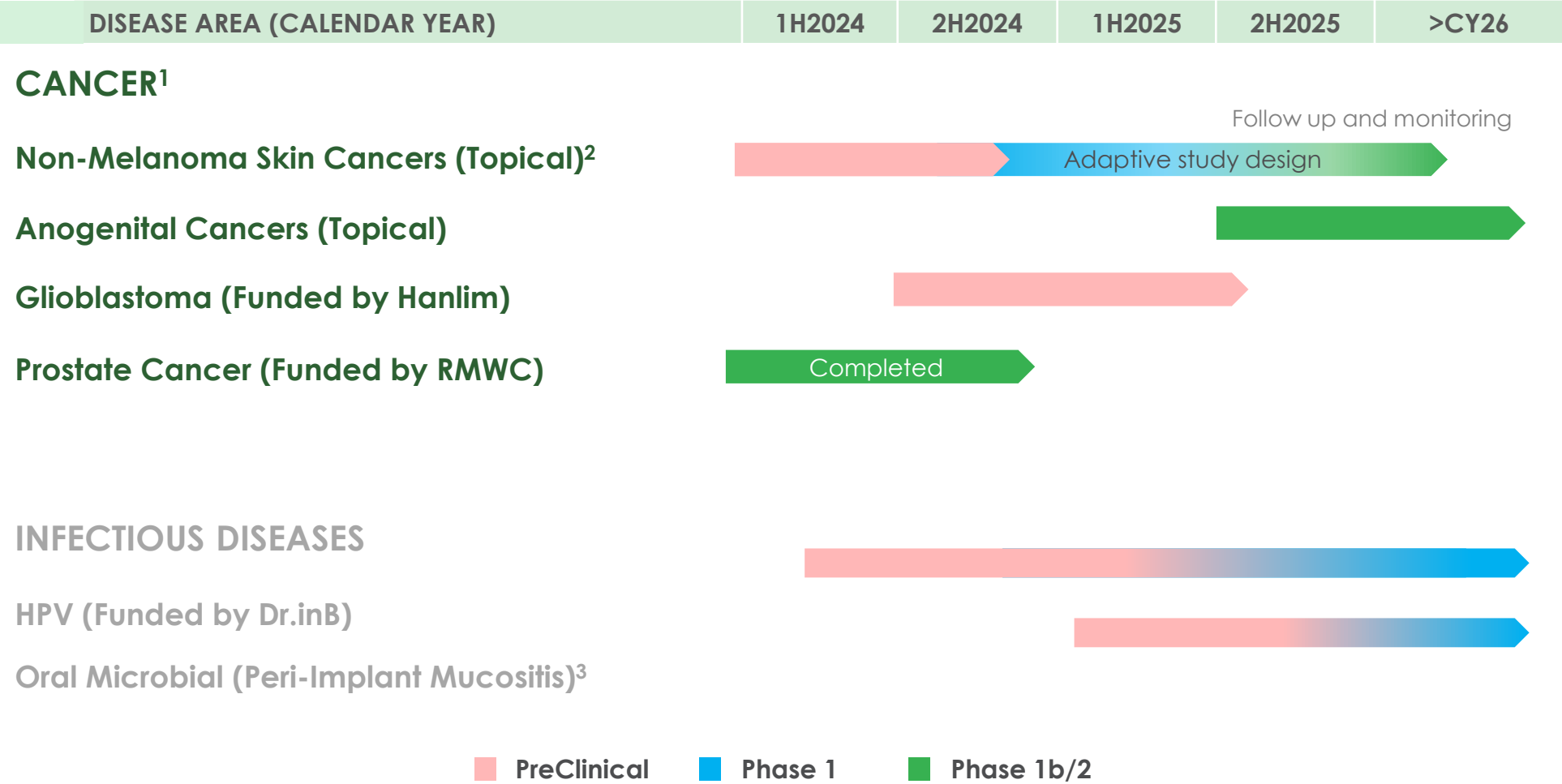
## MULTIPLE PATHWAYS FOR DRUG AND TARGETED LIGHT DELIVERY

INV043 can be administered to multiple target indications via different drug and light delivery options



# TARGET INDICATIONS AND TIMEFRAMES

## MULTIPLE CLINICAL TRIALS AND INDICATIONS



# WHY SKIN CANCER?

## ATTRACTIVE CLINICAL TRIAL INDICATION

### Relatively Cost Effective



Costs to undertake skin cancer trials typically lower than for other routes of administration (eg, intravenous)

### Faster Path to Market



Trials with topical treatments often quicker to complete due to fewer safety concerns and effects can be more readily observed

### Synergies with Other Studies



Safety data from same topical formulation may enable a faster path to a Phase II trial for anogenital cancers

### Large Attractive Market



One of the world's most common cancers with the skin cancer treatment market expected to hit US\$18.1B in 2030 (7.7% CAGR<sup>1</sup>)

### Unmet Medical Need



NMSC comprise 98% of all skin cancers and deaths exceed melanoma globally<sup>2</sup> Standard of care can result in scarring and pain

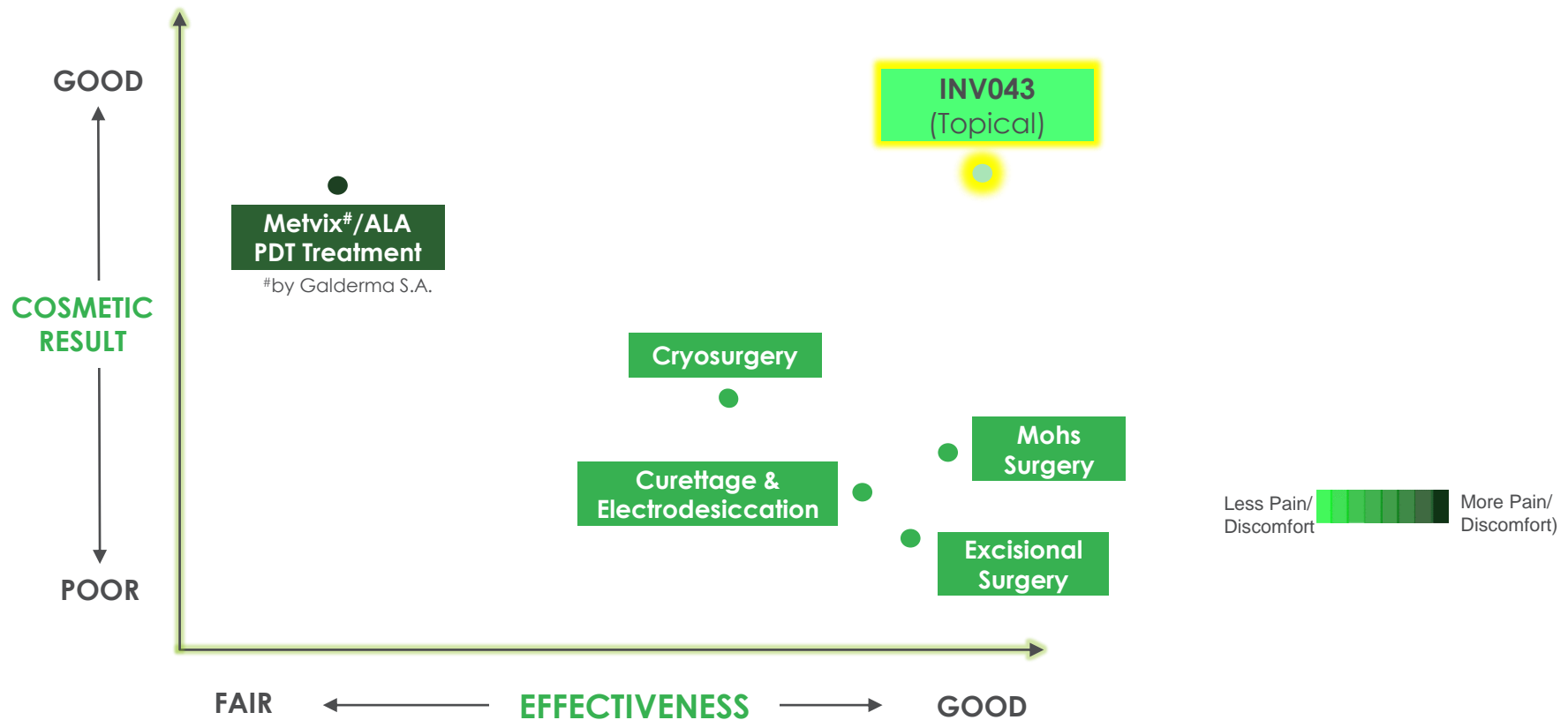
<sup>1</sup> <https://finance.yahoo.com/news/skin-cancer-treatment-market-surpass-130500291.html>

<sup>2</sup> GLOBOCON 2020, WHO

# EVALUATION OF NMSC THERAPIES<sup>1</sup>

## POTENTIAL TO DISPLACE STANDARD OF CARE

Non-Melanoma Skin Cancer (NMSC) Phase I/II Clinical Trial (Adaptive Trial Structure):  
Addressing the unmet need for one of the world's most common cancers<sup>2</sup>



<sup>1</sup> Based on management views

\* <https://www.aad.org/news/guidelines-to-treat-nonmelanoma-skin-cancer>

\* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5746716/>

\* <https://amp.cancer.org/cancer/types/melanoma-skin-cancer/about/key-statistics.html>

<sup>2</sup> <https://amp.cancer.org/cancer/types/melanoma-skin-cancer/about/key-statistics.html>

# CREATING IMPACT FOR TREATING CANCERS GLOBALLY

## NEED FOR MORE AFFORDABLE NEW TREATMENTS

**Cost of new FDA drugs in 2023 jumped 35% YoY at median price of US\$300K<sup>1</sup>, making affordability even harder for the majority of the world's patients.**

Trends towards personalised medicines and targeted therapies (e.g. CAR T / cell therapies, immunotherapies, antibody drug conjugates which can cost US\$100-500k<sup>2</sup>),

Half of new drugs are orphan<sup>3</sup>, which cost 5.5 times more than non-orphan<sup>4</sup>

### Commercial Rationale for Photosoft™



Works across multiple cancers without need to personalise – precision with less complexity



INV043 is a small molecule based therapy that is highly scalable



Photosoft solution has lower development and manufacturing costs



Equipment and treatment process is not complex - helps reach a larger patient base

<sup>1</sup> <https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/>

<sup>2</sup> <https://www.mdpi.com/1999-4923/15/6/1761#:~:text=Additionally%2C%20the%20cost%20of%20ADC,a%20barrier%20for%20some%20patients>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10290406/#:~:text=There%20has%20been%20significant%20policy,being%20approved%20in%20recent%20years>

<sup>4</sup> <https://www.mdpi.com/1999-4923/15/6/1761#:~:text=Additionally%2C%20the%20cost%20of%20ADC,a%20barrier%20for%20some%20patients>

# FUTURE ADDITIONAL INDICATIONS

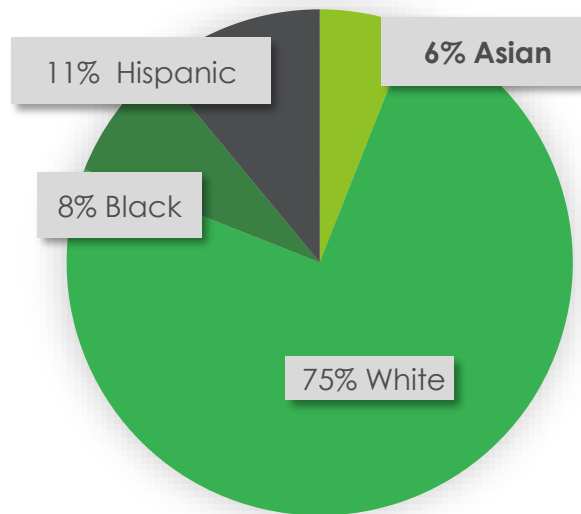
## ADDRESSING UNMET NEEDS OF ASIAN-CENTRIC CANCERS, A US\$40B MARKET<sup>5</sup>

Asians comprise 6% of clinical trial patients in FDA approved drugs<sup>2</sup> ... yet 60% of the world is Asian

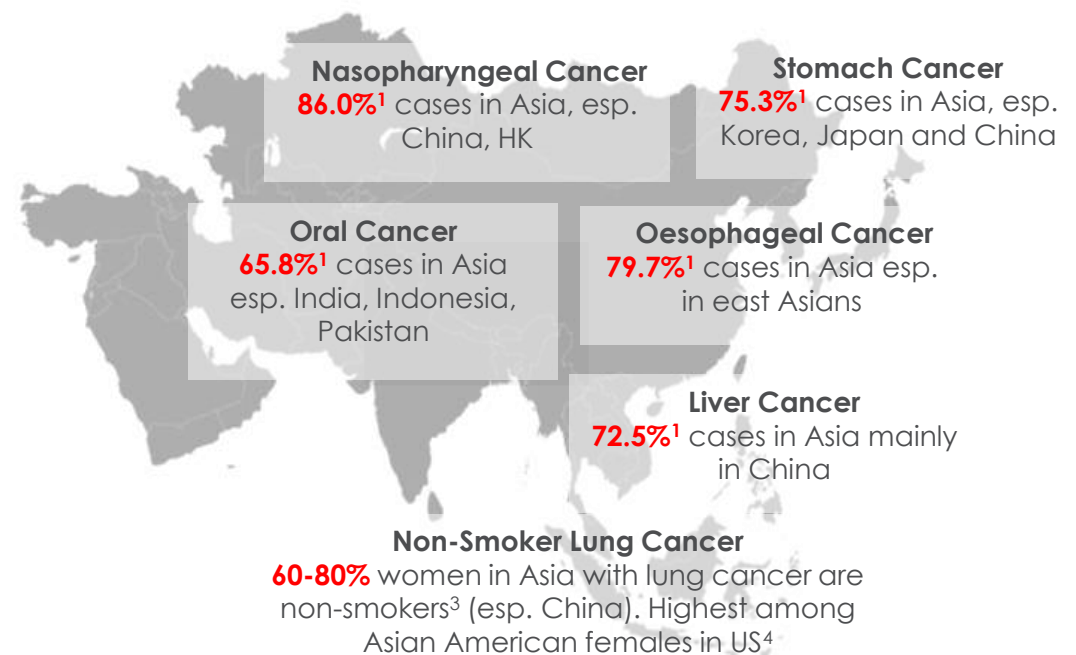


### UNDER-REPRESENTATION IN DRUG DEVELOPMENT

Ethnic Breakdown of Clinical Trials for 2020 Approved Drugs<sup>2</sup>



### MISMATCH WITH GLOBAL INCIDENCE



<sup>1</sup> <https://gco.iarc.fr/today/fact-sheets-cancers> GLOBOCON 2020

<sup>2</sup> Source: Food and Drug Administration – 2020 Drug Trials Snapshots Summary

<sup>3</sup> [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7431055/#b12-ms117\\_p0375](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7431055/#b12-ms117_p0375)

<sup>4</sup> <https://med.stanford.edu/content/dam/sm/care/communityhealthtalk/Stanford-Community-Health-Talk-LCINF-FANS-2-21-2022.pdf>

<sup>5</sup> Oncology Drugs - Asia | Statista Market Forecast





# INFECTIOUS DISEASES

Commercialisable Pipeline

**INVION**<sup>™</sup>

# BROAD-SPECTRUM ANTI-MICROBIAL POTENTIAL

## ANTI-MICROBIAL TREATMENTS – WITHOUT RESISTANCE

“Antimicrobial resistance (AMR) is one of the top 10 threats facing humanity”

World Health Organisation<sup>1</sup>

**Leading Institutions:** Viroclinics conducted virus tests & ACARE (University of Adelaide) conducted bacteria and fungi tests

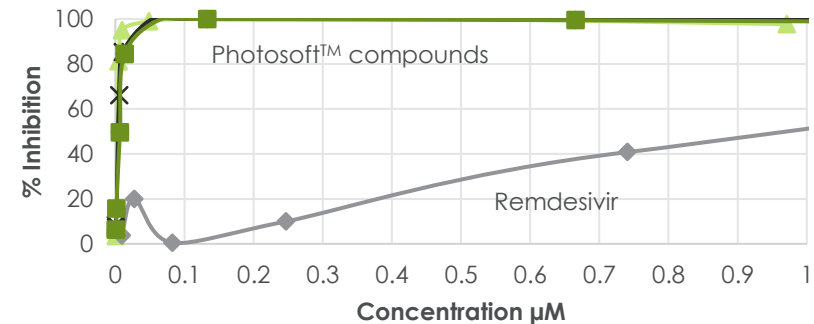
**Broad Spectrum Potential:** *In vitro* tests showed Photosoft™ to be effective against several types of pathogens, including antibiotic-resistant superbugs

**Need for New Treatment Options:** Potential for Photosoft™ as a new treatment class for polymicrobial infections and/or where pathogens cannot develop drug resistance

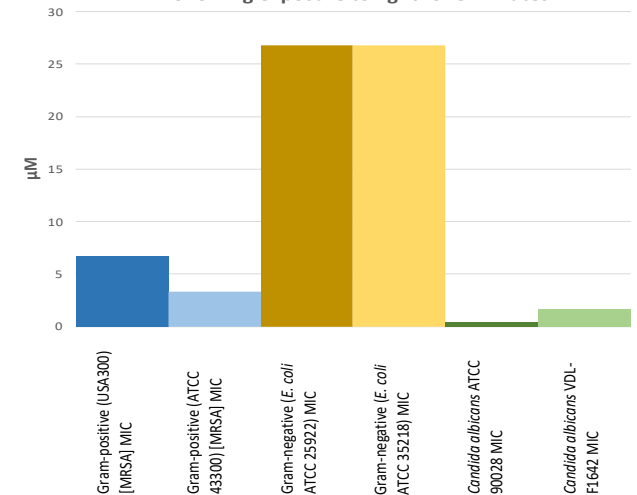
“ Given the general mode of action of PDT... it is unlikely for superbugs to develop resistance to the compounds ”

Prof Darren J. Trott, Director, Australian Centre for Antimicrobial Resistance Ecology (ACARE), University of Adelaide

SARS-CoV-2: Omicron  
Selected Photosoft™ Compounds vs. Remdesivir



Broad Spectrum Activity: Minimum Inhibition Concentration (MIC50) of Selected Photosoft Compound following exposure to light for 5 minutes

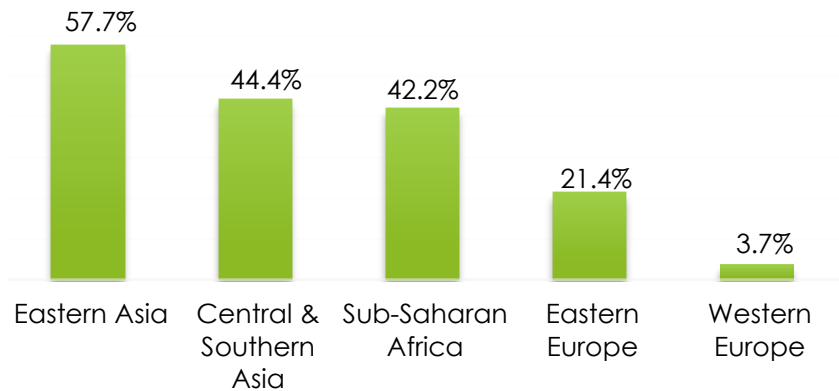


# TARGET ANTIMICROBIAL INDICATIONS

## COST EFFECTIVE AND ACCELERATED PATHS TO CLINICAL TRIALS

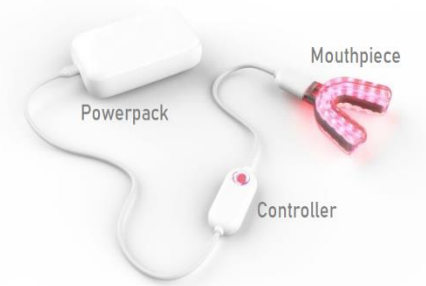
### HPV PROGRAM FUNDED BY DR.INB

#### HPV distribution profile in women<sup>1</sup>



- **Undertake and fund to Proof-of-Concept clinical trials** to test patient safety and efficacy
- Dr.inB is a leading developer of PDT treatments in South Korea backed by Hanlim Pharma. Co., Ltd.
- Collaboration provides **accelerated pathway to demonstrate clinical potential** of Photosoft in infectious diseases like HPV
- **Invion retains all rights** to Photosoft and any new IP from the collaboration

### PERIODONTAL DISEASE



#### Addressing a Growing Unmet Need

- Per CDC, **47.2% in US >30 years, have a form of periodontal disease**, increasing 70.1% of those >65 years<sup>2</sup>
- Global periodontal market size US\$ 9.1 billion in 2022, to reach ~US\$ 24.4 billion by 2032<sup>3</sup>
- **28-56% of implant patients develop peri-implantitis<sup>4</sup>**, an inflammatory reaction, with loss of supporting bone around an implant
- **Photosoft™ PDT advantages**
  - No resistance development
  - Non-invasive treatment
  - Ease of application
  - Repeated treatment possible

**INVION**

<sup>1</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0264410X12010808>

<sup>2</sup> <https://www.cdc.gov/oralhealth/conditions/periodontal-disease.html>

<sup>3</sup> <https://www.futuremarketinsights.com/reports/periodontal-market#:~:text=Periodontal%20Market%20Size%20%2D%20Industry%20Outlook,billion%20by%20the%20year%202032>

<sup>4</sup> <https://pubmed.ncbi.nlm.nih.gov/18724856/> and Carl E. Misch 4th Edition

# EXPERIENCED TEAM

## THE RIGHT EXPERTISE FOR SUCCESS



**THIAN CHEW**

**EXECUTIVE CHAIRMAN & CEO**

- Co-Founder, Chronic Airway Therapeutics
- Advisory Board, Stanford Medicine CARE
- Executive Director, Goldman Sachs
- Director, KPMG Consulting, Senior Manager KPMG
- Adj. Prof. HKUST, MBA/MA Wharton School



**DR AMY PRAWIRA**

**MEDICAL CONSULTANT**

- Founder/CEO, Obatica Pty Ltd (engaged to assist with clinical trials)
- 12+ years in clinical oncology and trials
- Investigator with experience in over 90 early phase clinical trials
- Head, Cancer Trials and Research Unit, Prince of Wales Hospital (Sydney)



**KIM STEEL**

**CLINICAL TRIAL MANAGEMENT**

- 18+ years managing global and clinical drug and device studies from Phase 1-IV across 14 countries
- Managing Director, SAPRO Consulting
- Project Director, Novotech
- Project Manager, Pacific Clinical Research Group



**ALEXANDER BENNETT**

**TECHNICAL ADVISOR, LIGHT DEVICES**

- 35+ years in R&D, manufacturing and commercialisation of scientific instrumentation incl. ISO certifications
- GM Forensic Light Sources, Rofin Australia.
- Led Medical Light Source trial for PDT in skin cancers Peter MacCallum Cancer Centre



**SCOTT CARPENTER**

**PROGRAM DIRECTOR**

- Director Business Development, Starpharma
- Program Manager, AusBiotech
- Regulatory Affairs, Bayer CropScience
- MBA Melb Business School, B. Applied Science RMIT



**NICOLETTA MUNER**

**REGULATORY AND CLINICAL DEVELOPMENT**

- 20+ years non-clinical and clinical drug development, quality, manufacturing, incl. EMA and US FDA approval
- Founder Canary Regulatory Affairs
- Global Regulatory Affairs, Clinuvel Pharmaceuticals
- Pre-clinical and regulatory affairs, Pfizer



**DR SEBASTIAN MARCUCCIO**

**MEDICINAL CHEMISTRY**

- 35+ years in pharmaceutical/organic chemistry drug discovery and development (co-inventor recent PDT patents)
- Founder / Director Advanced Molecular Technologies
- Previously in Pharmaceutical Chemicals Research, CSIRO
- Adj. Prof. La Trobe University, PhD Organic Chemistry ANU



**LOUISE WHITE**

**MANUFACTURING AND QUALITY**

- 35+ years in the pharmaceutical industry, 13 years in vaccine manufacturing, CSL, Partner SeerPharma
- Experience in virology R&D, bacterial vaccines production, quality control and production planning
- Registered auditor for APVMA



For more information, go to [www.inviongroup.com](http://www.inviongroup.com)

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