

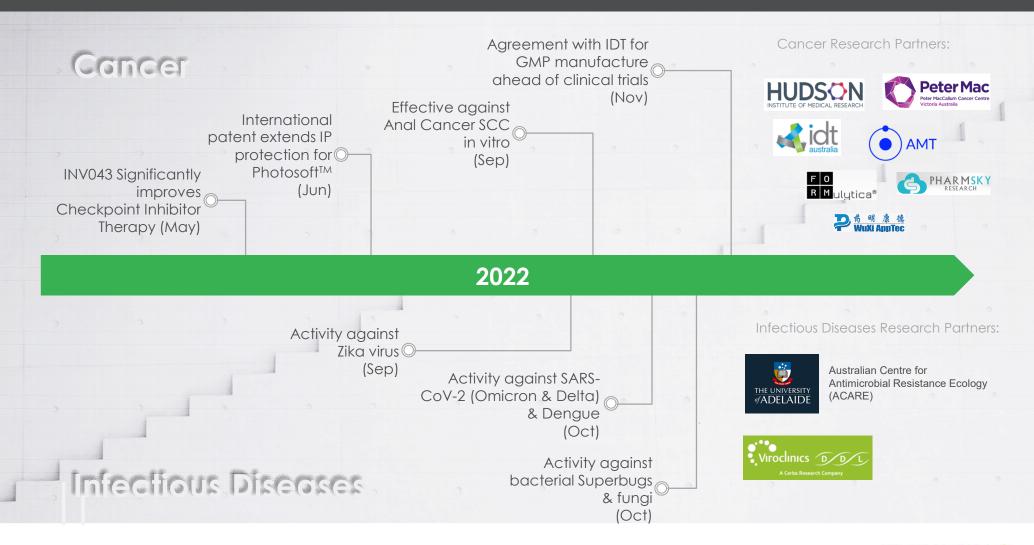
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# **KEY ACHIEVEMENTS**

#### HIGHLIGHTS OVER THE PAST YEAR





## LEAD CANCER DRUG CANDIDATE INV043

#### PATHWAY TO PARTICIPATE IN A US\$271B MARKET OPPORTUNITY<sup>1</sup>



#### Proof-of-Concept studies of lead candidate INV043 has been shown to:



Selectively absorbed by cancer cells and not healthy tissue



Effective in regressing multiple types of cancer in vivo



Stimulate the body's natural immune response



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



Be non-toxic, safe and have limited side effects



Support the translation into successful clinical trials<sup>3</sup>



Oncology market exceeded US\$270.5 billon in 2021 and is forecast to grow at 10.2% CAGR between 2022 and 2028, according to GMI

<sup>&</sup>lt;sup>2</sup> Immune Checkpoint Inhibitor (ICI) therapies are part of the Immunotherapy market

<sup>&</sup>lt;sup>3</sup> Scheduled for 2H CY2022 or 1H CY2023

# **IMPROVED API: INV043**

#### **KEY CHARACTERISTICS\***

#### Active against multiple cancers

- INV043 successfully regressed established T-cell lymphoma, triple negative breast and pancreatic cancers in vivo (n=4-8/group).
- Formulations enable multiple routes of administration.
- Treatment activates an immune response.

#### Strong therapeutic profile

- No toxicity identified up to 100x the therapeutic dose
- Selectively retained into tumours in vivo:
  - Within hours accumulates in tumour mass
  - Within a day INV043 is not detectible in healthy tissue
  - Remains concentrated within tumour mass for >3 days

#### Highly potent and selective

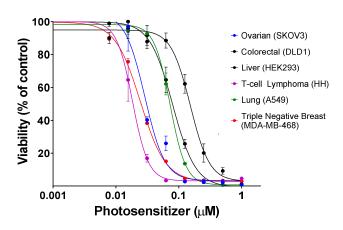
- ~600x greater photoxicity than Talaporfin sodium (a widely used photosensitiser).
- No observed off target toxicity.
- No "dark" toxicity" until 20 to 300 times the therapeutic dose.

#### Theragnostic potential

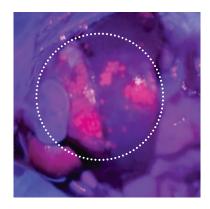
Two distinct light activations wavelengths

- Diagnostic: Fluorescence providing highly visible definition of tumour mass and margins.
- Therapeutic: Activation of INV043 causes rapid cancer cell death and tumour regression.

#### INV043 activity against multiple cancer cell types



#### INV043 fluorescing in a tumour under light



\*Studies carried out by Hudson Institute

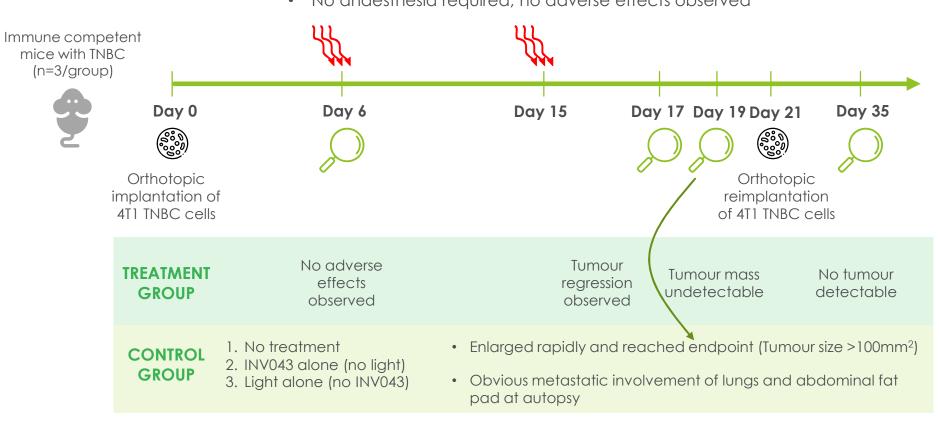


# PROOF OF CONCEPT: PRIMARY TUMOUR PILOT STUDY

#### **REGRESSION AND PROTECTIVE IMMUNITY**

## Treatment with established tumours (INV043 with light)

- INV043 was injected intratumorally (0.1mg/kg)
- 16 hours later, illuminated with red light
- · No anaesthesia required, no adverse effects observed

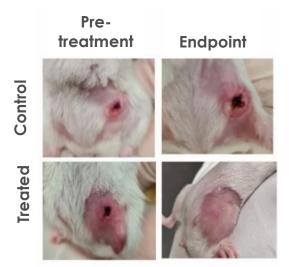




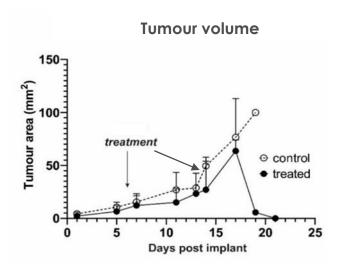
# PROOF OF CONCEPT: PRIMARY TUMOUR PILOT STUDY

#### **REGRESSION AND PROTECTIVE IMMUNITY**

- Triple Negative Breast Cancer (TNBC) is a hard-to-treat cancer resistant to most chemotherapies
- 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
- Additional PoC tests being carried out by Hudson Institute







# results in complete regression of established tumours.

Mice with established 4T1 breast tumours treated with INV043 PDT at days 6 and 13 post-implant. Tumour size monitored until endpoint (≥100mm²). Treatment regressed established tumours to an undetectable level within 14 days of treatment. No tumour regrowth observed. n=3/group; mean +/- SD



## ANAL CANCER SCC

## PROMISING RESULTS AGAINST NEW CANCER CLASS\*

In vitro study showed INV043's effectiveness against six squamous cell carcinoma (SCC) cell lines that represent the full range of anal cancers

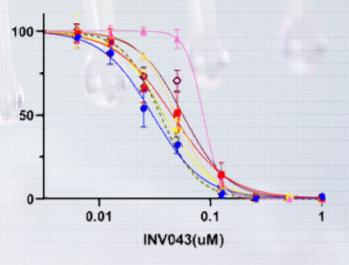
Most anal cancers are SCCs and are difficult to treat with the global market estimated to be worth US\$1.3bn by 2028 (6.3% CAGR)<sup>1</sup>

Findings were consistent with the results of work done at the Hudson Institute on other cancer types

Preclinical testing using topical delivery of INV043 started as a prelude to moving to clinical human testing of anal SCC

<sup>1</sup>Source:https://www.coherentmarketinsights.com/ market-insight/anal-cancer-market-4701

#### Cytotoxicity data of human anal SCC cells lines



- PMAC1 ASCC CL BB (Human HPV+ Primary)
- PMAC4 ASCC CL BB (Human HPV+ Recurren)
- PMAC5 ASCC CL BB

  (Human HPV-Recurrent)
  ASCC Org CL 6
- (Human HPV+ Metastatic)
- ASCC Org CL 3
  (Human HPV-Primary)
  ASCC Org CL 5

  HEK293 GP
- (Human HPV+Recurrent)

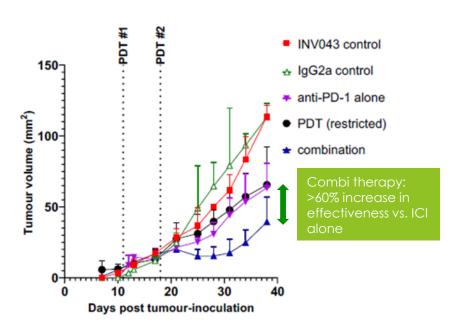
\*Studies carried out by Peter Mac



# PROOF OF CONCEPT: IMMUNE CHECKPOINT INHIBITORS (ICI)

COMBINATION THERAPY FOR PARTICIPATION IN THIS US\$140B MARKET (BY 2030)

- Immune checkpoint inhibitors are widely used for the treatment of lung cancer and melanoma. However, ICI treatments are typically only effective on a small proportion of patients
- Proof of Concept (PoC) pilot by Hudson Institute showed both INV043 (under restricted administration) and anti-PD-1 therapies achieved a very similar level of tumour growth restriction following therapy, with tumour growth reduced by ~40% compared to controls
- A combination of INV043 with anti PD-1 provided substantially enhanced restriction (~65%) of tumour growth, with clear tumour regression despite the sub-optimal INV043 treatment protocol used



# Figure 5. INV043-PDT combines with immune checkpoint inhibition to regress tumour mass.

Mice with established 4T1 breast tumours were treated using a restricted INV043 PDT protocol and / or anti PD-1 antibody over a period of 14 days. Tumour size was monitored until endpoint (tumour size  $\geq$ 100mm<sup>2</sup>).

Monotherapies restricted tumour growth compared to untreated controls; combination therapy regressed and stabilized tumours and achieved a  $\sim\!65\%$  reduction in tumour size at endpoint. INV043 control, no light activation; IgG2a control, isotype antibody control; combination, PDT+ anti PD-1. Additional control groups have been omitted for clarity. *mean* +/- SD, n=4/group.

The research activities involving the use of animals were carried out in accordance with relevant guidelines and regulations as well as with appropriate Animal Ethics Committee approval.

<sup>1</sup> https://www.alliedmarketresearch.com/immune-check-point-inhibitors-market





# **BROAD-SPECTRUM ANTI-MICROBIAL POTENTIAL**

### INFECTIOUS DISEASES: EFFECTIVE AGAINST VIRUSES, BACTERIA AND FUNGI IN VITRO

## "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<sup>™</sup> to be effective against several types of pathogens, including antibiotic-resistant superbugs

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

Given the general mode of action of PDT, we surmise that 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



# **EFFECTIVE AGAINST SARS-CoV-2 IN VITRO**

#### ANTIVIRAL ACTIVITY AGAINST DELTA AND OMICRON VARIANTS

Nine out of ten Photosoft™ compounds tested displayed antiviral activity against both Delta and Omicron variants of SARS-CoV-2

Multiple Photosoft™ compounds show effectiveness against SAR-CoV-2 at far lower concentrations than Remdesivir

Antiviral activity occurred once Photosoft<sup>TM</sup> compounds were activated with red light

Photosoft<sup>™</sup> compounds tested demonstrated either no or low cytotoxicity

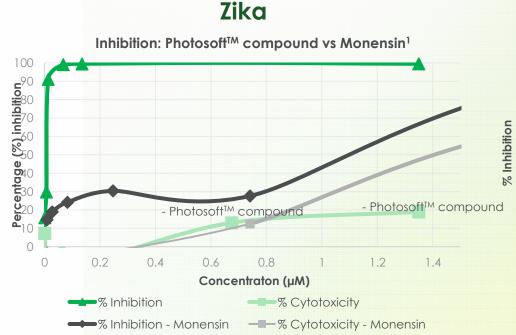
The global coronavirus treatment market is forecast to reach US\$49bn by 2027 (17.5% CAGR)\*

#### SARS-CoV-2: Delta Selected Photosoft<sup>TM</sup> Compounds vs. Remdesivir 100 80 % Inhibition 60 40 20 0 \* 0.1 0.2 0.3 0.4 0.5 0.7 0.8 0.9 Concentration µM SARS-CoV-2: Omicron Selected Photosoft<sup>TM</sup> Compounds vs. Remdesivir 100 80 % Inhibition 60 40 20 0 0.1 0.2 0.3 0.7 0.9 Concentration µM % Inhibition - Compound 7 —— % Inhibition - Remdesivir ─ % Inhibition - Compound 9 — % Inhibition - Compound 10

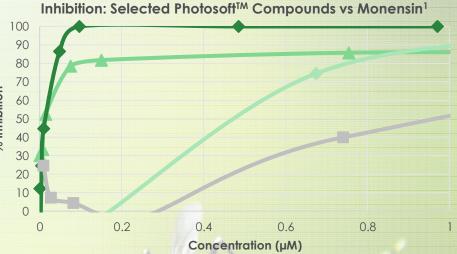
<sup>\*</sup>https://www.coherentmarketinsights.com/market-insight/coronavirus-treatment-drugs-market-4312

# EFFECTIVE AGAINST ZIKA AND DENGUE IN VITRO

#### ANTIVIRAL ACTIVITY AGAINST ZIKA AND DENGUE



## Dengue



<sup>1</sup> Monensin is an antibiotic known to have activity against Zika in *in vitro* laboratory tests and was a control (benchmark) in these studies, but due to its *in vivo* toxicity cannot be used in humans

Several Photosoft<sup>™</sup> compounds had >100x the activity of Monensin<sup>3</sup> (selected control) in vitro

Zika virus is found in 86 countries and is linked to birth defects and other neurological complications Market is ~US\$17 billion in 2022<sup>1</sup> with no vaccines or treatments currently available<sup>2</sup>

One compound had an EC50 (half max effective concentration) >90 times lower than Monensin

Dengue causes intense pain in joints and muscles, hence its nickname "breakbone fever" Treatment market is forecast to hit US\$1.3 billion by 2030<sup>4</sup>



<sup>2</sup>https://www.marketdataforecast.com/market-reports/zika-virus-vaccines-market

<sup>3</sup>https://www.who.int/news-room/fact-sheets/detail/zika-virus

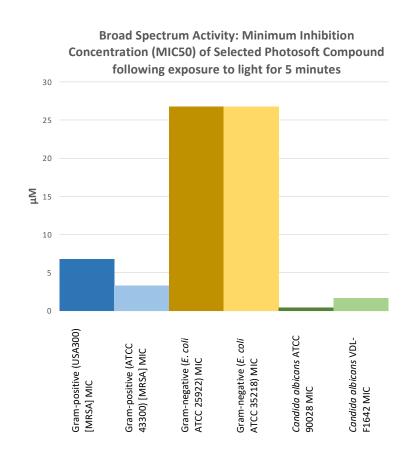
https://www.biospace.com/article/-dengue-vaccines-market-size-to-reach-us-1-3-billion-by-2030/

## **EFFECTIVE AGAINST BACTERIA AND FUNGI**

#### MRSA SUPERBUG, E.COLI BACTERIA & CANDIDA ALBICANS FUNGUS

- Several Photosoft<sup>TM</sup> compounds showed activity in vitro against multiple strains of antibiotic-resistant MRSA bacteria, Escherichia coli bacteria and Candida albicans fungus\*
- MRSA is an antibiotic resistant bacteria that is difficult to treat, with the World Health Organisation (WHO) having declared antimicrobial resistance (AMR) as one of the top 10 threats facing humanity
- Photosoft<sup>TM</sup>'s mode of action has the potential to make it unlikely for superbugs to develop resistance

\*Tests undertaken at the Australian Centre for Antimicrobial Resistance Ecology (ACARE), University of Adelaide



Note: The *in vitro* studies that were conducted at the University of Adelaide used enrofloxacin and amphotericin B as control antibiotics for the antibacterial and antifungal tests, respectively.



# THE WAY FORWARD

## MULTIPLE CATALYSTS AND MILESTONES

#### **Australia**

- Proof of Concept (PoC) Building on in vivo work further demonstrating both safety and efficacy profiles
- **Pre-clinical Preparations**: Building foundations for clinical trials in multiple indications and internationally
- Clinical Trials: With strong in vitro and in vivo results demonstrating both safety and efficacy profiles, and across multiple cancer types, the next steps will be to conduct clinical trials in multiple indications, including
  - Skin Cancer (superficial basal cell carcinoma)
  - Anogenital Cancer
  - Other solid tumour cancers TBC<sup>1</sup>
- **GMP manufacturing and scale up**: Building capacity to scale up for global late-stage trials and commercialisation

Expand
Internationally:
Leveraging

Globa

Leveraging
Australian clinical
trial data into later
stage programs in
other major
markets

Atherosclerosis and Infectious Diseases (AID)

Early stage broad based discovery Identification of target indications

Proof of Concept on targeted indications

<sup>1</sup> RMW Cho Group ("RMW") as licensor of Photosoft<sup>TM</sup> technology, is pursuing independent research in parallel with Invion's R&D efforts including a prostate cancer trial. The research is complementary/supplemental to Invion's development program. To the extent that Invion becomes aware of material information relating to RMW's studies, Invion will release the information to the ASX in compliance with its disclosure obligations (noting however that Invion is not involved in RMW's studies and does not have direct access to information)

Cancer

## MANAGEMENT TEAM

#### THE RIGHT EXPERTISE FOR SUCCESS



THIAN CHEW EXECUTIVE CHAIRMAN & CEO

- Managing Partner, Polar Ventures
- Executive Director, Goldman Sachs
- Director, KPMG Consulting, Senior Manager KPMG
- Adj. Prof. HKUST, MBA/MA Wharton School



DR ANDREW STEPHENS HUDSON INSTITUTE, R&D

- 15+ years in novel treatment R&D
- Founder, Ovarian Cancer Biomarker Group, Hudson Institute
- Postdoc. positions, the Uni. of Sydney and Prince Henry's Institute, PhD Biochemistry Monash Uni
- Published extensively, holds several patents



DR SEBASTIAN MARCUCCIO CHEMISTRY

- 15+ years in Pharmaceutical and organic chemistry developmental research
- 16+ years commercial experience in molecular based companies (Managing Director / Founder)
- Adj. Prof. La Trobe University, PhD Organic Chemistry ANU



ALEXANDER BENNETT TECHNICAL ADVISOR, LIGHT

- 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



MELANIE LEYDIN

- 25+ years in accounting profession
- Partner, Vistra
- CFO and Co. Secretary multiple biotech companies
- Fellow Gov. Institute of Australia, Chartered Acc't



# 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



LOUISE WHITE
MANUFACTURING AND QUALITY

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



KIM STEEL
CLINICAL TRIAL MANAGEMENT

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



## **SUMMARY**



#### **Cancer - Promising Results:**

Total tumour regression, immune response, potential ICI combination therapies



#### Infectious Diseases – Early Findings:

In vitro effectiveness against multiple viruses & bacteria including SARS-CoV-2 (Delta and Omicron) and MRSA



Cancer - Clinical Trials: Human trials across several cancer types expected to commence 2023



**Well Funded**: Cancer program fully funded & AID partially funded by RMWC.



Multiple Growth Options: Large addressable markets, multiple indications, partnership opportunities



#### Experienced Management, World-Leading Partnerships:

Balance of expertise in life sciences and commercialisation combined with world-renowned partnerships

