

INVESTOR **PRESENTATION**
February 2014

PharmAust LIMITED

ASX: PAA
ACN 094 006 023

PharmAust Corporate Structure

PHARMAUST LIMITED

ASX:PAA



PPL Pitney Pharmaceuticals Pty Limited

epichem molecules made to order

Sydney-Based

Perth-Based

Commercial Cornerstones

UNSW AUSTRALIA

NEWSOUTH INNOVATIONS

Strategic Alliances Global Corporations

IP - Granted and Pending Patents

THE ST. GEORGE HOSPITAL SYDNEY



PharmAust LIMITED

PPL Pitney Pharmaceuticals Pty Limited

epichem monocules made to order

What Does PharmAust Do?

- We do not take drugs from the bench to the market place which often takes **12 YEARS** to achieve and 100s of millions of dollars and also we do not create generics (copies)

- **We find new uses for approved drugs in oncology:**
  - Often drugs are already on the market so toxicology, safety and manufacture are established
  - Often oncology would be a new application – so patentable
  - Often there is a global distributer that wishes to acquire a new drug application

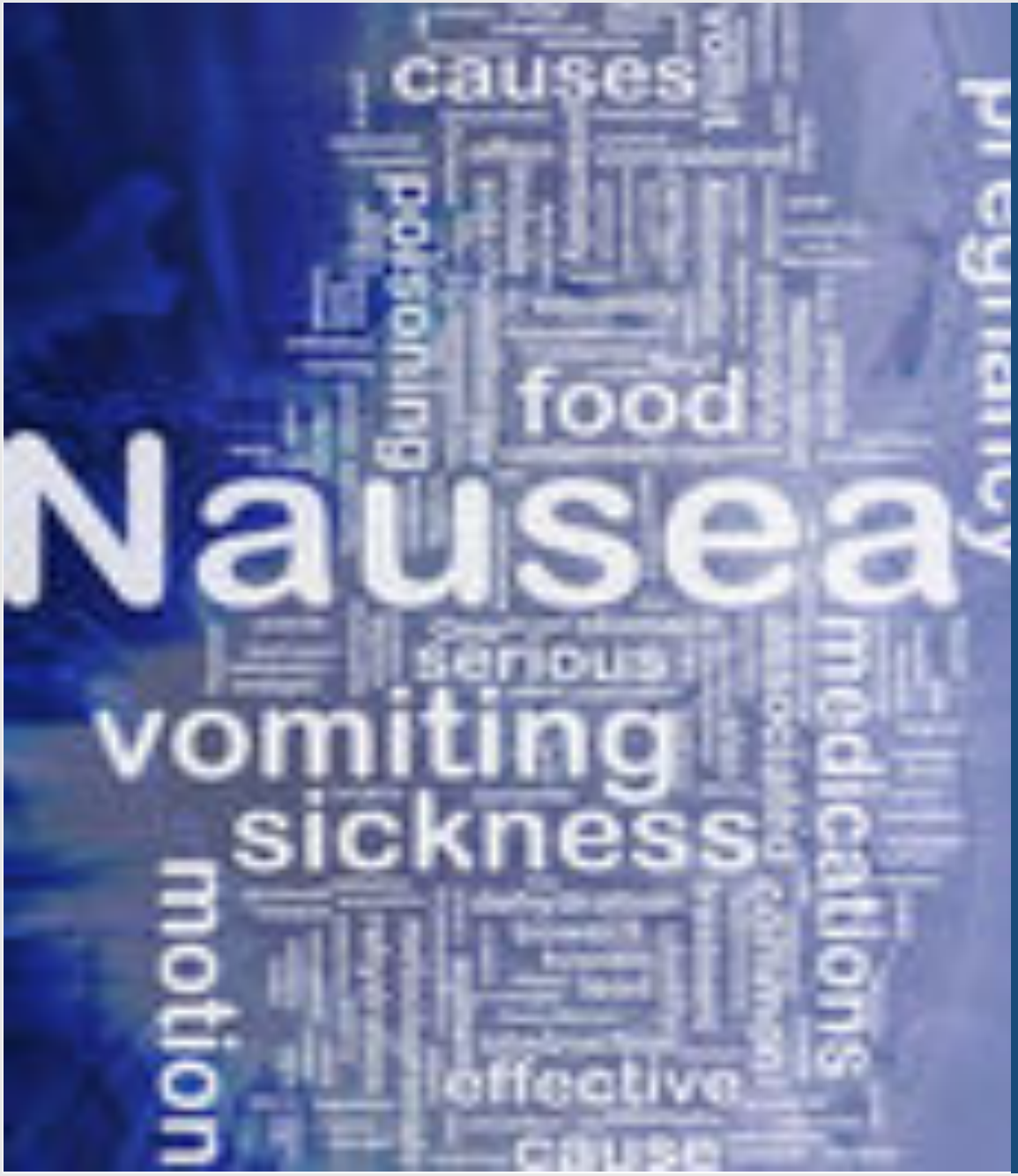
Is there a "Silver Bullet" for cancer out there?

NOT YET!

PharmAust has Identified a New Pathway for Cancer Treatment

Traditional chemotherapy targets one of four mechanisms, all of which carry side effects – monoclonals and vaccines provide a further approach





PharmAust is not only targeting Cancer but also the associated side effects

The new anticancer pathway identified appears to have far fewer side effects than chemotherapy

Purposes of Chemotherapy Treatment

1. Chemotherapy may be used with the aim of curing cancer

2. Sometimes (1) is not possible or likely so chemotherapy is used to slow progression

3. Chemotherapy is sometimes used to ease the symptoms of advanced cancer (palliative)

4. Sometimes chemotherapy is used to prepare for other treatments e.g. Shrink a tumour to make it eligible for surgery

THE GOAL IN CANCER THERAPY EFFICIENCY

Ultimately the efficacy of a cancer treatment depends on its “therapeutic index” or the ability to kill cancer cells versus normal cells

Typically, the narrower the margin between efficacy and toxicity the higher the side effects

PharmAust is Developing a New Class of Anti-Cancer Drug

1. One of this class is already registered as veterinary drug by a major Pharmaceutical company

2. PharmAust has undertaken extensive preclinical studies and based on the manufacture and safety of this class of drug PAA has submitted a clinical trial application for approval in Australia to evaluate PPL-1 in man

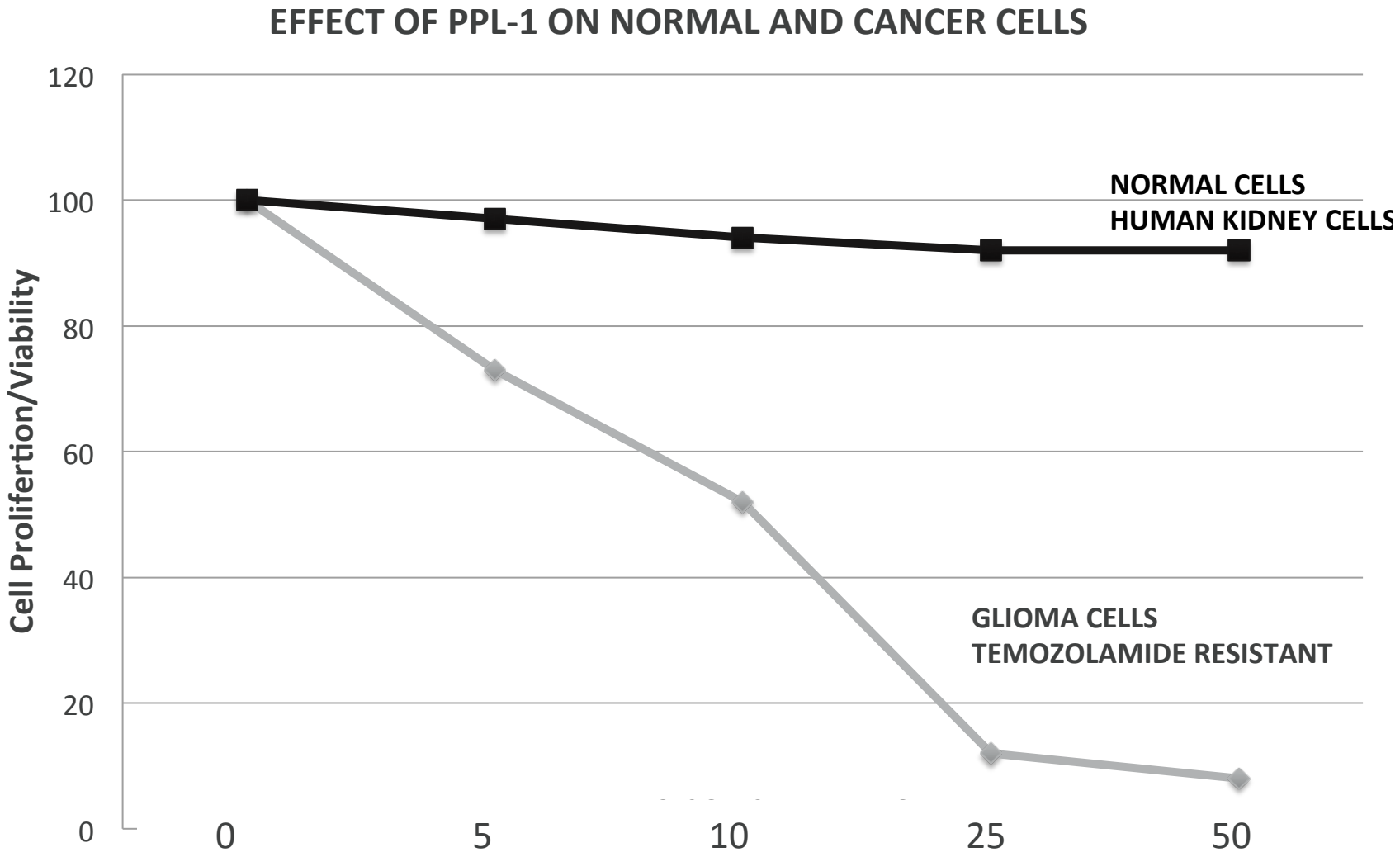
3. As the product is already approved for Veterinary use, PharmAust has also applied to undertake a clinical study in companion animals (dogs) with cancer

Important Collaborators

1. PAA has a Research and Option Agreement with Major Pharma for the Veterinary applications of PPL-1

2. PAA has a second relationship with another significant overseas listed pharmaceutical/agricultural company for the human co-development programme

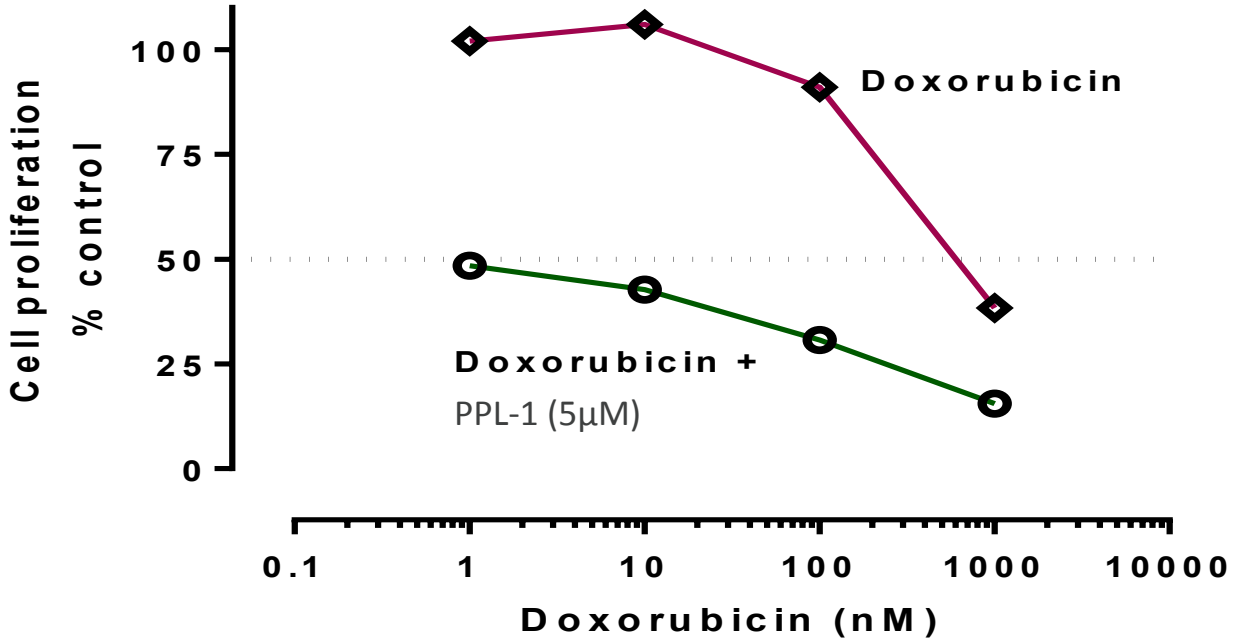
Effect of PPL-1 on Cancer Cells



Synergy Between PPL-1 and Cytotoxic Drugs

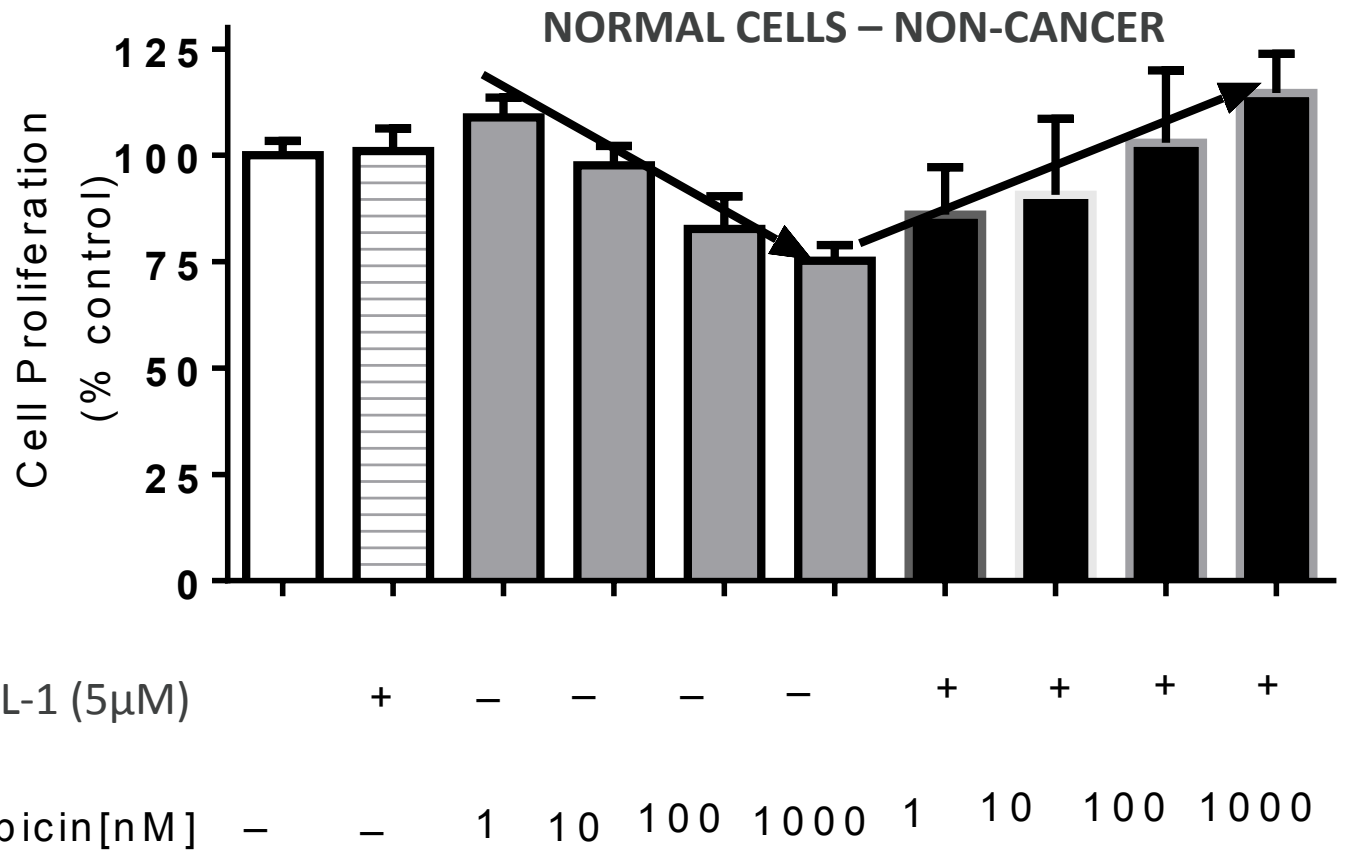
1. Selective Synergy between PPL-1 and cytotoxic drugs on “cancer” cells
2. No synergy between PPL-1 and cytotoxic drugs on “normal” cells
3. Opportunity for new class of drug for cancer therapy in conjunction with standard clinical practice
4. Next steps - Optimization of Synergy

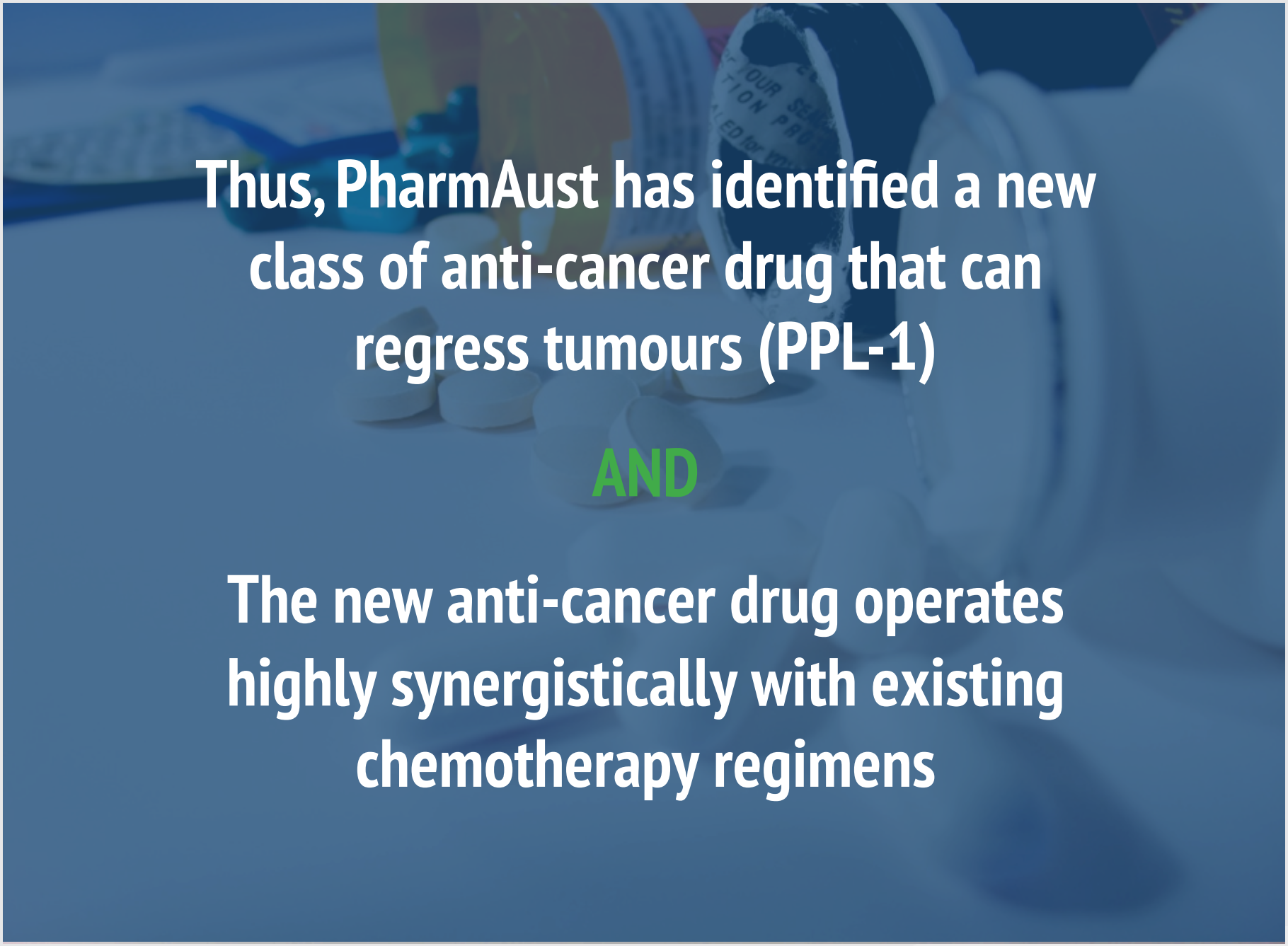
Combined effect of Doxorubicin plus PPL-1 on cell proliferation in A2780 cells



Addition of 5 uM PPL-1 to doxycycline treatment schedule reduced the IC_{50} value from **500 nM to 1 nM** (approximate values)

Human ovarian surface epithelial cells, 24 hours treatement with MPL + Doxorubicin





Thus, PharmAust has identified a new class of anti-cancer drug that can regress tumours (PPL-1)

AND

The new anti-cancer drug operates highly synergistically with existing chemotherapy regimens

NEXT STEPS WITH PPL-1

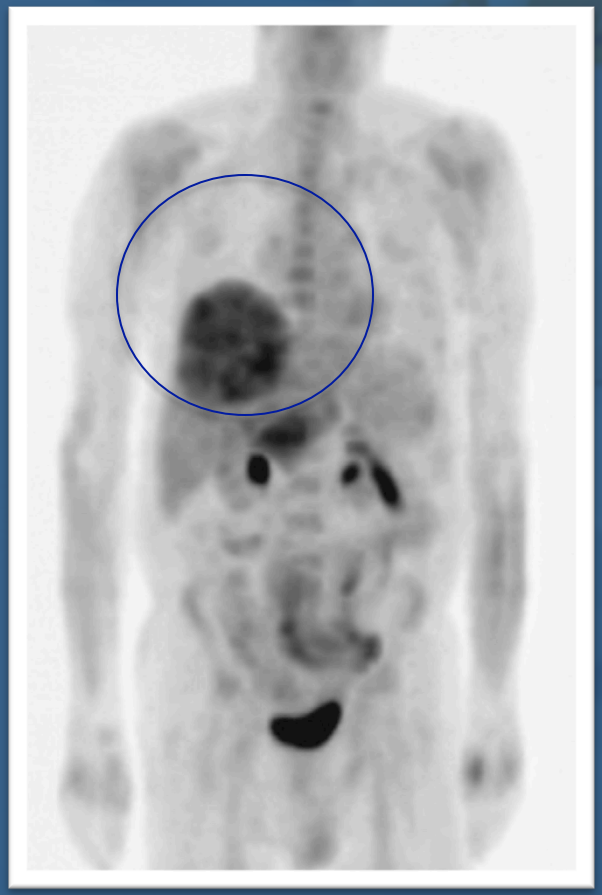
1. Phase II trial in human Cancer patients

2. Phase II trial in Companion animals to further Research and Option to Licence

PET Scan

Example of Measurement of Tumour Metabolism

A similar approach will be taken with PPL-1 when it is evaluated in man.



PRE - TREATMENT



POST - TREATMENT

Albendazole Ascites I

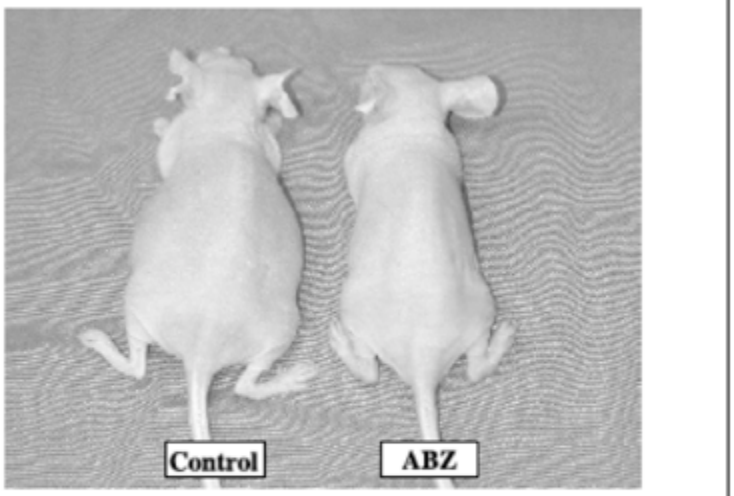


Fig. 1. Effect of albendazole (*ABZ*) on ascites development. Nude mice inoculated i.p. with OVCAR-3 cells were left to develop ascites and then randomly assigned to one of control or albendazole treatment groups (n = 10 per group). Whereas all mice in the control group developed overt ascites, there were no macroscopic signs of ascites formation in albendazole-treated mice.

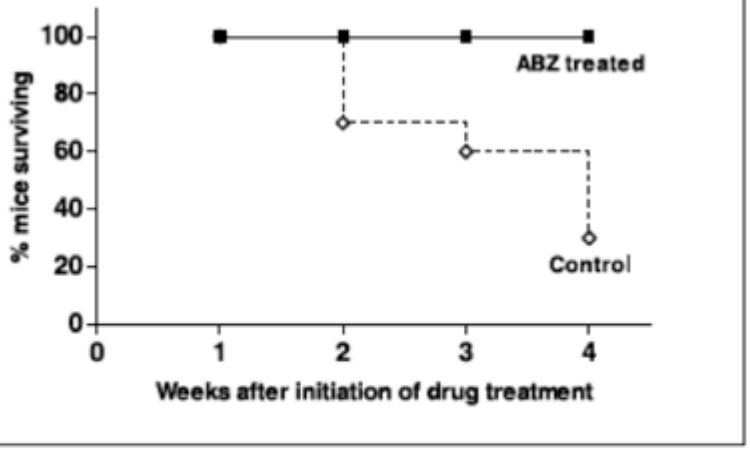
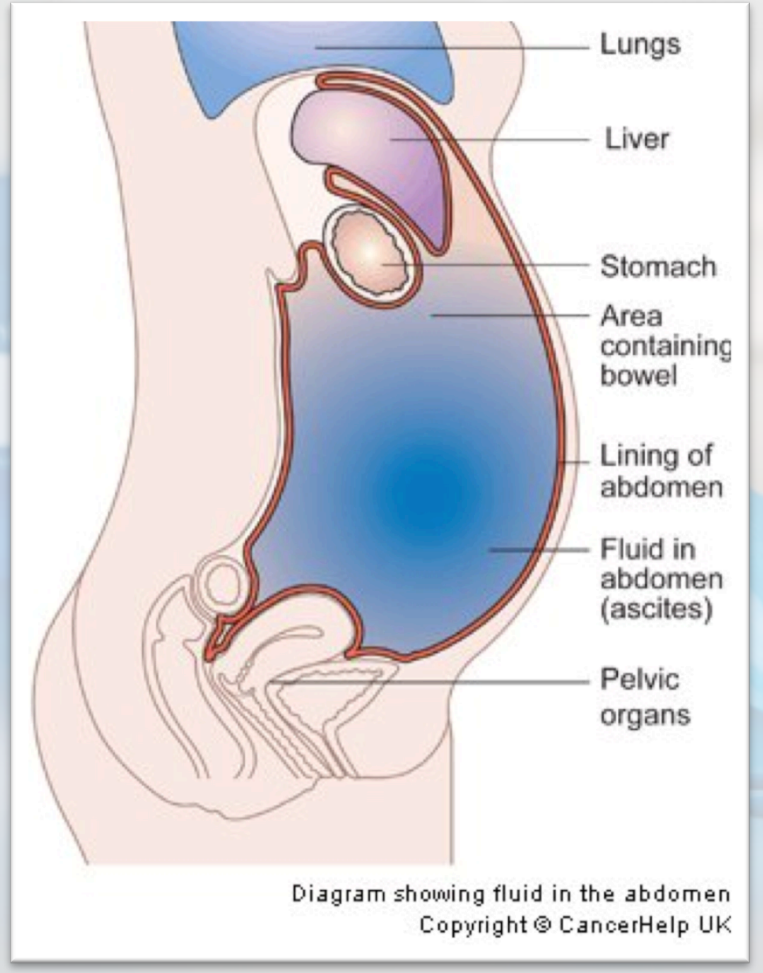


Fig. 3. Survival curve showing the effect of albendazole (*ABZ*) on survival. Whereas for all animals the intended duration of treatment was 4 weeks, mice (10 per group) were euthanized if due to ill health, they were expected to become moribund within a short time. Survival was calculated as the number of days lapsed between initiation of treatment and euthanasia, and % mice surviving was the number of animals remaining in each group (×10) at the end of each week following initiation of treatment.

Ascites in Man





Key Milestones for PharmAust In 2014

Q1

- Approval of first in man study in cancer patients
- Approval for treatment of companion animal cancers

Q2

- Execution of second strategic alliance for human anticancer applications
- Interim trial report on human cancer therapy
- Ind for PPL-1 approved by FDA

Q3

- Exercise of research and option to licence agreement by Pharma partner
- Results of first in man cancer trial
- Albendazole approval of Phase II in Australia

Q4

- Initiation of phase ii with PPL-1 USA-Australia
- Initiation of albendazole Phase II in Australia

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