AUSTRALIS
PHARMACEUTICALS

Corporate Presentation

January, 2026

Australis Pharmaceuticals – Harnessing Nature to Fight Cancer

- Australis Pharmaceuticals (Australis) was founded to develop naturally derived compounds into **cancer therapeutics**
- The original compounds were discovered in honey bee propolis on Kangaroo Island in South Australia and characterized as **microtubule-destabilizing agents (MTAs)**
- **AUS_001, oncology lead compound,** has demonstrated encouraging in-vitro and in-vivo data in efficacy and toxicity studies across multiple tumor lines
- Given the broad anti-cancer activity against solid tumors demonstrated by AUS_001 and the ability to cross the **blood brain barrier**, the Phase 1 study will have a broad inclusion criteria for tumor types
- **Orphan Drug Designation** issued for AUS_001 for **malignant gliomas** in February, 2025 and **Rare Pediatric Disease Designation** issued for AUS_001 for **pediatric high grade gliomas** in March, 2025
- Pre-IND meeting completed with FDA: confirmed our pre-clinical approach
- Team in place has strong research and clinical development expertise

Australis Research Focus: The Patients In Need*

	Pancreatic Cancer [1]	Malignant Glioma[2]	Pediatric-type Glioma[3]
US Incidence	66,440	22,654	~8,800
Estimated Survival	12.8% (5 year survival)	~10% (5 year survival)	Most patients do not survive more than 1 – 2 years

No therapies currently in clinical trials identified as having viable potential to address these great unmet needs for patients

*: these represent just a few of the potential tumor types that AUS_001 can target

[1] National Cancer Institute SEER database; [2.] Mesfin, et al. 2024; Ostrom et al., 2022 [3] Gaijjar et al., 2022

AUS_001 Differentiators Which Have The Potential To Benefit Patients

Efficacy

- **Pre-clinical efficacy:** Demonstrated across a range of tumor types, including **glioma and other tumor types representing unmet needs for patients**
- **Crosses the blood brain barrier**

Safety

- **Safety margin: ~20x** more of AUS_001 needed to inhibit growth of healthy non-neoplastic counterpart cells
- **Peripheral neuropathy**: Reversible neurotoxic effect
- **Drug-Drug interactions:** Poor inhibitor of CYP enzymes, common pathway for drug metabolism

Patient Focus

- **Developed an oral formulation***
- **Potential balance of efficacy and safety,** based on pre-clinical therapeutic index

*: Final decision still pending on encapsulation vs maintaining a liquid form for the clinical trial

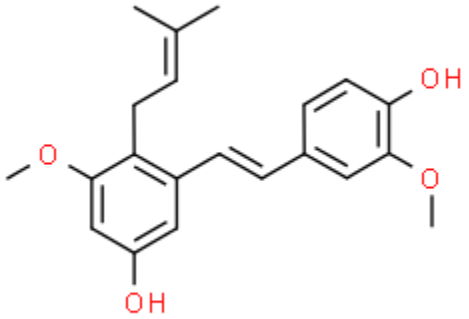
AUS_001: Product Summary

AUS_001 extracted from the sedge plant (source of Kangaroo Island propolis)

AUS_001 Structure

(E-stilbene)

MW=340.42 g/mol



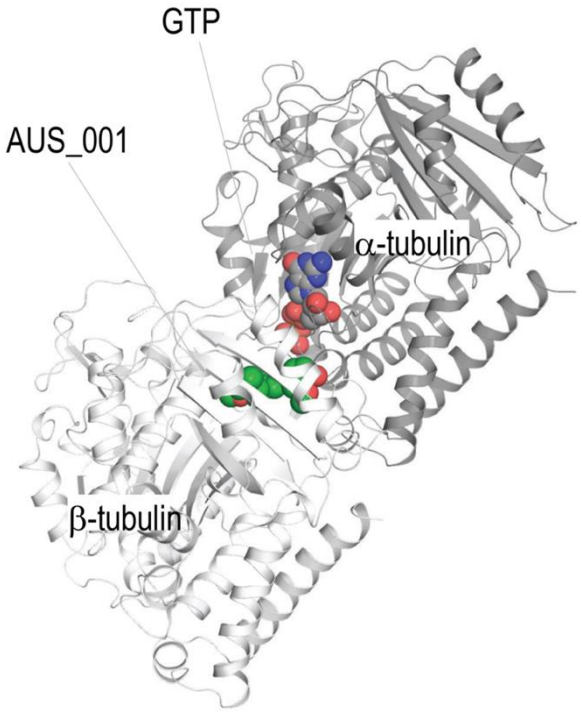
Common name:

(3-[(E)-2-(4-Hydroxy-3-methoxyphenyl)vinyl]-5-methoxy-4-(3-methyl-2-buten-1-yl)phenol

MECHANISM OF ACTION (MOA)*:

AUS_001 is characterized as a microtubule-destabilizing agent and has demonstrated cell cycle inhibition and induction of programmed cell death. Reversible mode of target engagement and increased uptake by cancer vs. normal cells

X-ray Crystal Structure of the tubulin-AUS_001 complex



*: MOA data presented at AACR 2024

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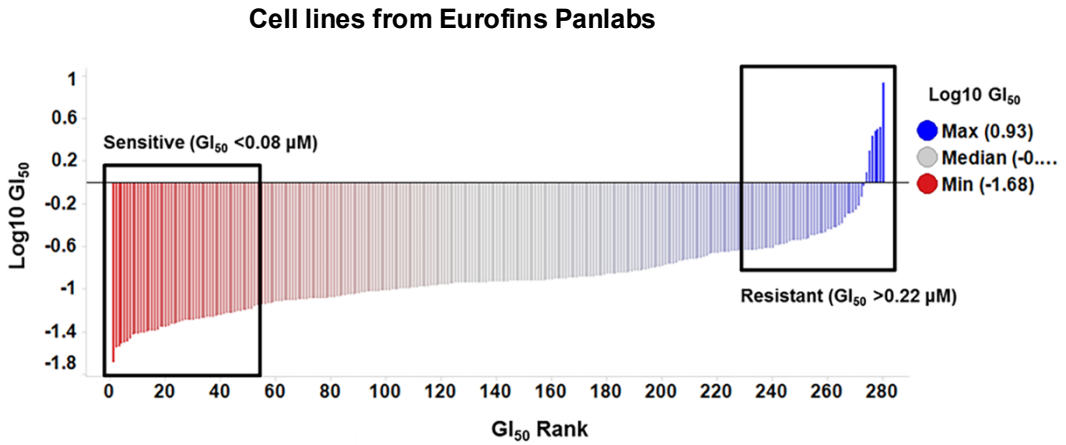
Data Summary for AUS_001: Encouraging In Vitro Data

In Vitro Data

- High potency against **24 types of cancer*, including glioblastoma and other tumor types representing unmet needs for patients**
- Encouraging safety margin: **~20x** more of AUS_001 needed to inhibit growth of healthy non-neoplastic counterpart cells
- Reduced concern for **peripheral neuropathy**: Drug treated midbrain and cortical neurons showed reversible neurotoxic effect for AUS_001 but Paclitaxel-treated neurons suffered sustained neurotoxicity even after discontinuation of treatment. This is a key finding especially for the pediatric population
- Less susceptibility to **Drug Resistance-related mechanisms**



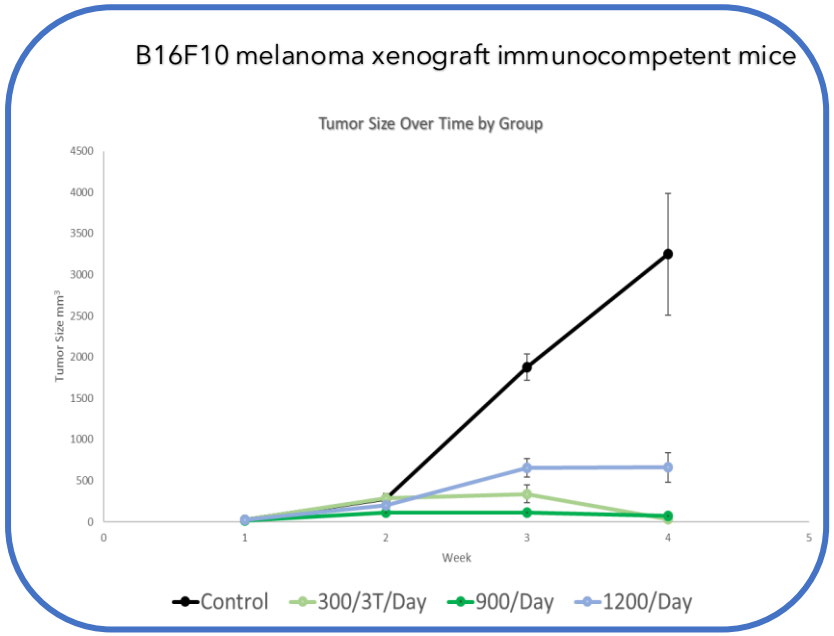
The proliferation response of 280 cancer cell lines to AUS_001 treatments as assessed by high-content fluorescence imaging (Eurofins Panlabs): All cell lines with cell count GI50 <0.08 uM were classified as sensitive to AUS_001, while those with GI50 >0.22 uM were classified as resistant.

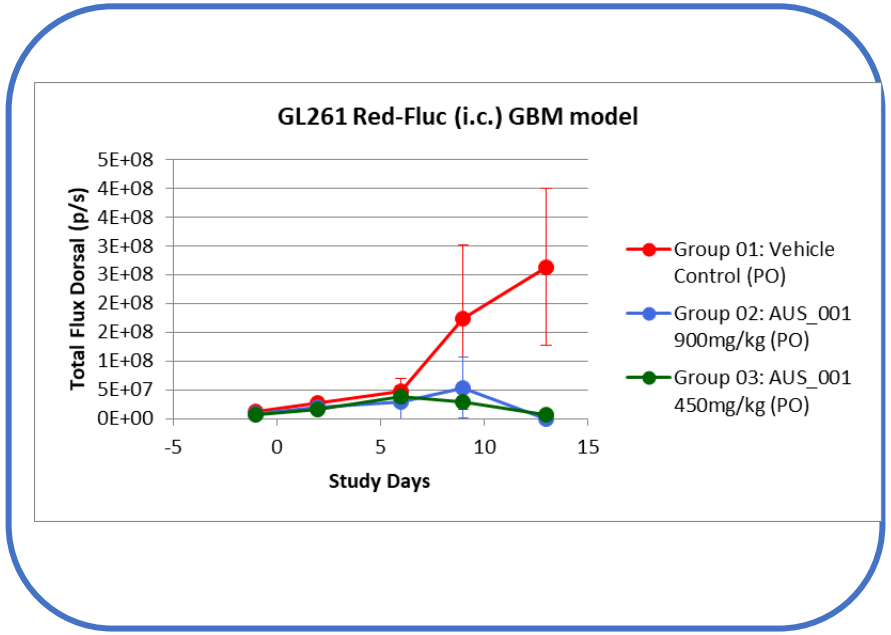
*as viewed in 273 of 280 Cancer Cell lines

Data Summary for AUS_001: Encouraging In Vivo Data

In Vivo Data

- Efficacy established in **7 different in vivo cancer models***
- Crossing of **blood-brain barrier****
- Pharmacokinetics/Pharmacodynamics: **Accumulation** in tumors, organs and brain tissues
- **Lack of myelosuppression** or other overt toxicities in immunocompetent mouse study (21 days, P.O.)
- **Non-emetic** response in ferrets





*: Figures to the right depict a few in vivo models; Additional data available upon request
**: Assessed using the 3D Human Blood Brain Barrier Model

Safety AUS_001 Demonstrated an Encouraging Safety Profile in Predictive Toxicology Screen

Study	Results
AMES Test	No mutagenic potential up to 100 µM doses of AUS_001
Cardiotoxicity	Low hERG-blocking liability with a half-maximal inhibitory concentration of 65 µM
Hepatotoxicity	**Poor inhibitor of CYP enzymes**, except for CYP1A
Vascular Toxicity	AUS_001 affects activated Human Umbilical Vein Endothelial Cells (HUVECs) at lower doses relative to those required for cytotoxicity induction of quiescent endothelial cells
P-glycoprotein (P-gp) model	P-gp overexpressing cellular models do not confer resistance to AUS_001
βIII-tubulin model	AUS_001 significantly retains its ability to sensitize βIII-tubulin overexpressing cells
Neurotoxicity	Drug treated midbrain and cortical neurons showed **reversible neurotoxic effect for AUS_001,** while Paclitaxel-treated neurons suffered sustained neurotoxicity after discontinuation of treatment

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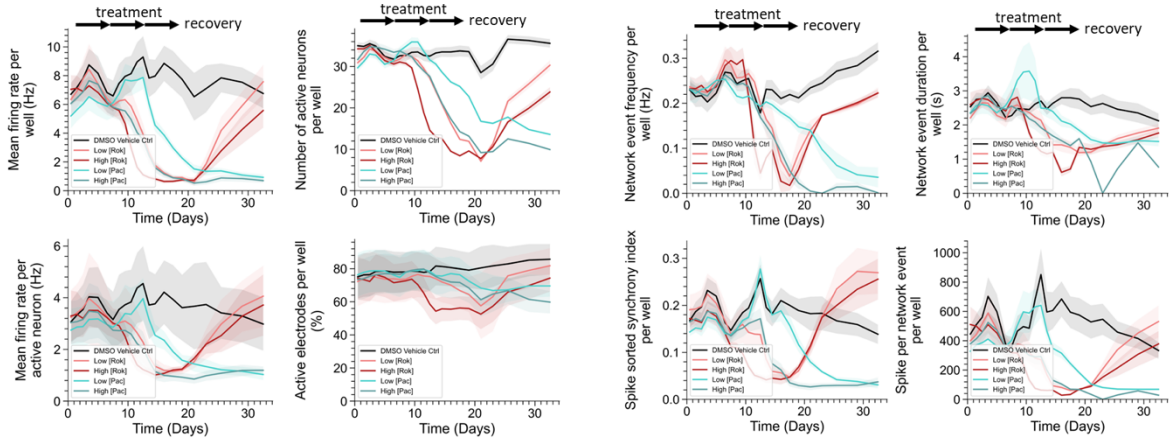
AUS_001 exerts reduced concern for neurotoxicity

Midbrain Neurons Exposed to Paclitaxel and AUS_001

Experiment started at Day 192 of Neuronal Maturation in plate NE245

7-8 wells per condition



Drug concentrations increased roughly every 5 days

Low AUS_001: 0.1uM → 2uM → 8uM

High AUS_001: 1uM → 4uM → 16uM

Low Pac: 0.1uM → 2uM → 8uM

High Pac: 1uM → 4uM → 16uM

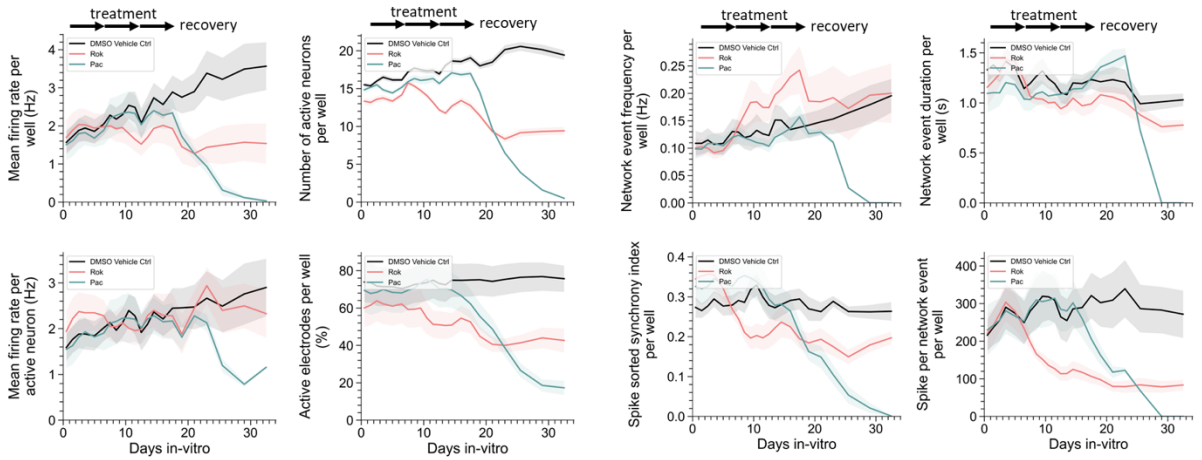
- ✓ *Drug treated midbrain and cortical neurons showed reversible neurotoxic effect for AUS_001 but paclitaxel-treated neurons suffered sustained neurotoxicity even after discontinuation of treatment*

Methods: The cells were maintained in 16 electrode per-well 48-well MEA plates and were fed by half-media change three times per week. Culture media and method for midbrain and cortical neurons is as defined previously in Milky et al 2022. Paclitaxel and AUS_001 treatment media was prepared fresh for every feed using individual frozen drug aliquots to avoid repeated freeze-thaw cycles. The DMSO vehicle control media was matched to the highest concentration of DMSO in the drug media (the High Paclitaxel condition). When drug treatment was initiated, the midbrain neurons had been maintained in culture for 192 days and the cortical for 137 days. Drug treatments increased in concentration roughly every 5-6 days depending on the feeding schedule. A full media change was performed to wash out the drugs to begin the recovery period. Recordings were taken daily during drug exposure, and at least twice a week during recovery, by a Maestro pro MEA system (Axion Biosystems). The MEA maintained a 37°C and 5% CO2 environment for the recordings. MEA Recordings were single-cell spike sorted using Plexon Offline Sorter version 4.5 (Plexon Inc) to isolate individual neurons from the electrodes and analyzed with Neural Metric Tool (Axion Biosystems).

Cortical Neurons Exposed to Paclitaxel and AUS_001

Experiment started at Day 137 of Neuronal Maturation in plate NE258

5-6 Wells per Condition



Drug concentrations increased roughly every 5 days

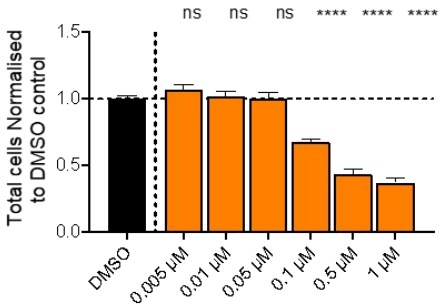
AUS_001: 0.1uM → 1uM → 2uM

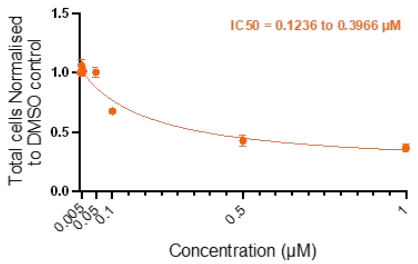
Pac: 1uM → 2uM → 4uM

Data collection and analysis were performed by Cedric Bardy's Lab at the South Australian Health and Medical Research Institute (SAHMRI)

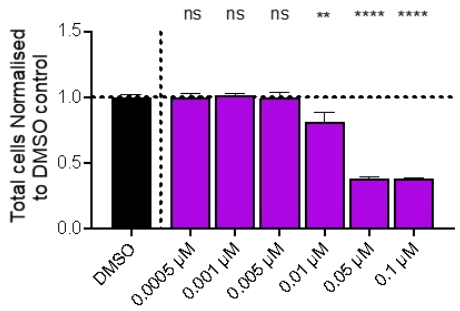
Human Neural Midbrain Progenitors Tolerate Higher Concentrations of AUS_001 Relative to Other Microtubule Targeting Agents

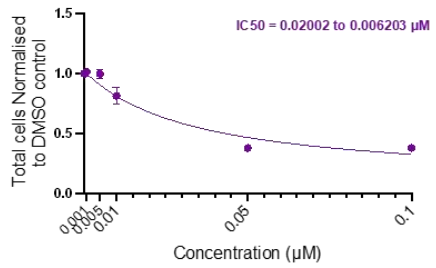
Aus001



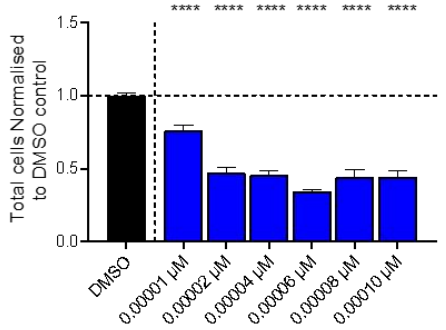


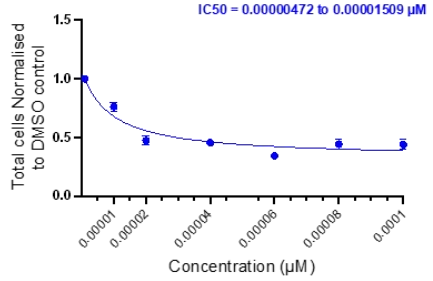
Avanbulin





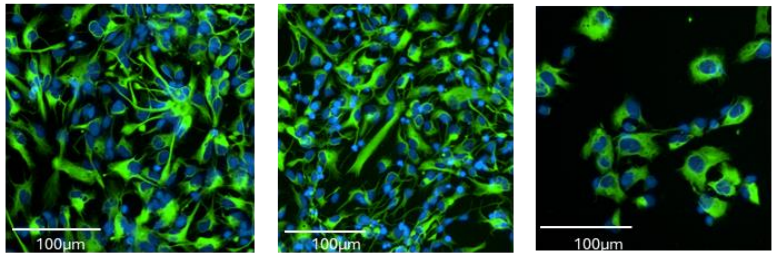
Vincristine



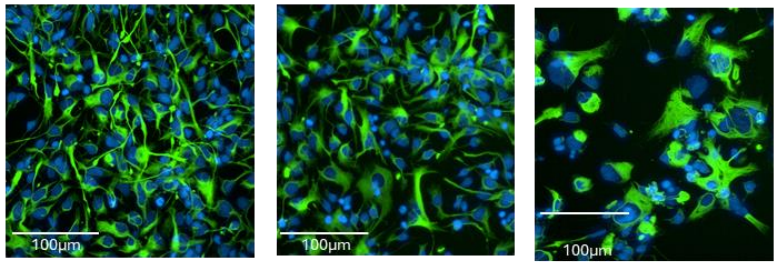


Nestin/DAPI

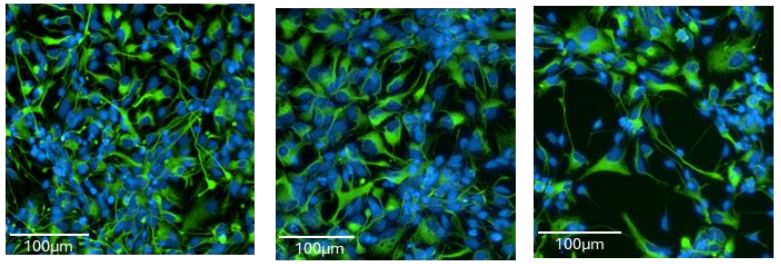
DMSO control | 0.1µM | 1µM



DMSO control | 0.01µM | 0.1µM

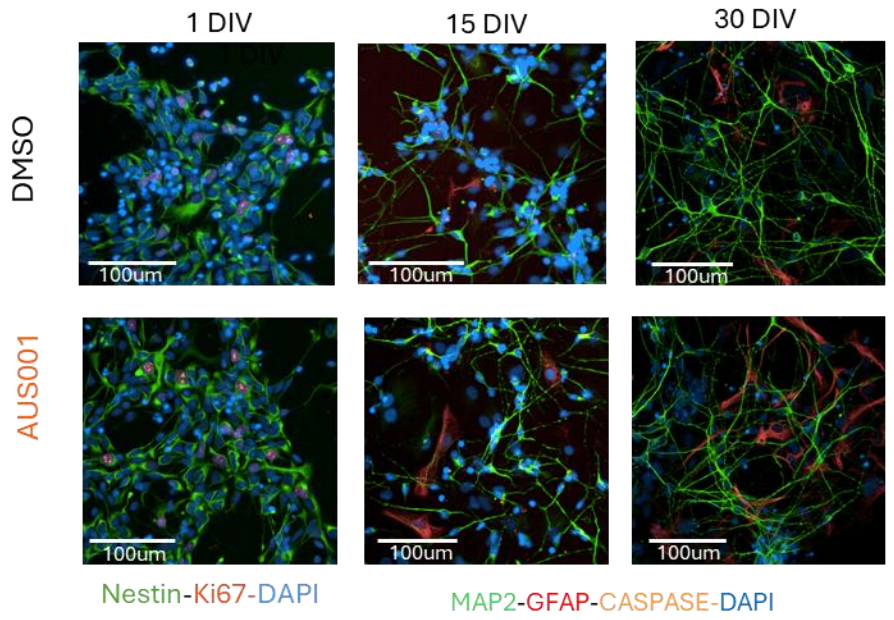


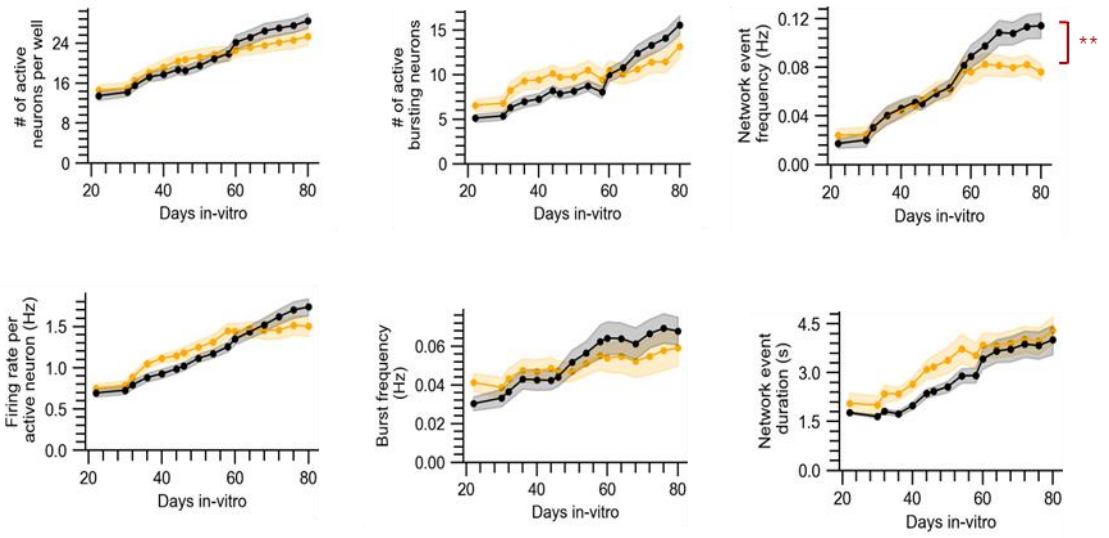
DMSO control | 0.00001µM | 0.00002µM

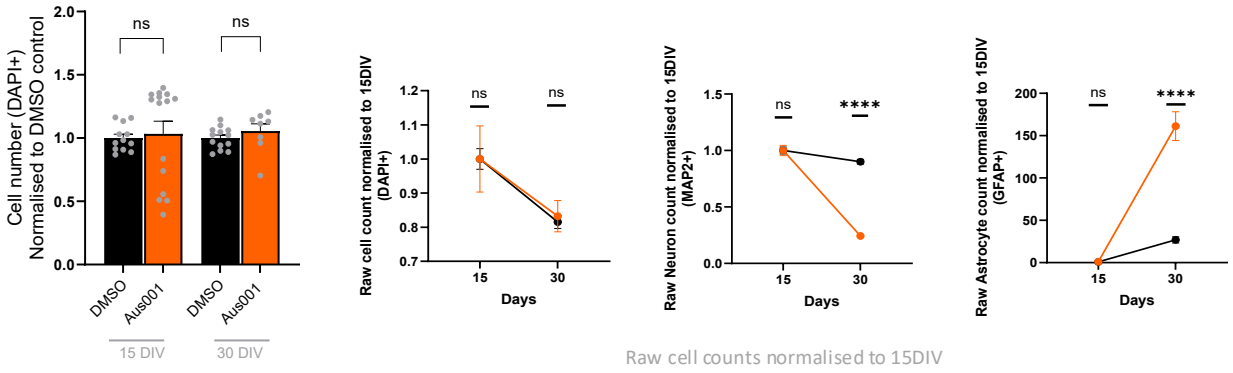


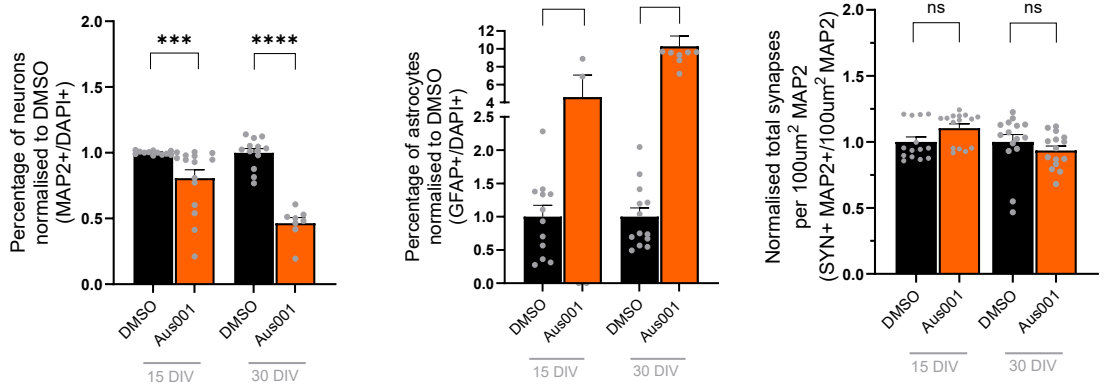
Data collection and analysis were performed by Cedric Bardy's Lab at the South Australian Health and Medical Research Institute (SAHMRI)

Recovery of AUS_001-treated Midbrain Neural Progenitor Cells Points to Maintenance of Functional Integrity - Potential Clinical Relevance for Patients with Pediatric Gliomas







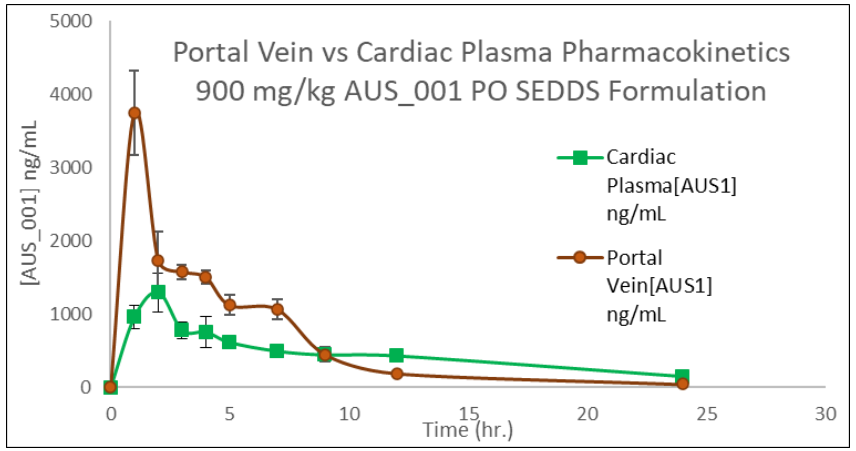


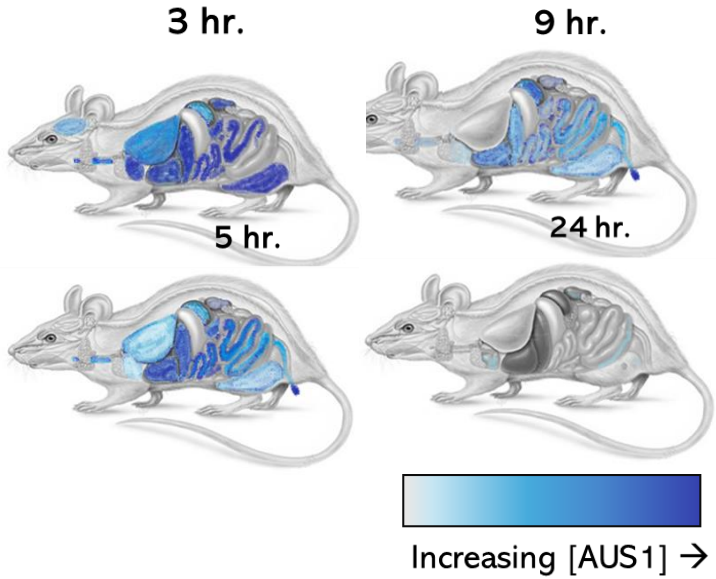
Data collection and analysis were performed by Cedric Bardy's Lab at the South Australian Health and Medical Research Institute (SAHMRI)

Characterized the PK/PD Profile for the Oral Administration of SEDDS-formulated AUS_001

PK/PD Data for the AUS_001 Self-Emulsyfing Drug Delivery System (SEDDS) Formulation Development and Efficacy

- Solubility up to 400 mg/mL
- Tmax: 3 hrs
- $T_{1/2}$ elimination: **8.29 hr**
- 72% escapes first pass-metabolism
- Bioavailability: 15-20%
- Excipients inhibit UGT enzymes





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AUS_001 Demonstrated an Encouraging Safety Profile in *In Vivo* Studies

- Upon single oral administration, there were **no deaths, and no overt toxicity** observed for the SEDDS formulated AUS_001 **at the 2,000 mg/kg dosage** in Balb/c mice

- Of note, the **vehicle does not exhibit any toxicity** on its own at **>10,000 mg/kg** (highest dose tested)

- A **repeat dose range-finding (DRF) study in mice** was conducted with a 14 daily repeat dosing of the SEDDS formulated AUS_001 at 100, 500, or 1,500 mg/kg. Generally, **oral doses up to 1,000 mg/kg were well-tolerated in mice**, with no myelotoxicity toxicity and no toxicity detected in all tissues analyzed except the cecum. Soft stools were noted 1-5 hours post dose.

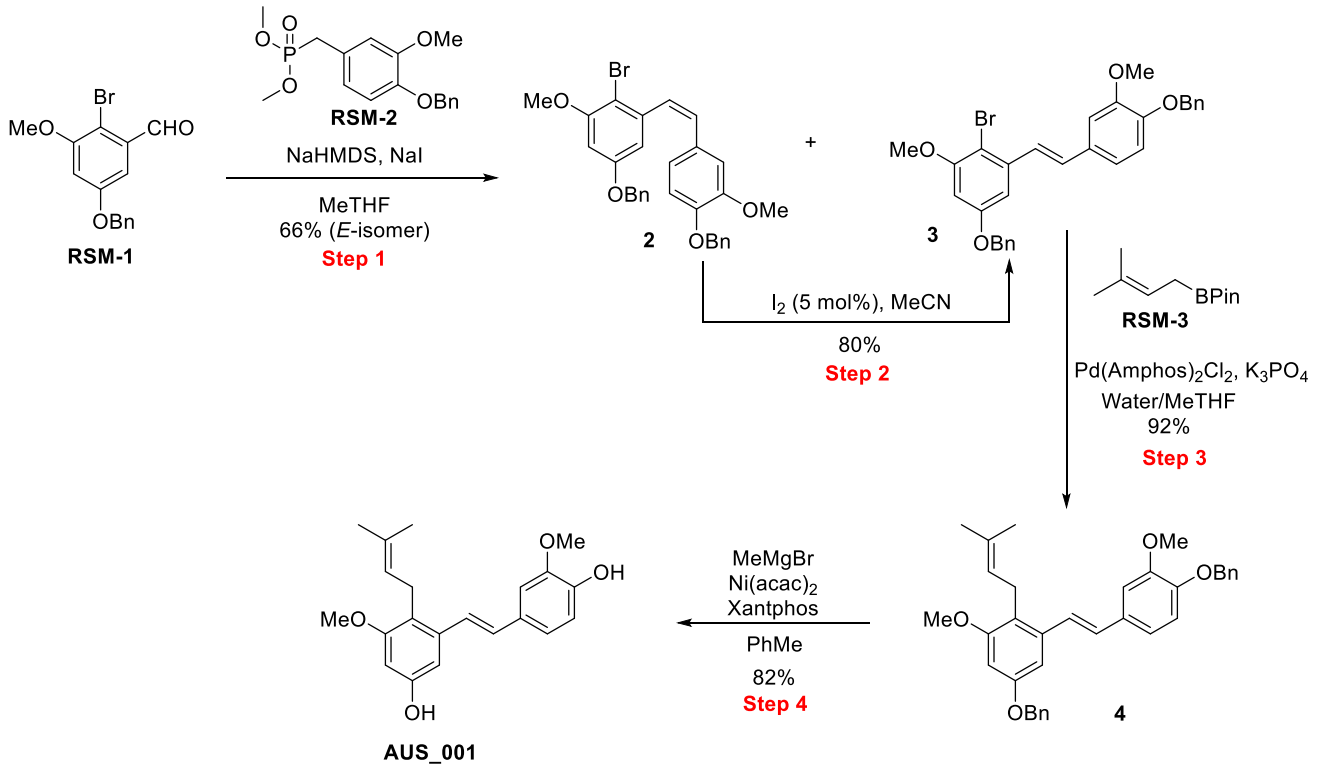
- The **non-GLP DRF 7-day toxicology study in rats and the 28-day GLP toxicology study** indicates that **oral doses up to 1,000 mg/kg/day were well tolerated.** At the highest dose tested (1,000mg/kg), gas in caecum and intestine, as well as soft stools were noted.

Chemistry and Manufacturing Established for AUS_001

Synthesis and Manufacturing

- 4 step scalable GMP manufacturing synthesis of drug substance established.

Synthesis Process



AUS_001 Data Accepted for Presentation at Multiple Peer Reviewed Meetings

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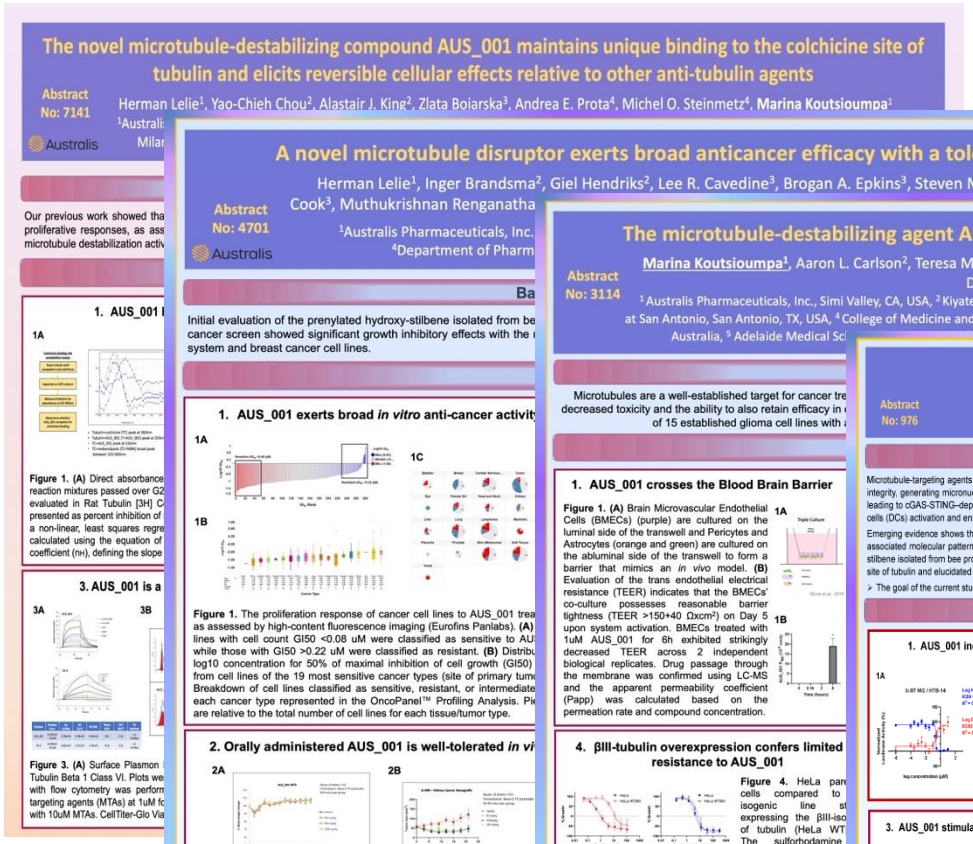
AACR 2024

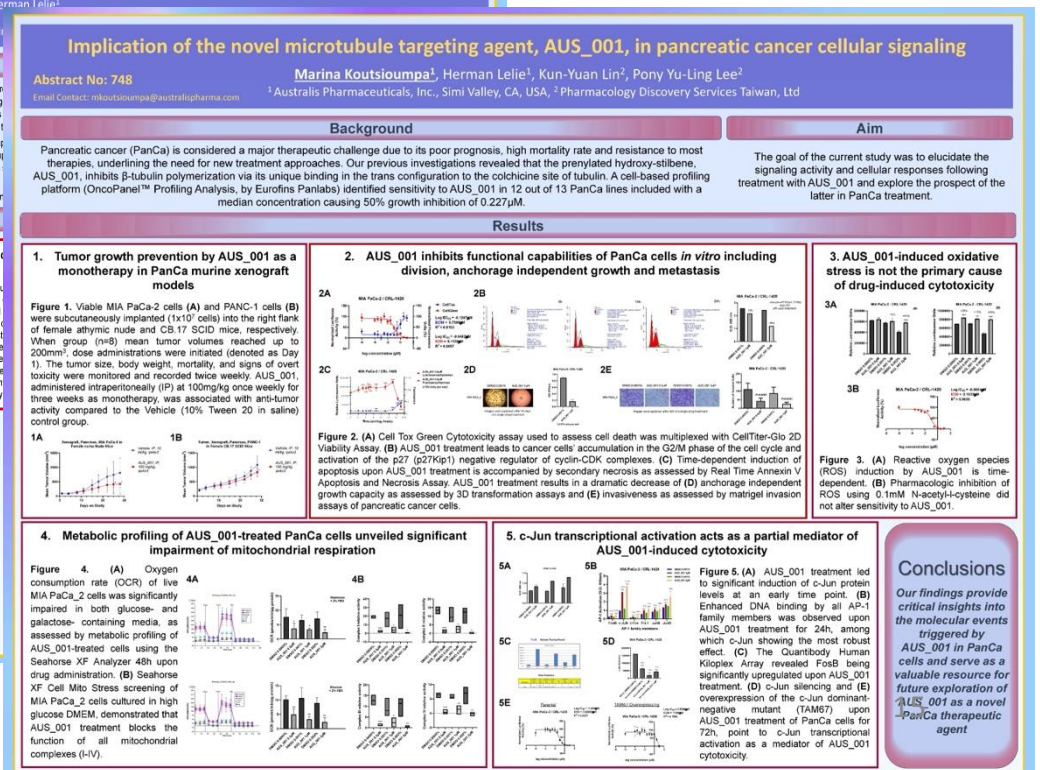


AACR 2024

ASCO 2024

SITC 2024

ASCO GI 2025



AACR: American Association for Cancer Research
ASCO: American Society of Clinical Oncology
SITC: Society for Immunotherapy of Cancer

Intellectual Property

Global Patents/Exclusivity	Expiry
2012: Use and synthesis of AUS_001 and one pipeline asset	2032
2020: Covers 4 pipeline assets, new synthesis route and 5000+ potential new chemical entities	2040
Orphan Drug and Rare Pediatric Designations	~ 7 year extension following approval

Australis Key Achievements To Date

2020 - 2024

- In vitro and in vivo data demonstrating efficacy and safety
- Mechanism of action characterized
- Pharmacokinetic, absorption, distribution, metabolism, and excretion data generated
- First abstracts and posters presented at medical meetings, including work with academic partners
- Toxicology testing – 14 day dose response

1Q2025

- Orphan Drug Designation received
- Rare Pediatric Disease Designation received

2Q2025

- Scalable GMP manufacturing
- GLP Toxicology initiated in rodent
- Continued to advance in vivo data in glioma and pediatric high grade glioma: partnerships with Mayo Clinic, Children's Hospital, and Newcastle (Australia)

3Q2025

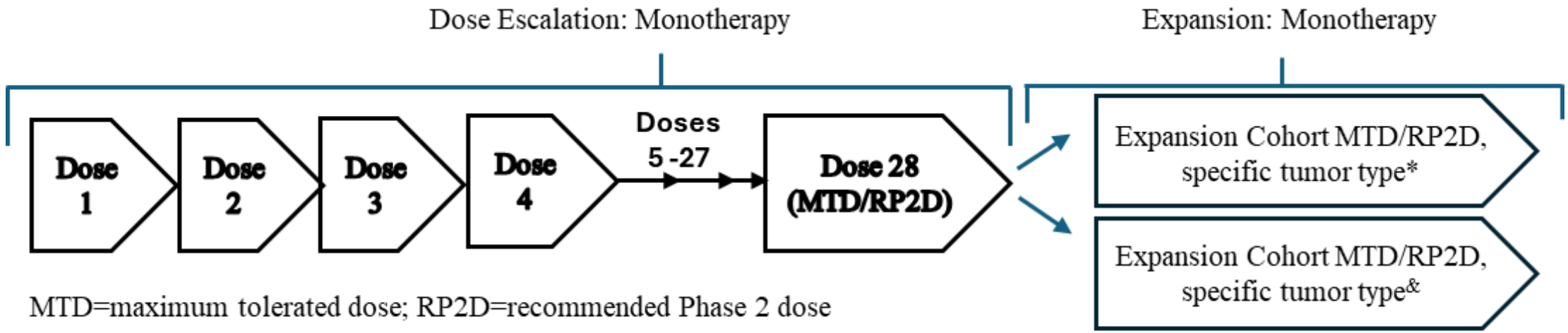
- Continued GLP Toxicology in rodent
- FDA Pre-IND meeting

4Q2025

- Finish GLP Toxicology in rodent and initiate GLP Toxicology in dogs
- Preparation for Australia first in human study dose escalation study – anticipated to start ~2Q26

AUS_001 Clinical Development Plan: What is Next – Phase 1

A Multi-Institutional Study of AUS_001, as Monotherapy in Patients With Solid Tumors



MTD=maximum tolerated dose; RP2D=recommended Phase 2 dose

*Adults with metastatic and/or locally advanced solid tumors
&Pediatrics aged 5-17 years with pediatric-type diffuse high-grade glioma

- **The Dose Escalation Phase will be a 3+3 design and is expected to enroll patients at approximately 2-4 sites in Australia**
- **The Expansion Phase would also be planned to include US sites**
- **Proposed clinical paths for glioma will focus on pediatric high grade glioma and adult glioma with an initial focus on relapsed patients, including Temozolomide resistant, then moving to first line**

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Strongly Positioned with Capital to Continue to Advance AUS_001

Successfully raised ~$30M over the last 10+ years

No debt on the balance sheet

Enough cash on hand to proceed through Phase 1

Currently seeking to enhance our capital with ~$15 Million raise in 2026 for clinical trials beyond Phase 1

Note: Cost estimates for Phase 1 based on initial proposals for first in human in Australia

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Australis Pharmaceuticals Executive Team

Team Member	Role	Expertise	Past Experiences
Michele Korfin, RPh, MBA	CEO	~30 years as a Biotech leader focused on clinical development, regulatory, and commercialization	Merck, Celgene, Kite, TYME, Gamida Cell
Caroline Carr, CPA	CFO	Finance leader in Biotechs and Pharma companies with expertise in investor relations	Mycovia, Dara, Pfizer, Deloitte
Marina Koutsioumpa, PhD	VP, Cancer Biology	PhD-trained cancer biologist specializing in molecular pharmacology and preclinical development (*in vitro* and *in vivo* models)	UCLA Center for Systems Biomedicine
Herman Lelie, PhD	VP, Research and Development	PhD with expertise in analytical chemistry and pre-clinical development	MIT, UCLA, Bruin Biometrics, Constitution Labs
John Heyburn, MBA	Clinical Operations	Expertise in hematology/oncology clinical trials	Morphotek, Advaxis, Tmunity, Gennao Bio
Todd Robinson	Founder	Entrepreneur with business and financial expertise. Owner of the land where AUS_001 was discovered	Building and leading organizations across many industries

Australis Pharmaceuticals – Summary

- AUS_001 has demonstrated **encouraging pre-clinical efficacy with a large safety margin**
- Completing IND enabling studies this year and will plan to be **ready for first in human studies in ~2Q 2026**
- **Experienced scientific team** who have partnered very effectively with academic institutions
- Leadership team with **expertise** in advancing oncology therapies through FDA approval and launch

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