

## ASX Announcement

### Race to Present at E&P Small Caps Healthcare Conference

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**26 September 2024** – Race Oncology Limited (“Race”) is pleased to share a copy of the presentation that will be given by Race’s Executive Chair, Dr Pete Smith, at the E&P Small Cap Healthcare Conference in Sydney today.

The presentation provides an overview of Race’s lead oncology drug RC220 bisantrene, an update on development progress, and the latest clinical plans.

A copy of the presentation is appended to this announcement.

-ENDS-

#### About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

Race’s lead asset, bisantrene, is a small molecule chemotherapeutic. Bisantrene has a rich and unique clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well-characterised safety profile, and compelling clinical data demonstrating an anticancer effect and less cardiotoxicity over certain anthracyclines, such as doxorubicin.

Race is advancing a reformulated bisantrene (RC220) to address the high unmet needs of patients across multiple oncology indications, with a clinical focus on anthracycline combinations, where we hope to deliver cardioprotection and enhanced anticancer activity in solid tumours. Race is also exploring RC220 as a low intensity treatment for acute myeloid leukaemia.

Race is investigating the effect of bisantrene on the m<sup>6</sup>A RNA pathway, following independent research published by the City of Hope identifying bisantrene as a potent inhibitor of FTO (Fat mass and obesity-associated protein). Dysregulation of the m<sup>6</sup>A RNA pathway has been described in numerous peer reviewed studies to be a driver of a diverse range of cancers.

Race Oncology has collaborated with Astex, City of Hope, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong and University of Newcastle, and is actively exploring partnerships, licence agreements or a commercial merger and acquisition to accelerate access to bisantrene for patients with cancer across the world.

Learn more at [www.raceoncology.com](http://www.raceoncology.com).

If you have any questions on this announcement or any past Race Oncology announcements, please go to the Interactive Announcements page in our Investor Hub <https://announcements.raceoncology.com>



*Race encourages all investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, at [www.automicgroup.com.au](http://www.automicgroup.com.au).*

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# AT THE HEART OF CANCER CARE

Pete Smith PhD, Executive Chair

E & P Small Cap  
Healthcare Conference

# Important Notice and Disclaimer

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# Corporate snapshot

Race Oncology is an ASX-listed, clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

## Key Data

ASX code	RAC
Share price	\$1.74 <sup>1</sup>
Market capitalisation	\$296.5m <sup>1</sup>
Cash at bank	\$17.2m <sup>2</sup>
Debt	Nil
Enterprise value	\$279.3m <sup>1</sup>
Shares on issue	170,423,606 <sup>1</sup>
Options on issue	35,176,756 <sup>1</sup>

1. As at 23 September 2024

2. As at 30 June 2024

## Race 12-month trading history



## Current Options

On 22 November 2023, Race issued a 1 for 20 bonus and piggyback option series to existing shareholders. The conversion of bonus options (\$0.75) raised \$5m and the 19.9m piggyback options (\$1.25) could raise an additional \$25m before expiry 29 May 2026

# Race Oncology Board



**Dr Daniel Tillett, PhD**  
Managing Director / CEO

- Former CSO and Executive Director of Race Oncology (2019-2023)
- Responsible for development of RC220 & cardioprotection discoveries
- >25 years of biotech management experience (Nucleics)
- Largest Race Oncology shareholder (>10%)



**Dr Peter Smith, PhD**  
Executive Chair

- >30 years' experience in healthcare with focus on therapeutics / oncology
- Non-Executive Director at MycRx, and Founder and CEO of Amala.
- Former top-rated pharma analyst with UBS and HSBC



**Dr Serge Scrofani, PhD MBA**  
Non-Executive Director

- >28 years' experience in healthcare including research, strategy, licensing, M&A
- Principal at Poplar Advisory Pty Ltd, Executive Director at FinCap Pty Ltd, Non-Executive Director at Burnet Institute & The Centre for Eye Research Australia
- Former Vice President of Strategy & Corporate Development at CSL.



# Race Oncology Management Team



**Dr Daniel Tillett, PhD**  
Managing Director / CEO

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- Responsible for development of RC220 & cardioprotection discoveries
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**Dr Michelle Rashford, MBBS**  
Chief Medical Officer

- Former physician, with >25 years expertise in the successful development and commercialization of pharmaceuticals across oncology, virology, and immunology
- Former Head of Global Clinical Sciences with Kyowa Kirin, 5 years BMS and 20 years with Roche



**Dr Sophia Moscovis, PhD**  
Vice President  
of Operations & Strategy

- >20 years experience in healthcare with 10+ years in the pharmaceutical industry
- Scientist with a PhD in Immunogenetics
- >10 years with Novartis across a range of areas including cardiology and business transformation



**Prof Michael Kelso, PhD**  
Vice President of Research

- Internationally experienced researcher, with >25 years R&D experience across a wide range of areas in medicinal chemistry, incl. oncology, antimicrobial drug development and drug formulation
- 69 scientific research papers, 7 patents and 18 grants achieved



**Dr Marinella Messina, PhD**  
Vice President  
of Clinical Development

- Highly experienced oncology clinical trials specialist, having managed a wide range of clinical trials over >10 years, across all development phases (I, II, III and IV)
- Former Noxopharm Clinical Operations Manager and Clinical Program Manager



# Cancer survivorship



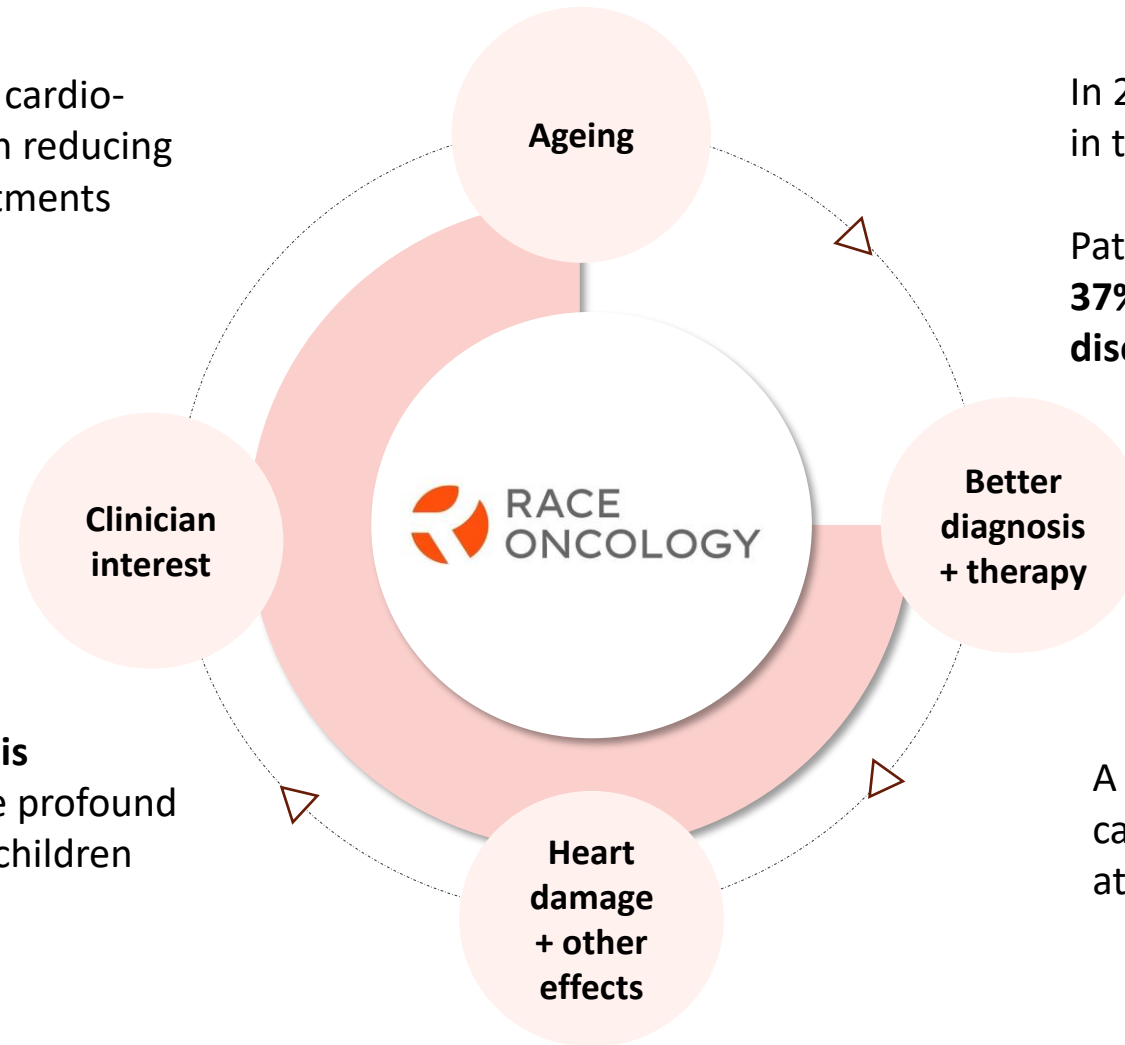


# Cancer survivorship – life after treatment

New specialties such as cardio-oncology are focused on reducing damage caused by treatments

In 2022, there were 18m cancer survivors in the US, growing to 22.5m by 2032 <sup>1</sup>

Patients receiving chemotherapy have a **37% increased risk of cardiovascular disease** <sup>2</sup>



**Cardiovascular toxicity is permanent** <sup>4</sup> and can be profound for certain groups, e.g. children

A single dose of chemotherapy can cause cardiotoxicity <sup>3</sup> and muscle atrophy <sup>4</sup>

1. [www.cancer.gov](http://www.cancer.gov)  
2. Florido R, *et al.* J Am Coll Cardiol, 2022

3. Dillon HJ, *et al.* J Am Coll Cardiol, 2024  
4. Mallard J, *et al.* J Cachexia Sarcopenia Muscle, 2024

# Chemotherapy needs improvement



**Anthracyclines\*** are the most widely used class of chemotherapeutics. They are highly effective, but can **cause permanent damage** to the cardiovascular system



**Current solution** – **exclude use** in high-risk patients and **limit dosing** of the drugs



**Issue** – patients not given full effective dose, and heart damage with serious long-term health consequences remains



**Opportunity** – if the cardiovascular toxicity could be reduced, **more patients could be treated and more effective regimens delivered**



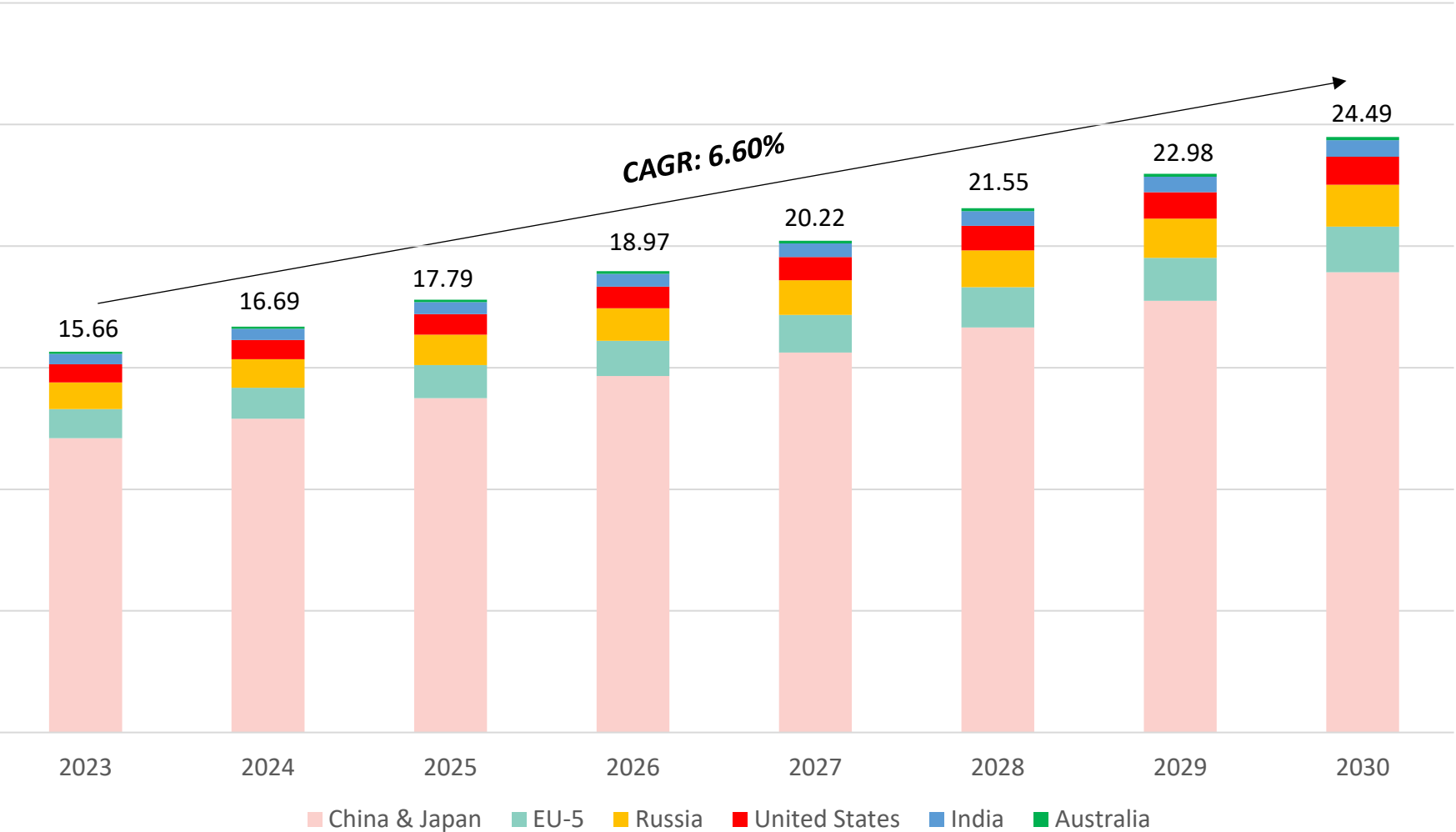
***“Cardiotoxicity, which includes heart failure, is one of the main side effects limiting the use of these effective therapies.”***

Professor Aaron Sverdlov, University of Newcastle

\* Approved anthracyclines include doxorubicin, daunorubicin, epirubicin, idarubicin and valrubicin

# Anthracycline use is growing<sup>1, 2, 3</sup>

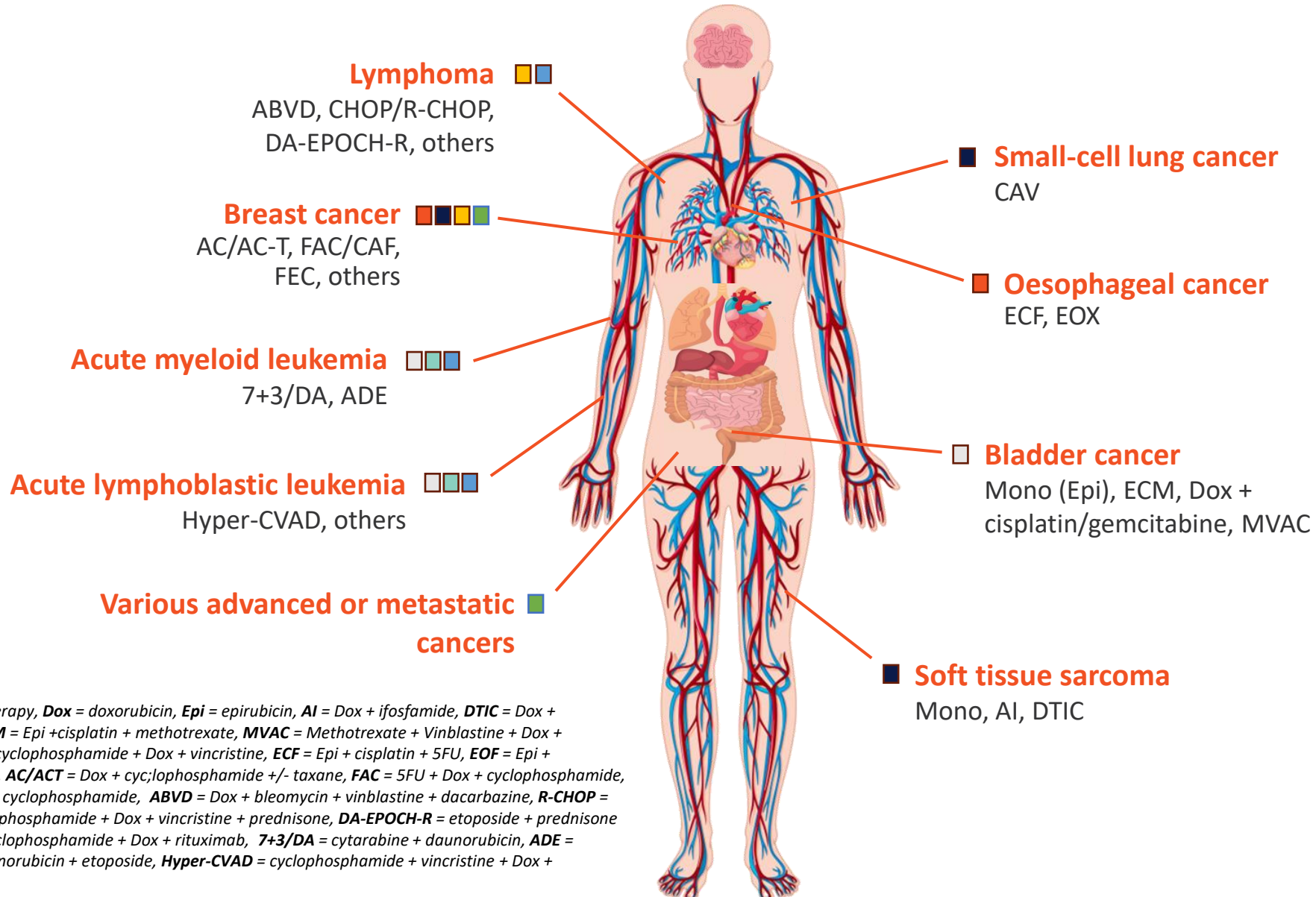
Estimated number of anthracycline doses used per year<sup>1</sup>



- According to [Data Bridge Market Research](#), global anthracycline usage is expected to increase by a CAGR of 6.60% between 2023 and 2030

1. IQVIA MIDAS AUDITED US VOLUME Anthracycline Data, Triangle Insights (ASX Announcement, slide 16: 14 April 2023)  
2. Daunorubicin, doxorubicin, liposomal doxorubicin (Doxil), epirubicin, idarubicin, mitoxantrone, and valrubicin  
3. Triangle Insights (ASX Announcement: 14 April 2023)

# Anthracyclines continue to be widely used



# Clinical development of bisantrene





# Bisantrene's history of clinical success

## Breast cancer <sup>1</sup>

471 patients across 9 Phase 2 & 3 clinical trials

Less toxic than standard-of-care doxorubicin

- reduced myelosuppression
- reduced alopecia (hair loss)
- no cardiac failures

**Phase 3.** Overall patient survival greater in bisantrene treated patients (HR 0.92 95%CI = 0.7-1.21)

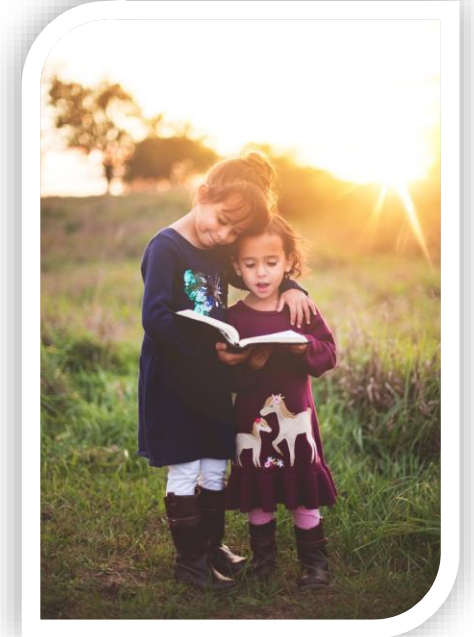
1. Cowan, J. D. et al. . Natl. Cancer Inst. 83, 1077–1084 (1991)

## Acute Myeloid Leukaemia

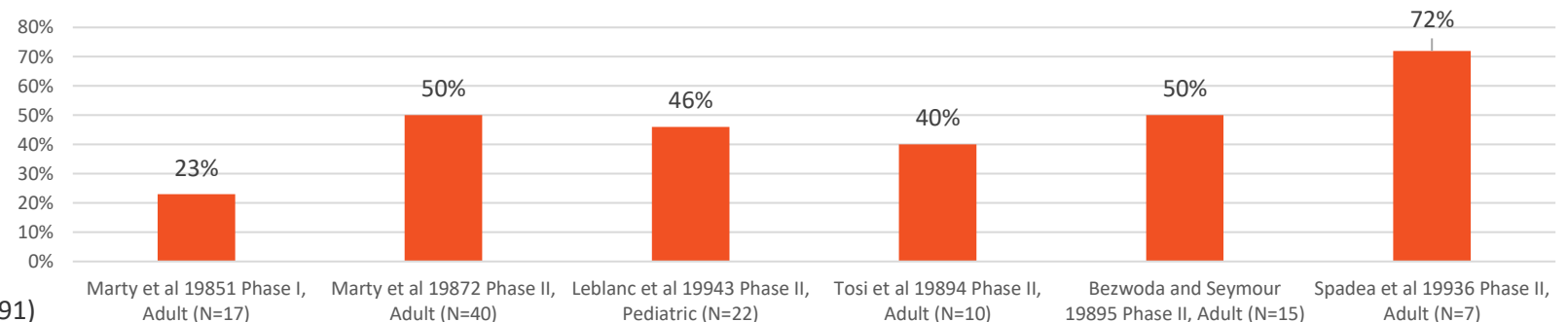
Approved in France in 1988, but Lederle (Pfizer) ended commercial development of bisantrene due to solubility issues

Complete response rates above 40% as a salvage agent for Acute Myeloid Leukaemia (AML)

Bisantrene cured two French girls with r/rAML in the 1980 & 90s. Both women are alive today and have their own families



Complete responses with bisantrene in paediatric and adult Acute Myeloid Leukaemia patients



# Building on bisantrene's history

## Race has...

- Created RC220, a **new formulation** of bisantrene which is more soluble and can be delivered intravenously <sup>1</sup>
- RC220 **preserves the PK/PD** properties of the earlier clinically validated formulations of bisantrene
- Created **new intellectual property** with a long lifespan (20 years)
- Leveraged new science to understand bisantrene's **anti-cancer** and **cardioprotective** mechanism of action <sup>2</sup>
- Built on the >1,500 patients' worth of clinical data across a broad range of cancer indications, and generated **new Phase 2 clinical data in AML**
- RC220 is a new drug product, requiring a full non-clinical toxicology & safety data package – **delivered in June 2024** <sup>3</sup>



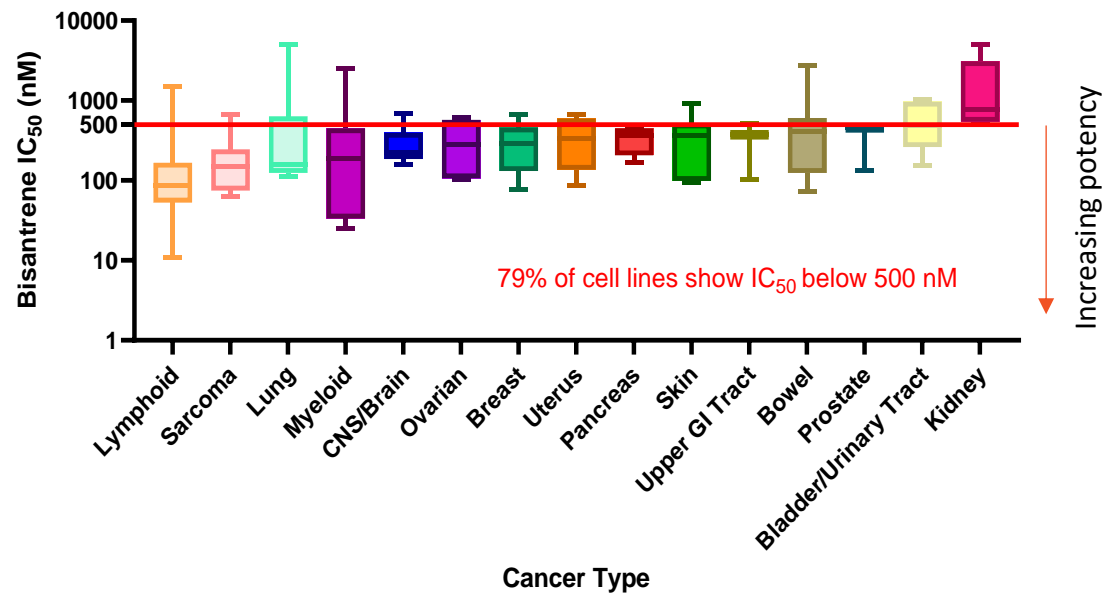
**RC220 is a clinically and commercially attractive formulation with long IP life**

# RC220 overcomes significant challenges

	Bisantrene/RC110	RC220	Comment
Clinical efficacy established	✓	✓	Data from 1,500 patients in 50 trials, Approved in France
Clinical safety established	✓	✓	Data from 1,500 patients in 50 trials, Approved in France
Able to treat haematological cancers	✓	✓	Must be delivered by central line
Ease of delivery		✓	Can be delivered by central line or intravenously
Able to treat solid cancers		✓	Intravenous delivery needed to treat solid tumours
Large addressable patient population		✓	Solid cancer market presents much larger opportunity
IP protection		✓	New formulation = new IP

# Bisantrene + doxorubicin = improved anti-cancer activity <sup>1</sup>

Bisantrene shows potent cell-killing activity against a diverse range of human cancers when used alone and in combination with doxorubicin, the most commonly used anthracycline



**Bisantrene shows broad anti-cancer activity.** The half-maximal inhibitory concentration (IC<sub>50</sub>) was determined for bisantrene against 143 cancer cell lines derived from diverse human tumour types. Boxes show the 25%-75% range, with the line within each box representing the median IC<sub>50</sub> value. The upper and lower edges of the box represent the 75th and 25th percentiles, respectively. Whiskers show the minimum and maximum IC<sub>50</sub> values observed for each cancer cell type.

Bisantrene improves doxorubicin anti-cancer activity in

85% of all cancers<sup>2</sup>

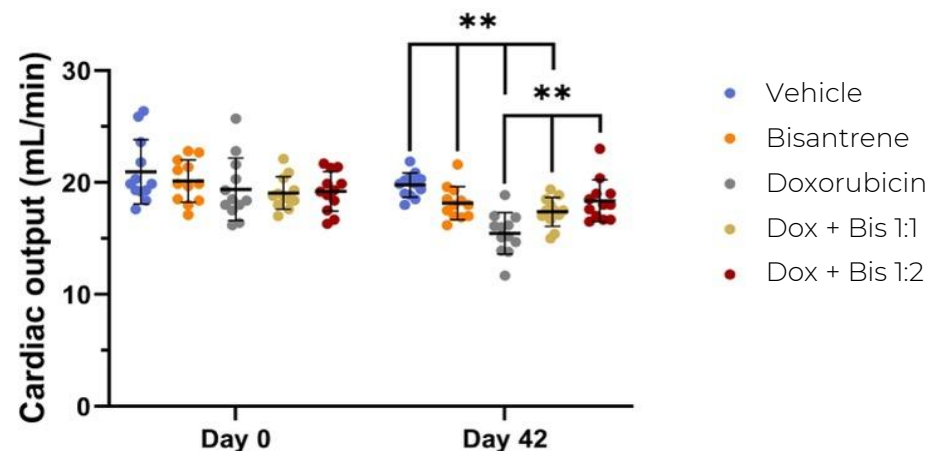
# Bisantrene + doxorubicin = protecting the heart <sup>1</sup>

Bisantrene protects the hearts of mice from permanent damage caused by the anthracycline, doxorubicin

Heart protection was achieved using higher levels of chemotherapy treatment with no extra toxicity observed

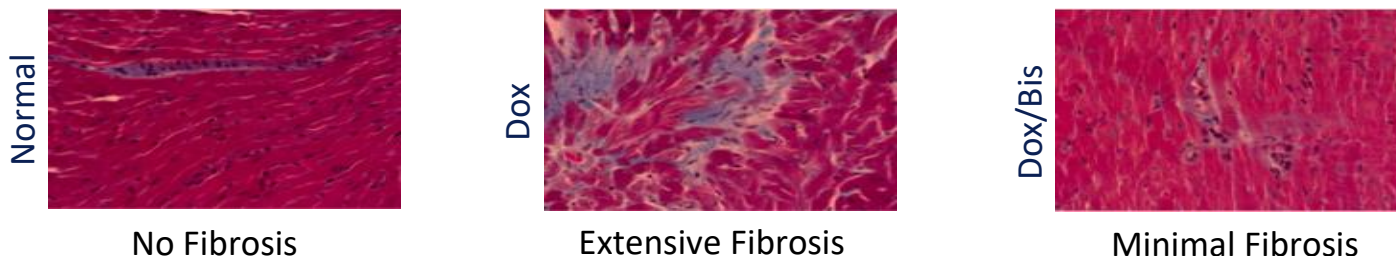
Data supports using bisantrene with anthracyclines to protect the hearts of patients from chemotherapy

Promise of better cancer treatment with reduced side effects



Cardiac output of C57BL/6 mice treated with either vehicle control (blue), bisantrene alone (orange), doxorubicin alone (grey), 1:1 molar ratio doxorubicin + bisantrene (yellow), or 1:2 molar ratio doxorubicin + bisantrene (red) at Day 0 and Day 42. All mice were dosed intravenously weekly with either: vehicle control, 7.33 mg/kg bisantrene, 5 mg/kg of doxorubicin, 5 mg/kg of doxorubicin + 3.67 mg/kg of bisantrene, 5 mg/kg of doxorubicin + 7.33 mg/kg of bisantrene. n=12 per group. Error bars = SEM. \*\*p < 0.01.

## Strong protection from anthracycline-induced cardiomyopathy



*In vitro studies in human primary cardiomyocytes and in vivo studies in mice have demonstrated cardioprotection for the bisantrene + doxorubicin combinations, including increased cardiac function and reduced fibrosis when compared to doxorubicin alone*



# Clinical pipeline

Asset	Indication	Sponsor	Discovery	IND enabling	Phase 1	Phase 2	Phase 3	Next milestone
RC110	Acute Myeloid Leukaemia	Chaim Sheba Medical Centre, Israel	Phase 2					Successfully concluded in July 2024 <sup>1</sup>
RC220	Cardioprotection + m6A RNA + anti-cancer efficacy - solid tumours	Race Oncology <sup>2</sup>	Phase 1a/b		H2 CY24	2026		Ethics / governance approvals First patient dosed
RC220	Acute Myeloid Leukaemia	Investigator sponsored <sup>2</sup>	Phase 1/2		H2 CY24			Confirmation of trial
m <sup>6</sup> A RNA molecule development	Next generation bisantrene	Race Oncology	Preclinical					Preliminary results

1. <https://announcements.raceoncology.com/announcements/6454612> | 2. <https://announcements.raceoncology.com/announcements/6429352>

# RC220 cardioprotection clinical program

**An 'all comers' Bayesian dose escalation Phase 1a trial of RC220 in any solid tumour patient where anthracycline use is indicated**

**Size:** 25-50 patients; up to 10 sites in Australia and internationally

**Sponsor:** Race Oncology

**Primary endpoints:** Safety & optimal Phase 2 dose

**Exploratory endpoints:** Standard & advanced cardiac markers including VO<sub>2</sub>Peak, m<sup>6</sup>A RNA levels, & anticancer efficacy

**Start:** First patient H2 CY2024 (subject to RC220 availability)

**Timeline:** 12–18 months due to Bayesian design uncertainty around total patient number (patient recruitment)

Expands market potential of bisantrene beyond breast cancer to all cancers where anthracyclines are used

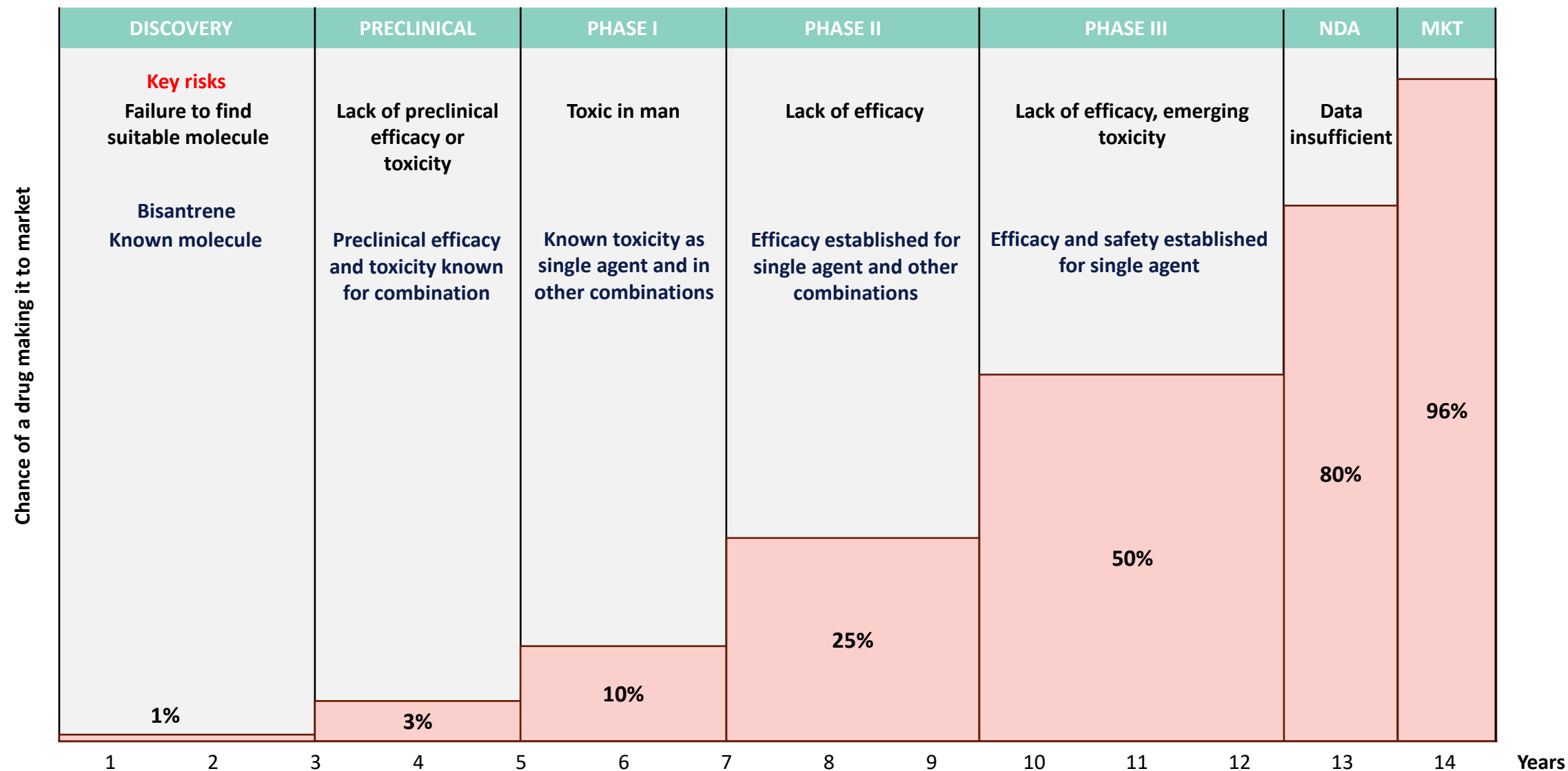
Effect of bisantrene on the m<sup>6</sup>A RNA system will be collected by using a lead-in dose of bisantrene given 7 days prior to the first anthracycline combination dose – provides 'clean' PK/PD, m<sup>6</sup>A RNA & single-agent anticancer efficacy data

**Cost: A\$11 million, fully funded (based on 50 patients)**



*VO<sub>2</sub>Peak offers a clinically relevant endpoint that can provide clear evidence of cardioprotection and improvement in patient Quality of Life*

# Typical risks in drug development (illustrative)



# Bisantrene market potential – world

Annual revenue generic  
doxorubicin - 2023<sup>1</sup>



USD\$100 base price/cycle for 4 cycles

Annual revenue bisantrene  
cardioprotection + anti-cancer<sup>2</sup>



USD\$15,000 base price/cycle for 4 cycles with a 3% yearly  
net price increase after launch

Note: Forecasted revenue  
reflect a 50% reduction to the  
physician-stated adoption rate

1. <https://www.theinsightpartners.com/reports/doxorubicin-market>  
2. Triangle Insights (ASX Announcement: 14 April 2023)

# Recent & upcoming milestones<sup>1</sup>

H2 CY2023 / H1 CY2024	H2 CY2024	H1 CY2025
✓ Interim results released from Sheba 2 study of bisantrene RC110 in AML patients – 40% response rate	✓ Distinguished Oncologist Daniel Von Hoff Joins as Consultant	🎯 Additional preclinical results on bisantrene mechanism of action
✓ Proposal received for investigator led study of RC220 in AML patients	🎯 Ethics submission for Phase 1a/1b trial in solid tumours	🎯 File Investigational New Drug (IND) application with US Food and Drug Administration for RC220
✓ cGMP RC220 manufacturing campaign completes	🎯 Governance approval for Phase 1a/1b trial in solid tumours	🎯 First patient treated in Phase 1/2 AML study
✓ Leading cardiorespiratory expert, A/Prof Erin Bowden joins SAB	🎯 First patient treated in the RC220 solid tumour (all comers) Phase 1a/b Trial	🎯 Initial results from RC220 Phase 1 solid tumour trial
✓ cGMP RC220 released by Ardena for use in human clinical trials	🎯 Updates on new molecules to target the m <sup>6</sup> A RNA pathway	
✓ Bisantrene shows potent anti-cancer activity in AML models	🎯 Publication of results from Sheba Phase 2 clinical study in AML	
✓ Completion of RC220 non-clinical safety and toxicology studies	🎯 Updates on clinical trial progress for RC220 cardioprotection study	
✓ Appoints George Clinical as CRO	🎯 Commence Phase 1/2 AML study	

1. All dates are estimates and subject to change



# Questions


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Race Oncology

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