RACE ONCOLOGY

ASX Announcement

Race Strategic Update August 2023

- New corporate strategy launched, detailing Race's optimised clinical program and key areas of discovery, placing Race at the heart of cancer care
- Lead clinical focus on investigating anti-cancer, plus cardio-protective and FTO properties in metastatic breast cancer, using the peripherally administered bisantrene formulation, RC220 with a view to improving therapeutic outcomes and heart health for patients with cancer
- Secondary focus on pursuing increased anti-cancer / FTO benefits of bisantrene combined with current standard of care therapies in acute myeloid leukaemia (AML)
- Targeted R&D program designed to maximise bisantrene's partnering potential
- Video update, presentation and shareholder information sessions available to provide additional background and offer Q+A opportunities
- Investors are also invited to visit the Interactive Announcements page in Race's Investor Hub to submit questions https://announcements.raceoncology.com

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8 August 2023 – Race Oncology Limited ("Race") is pleased to provide shareholders with a strategic update, including an overview of revisions to corporate strategy, designed to optimise use of existing resources, while driving bisantrene's commercial partnering and collaboration potential.

Non-Executive Chair, Mary Harney commented: *"Through the course of conducting this review of strategy, Race drew upon a rich set of insights. We further reviewed our deep historic clinical dataset, as well as many preclinical studies across a range of indications. We investigated the many market opportunities for bisantrene and engaged with key opinion leaders to inform our view of unmet patient need. Finally, and of critical importance, we reviewed the paths to market which would position our lead asset most strongly with potential partners.*

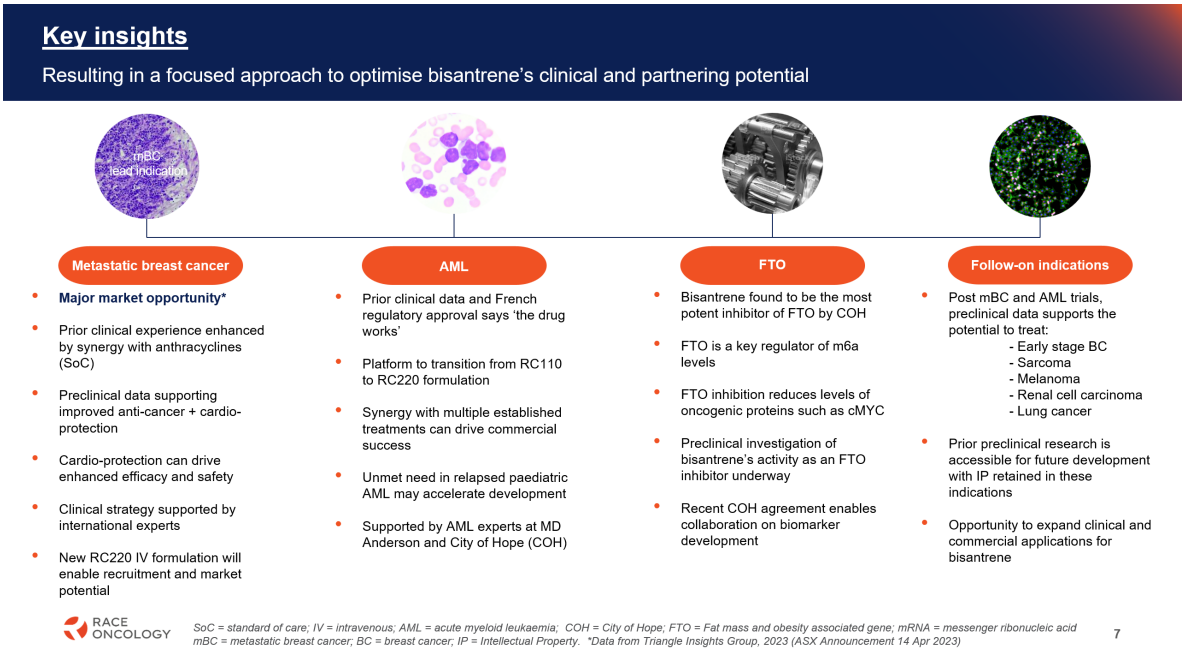
This strategic update delivers committed and planned programs, designed to optimally leverage bisantrene RC220's potential in the areas of anti-cancer, cardio-protection and FTO[1] inhibition. This has been a significant body of work - I thank the Race team for their dedication in driving toward the best outcome and am also grateful for the ongoing interest and support of our shareholders."

Race CEO and Managing Director, Damian Clarke-Bruce commented: *"Race's revised development program has been designed in such a way that our new bisantrene formulation can fit straight into a global pharmaceutical partner's pipeline. Through our rigorous clinical development plan, Race will investigate bisantrene RC220 in both metastatic breast cancer and continue our clinical experience in AML, while investigating and expanding our knowledge of its mechanism of action. We have a clear regulatory pathway and a program that is supported by international key opinion leaders, for a drug candidate which has already been shown to improve patients' lives.*

[1] Fat mass and obesity associated protein

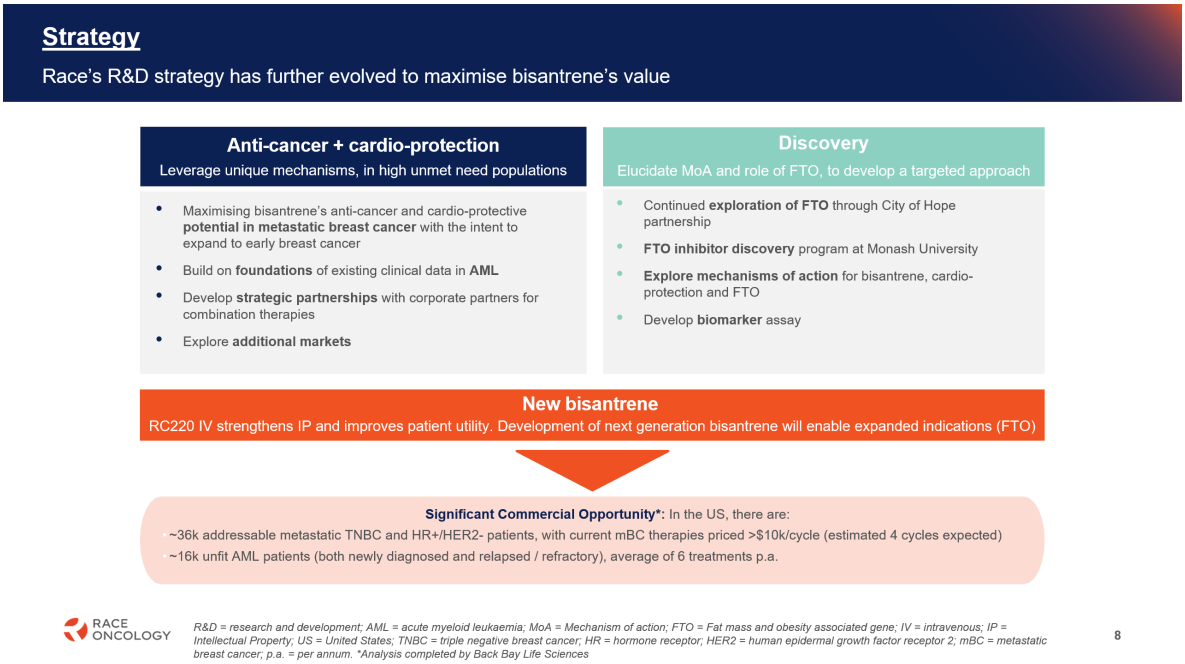
We look forward to presenting the strategy to existing and potential new shareholders over the coming weeks as we seek to advance our position as a commercial partner with a life-changing therapeutic asset in bisantrene RC220."

Several key recent insights have driven the strategic revisions as summarised in the following slide extracted from Race's investor presentation, appended with this announcement:



Evolving the corporate strategy

Race's new strategy has been designed to maximise the inherent value of bisantrene:



Anti-cancer + cardio-protection

Race's core focus is to impact cancer outcomes and address the challenges of chemotherapeutic cardiotoxicity. Studies will leverage the unique mechanisms of bisantrene in mBC and AML, both cancer patient populations with a high unmet need, paving the way to a host of future indications.

Metastatic breast cancer (mBC)

Breast cancer has the highest use of a class of drugs called anthracyclines. While highly effective anti-cancer drugs, anthracyclines may cause serious and permanent damage to the heart in many patients, limiting the total dose that can be administered. Several studies have estimated that over half of the patients exposed to anthracyclines will develop some form of heart disease within six years of treatment[2] despite those limits. The mBC patient population would strongly benefit from a therapeutic approach that could provide both anti-cancer and cardio-protection by allowing more doses to be delivered with an improved safety profile.

mBC has been identified as the lead indication for bisantrene as it provides Race with the opportunity to address this clear high unmet patient need and, with around 36,000 mBC patients in the US per annum, it represents a large commercial opportunity.

Historical anti-cancer data exists for bisantrene as a monotherapy across 471 advanced/mBC patients in Phase 2/3 studies. Race has also demonstrated preclinically, that bisantrene can protect the heart from anthracycline-induced cardiomyopathy *in vitro* and *in vivo*.

Race plans to take bisantrene RC220 into a Phase 1/2 clinical trial in combination with the anthracycline doxorubicin, the most widely used chemotherapy agent in mBC. This trial will establish the dosing regime for bisantrene RC220 in combination with doxorubicin, and evaluate bisantrene RC220's performance as both an anti-cancer and cardio-protective agent. Exploratory endpoints have also been built into the trial to evaluate FTO expression, assessment of biomarkers, and downstream pathways.

This trial will be initiated once GMP RC220 is available, and after the completion of toxicology studies, ethics submission, and regulatory approvals. The expected timeframe for trial commencement is Q3 CY 2024.

Acute myeloid leukaemia (AML)

The AML program remains a key part of Race's strategy as there remains a need for a new therapeutic which improves on current cancer treatment options, while limiting toxicity for the ~16,000 AML patients in the US each year who are considered unfit for other treatments.

Bisantrene monotherapy has demonstrated efficacy and a well characterised safety profile in AML. Across 146 patients in 10 relapsed or refractory (r/r) AML studies, bisantrene has historically demonstrated an average complete response rate of 46%. Race has promising preclinical data to support anti-cancer efficacy in AML with bisantrene in combination with standard of care. Having been approved in France for AML in the 1980s, these additional insights provide confidence in Race's AML clinical program.

[2] Swain SM, Whaley FS, Ewer MS. Congestive heart failure in patients treated with doxorubicin: a retrospective analysis of three trials. (2003) Cancer 97:2869–79.

Race plans to take bisantrene into a Phase 1b/2a clinical trial where it will be investigated in combination with oral decitabine/cedazuridine in dose escalation studies, followed by a triple combination with a standard of care treatment, such as venetoclax. The initial phase will provide a transition from the original RC110 (central vein administration) formulation to RC220.

The AML trial is an evolution of the RAC-006 study (which will now be called RAC-009) and enables the broader recruitment cohort of unfit AML patients (including those with relapsed/refractory AML) and can also include patients with extramedullary disease. The trial is planned to start in late Q4 CY 2023, with transitional phases from RC110 to RC220 in 2024.

Race believes the AML program offers significant opportunities to enter into early commercial partnerships.

Discovery

Our discovery program is designed to further elucidate both cardio-protective mechanisms of action and the findings by City of Hope that bisantrene is the most potent inhibitor of FTO. This finding is suggestive of an option to deliver targeted therapy to the right patient, identified with an overexpression of FTO.

The discovery program will:

- Continue to build knowledge around the unique MOA of bisantrene that enables reduced cardiotoxicity and related cardio-protection in combination with anthracyclines
- Help to define the individual clinical benefits of anthracenes vs anthracyclines like doxorubicin
- Enhance exploration of FTO through the recently announced City of Hope alliance
- Further pursue the FTO inhibitor discovery program with Monash University
- Provide an understanding of the MOA within the m6A pathway
- Develop a biomarker assay that can be used in clinic

New bisantrene

Activities conducted under this program are designed to strengthen intellectual property for bisantrene and to develop the next generation of bisantrene to improve patient outcomes and experience.

This program will:

- Build upon and leverage the foundations of RC110, bringing RC220 to clinic
- Develop the next generation bisantrene to expand treatment indications, strengthen IP and enhance partnering options with potential for increasing the overall lifecycle of bisantrene

Additional follow-on indications

In order to ensure targeted application of resources and funding, Race's focus on mBC and AML has led the Company to categorise other investigated indications where it has produced promising data as "follow-on indications". These disease areas include melanoma, soft tissue sarcoma, renal cell small cell carcinoma and lung cancer. Early-stage breast cancer has been added to this category due to the likelihood that bisantrene's use could be expanded from mBC to early stage breast cancer, later in its development. In addition, further exploration of a paediatrics program will evolve as human safety data is generated with RC220.

Commercialisation strategy

Race is now commercially prepared and positioned to engage in international biopharma dialogues, so enabling partnership opportunities. This follows a critical evaluation of the clinically impactful features and benefits of bisantrene, and insights from local and international key opinion leaders and experienced industry agencies. This has enabled a definitive focus in developing target product profiles to meet high unmet needs and to tailor our proposed clinical development plan to enable recruitment, while providing a positive patient experience and clear regulatory pathways. Race believes its clinical program enhances and delivers a unique commercial opportunity that can now be realised by the appropriate in-market pharmaceutical company.

Race retains a solid cash reserve. Both the AML Phase 1b/2a study and committed preclinical programs are fully funded. Race is investigating a variety of avenues for funding the mBC study due to start in late 2024, including non-dilutive sources and partnerships.

Other assets describing the strategic update and rationale

Presentations

Appended with this announcement is an investor presentation which includes within it an updated activities pipeline and clinical development plan.

Investors are also **invited to view a video copy of the presentation** as delivered by CEO and Managing Director, Damian Clarke-Bruce and Chief Medical Officer, Dr Michelle Rashford. To view the video presentation, please click here: https://raceoncology.com/?p=5619

Investor briefings

Shareholders and potential new investors are also invited to attend an online investor Q&A session, and/or in-person briefings in Sydney, Melbourne and Perth over the coming weeks. The Race team looks forward to welcoming all those shareholders and potential investors who can attend.

Please see our other ASX announcement being lodged today (8 August 2023) for further details.

-ENDS-

About Race Oncology (ASX: RAC)

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

Race's lead asset, bisantrene, is a small molecule anthracene chemotherapeutic. Bisantrene has a unique and rich clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well characterised safety profile, and compelling clinical data demonstrating an anti-cancer effect and a lack of cardiotoxicity.

Race is developing bisantrene to address the high unmet need of patients across multiple oncology indications, with an initial focus on metastatic breast cancer (lead indication) and acute myeloid leukaemia (AML), exploring anti-cancer plus cardio-protection in synergy with known standards of care.

As part of its clinical program, Race is also investigating the impact bisantrene and new molecules have on the m^6A RNA pathway, following independent research describing bisantrene as the most potent inhibitor of FTO (Fat mass and obesity-associated protein). Dysregulation of RNA (over expression of FTO) has been shown to be a driver of a diverse range of cancers.

Race Oncology is in collaboration with City of Hope, MD Anderson, Sheba City of Health and UNC School of Medicine, 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

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.

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Corporate strategy & business update

8 August 2023

At the heart of cancer care

RACE ONCOLOGY

(ASX: RAC)

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Agenda

1. About Race
2. Honing our focus
3. Clinical development plan
4. Bisantrene in metastatic breast cancer
5. Bisantrene in acute myeloid leukaemia
6. Discovery programs
7. New bisantrene
8. Corporate snapshot and next steps
9. Appendix

Corporate overview

Race Oncology (ASX: RAC) is developing bisantrene in high unmet need indications

Background

Established in 2016
HQ in Sydney, Australia

Technology

Bisantrene is a small molecule anthracene-based chemotherapeutic shown to have anti-cancer and cardio-protection effects

Mission

Address the high unmet need across multiple oncology indications, leveraging bisantrene's unique mechanism to benefit patients

Race has partnered with various institutions to further validate bisantrene's value proposition

City of Hope

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

SHEBA Tel HaShomer City of Health

UNC SCHOOL OF MEDICINE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

HMRI Hunter Medical Research Institute

MONASH University

ASX = Australian Securities Exchange; HQ = headquarters

Investment highlights

We know bisantrene works, and it keeps delivering

Building on the past…

Well characterised efficacy and safety profile as a monotherapy in 1800 patients, 46 trials, 70 peer reviewed publications

Anti-cancer and reduced cardiotoxicity data in AML and breast cancer patients

Bisantrene was registered* for AML in France in 1988

Validated in solid organ tumours and hematological malignancies

… with new discoveries to help tomorrow's patients

Potent anti-cancer + cardio-protection in **Breast Cancer**

Synergy with SoC for enhanced activity in **AML**

Novel mechanism with **FTO Inhibitor** as identified by City of Hope

Across many cancers, bisantrene has the potential to change patient outcomes and represents a significant commercial opportunity

*AML = acute myeloid leukaemia; SoC = standard of care; FTO = Fat mass and obesity associated gene. *It was never marketed*

Burden of disease

It's our Race to succeed for patients and be at the heart of patient care

“The chemo is working, but it's also causing heart failure. Is there an option to help these side effects so it doesn't affect my life after chemo?”

“How do I know if this chemo is going to work for my particular cancer? Is there a test we can do?”

"I want the strongest therapy, but I’m at my limit on anthracyclines. Is there some way around this limit?"

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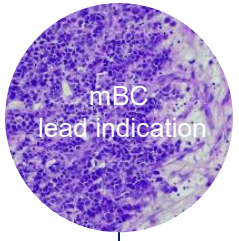
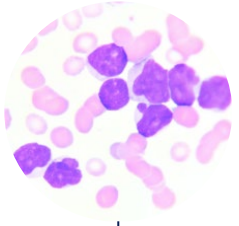
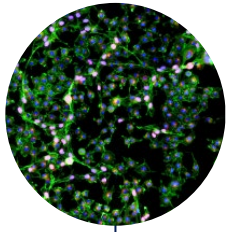
These quotes were provided by physicians, Dr Susan Dent and Amit Mehta, who treat cancer patients with the above unmet needs. Pictures are not the real patients.

Key insights

Resulting in a focused approach to optimise bisantrene's clinical and partnering potential







Metastatic breast cancer

- **Major market opportunity***
- Prior clinical experience enhanced by synergy with anthracyclines (SoC)
- Preclinical data supporting improved anti-cancer + cardio-protection
- Cardio-protection can drive enhanced efficacy and safety
- Clinical strategy supported by international experts
- New RC220 IV formulation will enable recruitment and market potential

AML

- Prior clinical data and French regulatory approval says 'the drug works'
- Platform to transition from RC110 to RC220 formulation
- Synergy with multiple established treatments can drive commercial success
- Unmet need in relapsed paediatric AML may accelerate development
- Supported by AML experts at MD Anderson and City of Hope (COH)

FTO

- Bisantrene found to be the most potent inhibitor of FTO by COH
- FTO is a key regulator of m6a levels
- FTO inhibition reduces levels of oncogenic proteins such as cMYC
- Preclinical investigation of bisantrene's activity as an FTO inhibitor underway
- Recent COH agreement enables collaboration on biomarker development

Follow-on indications

- Post mBC and AML trials, preclinical data supports the potential to treat:
  - Early stage BC
  - Sarcoma
  - Melanoma
  - Renal cell carcinoma
  - Lung cancer
- Prior preclinical research is accessible for future development with IP retained in these indications
- Opportunity to expand clinical and commercial applications for bisantrene

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*SoC = standard of care; IV = intravenous; AML = acute myeloid leukaemia; COH = City of Hope; FTO = Fat mass and obesity associated gene; mRNA = messenger ribonucleic acid mBC = metastatic breast cancer; BC = breast cancer; IP = Intellectual Property. *Data from Triangle Insights Group, 2023 (ASX Announcement 14 Apr 2023)*

Strategy

Race's R&D strategy has further evolved to maximise bisantrene's value

Anti-cancer + cardio-protection

Leverage unique mechanisms, in high unmet need populations

- Maximising bisantrene's anti-cancer and cardio-protective **potential in metastatic breast cancer** with the intent to expand to early breast cancer
- Build on **foundations** of existing clinical data in **AML**
- Develop **strategic partnerships** with corporate partners for combination therapies
- Explore **additional markets**

Discovery

Elucidate MoA and role of FTO, to develop a targeted approach

- Continued **exploration of FTO** through City of Hope partnership
- **FTO inhibitor discovery** program at Monash University
- **Explore mechanisms of action** for bisantrene, cardio-protection and FTO
- Develop **biomarker** assay

New bisantrene

RC220 IV strengthens IP and improves patient utility. Development of next generation bisantrene will enable expanded indications (FTO)

Significant Commercial Opportunity*: In the US, there are:

- ~36k addressable metastatic TNBC and HR+/HER2- patients, with current mBC therapies priced >$10k/cycle (estimated 4 cycles expected)
- ~16k unfit AML patients (both newly diagnosed and relapsed / refractory), average of 6 treatments p.a.

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*R&D = research and development; AML = acute myeloid leukaemia; MoA = Mechanism of action; FTO = Fat mass and obesity associated gene; IV = intravenous; IP = Intellectual Property; US = United States; TNBC = triple negative breast cancer; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2; mBC = metastatic breast cancer; p.a. = per annum. *Analysis completed by Back Bay Life Sciences*

Pipeline and program overview

RACE SPONSORED PROGRAMS		Discovery	PRECLINICAL *In Vitro*	PRECLINICAL *In Vivo*	CLINICAL Phase 1	CLINICAL Phase 2	CLINICAL Registration	
ANTI-CANCER / CARDIO-PROTECTION	Metastatic breast cancer			Bisantrene + doxorubicin (Ph1b/2a)				• Leveraging anti-cancer efficacy and cardio-protection data • Opportunity to address significant unmet need in large patient population
	Acute myeloid leukaemia			Bisantrene + decitabine / venetoclax (Ph1b/2)				• Leveraging strong historical data • Synergistic with multiple standards of care
DISCOVERY	FTO biomarker assay*		City of Hope; The University of Newcastle Australia					• Precision approach to identify future target patient populations
	Mechanism of action		UNC School of Medicine; The University of Newcastle Australia					• Understand anti-cancer and cardio-protection mechanisms to inform future biomarker development
NEW BISANTRENE	Peripheral IV formulation							• Robust new IP protection • More convenient administration via peripheral IV
	Next generation							• Further strengthen IP • Expansion opportunity into earlier settings and additional tumour types
INVESTIGATOR LED TRIAL				Bisantrene + fludarabine + clofarabine (Ph2) r/r AML, investigator led, Israel				• Builds on clinical experience with bisantrene in successful 2020 AML trial

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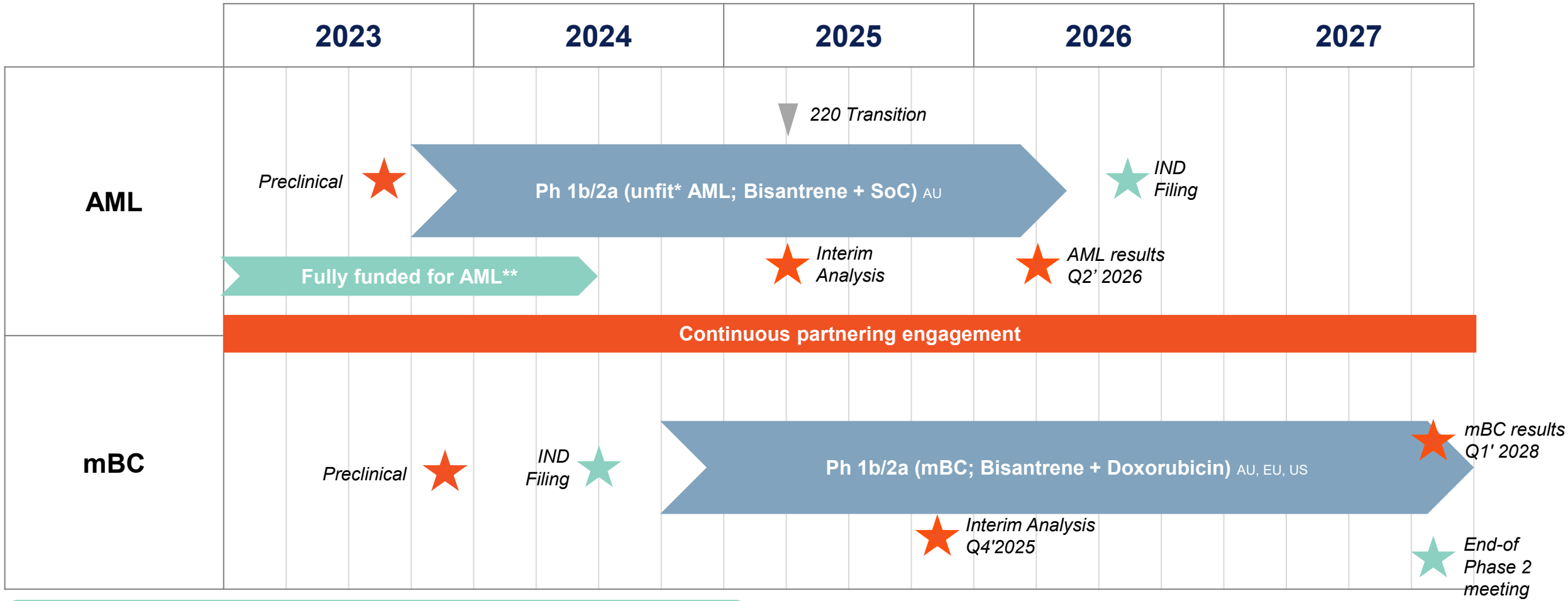
*FTO = Fat mass and associated-obesity protein; IV = intravenous; IP = intellectual property; r/r AML = relapsed or refractory acute myeloid leukaemia *Companion diagnostic*

Clinical development plan

Inflection points from these trials will drive increased value for the company



**Race retains a solid cash reserve. The AML Phase 1b/2a study and both preclinical programs are fully funded. Race is investigating a variety of avenues for funding the mBC study due to start in late 2024, including non-dilutive sources, R&D tax rebates, and partnerships.

Current plan

Trial Results / Milestones

Regulatory Milestones

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*AML = acute myeloid leukaemia; mBC = metastatic breast cancer; SoC = standard of care; IND = investigational new drug; NDA = new drug application; AU = Australia; EU = Europe; US = United States; R&D = research and development. *Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy. NB. Received US Orphan Drug Designation (ODD) in AML, Rare Paediatric Disease designation and eligibility for Priority Review Voucher*

Publication and IP plan

Communication will be driven by inflection points to protect Race's value and partner expectations

IP protection sought for preclinical and clinical discoveries to secure Race's commercial value before any publication

Data to be published in high-impact international **peer-reviewed medical journals** and presented at **globally recognised scientific conferences**

Data shared to shareholders via **ASX announcements** at the time of publication

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ASX = Australian Securities Exchange; IP = intellectual property

Bisantrene in metastatic breast cancer (mBC)

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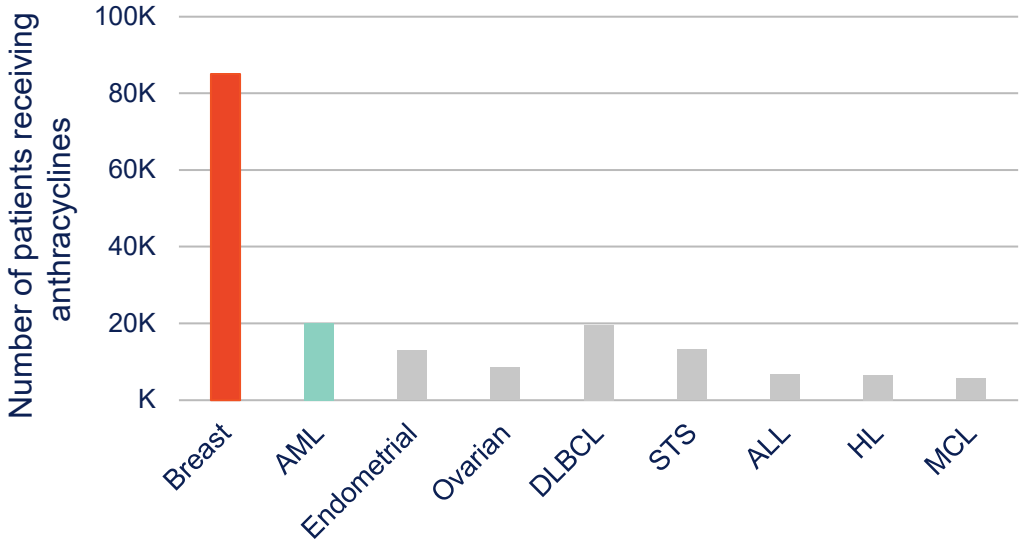
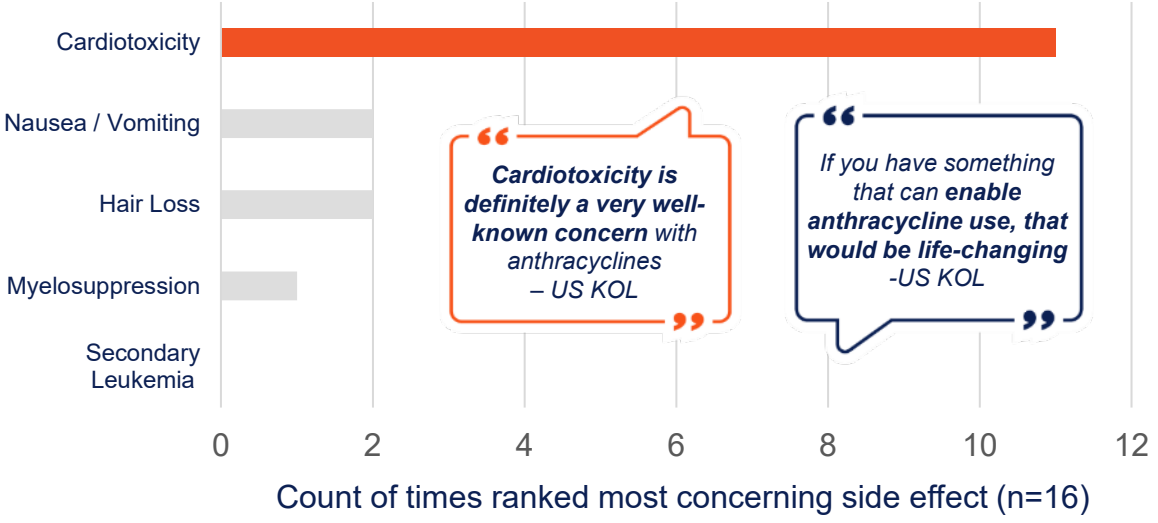
Anthracycline use in oncology

Anthracycline use is highest in breast cancer, with cardiotoxicity being the major side effect of concern

Anthracyclines are still used as the main agent in various settings across a range of tumour types due to strong clinical efficacy and survival benefits



On a scale from 1 to 7, with one being 'not at all concerning' and 7 being 'extremely concerning', **how concerning are the following anthracycline adverse events**?



Bisantrene: an anthracene agent addressing unmet needs across a range of tumours

1. Adding to the **anti-cancer efficacy** of existing therapies
2. **Protecting against anthracycline-associated cardiotoxicity** to improve cancer outcomes and quality of life

Race areas of focus
Metastatic breast cancer with the intention of expanding to early breast cancer

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AML = acute myeloid leukaemia; DLBCL = diffuse large B cell lymphoma; STS = soft tissue sarcoma; ALL = acute lymphoblastic leukaemia; HL = Hodgkin's lymphoma; MCL = mantle cell lymphoma; US = United States; KOL = key opinion leader

Metastatic breast cancer - unmet patient need

Bisantrene has the potential to address unmet needs in metastatic breast cancer when used in combination with anthracyclines

Metastatic breast cancer prognosis remains poor

- PFS is ~6 months
- TNBC has the worst prognosis, with an OS of ~15-20 months
- Anthracyclines remain standard of care and are the preferred treatment when possible

Cardiotoxicity is the main burden of anthracycline treatment

- ~22% incidence of cardiotoxicity

Anthracyclines are restricted by lifetime limit – this is the most significant concern for oncologists

- 80-85% mBC patients in the US will have already reached their lifetime limit

Bisantrene value proposition

→ Bisantrene delivers anti-cancer effects and protects against anthracycline associated cardiotoxicity

→ Bisantrene is expected to allow for expanded anthracycline utilisation

→ Race is targeting a clinically meaningful increase in PFS and OS

The bisantrene RC220 IV formulation is critical for future breast cancer indications

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PFS = progression free survival; TNBC = triple negative breast cancer; OS = overall survival, mBC = metastatic breast cancer; US = United States; IV = intravenous

Key opinion leader insights

Scope for new cardio-protective therapy in addition to doxorubicin if it increases anti-cancer efficacy

Dr Dang
Medical Oncologist (Breast Cancer)
Memorial Sloan Kettering Cancer Center
NY, USA

Memorial Sloan Kettering Cancer Center

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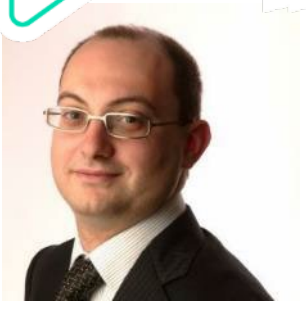
9-14% of patients on anthracycline regimes develop symptomatic cardiac dysfunction

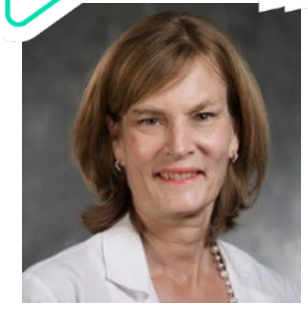


Prof Aaron Sverdlov
Cardiologist
University of Newcastle, NSW, Australia

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

CARDIO-ONCOLOGY NEWCASTLE

Before considering early-stage breast cancer, a novel treatment should demonstrate efficacy in the metastatic setting



Prof Susan Dent
Medical Oncologist
Duke University, Durham, NC, USA

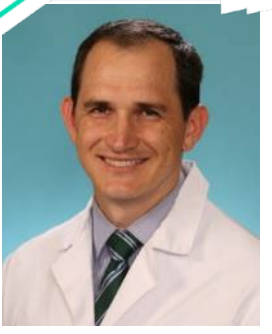
Duke UNIVERSITY

It depends how carefully you look, but at least 30% of patients who are treated with anthracyclines have evidence of cardiac toxicity

Prof Tom Neilan
Cardio-Oncologist
Harvard Medical School, Boston, MA, USA

HARVARD MEDICAL SCHOOL

Toxicity is highest in the first year, but risk of heart failure remains increased for the rest of their life

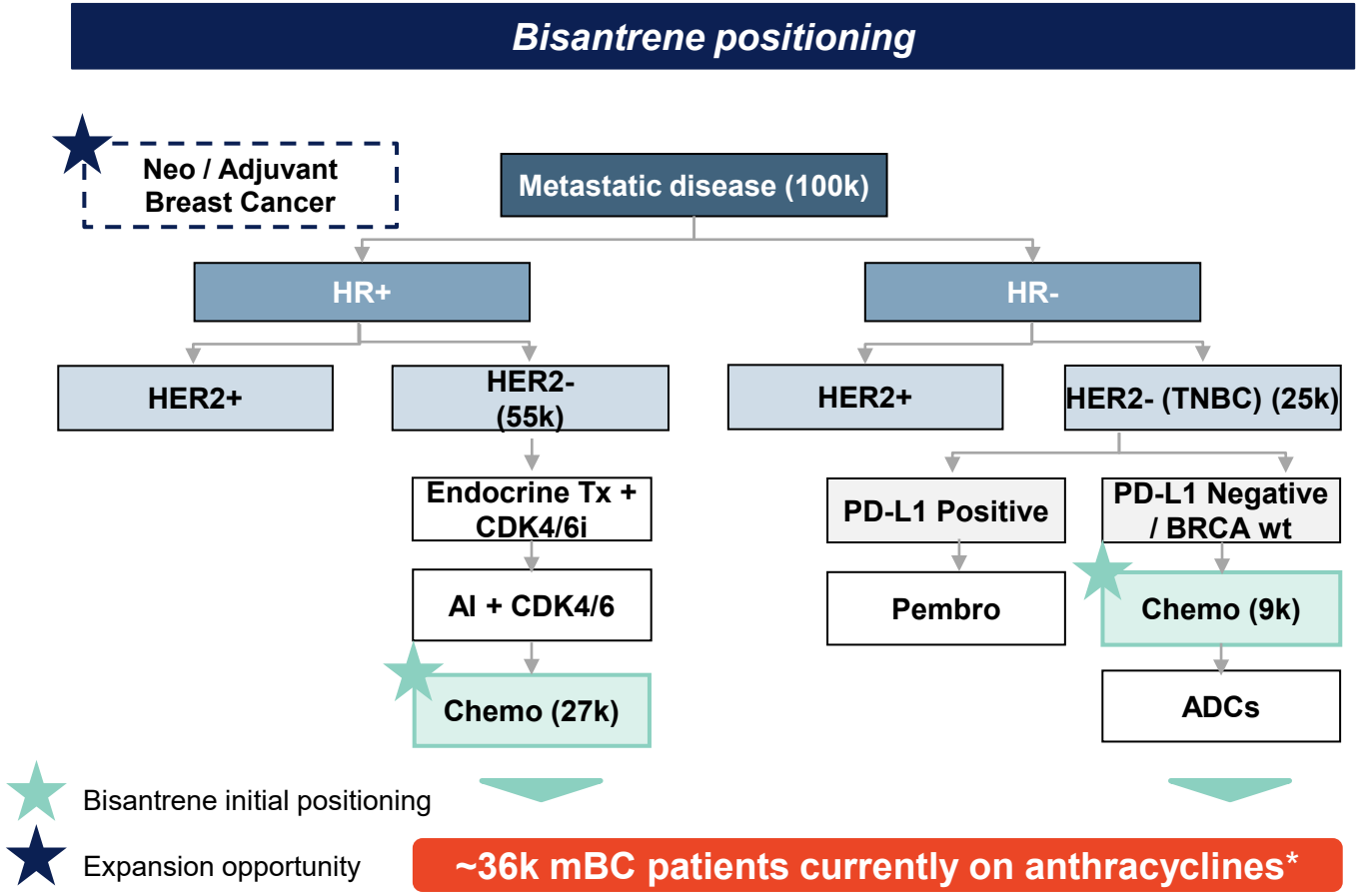


Prof Josh Mitchell
Cardio-Oncologist
Washington University, St Louis, MO, USA

Washington University in St. Louis

Metastatic breast cancer - target patient population

Bisantrene's positioning in combination with SoC to address current unmet needs drives significant market opportunity



→ Bisantrene has the opportunity to increase PFS and reduce cardiotoxicity in ~36k TNBC and HR+/HER2- metastatic breast cancer patients in the US

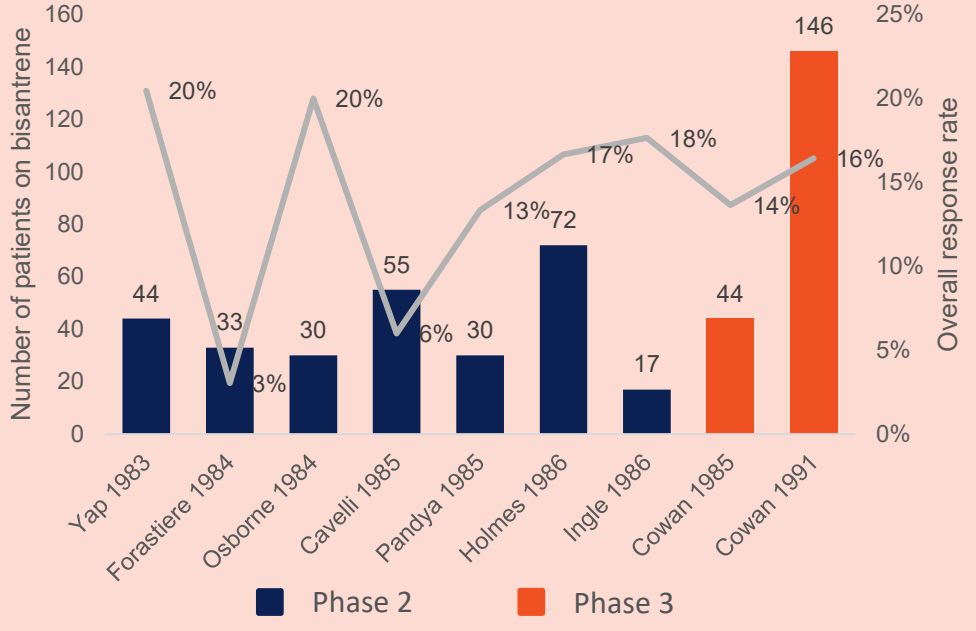
RACE ONCOLOGY

*SoC = standard of care; HR = Hormone receptor; HER2 = Human epidermal growth factor receptor 2; TNBC = triple negative breast cancer; Tx = treatment; CDK = cyclin-dependent kinase; PD-L = Programmed death-ligand 1; BRCA = BReast CAncer gene 1; wt = wild type; AI = aromatase inhibitor; ADC = antibody drug conjugates; mBC = metastatic breast cancer; PFS = progression free survival; US = United States. *Patient numbers are based on US metastatic breast cancer figures per annum.*

Bisantrene's strong monotherapy performance in breast cancer

Demonstrated substantial anti-cancer activity, with reduced cardiotoxicity, and similar OS rate to doxorubicin

Nine Ph 2/3 monotherapy bisantrene metastatic / advanced breast cancer trials (n= 471)



Partial response rates up to 20%

Cowan 1991 Ph 3 trial

Randomized Trial of Doxorubicin, Bisantrene, and Mitoxantrone in Advanced Breast Cancer: A Southwest Oncology Group Study

John D. Cowan, James Neidhart, Suzanne McClure, Charles A. Coltman, Jr., Conrad Gumbart, Silvana Martino, Laura F. Hutchins, Ronald L. Stephens, Clarence B. Vaughan, C. Kent Osborne*

Table 2. Pre-crossover best response rates for all eligible patients

	No. of patients in treatment group (%)		
	Doxorubicin	Bisantrene	Mitoxantrone
Pre-crossover patients			
Eligible patients	117	128	120
Complete responders	1 (1)	2 (2)	1 (1)
Partial responders	32 (27)	15 (12)	16 (13)
Total responders*	33 (28)	17 (13)	17 (14)
Post-crossover patients			
Eligible patients	66	39	63
Total responders	5 (8)	1 (3)	1 (2)
Pre-crossover responder	1	0	0

*P = .004.

Table 4. Cardiac toxic effects

	Treatment group		
	Doxorubicin	Bisantrene	Mitoxantrone
1-7 courses			
No. of patients	128	138	133
Average No. of courses	5	4	4
No. of patients with CHF* (%)	2 (2)	0	0
>7 courses			
No. of patients	42	25	35
Average no. of courses	10	17	11
No. of patients with CHF* (%)	7 (17)	0	2 (6)
All courses			
No. of patients	128	138	133
Average No. of courses	6	5	5
No. of patients with CHF* (%)	9 (7)	0	2 (2)

*CHF = congestive heart failure.

Similar complete and partial response to mitoxantrone

No sign of heart failure with bisantrene

Overall survival at 2 years similar for all agents

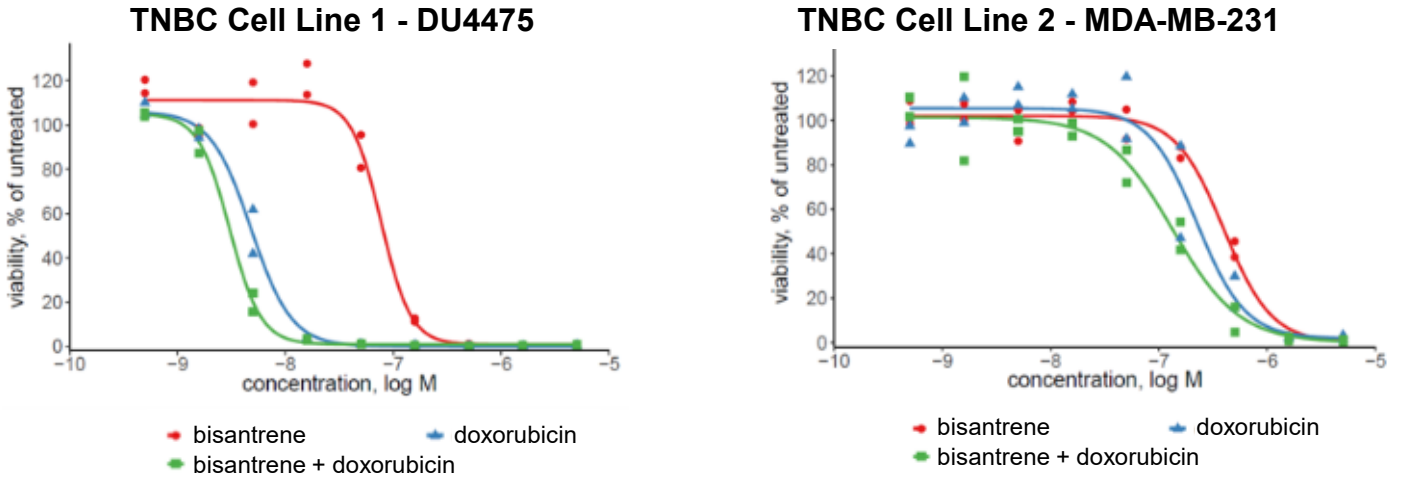
RACE ONCOLOGY

**Doxorubicin monotherapy showed higher efficacy compared with bisantrene or mitoxantrone monotherapy (p=0.004)*

Bisantrene's strong preclinical combination therapy performance in breast cancer

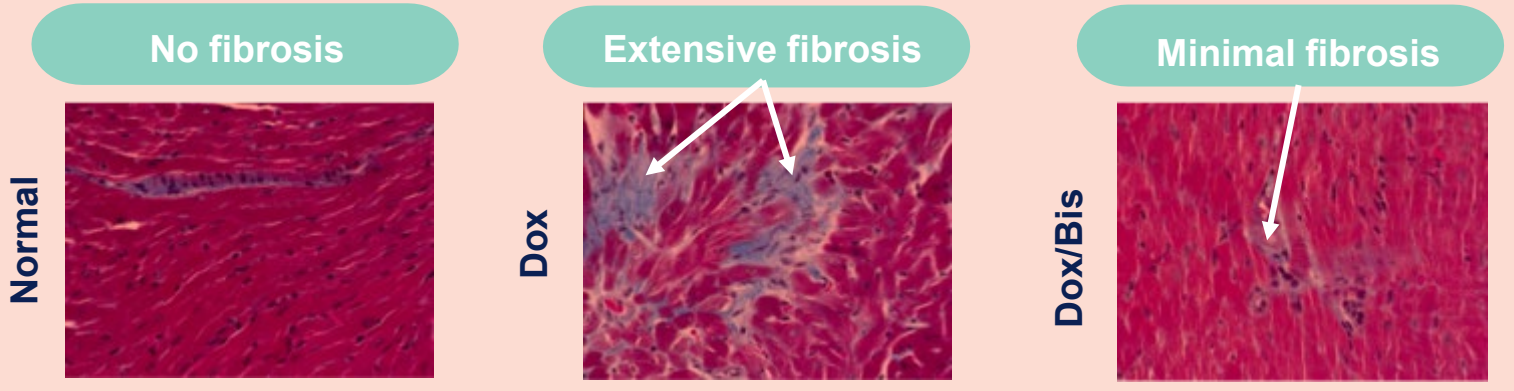
Bisantrene demonstrates strong anti-cancer and cardio-protective activity

Evidence of enhanced anti-cancer activity in mBC in combination with doxorubicin



In vitro studies in triple negative metastatic breast cancer cells have demonstrated that bisantrene in combination with doxorubicin (1:1) improved anti-cancer activity, when compared to doxorubicin alone.

Strong protection from anthracycline-induced cardiomyopathy



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

RACE ONCOLOGY

mBC = metastatic breast cancer; TNBC = triple negative breast cancer; Dox = doxorubicin; Bis = bisantrene

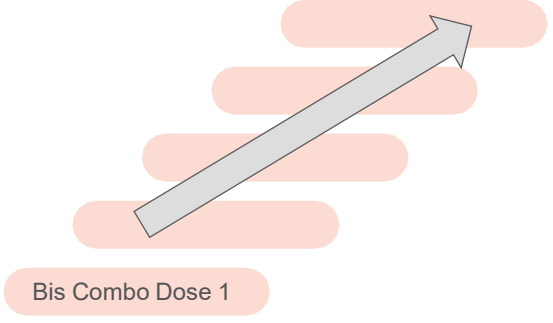
Planned mBC Phase 1/2 trial design

The goal of the initial study will be to determine optimal dosing and establish proof-of-concept data

Phase 1b/2a

mBC patients eligible for anthracycline based therapy

Part 1: Dose escalation
Add to proof of mechanism in mBC



mTNBC patients eligible for anthracycline based therapy

Part 2: Dose expansion
Establish early efficacy & confirm dose

Randomization of new subjects **with mTNBC**

Bis Combo RP2D Dose-X

Bis Combo RP2D Dose-Y

Recommended Phase 2 Dose (RP2D)

Phase 2b/3

TNBC + HR+/HER2- patients eligible for anthracycline based therapy

Pivotal Trial
Establish definitive efficacy

Goal

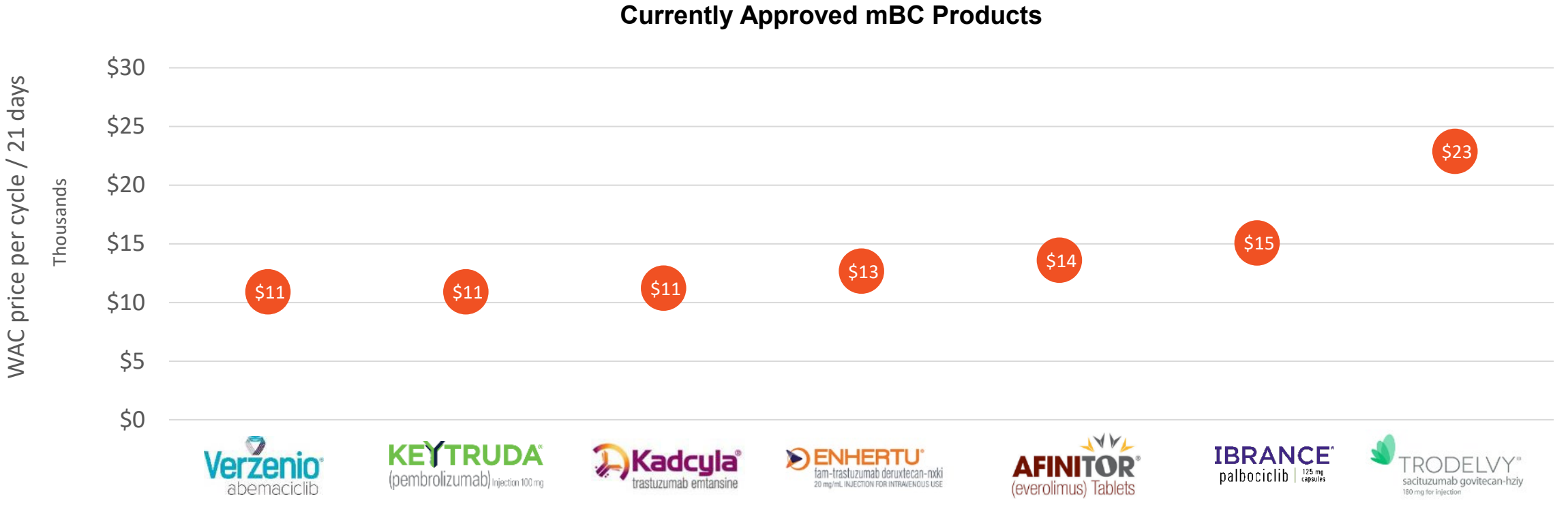
- Initial evidence of safety, establish a therapeutic dose range, generate bisantrene monotherapy pharmacokinetic data
- Evaluate safety and tolerability of range of doses of bisantrene in combination with anthracyclines
- Identify RP2D at end of Part 2
- Establish anti-tumor efficacy and cardio-protective effect of each dose cohort in the RP2D
- Exploration of FTO expression; assessment of biomarkers and downstream pathways

RACE ONCOLOGY

mBC = metastatic breast cancer; Bis = bisantrene; mTNBC = metastatic triple negative breast cancer; RP2D = recommended phase 2 dose; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2; FTO = fat mass and associated-obesity protein.

Metastatic breast cancer pricing

Approved and branded metastatic breast cancer therapies were utilised as pricing analogs for bisantrene



Relevant breast cancer indication*	HR+/HER2- BC: all stages	TNBC: neoadjuvant & adjuvant, PDL1+ unresectable / metastatic	HER2+: adjuvant, 2L metastatic	HER2+: 2L metastatic	HR+/HER2- BC: 2L+, advanced	HR+/HER2- BC: adv/mets in combination with AI or ET or fulvestrant	TNBC: 3L+ locally advanced / metastatic

RACE ONCOLOGY

*mBC = metastatic breast cancer; WAC = wholesale acquisition cost; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2; BC = breast cancer; TNBC = triple negative breast cancer; PDL1 = programmed death-ligand 1; 2L = second line; ET = endocrine therapy; 3L = third line. *Therapies may be approved in other indications as well. Source: RedBook*

Bisantrene in acute myeloid leukaemia (AML)

RACE ONCOLOGY

AML - unmet patient need

There is a need for a new therapeutic that improves cancer outcomes, while limiting toxicity

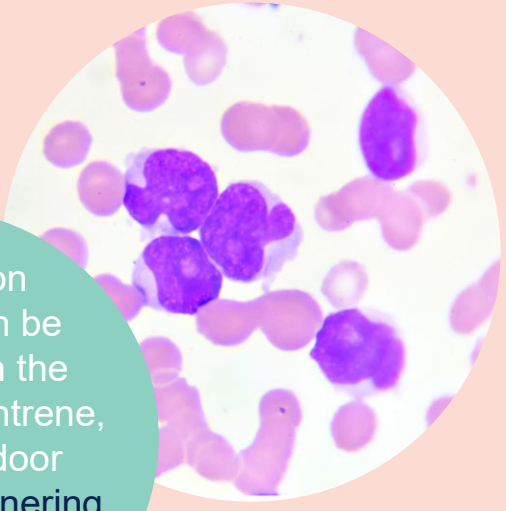
Median survival ~7-17 months

- Only ~5-15% of patients >60 years old are cured
- OS for unfit* patients is <1 year post-diagnosis
- Toxicity significantly impacts clinical outcomes and patient quality of life
- 60% r/r AML patients are unfit

Options are limited for r/r, unfit AML patients*

- Limited to current induction / maintenance therapies
- Physicians will often seek clinical trials at this point

→ Bisantrene on top of standard of care shows potential to improve overall survival with a clinically meaningful target of **~20-30%**[1]



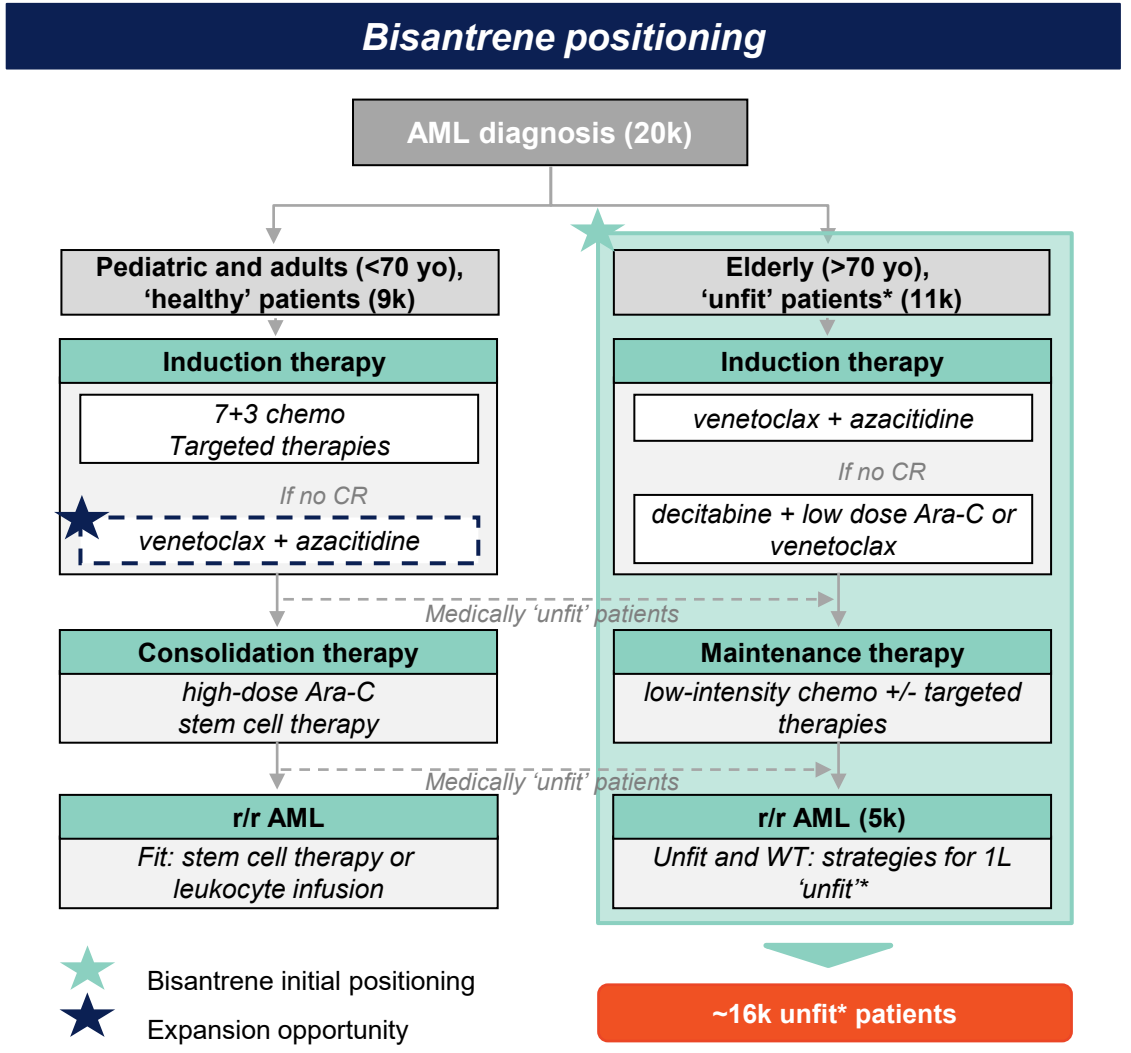
Combination treatment can be improved with the addition of bisantrene, opening the door to potential partnering and collaboration opportunities.

RACE ONCOLOGY

*AML = acute myeloid leukaemia; OS = overall survival; r/r = relapsed or refractory. *Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy.*
1. Clinical meaningful target as per insights from key opinion leaders, payors, and Triangle Insights Group (ASX Announcement 14 Apr 2023)

AML - target patient population

Bisantrene can potentially improve overall survival in unfit* AML patients



→ Bisantrene has the opportunity to improve overall survival with reduced cardiotoxicity and provides an option to help bridge to a life saving transplant for ~16k unfit* AML patients in the US.

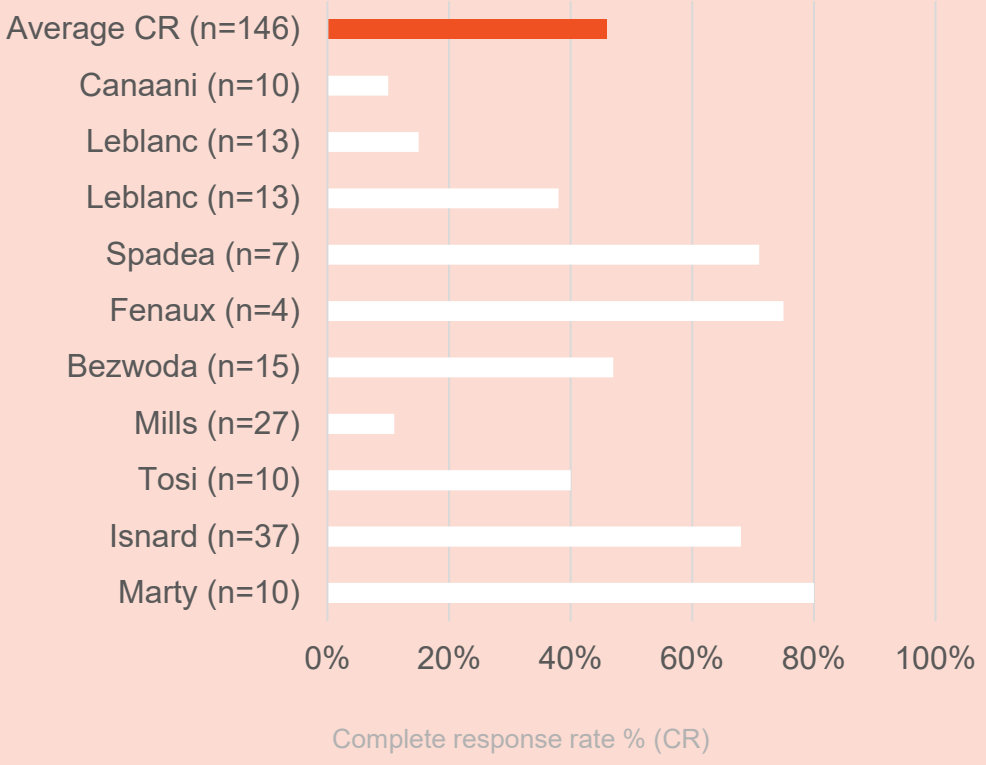
RACE ONCOLOGY

*AML = acute myeloid leukaemia; r/r = relapsed or refractory; CR = complete response; Ara-C = cytosine arabinoside; WT = wildtype; 1L = first line; US = United States. *Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy, comprised of ~11k new unfit AML patients and ~5k R/R unfit AML patients in the United States per annum.*

Bisantrene's strong past performance in AML

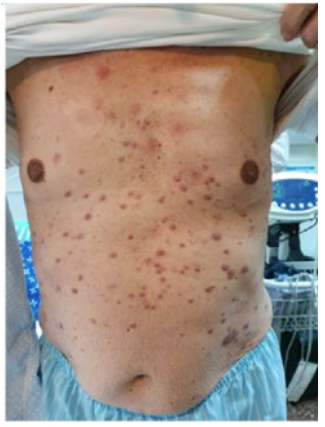
Wealth of data demonstrates that bisantrene monotherapy results in an average complete response rate of 46%

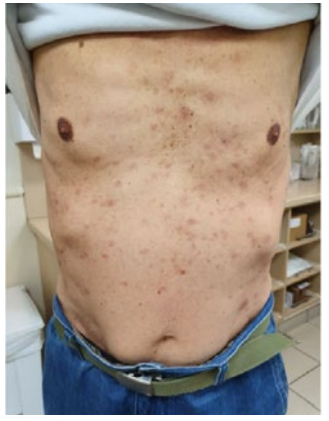
Historical Phase 2 bisantrene monotherapy studies in r/r AML
(from trials 1984 – 2020)



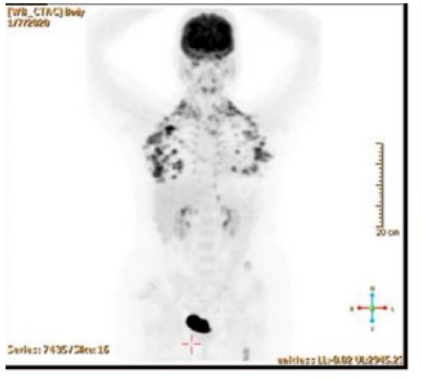
*Across the 10 monotherapy r/r AML studies and 146 patients, bisantrene demonstrated an average **complete response rate** of 46%*

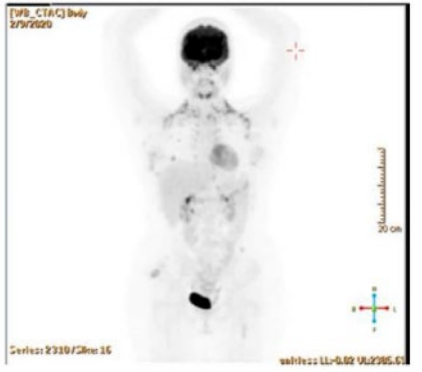
Patient with lesions treated with bisantrene achieved a complete remission and proceeded to SCT.





Positron emission tomography-computed tomography (PET/CT) scans from EMD AML patient who received bisantrene showing tumour regression[1]





The venetoclax/azacitidine combination phase 3 trial in unfit AML patients showed a **complete response rate of 37%**[2]*

RACE ONCOLOGY

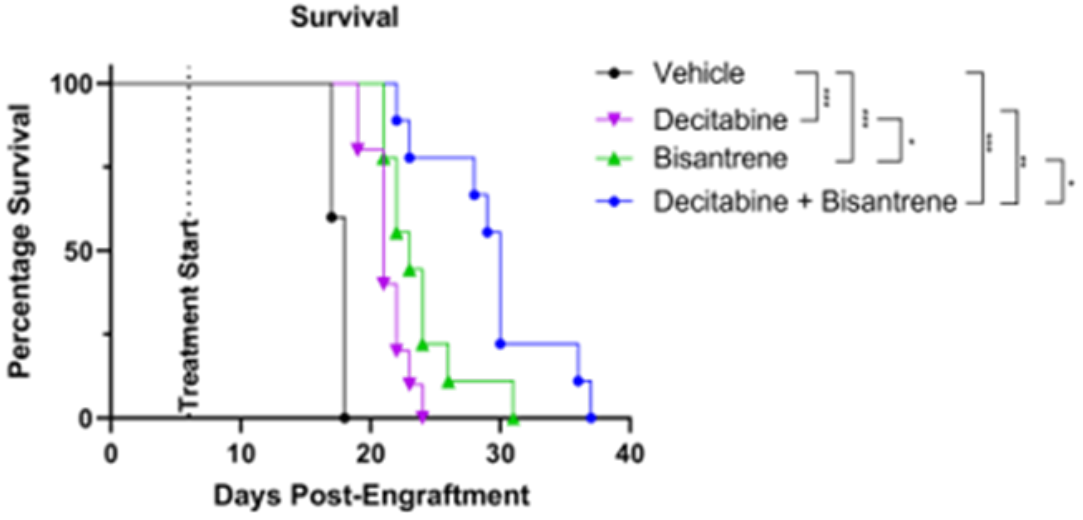
*AML = acute myeloid leukaemia; r/r = relapsed or refractory, CR = complete response rate; SCT = stem cell transplant. PET/CT: positron emission tomography–computed tomography; EMD = extramedullary disease. *Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy.*

1.Canaani et al. Eur J Haematol. 2020 2. DiNardo et al. 2020 N Engl J Med 383:617-629.

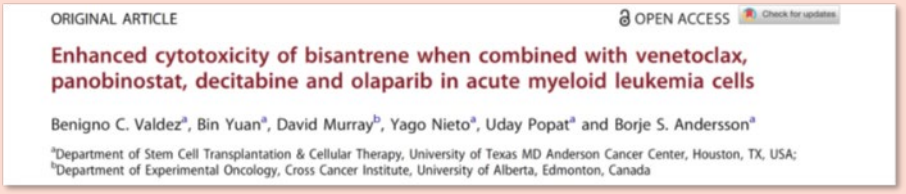
Evidence of bisantrene combination therapy in AML

Promising preclinical data to support anti-cancer efficacy in AML with bisantrene in combination with standard of care

In vivo mice studies demonstrated that bisantrene in combination with decitabine shows improved survival benefit relative to decitabine or bisantrene alone



In vitro studies demonstrated bisantrene combined with venetoclax increased cancer cell killing

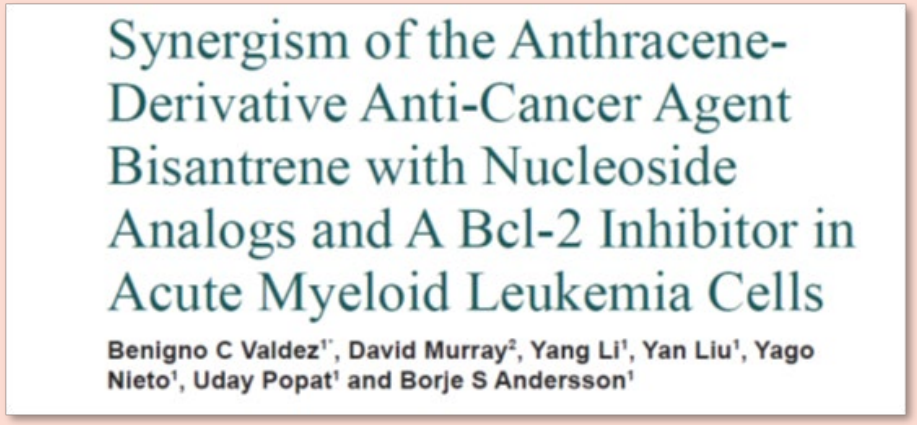

ORIGINAL ARTICLE

OPEN ACCESS

Enhanced cytotoxicity of bisantrene when combined with venetoclax, panobinostat, decitabine and olaparib in acute myeloid leukemia cells

Benigno C. Valdez[a], Bin Yuan[a], David Murray[b], Yago Nieto[a], Uday Popat[a] and Borje S. Andersson[a]

[a]Department of Stem Cell Transplantation & Cellular Therapy, University of Texas MD Anderson Cancer Center, Houston, TX, USA; [b]Department of Experimental Oncology, Cross Cancer Institute, University of Alberta, Edmonton, Canada


Synergism of the Anthracene-Derivative Anti-Cancer Agent Bisantrene with Nucleoside Analogs and A Bcl-2 Inhibitor in Acute Myeloid Leukemia Cells

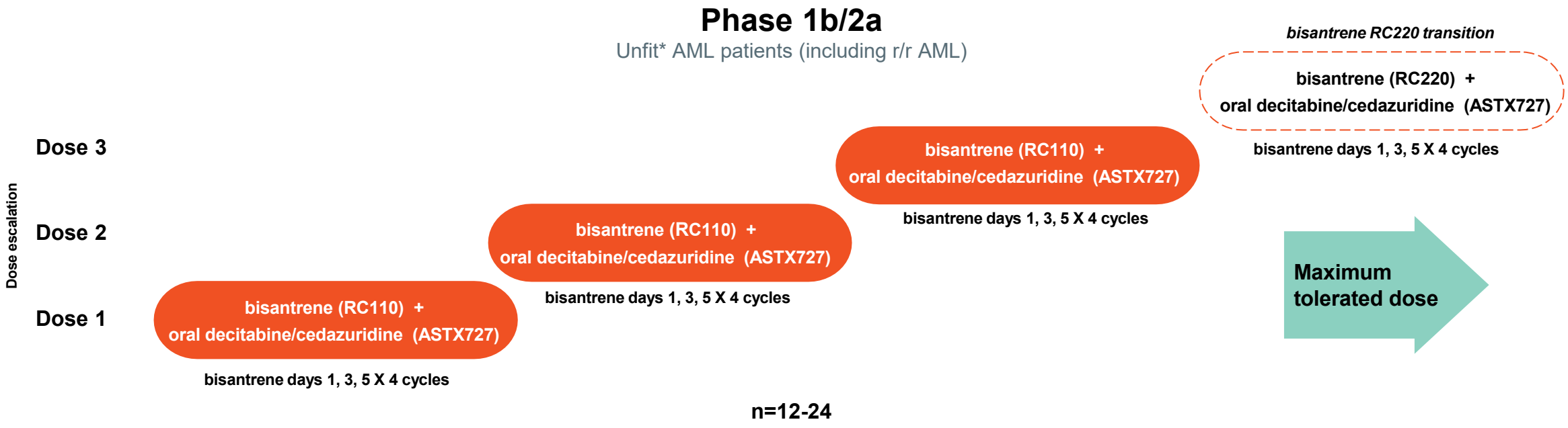
Benigno C Valdez[1*], David Murray[2], Yang Li[1], Yan Liu[1], Yago Nieto[1], Uday Popat[1] and Borje S Andersson[1]

RACE ONCOLOGY

AML = acute myeloid leukaemia

AML Phase 1/2 Trial Design: bisantrene + decitabine combination

Maximum tolerated dose: dose escalation PK study



Objectives

- Evaluate safety, tolerability, dose selection of bisantrene in combination with hypomethylating agent decitabine
- Identify RP2D at end of Phase 1b/2a
- Generate data with RC220 (peripheral administration) after transitioning from RC110 (central line) in AML

Design

- Up to 3 doses tested
- Mono lead in bis for PK (day 1 – 48 hours)
- Number of pts n=12-24
- Designed to assess MTD
- Efficacy endpoint: CRi (day 45)
- Exploration of FTO expression; assessment of biomarkers and downstream pathways

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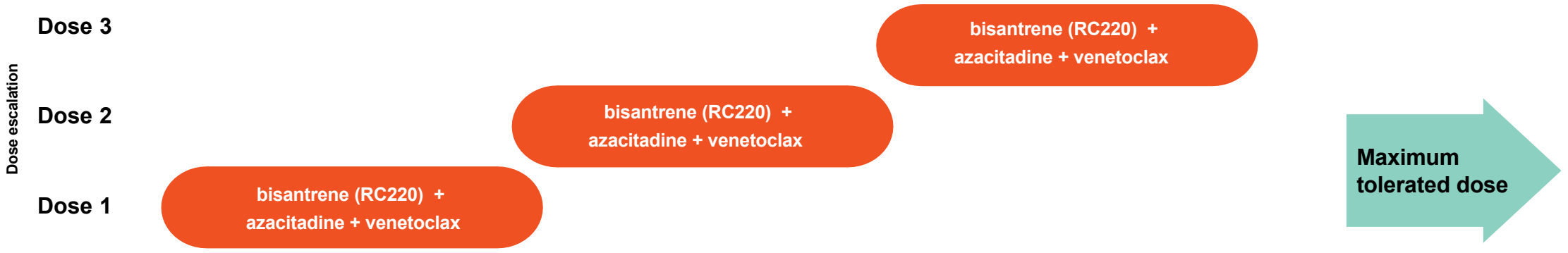
*AML = acute myeloid leukemia; PK = pharmacokinetics; r/r = relapsed or refractory; RP2D = recommended phase 2 dose; MTD = maximum tolerated dose; CRi = complete remission with incomplete hematological recovery; FTO = Fat mass and obesity associated gene. *Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy*

AML Phase 1/2 Trial Design*: bisantrene + azacitadine + venetoclax combination

Maximum tolerated dose: dose escalation PK study

Phase 1b/2a

Unfit** AML patients (including r/r AML)



n=12-18

Objectives

- Evaluate safety, tolerability, dose selection of bisantrene in combination with hypomethylating agent azacitadine and BCL-2 inhibitor venetoclax
- Identify RP2D at end of Phase 1b/2a

Design

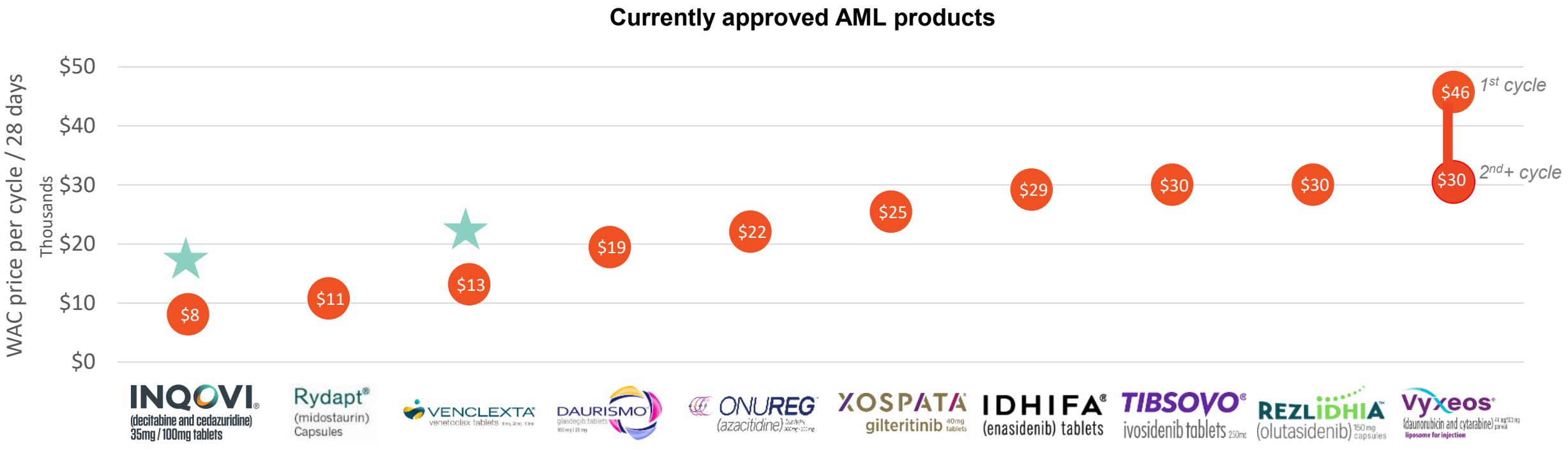
- Up to 3 doses tested
- Mono lead in bis for PK (day 1 – 48 hours)
- Number of pts n=12-18
- Designed to assess MTD
- Efficacy endpoint: CRi (day 45)
- Exploration of FTO expression; assessment of biomarkers and downstream pathways

RACE ONCOLOGY

*AML = acute myeloid leukemia; PK = pharmacokinetics; r/r = relapsed or refractory; BCL-2 = B-cell lymphoma 2; RP2D = recommended phase 2 dose; MTD = maximum tolerated dose; CRi = complete remission with incomplete hematological recovery; FTO = Fat mass and obesity associated gene. *Need to generate supportive preclinical data for study **Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy*

AML pricing

Approved and branded AML therapies were utilised as pricing analogs for bisantrene



Relevant AML indication*	1L+ MDS	FLT3+ AML: In combo with cytarabine and daunorubicin	Unfit** AML: In combo with azacitidine, decitabine, or low-dose cytarabine	Unfit** AML: In combo with low-dose cytarabine	AML maintenance therapy	FLT3+ r/r AML	IDH2+ r/r AML	IDH1+ unfit** patients and r/r AML	IDH1+ r/r AML	Newly diagnosed AML

Proposed bisantrene combination trial

RACE ONCOLOGY

*AML = acute myeloid leukaemia; WAC = wholesale acquisition cost; r/r = relapsed or refractory; 1L = first line; MDS = myelodysplastic syndrome; FLT3+ = cytokine receptor gene; IDH = isocitrate dehydrogenase. *Therapies may be approved in other indications as well. **Unfit AML defined as patients who are ≥70 and/or cannot tolerate high dose chemotherapy.*
Source: RedBook

Discovery programs

RACE ONCOLOGY

Discovery programs

Race has defined discovery activities to further elucidate bisantrene's mechanism to allow for a targeted approach

Better understanding of MoA

- Understand broad anti-cancer activity using current state-of-the-art methods
- Understand protection against anthracycline-induced cardiotoxicity

FTO biomarker development

- Further understand FTO to drive a targeted approach
- *In vitro* FTO/m6A biomarker discovery and *in vivo* biomarker validation
- Biomarker exploration through clinical program
- Development of clinical assay

RACE ONCOLOGY

MoA = mechanism of action; FTO = Fat mass and obesity-associated protein; m6A = N6-methyladenosine

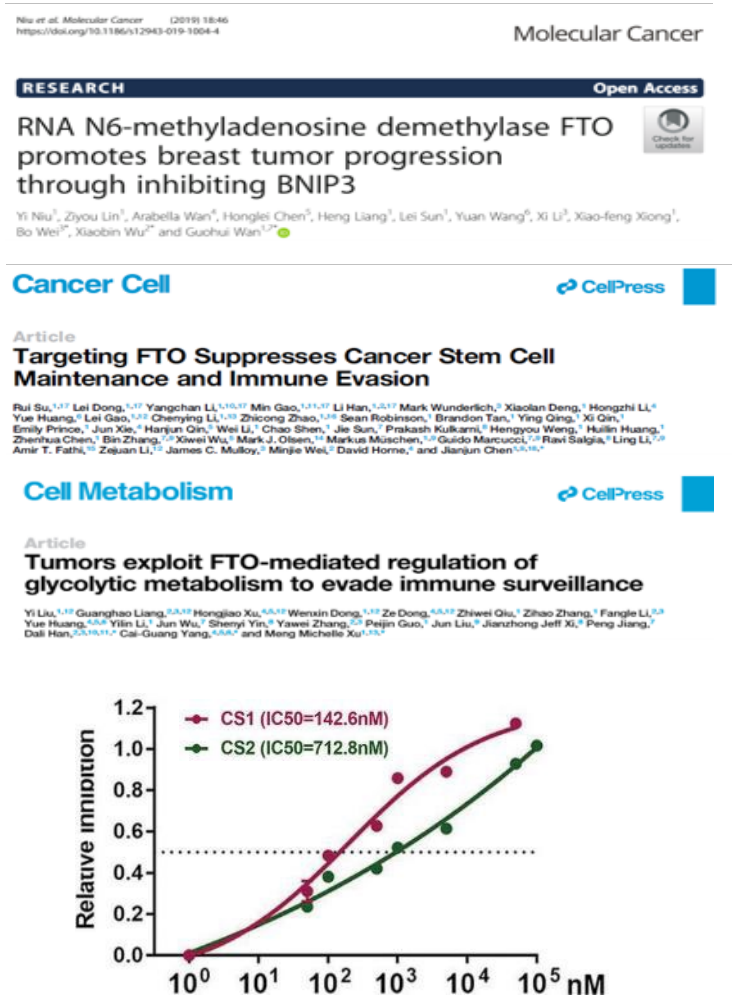
FTO

Continued assessment of FTO and related signaling in preclinical and clinical studies to understand anti-cancer properties

Prof J Chen

City of Hope®

- The m6A pathway has been linked to progression of multiple cancers
- FTO is a key regulator of m6A levels
- City of Hope identified bisantrene as the most potent inhibitor of FTO
- Inhibition of FTO has the potential to offer additional anti-cancer benefits
- Preclinical studies are being conducted by Race and partners to explore the synergies and impact of bisantrene on FTO and m6A regulation
- The City of Hope in-license provides Race freedom to operate in the FTO space



RACE ONCOLOGY

FTO = Fat mass and obesity-associated protein; m6A = N6-methyladenosine; CS1 = bisantrene

FTO/m6A biomarker assay development

Developing assays to maximise bisantrene's benefit for patients

In vitro FTO/m6A biomarker discovery

- Understand how bisantrene impacts FTO/m6A pathway in diverse cancer cells
- Assess different assay modalities and advance approach with the highest translational potential

City of Hope

The University of Newcastle Australia

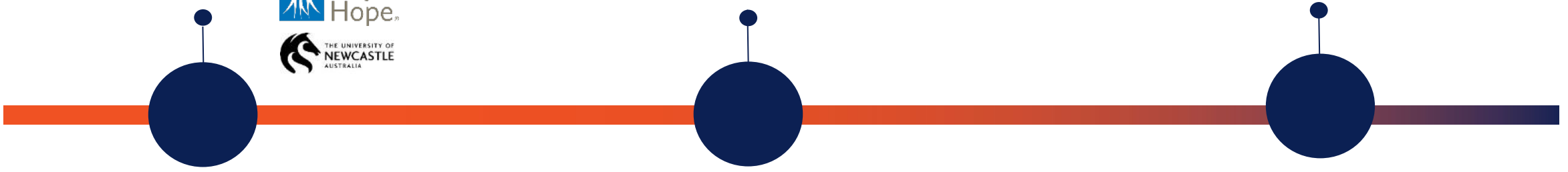
In vivo biomarker validation

- Apply assay protocols to demonstrate utility of response biomarker in mice
- Optimise sampling workflows to enable clinical translation

Oncolines
A SYMERES COMPANY

Clinical exploration

- Collect patient tissues across clinical programs
- Correlate patient bisantrene responses to FTO/m6A levels
- Understand downstream protein / enzyme impacts (e.g. Myc)



Targeted biomarker development

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FTO = Fat mass and obesity-associated protein; m6A = N6-methyladenosine

New bisantrene

RACE ONCOLOGY

Proprietary bisantrene formulations

Race continues to explore new formulations to improve patient clinical experience and strengthen IP

Recent key milestones in developing the bisantrene formulation:

- **Transition to manufacturing of RC220:**
  - Ease of administration via peripheral IV
  - Robust new IP protection
  - Increased patient convenience
- **Increased capacity to manufacture GMP RC220:**
  - Manufacture at scale and quality to enable clinical trials in Australia, Europe and the United States
- **Paused manufacturing of RC110:**
  - Required central venous access due to tendency to precipitate in and, therefore, damage the smaller peripheral veins

RC220 improves intellectual property, patient convenience and commerciality for bisantrene

RACE ONCOLOGY

IP = intellectual property; IV = intravenous; GMP = good manufacturing practice

Corporate snapshot and next steps

RACE ONCOLOGY

Race Oncology board

Strong Board with experience from early-stage drug development through to commercialisation

Mary Harney
Non-Executive Board Chair

- >20 years as Chair/ Director/ CEO for leading healthcare organizations
- Chair of Race, Oncology One and MicroBio
- Formerly CEO of $2b Breakthrough Victoria Fund

Damian Clarke-Bruce
CEO and Managing Director

- >25 years deep global experience in drug commercialization and portfolio strategy
- Former Global/US Executive Director, Pharming & Novartis

Dr Peter Smith
Non-Executive Director

- >30 years' experience in healthcare with focus on therapeutics / oncology
- CEO of oncology-focused Myrio and Hula Therapeutics
- Former top-rated pharma analyst with UBS and HSBC

Philip Lynch
Non-Executive Director

- >30 years' experience as commercial Director / leader
- Current Chair of Consumer Healthcare Products Australia
- Prior Race CEO (2020-2023)
- Formerly VP, Commercial Growth with J&J in Asia Pacific markets

Dr John Cullity
Non-Executive Director

- Hematological oncologist with >20 years deep domain experience across healthcare and banking with Torreya Partners
- Formerly held senior roles with Sanofi-Aventis and Schering-Plough. Has consulted to the WHO and the World Bank

Race Oncology management team

An expanded, deeply experienced team with commitment, drive and broad networks

Damian Clarke-Bruce
CEO and Managing Director

- >25 years deep global experience in drug commercialization and portfolio strategy
- >25 years deep global experience in drug commercialization and portfolio strategy
- Former Global/US Executive Director, Pharming & Novartis

Pharming 35 · Biogen · NOVARTIS

Dr Tim Hammond, PhD
Chief Scientific Officer (Interim)

- 35 years of experience in pharmaceutical drug discovery and development
- Former VP, Safety Assessment in UK for AstraZeneca - responsible for non-clinical safety development of the full oncology portfolio incl. Iressa and Olaparib registration

AstraZeneca

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

KYOWA KIRIN · Bristol Myers Squibb · Roche

Dr Sophia Moscovis, PhD
Program Management, Risk & Strategy Director

- >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

NOVARTIS · Forbes AUSTRALIA · Breast Cancer Trials

Prof Michael Kelso, PhD
Principal Scientist

- 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

University of Wollongong Australia · Scripps Research

Dr Marinella Messina, PhD
Clinical Director

- 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

NOXOPHARM · Datapharm Australia · KOLLING Institute of Medical Research

Corporate snapshot

An additional cash injection of $1.66m was received by Race post 30 June 2023 in relation to overseas finding for FY22

Issued capital	
Shares	163,068,780[1]
Options	9,411,282[1]
Shareholders	8,654[2]

Market capitalisation	
Share price	$1.27[3]
Market value	$207.1m[3]
Cash	$21.5m[2]
Enterprise value	$185.6m[3]

ASX 12-month price and volume[2]

Top shareholders[3]	
Dr Daniel Tillett	9.81%
Dr John Cullity (Non-Executive Director)	4.97%
Mr Phillip Richard Perry	4.76%
Mark Juan	3.42%
Merchant Opportunities Fund	2.73%

Race retains a solid cash reserve. The AML Phase 1b/2a study and both preclinical programs are fully funded. Race is investigating a variety of avenues for funding the mBC study due to start in late 2024, including non-dilutive sources, R&D tax rebates, and partnerships.

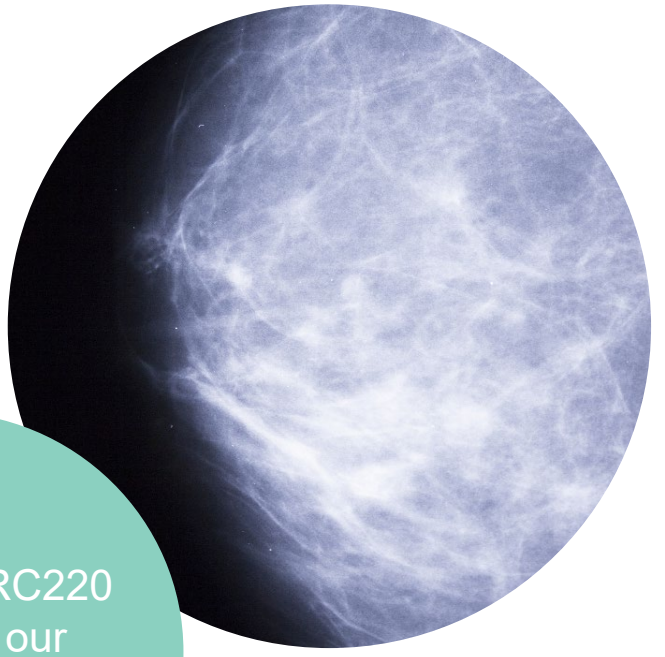
RACE ONCOLOGY

FY = financial year; ASX = Australian Securities Exchange; AML = acute myeloid leukaemia; mBC = metastatic breast cancer; R&D = research and development.
1. As at 8 August 2023, 2. As at 30 June 2023, 3. As at 4 August 2023

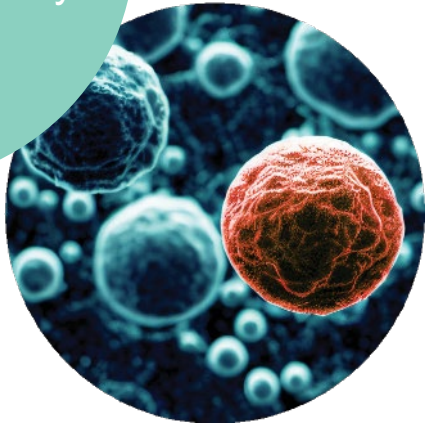
IP and exclusivity strategy

Race continues to foster commercial value by establishing a robust and overlapping portfolio of intellectual property

- **Granted US patents** covering bisantrene use in **oncology indications and formulation** approaches
- Exclusive access to **FTO license of IP**, potentially arising from a patent application filed by **City of Hope**
- Multiple PCT applications covering **method of use** of bisantrene + targeted drug combination therapy in solid tumour and haematologic oncology indications
- Patenting of lead asset, novel peripheral formulation RC220 strategically deferred to **maximise patent life**
- Key PCT application covering **discovery of and method of use** of bisantrene as a **cardio-protective combinational partner to anthracyclines** and other cardiotoxic oncology drugs



Bisantrene RC220 advances our intellectual property value



RACE ONCOLOGY

IP = intellectual property; US = United States; PCT = patent cooperation treaty; FTO = Fat mass and obesity-associated protein.

Recent and near-term value drivers and news flow

1H CY 2023	2H CY 2023	CY 2024
✓ New collaboration announced to better understand bisantrene's cardio-protection mechanism of action	RC220 safety pharmacology start	RC110 to RC220 transition in AML
✓ Cardio-protection market potential data released	RC220 GMP product release by Ardena	AML clinical trial interim analysis
✓ Preclinical and clinical programs update, refocus to RC220 formulation	AML clinical trial commences	Metastatic breast cancer IND filing
✓ Global agreement announced with City of Hope to open up access to FTO IP	RI-002 study (Israel) expected to recruit final two patients and proceed to read out	Metastatic breast cancer trial commences
✓ Agreement with Ardena for GMP manufacturing of RC220	Initiate first stage of collaborative preclinical work with City of Hope on FTO	Updates on mechanism of action studies

Drive further momentum around Race's partnering and collaboration strategy for bisantrene

RACE ONCOLOGY

CY = calendar year; FTO = Fat mass and obesity-associated protein; IP = intellectual property; GMP = good manufacturing practice; AML = acute myeloid leukaemia; IND = investigational new drug.

Conclusions

Metastatic breast cancer as the **lead indication** based on strong **anti-cancer** and **cardio-protection** potential and high unmet need

A strong value proposition for **anti-cancer in AML** built on **strong foundation** of clinical data demonstrating **efficacy and safety**

Elucidating role of **FTO** in bisantrene's mechanism to allow for a **targeted approach**

New bisantrene formulations to improve patient clinical experience and **strengthen IP and commercial value**

Commercially prepared and positioned to **engage with pharmaceutical companies**

RACE ONCOLOGY

AML = acute myeloid leukaemia; FTO = Fat mass and obesity-associated protein; IP = intellectual property

Thank you

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Asset overview

Bisantrene is built on a foundation of clinical data showing anti-cancer efficacy, a strong safety profile, and cardio-protection

Bisantrene is a small molecule anthracene-based chemotherapeutic, originally developed with the goal of creating a less cardiotoxic anti-cancer therapy

- Studied in over 46 clinical trials, 70 peer reviewed publications
- Treated ~1800 patients globally
- Confirmed anti-cancer efficacy and well characterised safety profile
- Reduced risk of cardiotoxicity and higher tolerability than anthracyclines, as well as cardio-protection when used with anthracyclines
- Works uniquely through multiple mechanisms of action


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