14 November 2019

ASX Announcement

Race reveals new strategy for cancer drug Bisantrene

- New clinical strategy targeting five cancer market segments
- Expanded total addressable market for Bisantrene
- Bisantrene trials in AML, breast cancer, and ovarian cancer

14 November 2019 – Race Oncology Limited (ASX: RAC) today revealed its new "5 Path" clinical strategy for its cancer drug, Bisantrene as detailed in the Investor Update (attached).

The strategy defines five paths for the clinical development of Bisantrene that greatly expands the addressable market for Bisantrene while reducing clinical development risk and targeting cancers beyond Acute Myeloid Leukaemia (AML). The new strategy builds on the value embedded in Bisantrene from its use in more than 40 prior human trials across a range of cancers.

Race Oncology will continue to prioritise the use of Bisantrene in treating AML, but will seek to introduce the drug earlier in the treatment pathway with the aim of improving patient survival and increasing Bisantrene's commercial potential.

"Recent changes in the medical understanding of AML has opened up an exciting opportunity to use Bisantrene earlier in AML treatment to improve patient outcomes," said Race's new Chief Scientific Officer, Dr Daniel Tillett. "The residual cancer often left after chemotherapy – referred to as measurable residual disease or MRD – means many patients face a bleak survival outlook."

New research suggests that Bisantrene could play an important and unique role in clearing this residual cancer before bone marrow transplantation. Race plans to conduct an AML MRD Phase II trial in the USA in partnership with a leading cancer centre.

"If successful, our MRD strategy could prove to be a breakthrough in the treatment of AML, greatly enhancing the value of Bisantrene to partners and potentially leading to an early approval by the FDA," said Race CEO, Peter Molloy.

In addition to the MRD opportunity, new preclinical research by Race's collaborators in the US has demonstrated that the clinical value of Bisantrene may be greatly enhanced by use in combination with other approved cancer drugs.

"The synergy between Bisantrene and other anti-cancer agents has been suggested by the historical data, but never confirmed using current research methodology, until now" said Dr Tillett. "We believe Bisantrene shows real promise when used in combination therapy for AML and other cancers."

"The new combination positioning for Bisantrene will make it easier to attract clinical support for our trials and increase the attractiveness and value of Bisantrene to potential licensing partners," said Mr Molloy.

To establish this in AML, the Company intends to run a Phase I/II combination trial in Australia for adult R/R AML. Conducting early stage trials in Australia (where suitable) will enable Race to lower trial costs and receive R&D tax credits, representing a 43.5% rebate on all eligible Australian R&D.

For paediatric AML, the Company is committed to running a registration trial in the United States with the goal of obtaining a Priority Review Voucher (PRV). Race's plan is that this trial may involve sites in Australia as well.

PRVs are offered by the US FDA to incentivise companies to pursue rare diseases. In July 2018, the Company announced that paediatric AML has been designated as a 'rare disease' by the FDA, which means that Bisantrene currently qualifies for a PRV upon approval. The PRV is a highly valuable and saleable voucher with an active secondary market.

Race Oncology will also be actively pursuing proof-of-concept (Phase I/II) trials for Bisantrene in combination treatment for breast and ovarian cancers, where considerable historical data suggests Bisantrene has significant clinical benefit. The Company intends to conduct these clinical trials in Australia to take advantage of the R&D tax rebate, as well as the reduced cost of conducting clinical trials.

"Our new MRD and combination strategy opens up valuable new markets for Bisantrene," said Mr Molloy. "Over the next months and years, we plan to see that value demonstrated in clinical trials and valuable partnerships."

- **ENDS -**

About Race Oncology (RAC: ASX)

Race Oncology is a specialty pharmaceutical company whose business model is to pursue later-stage drugs in the cancer field that have been overlooked by big pharma. The company's first drug is Bisantrene, a chemotherapy agent that was the subject of more than 40 clinical studies during the 1980s and 1990s before the drug was abandoned. Bisantrene has compelling clinical data in acute myeloid leukaemia (AML) as well as other cancers including breast and ovarian. Race is seeking to gain US FDA approval for Bisantrene. Bisantrene is the subject of three recently granted US patents owned by Race and has been awarded US Orphan Drug designation and a 'Rare Paediatric Disease' (RPD) designation that entitles Race to a valuable Priority Review Voucher (PRV) upon approval.

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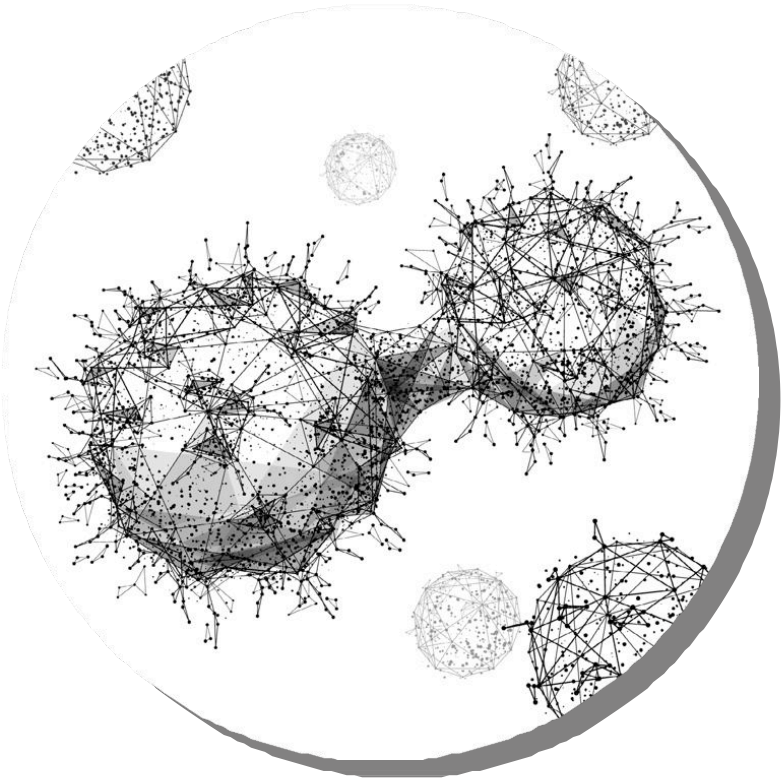
RACE
ONCOLOGY
Investor Update | November 2019
The New Race Strategy

Corporate snapshot

SHARES ON ISSUE	NOV 2019
Shares	109 m
Options	42 m
Shareholders	901
MARKET CAPITALIZATION	
Share price (30-day VWAP to 14 Nov '19)	$0.13
Market Capitalisation	$14 m
Cash	$2 m
Enterprise value (EV)	$12 m
MAJOR SHAREHOLDERS	
Bill Garner (Chair)	16.2%
Daniel Tillett (Dir & CSO)	8.3%
Peter Molloy (CEO)	3.9%



About
Bisantrene

Bisantrene is a cancer chemotherapy drug developed in the 1980s by Lederle Pharmaceuticals

Bisantrene was tested in more than 40 human trials and showed activity in AML (acute myeloid leukaemia), as well as breast and ovarian cancer

Bisantrene was approved for AML in France in 1988, but never commercialised and it disappeared after AHP/Wyeth acquired Lederle in 1994

Race was founded in 2016 with the mission to rescue Bisantrene and bring this valuable drug back into clinical practice

Race has successfully manufactured Bisantrene, built a strong patent position (3 granted) braced by a US Orphan Drug designation (7 years commercial exclusivity), and has secured a Rare Paediatric Disease (RPD) designation with the potential to win a valuable Priority Review Voucher (PRV)


Bisantrene remains an excellent
cancer drug with great potential in
modern cancer treatment for AML
and other cancers

Race's original plan for Bisantrene

1. **Adult AML** – Obtain FDA approval for Bisantrene under the 505(b)(2) pathway as a single agent for treatment of adult R/R AML.

   Filed IND to support a US registration trial, based on historical Phase II single agent studies; sought a commercial licensing partner to fund the registration trial

2. Develop Bisantrene for paediatric AML under the RPD designation and win a PRV valued at ~US$100m

3. In parallel, generate usage and revenues through Named Patient Programs (NPP) outside US (Europe)

However, the AML landscape has recently changed, which affects the adult AML registration plan and the viability of NPP

But these changes also point to exciting & valuable new opportunities for Bisantrene

AML landscape has recently changed

When Race started in 2016, there had been no advances in AML treatment for at least 30 years. However, since 2017

- 8 new drugs approved for AML
- 538 AML clinical trials currently recruiting
- 216 different drugs being trialled
- Many trials, few patients – competition for trial patients is intense, especially in relapsed/refractory (R/R) disease

R/R AML now focused on combination drug therapy, not single agent

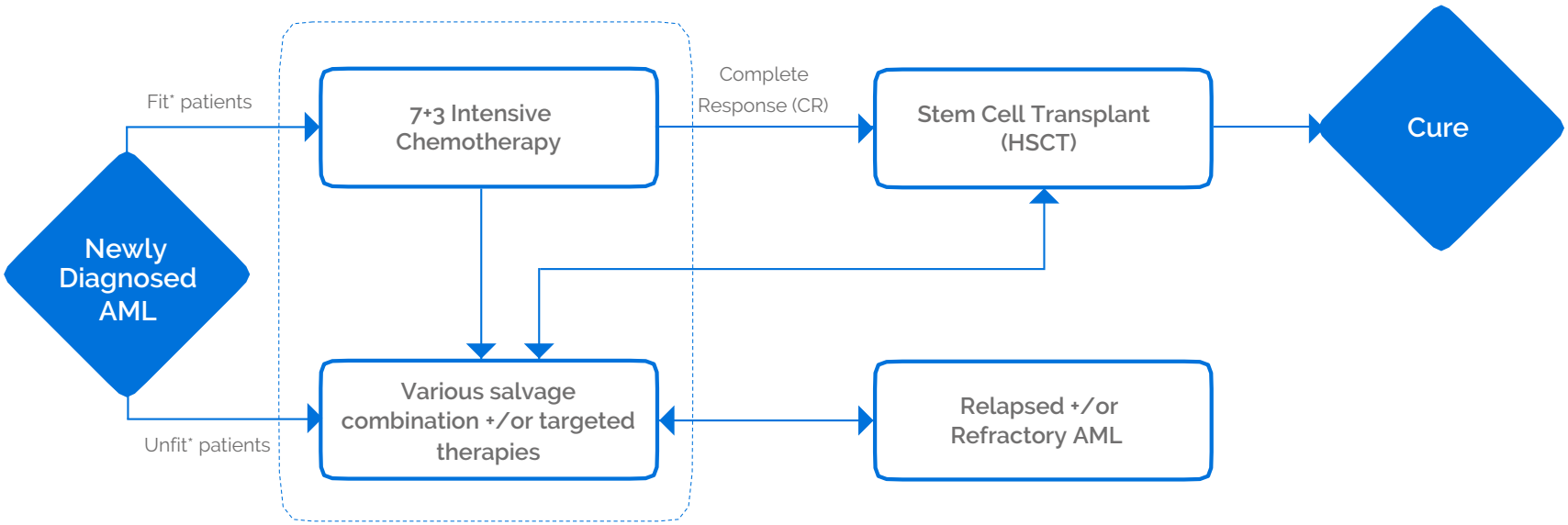
- A single-agent registration trial would be impossible to recruit given the competition for patients
- Also unattractive to licensing partners, because of the length and cost of the trial, and the limited market for a single agent approach in adult R/R AML

NPP opportunities are very limited, due to the abundance of clinical trials

- Clinical trials are a 'free' treatment for the patient and doctor
- NPP involves a bureaucratic approval process and payment for the drug

Current AML Treatment

Generalised overview – specific interventions vary greatly

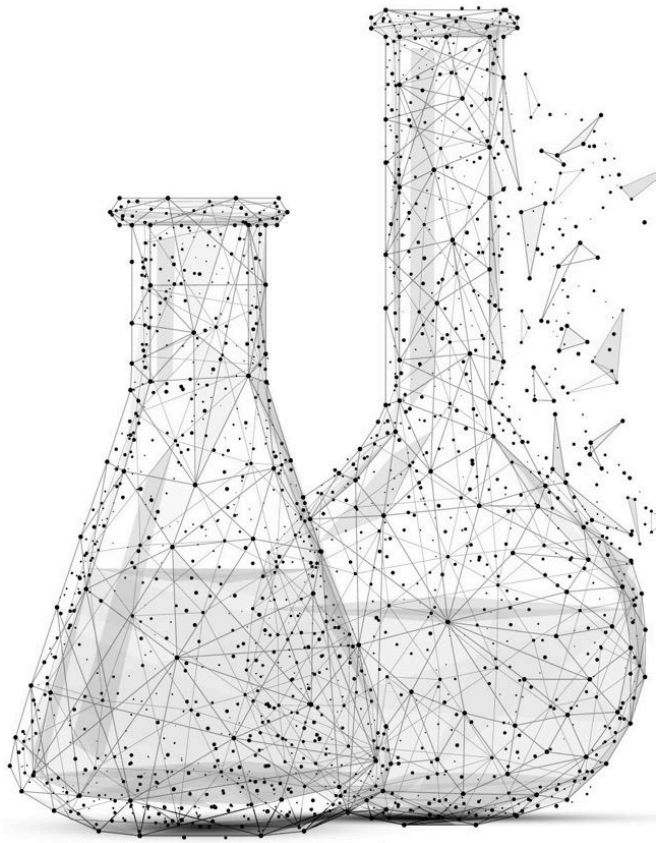


Treatment now dominated by combination therapies

* refers to 'fitness' for intensive chemotherapy

The new clinical strategy for Bisantrene

In October, Race held a company-wide strategy meeting in Houston (Texas) with consultants and advisors to develop a new strategy for Bisantrene



Two pillars of new strategy

Exciting new preclinical data was presented that shows synergy between Bisantrene and other agents in AML; similar synergies expected in other cancers

Bisantrene has a valuable opportunity in combination therapy in AML and other cancers

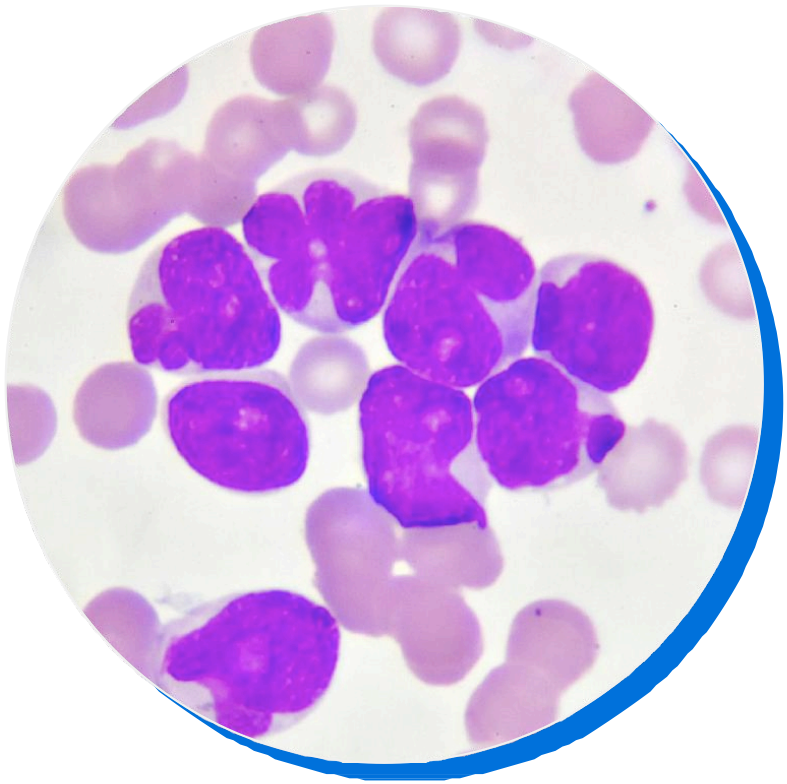
There is an exciting opportunity for Bisantrene to be used earlier in the AML treatment cycle, in a unique positioning for treating 'MRD' status

Measurable Residual Disease (MRD) is a major problem in AML and Bisantrene is the potential solution – could represent a 'real breakthrough'

The combination opportunity

Previous research (Lederle/NCI) showed that Bisantrene has differential activity over other chemotherapy agents

How does it stack up today using modern research techniques?



The combination opportunity

New preclinical data from ongoing research sponsored by Race shows

- Bisantrene has excellent activity in drug resistant AML cell lines with cancer mutations associated with poor patient prognosis
- Bisantrene has synergy with cytarabine (backbone of AML treatment), as well as nucleoside analogues and targeted drugs

Exciting potential for a series of proof-of-concept (POC) combination trials

- Adult R/R AML
- Paediatric R/R AML
- Breast cancer
- Ovarian cancer and/or other cancers

Recent clinical studies have demonstrated the importance of eliminating measurable residual disease (MRD) in AML patients

Why is MRD so important for curing AML patients and what can be done?

The MRD opportunity

The MRD opportunity

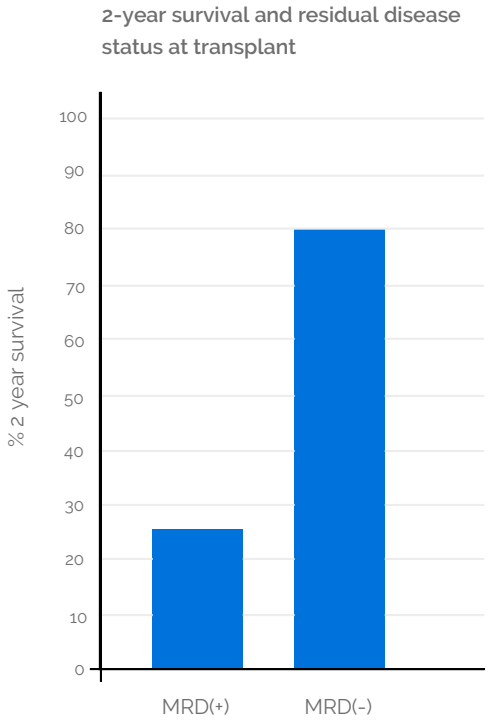
Up to 80% of AML patients who are fit enough for induction chemotherapy (3+7) with go into remission (CR) and may then be candidates for a human stem cell transplant (HSCT)

Whether the transplant is successful depends largely on the patient's MRD (Measurable Residual Disease) status at the time:

- MRD(+) patients (those with MRD) have less than 25% two-year survival time
- MRD(-) patients have a 80% survival post transplant = potential cure!

As yet, there are no approved treatments that can change MRD status from (+) to (-) for AML

- Bisantrene is potentially the answer



The MRD opportunity for Bisantrene

Proposed trial

- Patients that are still MRD(+) after induction chemotherapy receive Bisantrene treatment before receiving transplant
- Goal is to convert patients from MRD(+) to MRD(-) status and improve survival

US Key Opinion Leaders (KOL) have indicated that this would represent a 'breakthrough' in the treatment of AML

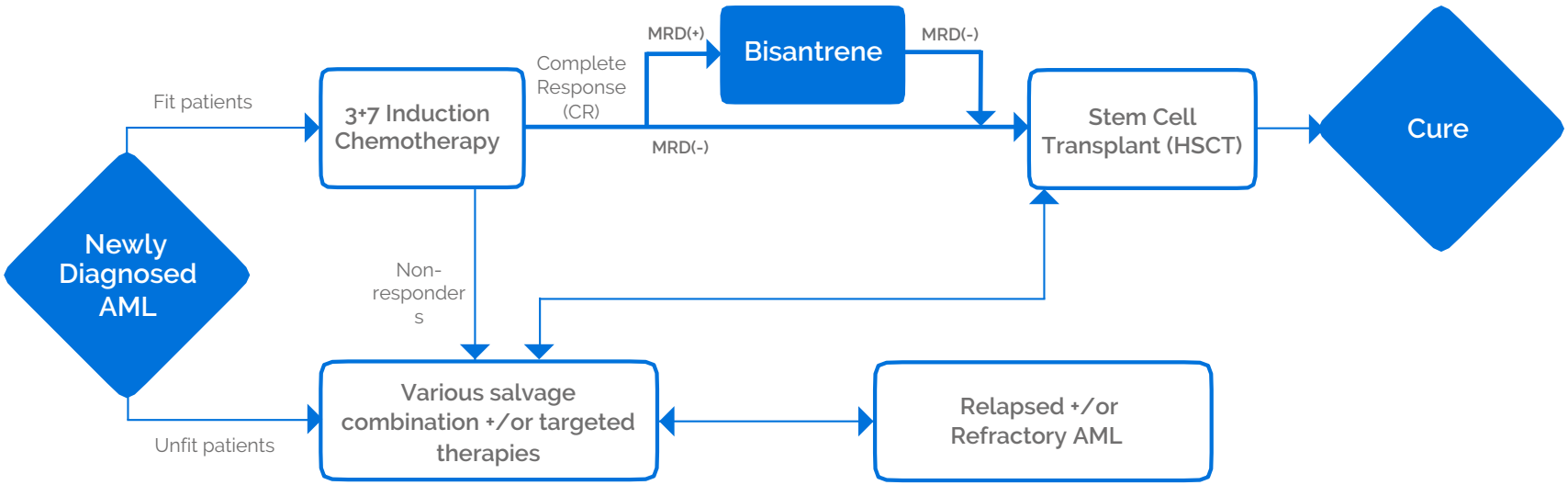
- Trial could lead to important publications, high visibility in the AML market and potentially early FDA approval for Bisantrene

The MRD positioning would put Bisantrene near the top of the AML treatment pathway

- Much larger market opportunity than R/R AML
- Easier to treat patient population
- Much more attractive for licensing partners

Bisantrene in AML treatment
for MRD

Bisantrene could transform cure rates by changing MRD status



Bisantrene's
new 5 Path strategy

1

Phase II MRD trial to advance Bisantrene towards FDA approval under the 505(b)(2) pathway in adult AML patients who are in CR but still MRD(+) (USA)

2

Phase I/II combination trial for adult R/R AML (Australia)

3

Phase I/II combination trial for paediatric R/R AML (Australia/USA)

4

Phase I/II combination trial for breast cancer (Australia)

5

Phase I/II combination trial for ovarian or other cancers (Australia)

1 Phase II MRD trial

Phase II study of Bisantrene treatment after (7+3) induction chemotherapy to change MRD status

Aim to run trial in USA in partnership with a leading US cancer center

Eligibility

MRD(+) patients in CR after induction chemotherapy

Study Design

Open label 7-day Bisantrene 250mg/m^2/day treatment

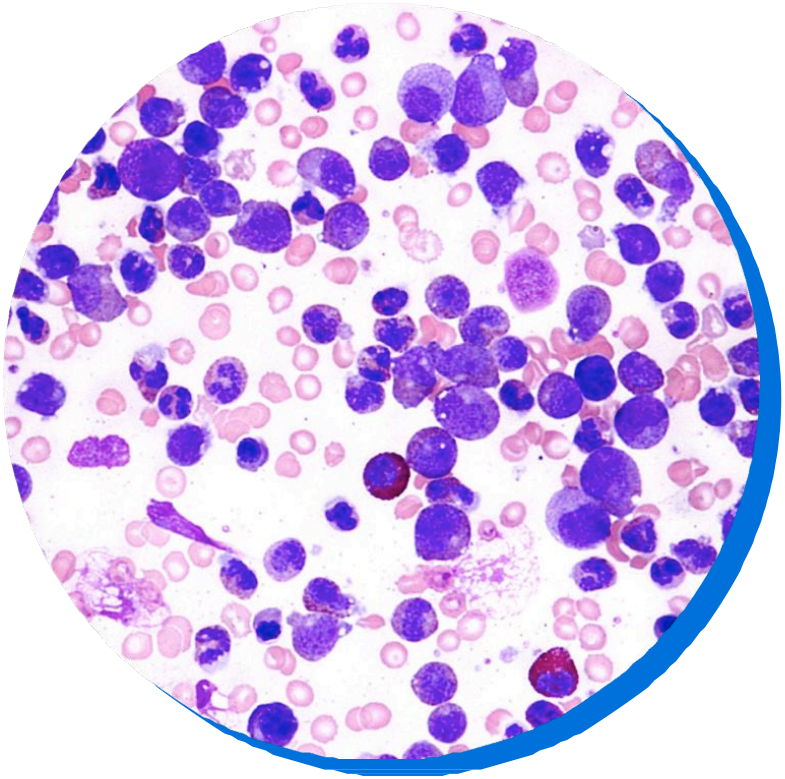
Endpoints

MRD status post-Bisantrene treatment

Post-transplant survival

Goal

Early FDA approval of Bisantrene for MRD(+) patients



2 Bisantrene adult R/R AML trial

Phase I/II Bisantrene combination AML study
Bisantrene plus other approved AML treatments

Aim to run trial in Australia
Lower cost
Does not require IND
R&D Tax credits (43.5% cash rebate)

Eligibility
All AML patients after first relapse

Endpoints
Pharmacokinetics, dosage and safety of the drug combination
CR and progression free survival

Goal
Attract partner for Phase 3 trial

3 Bisantrene paediatric AML trial

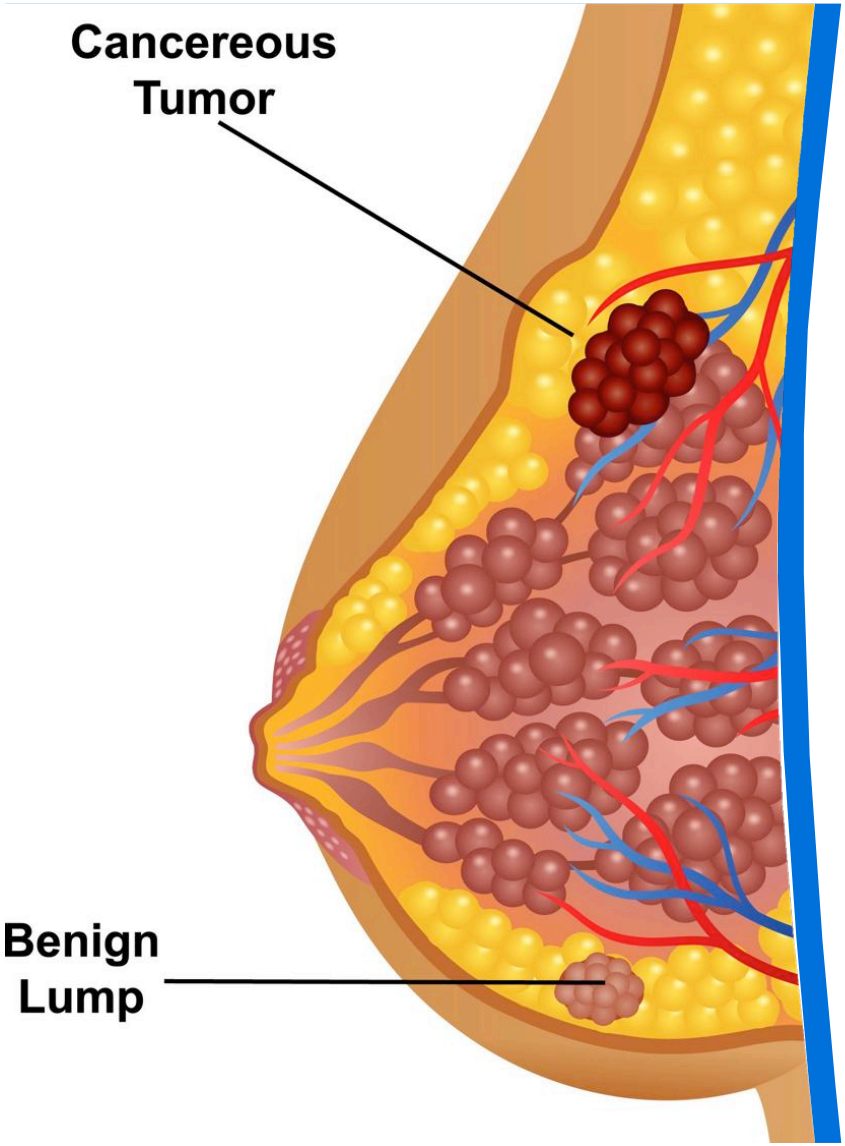
Phase I/II paediatric AML Bisantrene combination study
Bisantrene plus other approved AML treatments

Aim is to run trial in US and Australia under IND
Small trial – expected 25-40 patients

Eligibility
Childhood AML patients who meet 'rare paediatric disease' criteria under Race's RPD/PRV designation

Endpoints
Pharmacokinetics, dosage and safety of the drug combination in children
CR and progression free survival

Goal
Gain approval for Bisantrene in US for Rare Pediatric Disease and secure PRV
PRVs can be sold on secondary market (range US$75-$150 million)



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Breast cancer combination trial

Phase I/II proof-of-concept (POC) trial in breast cancer
Will use drug combinations which preclinical data show synergise with Bisantrene (studies ongoing)

Uses optimal dosing and administration of Bisantrene
Historical breast cancer trials used sub-optimal dosing and administration of Bisantrene (but still showed good activity!)

Aim to run trial in Australia
Lower cost
Does not require IND approval from FDA
R&D Tax credits (43.5% cash rebate)

Goal
Opens up much larger cancer market than AML (2 million cases each year)
POC trial to attract pharmaceutical partner for approval trials

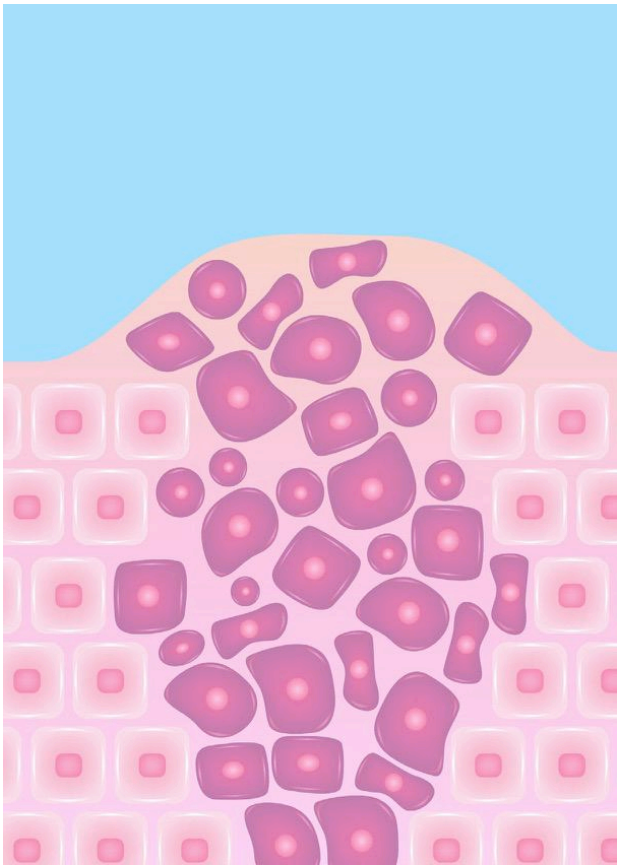
5 Ovarian or other cancer trial

Phase I/II proof of concept (POC) trial in ovarian or other cancer
Preclinical trials to be performed to identify those cancers that respond most to Bisantrene and which drug combinations show synergy

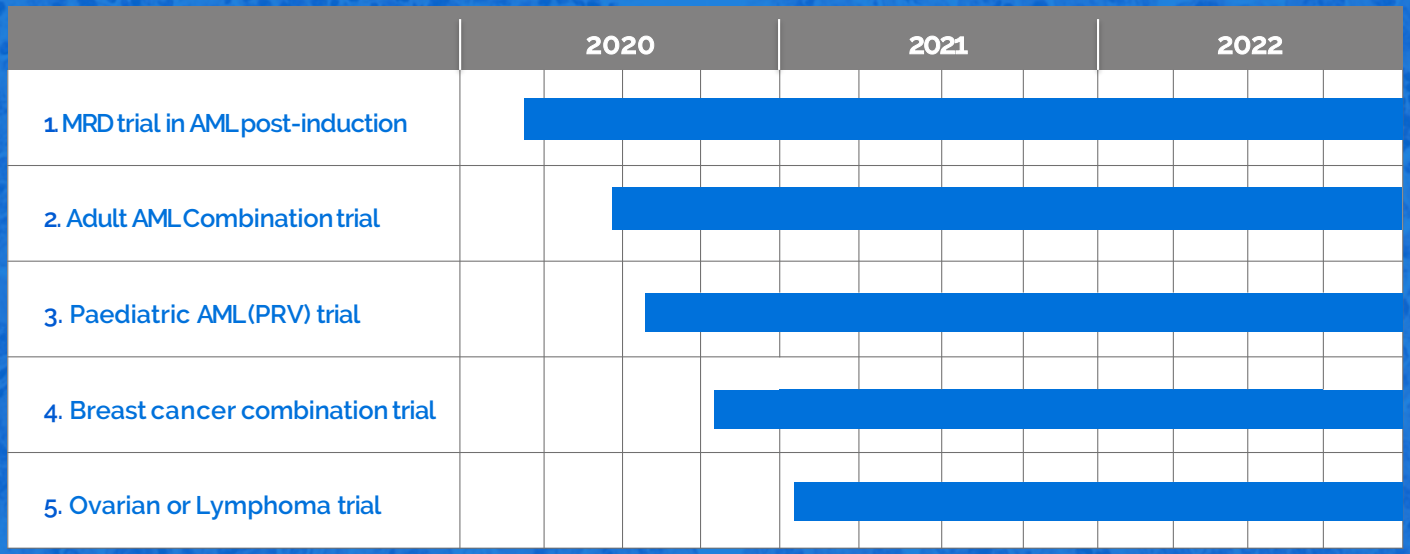
Uses optimal dosing and administration of Bisantrene
Historical non-AML cancer trials all used sub-optimal dosing and did not use combinations, but still showed activity for Bisantrene

Aim to run trial in Australia
Lower cost
Does not require IND approval from FDA
R&D Tax credits (43.5% cash rebate)

Goal
Opens up much larger cancer market than AML (2 million cases each year)
POC trial to attract pharmaceutical partner for approval trials



Race Oncology
clinical plan



Actual timings subject to site recruitment, IRB approval and other factors


The new Race Oncology
strategy

MRD and the synergy discoveries point to an exciting role for Bisantrene in early treatment of AML and for combination use in AML and other cancers

- These opportunities require earlier-stage clinical trials to establish POC
- Race has existing drug product available to complete these studies
- Refocus on earlier-stage proof-of-concept studies, not a large Phase III trial
- Minimises manufacturing and clinical costs – no need for a deep-pocketed partner to fund the POC trials
- Faster speed to market – no need to recruit hundreds of R/R AML patients
- Wherever possible, studies will be conducted in Australia to attract R&D tax credits and build local KOL support – NPP will become a secondary priority
- Current Israel investigator study – focus on demonstrating safety of Bisantrene in a contemporary R/R AML study
- Paediatric AML (and the PRV opportunity) remains a high priority
- Race continues to actively pursue funding and clinical partners for the paediatric trial

Benefits
of the 5 Path plan

1

De-risked

Multiple value pathways, rather than a single trial in adult R/R AML that would be impossible to recruit and with a binary outcome that is several years away

2

Faster clinical outcomes with multiple opportunities

Potential for early approval and/or a pharma deal will be greatly enhanced

3

Extends value of Bisantrene beyond AML

Potential in larger cancers markets such as breast

Expands Bisantrene's value proposition and the pool of potential partners

4

Focus for most clinical studies will shift to Australia

R&D tax credits (43.5%)

Studies can be conducted without the barriers of an IND

Overall costs of the new strategy will be modest and within budget

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