

For personal use only



AGM Presentation | Managing Director  
Peter Molloy  
November 2019

For personal use only

# Corporate snapshot

## SHARES ON ISSUE

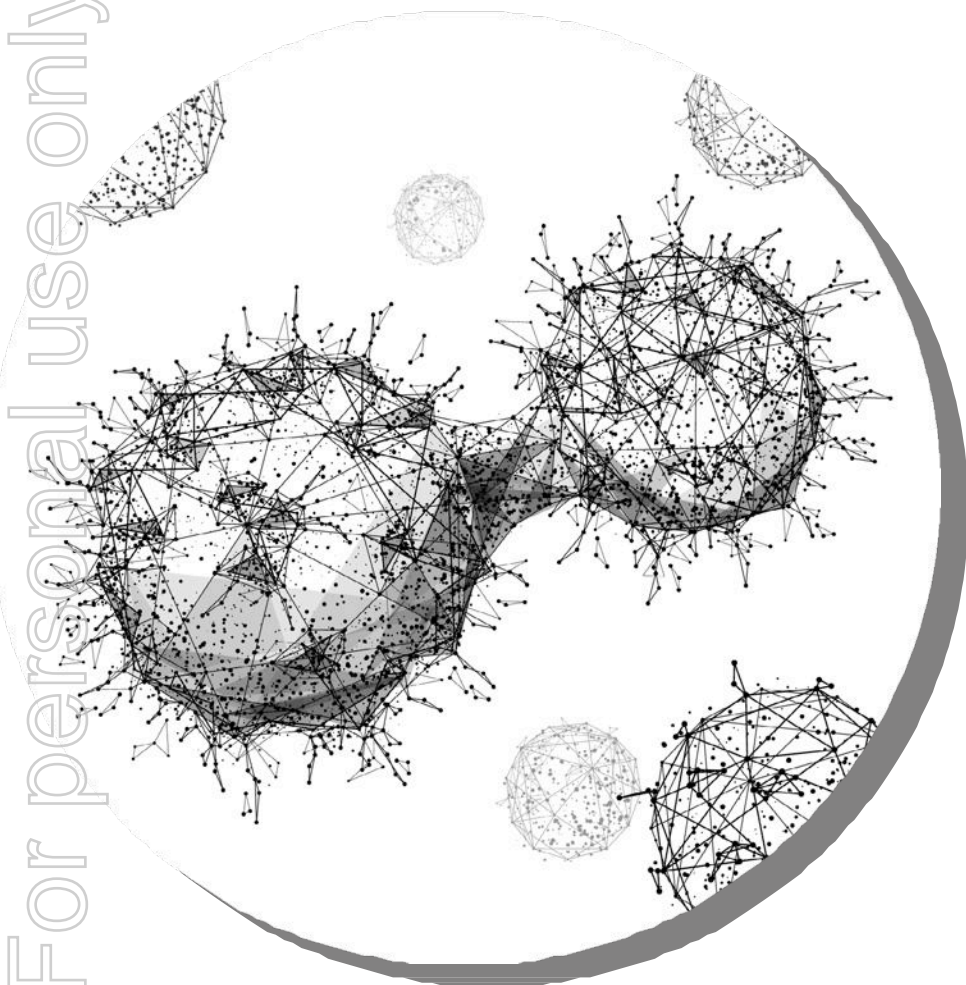
Shares issued	109 m
Options issued (excl. 4m expired 22 Nov 2019)	38 m
Shareholders (at 15/11/19)	903

## MARKET CAPITALISATION

Share price (30-day VWAP to 15 Nov '19)	\$0.127
Market value	\$14.7 m
Cash (15 Nov '19)	\$1.7 m
Enterprise value (EV)	\$13.1 m

## SIGNIFICANT SHAREHOLDERS

Bill Garner (Chair)	16.2%
Daniel Tillett (Director & CSO)	8.3%
Total shares held by directors	31.8%



# 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

Since then, Race has:

- Successfully manufactured Bisantrene
- Built a strong patent position (3 granted)
- Owns US Orphan Drug designation (7 years exclusivity)
- Secured Rare Paediatric Disease (RPD) designation with the potential to receive a 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

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

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

Develop Bisantrene for paediatric AML under the RPD designation and win a PRV valued at around US\$100m

In parallel, generate usage and revenues through a Named Patient Program (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 clinical opportunities for Bisantrene**



# How the AML landscape has changed



Up to 2017, 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 underway
- 216 different drugs being trialled
- Many trials, few patients – competition for trial patients is intense, especially in 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 competition for patients
- Also unattractive to licensing partners, because of the length and cost of the trial, and limited market for a single agent therapy in adult R/R AML

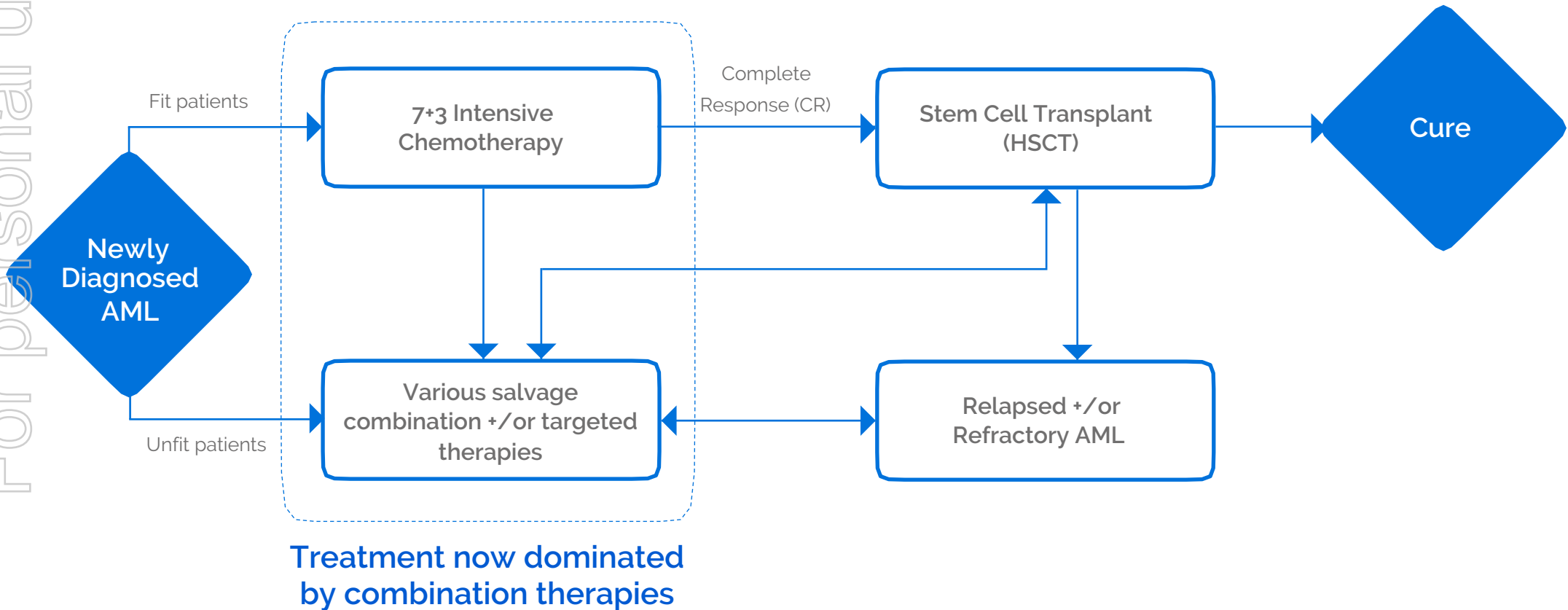


NPP opportunities are very limited, due to the abundance of clinical trials

- 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



# The new 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, called the '5 Path' strategy

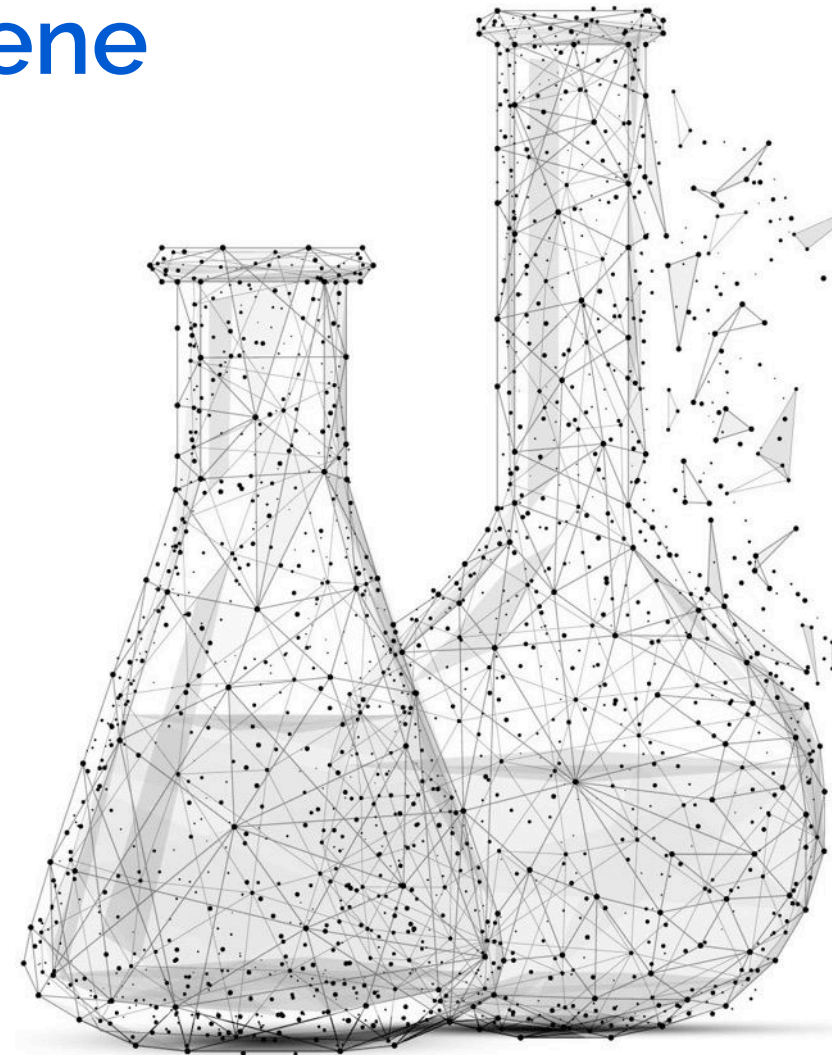
## Two pillars of new strategy

New preclinical data was presented showing 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 – potentially a 'real breakthrough'***





For personal use only

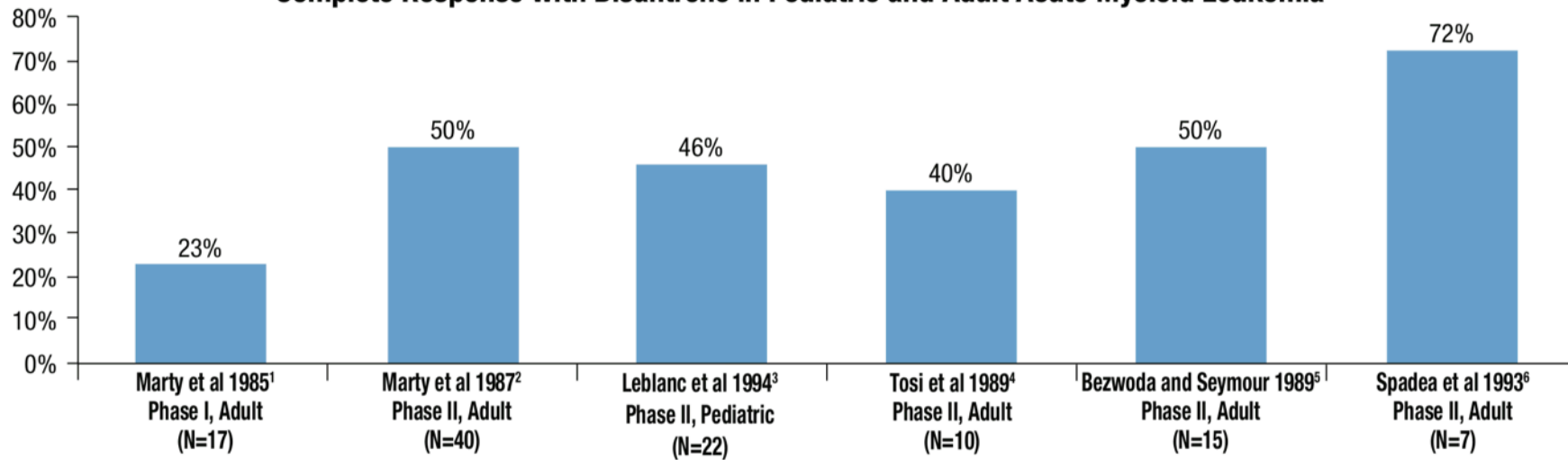


Chief Scientific Officer  
Daniel Tillett  
November 2019



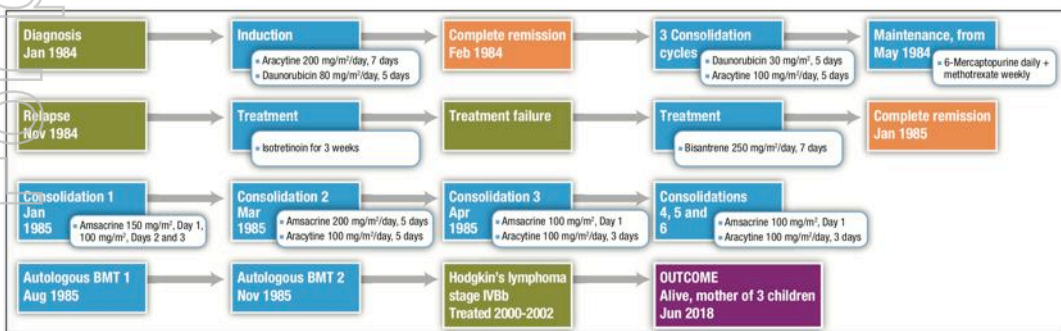
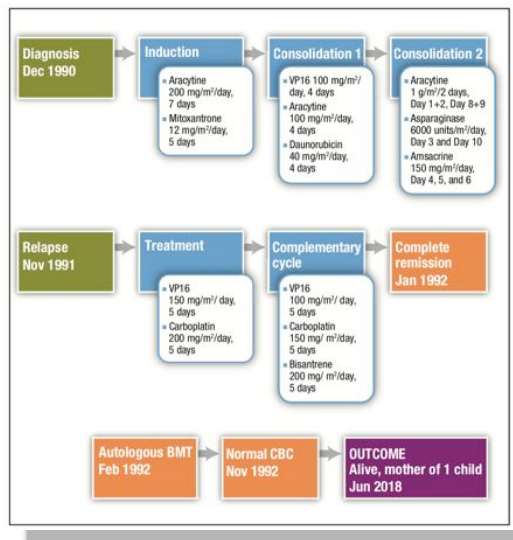
# Why Bisantrene?

**Complete Response with Bisantrene in Pediatric and Adult Acute Myeloid Leukemia**



# Why Bisantrene?

- Bisantrene cured two French girls with AML in the 1980 & 90s
- Both girls are alive today and have their own families



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) will go into remission (CR) and may then be candidates for a human stem cell transplant (HSCT)

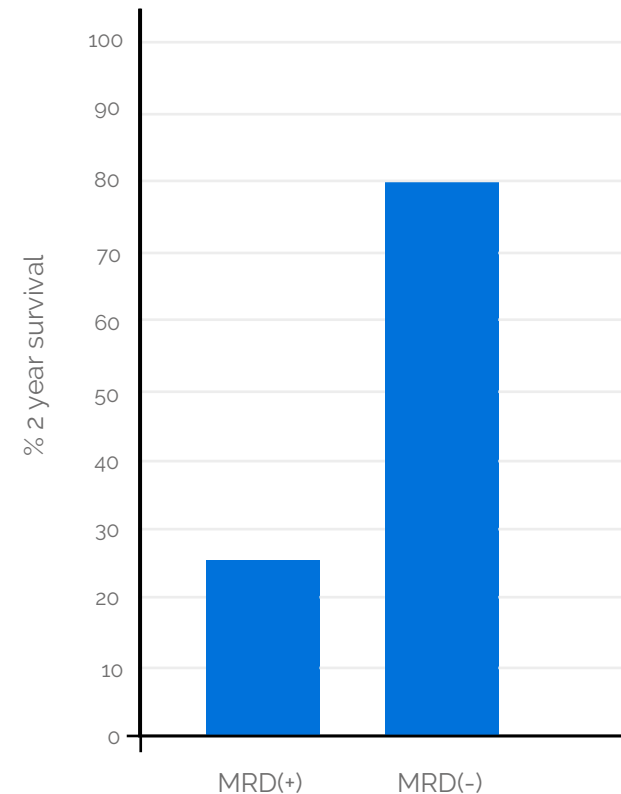
Whether the transplant is successful depends largely on the patient's MRD (Measurable Residual Disease) status at the time of transplant

- 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

2-year survival and residual disease status at transplant



# 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

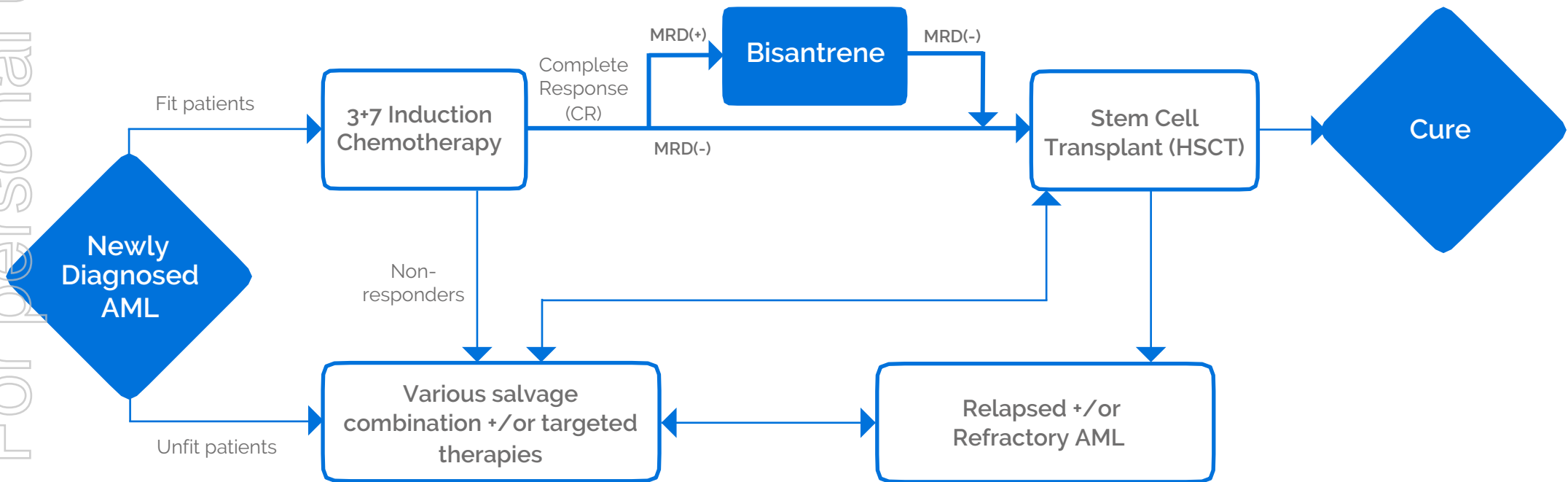


## The MRD positioning would put Bisantrene near the top of the AML treatment pathway

- 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

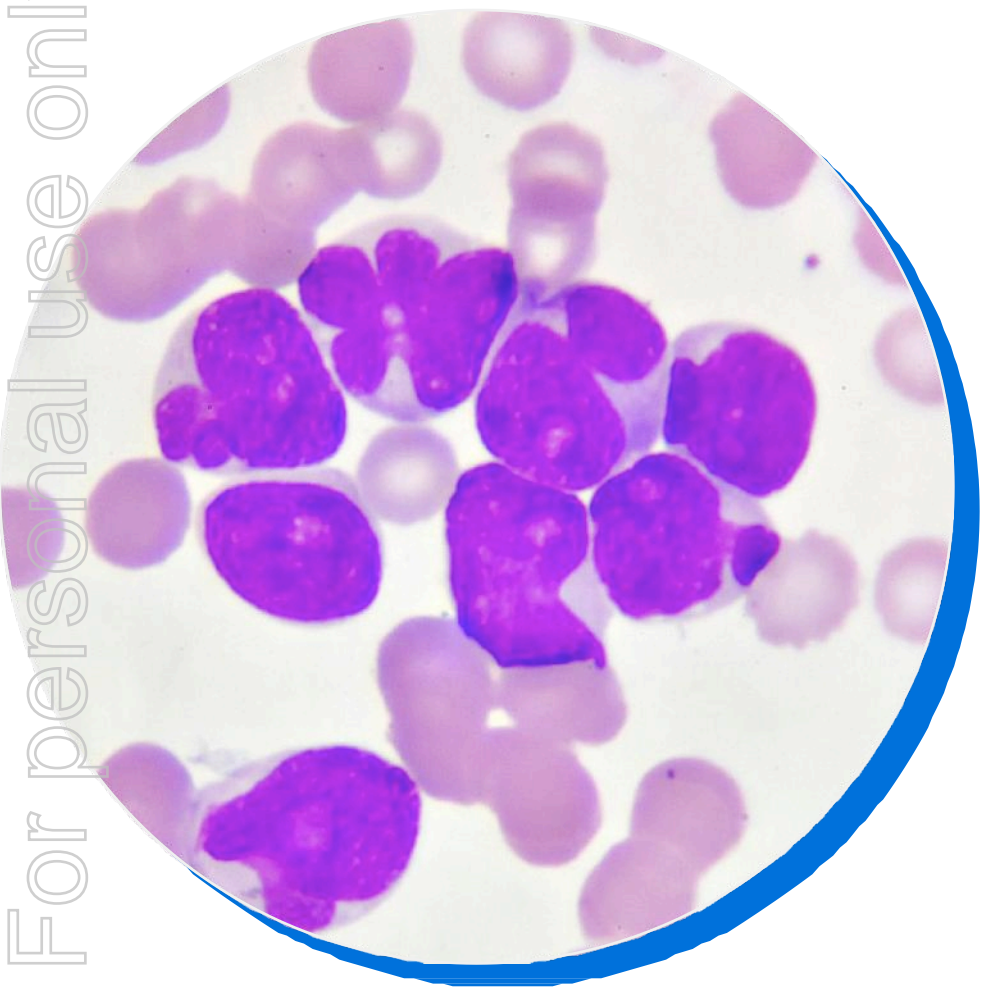


# The combination opportunity

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



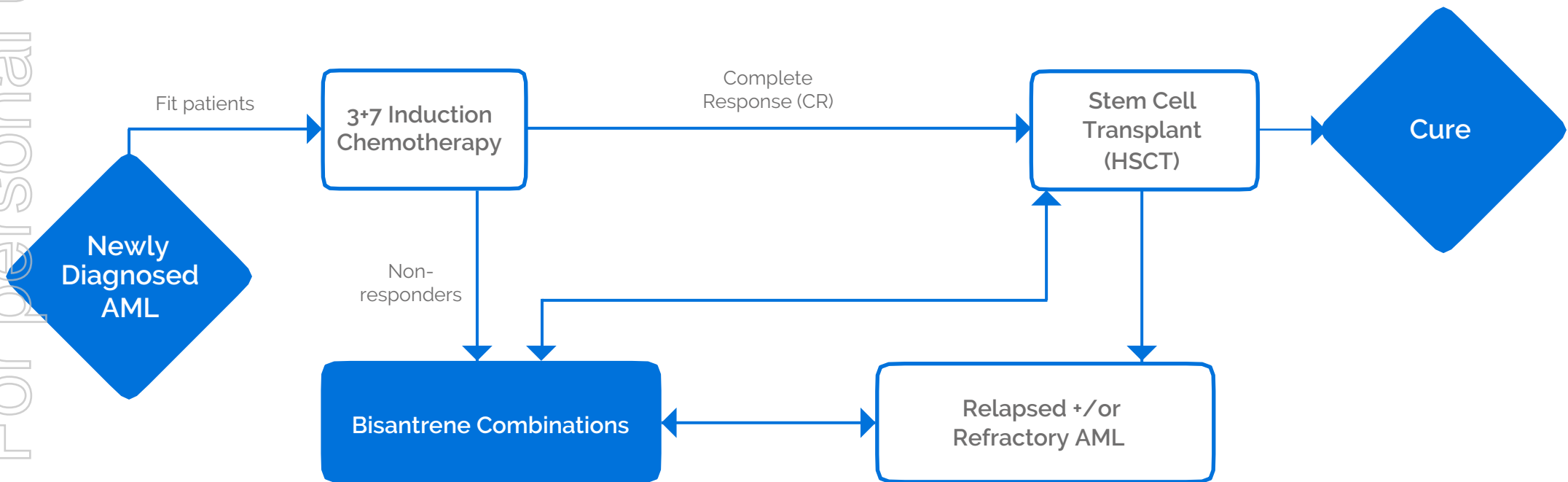
Exciting potential for a series of **proof-of-concept (POC) combination trials**

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



# Bisantrene combinations in AML Treatment

Bisantrene could transform R/R AML treatment



# 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)



# 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<sup>2</sup>/day treatment



## Endpoints

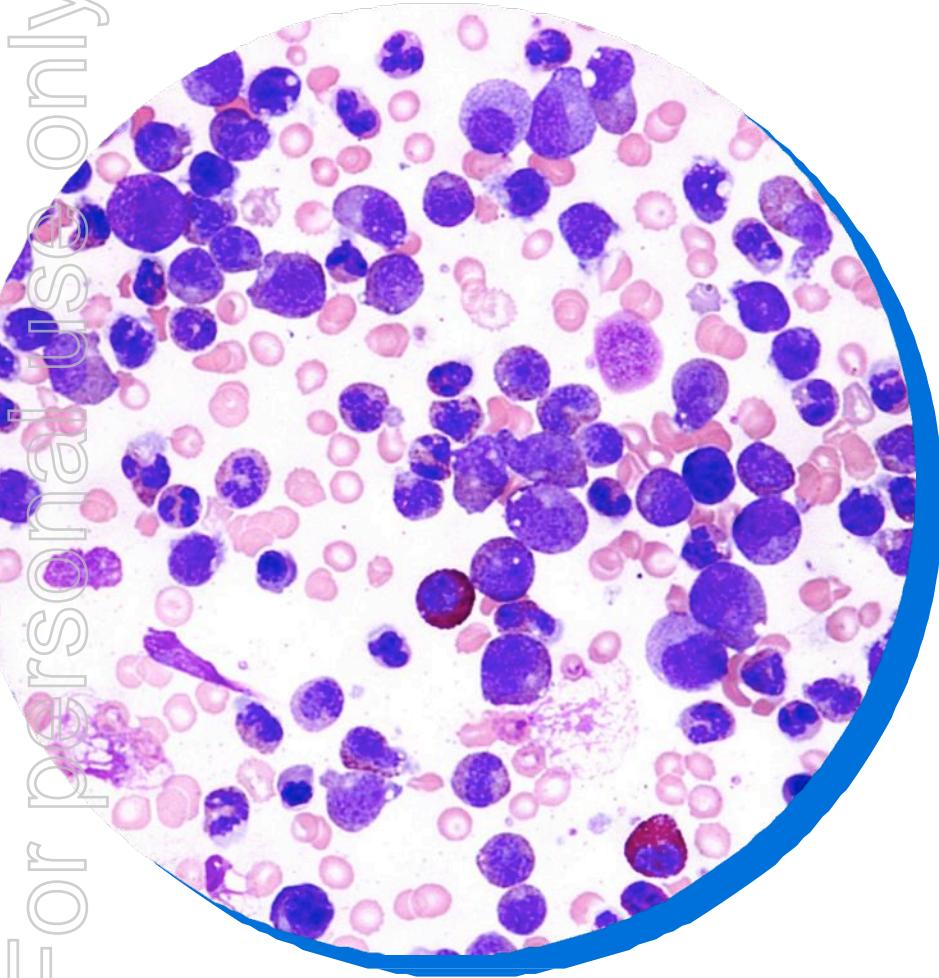
MRD status post-Bisantrene treatment  
Post-transplant survival



## 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



# 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)

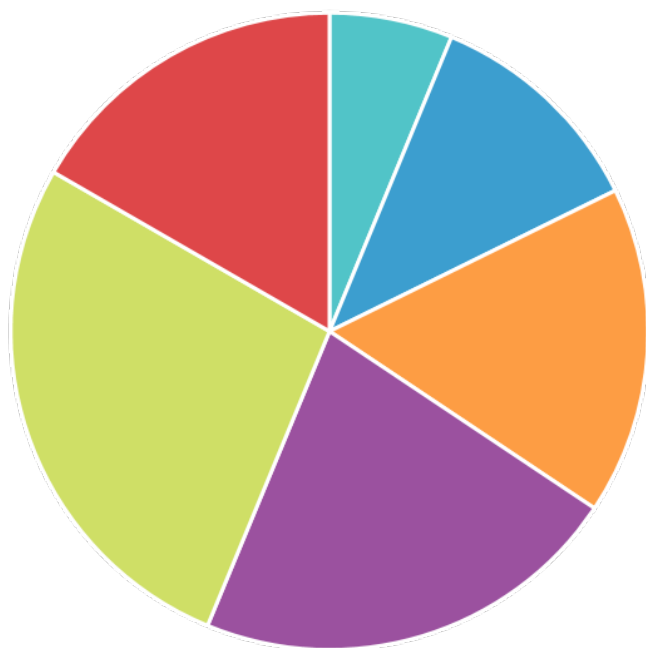




# Bisantrene

## other cancers

Doxorubicin Market: Revenue Share (%), By Application, Global, 2018



■ Bladder Cancer ■ Kaposi Sarcoma ■ Leukemia ■ Lymphoma ■ Breast Cancer ■ Others

Source: Mordor Intelligence



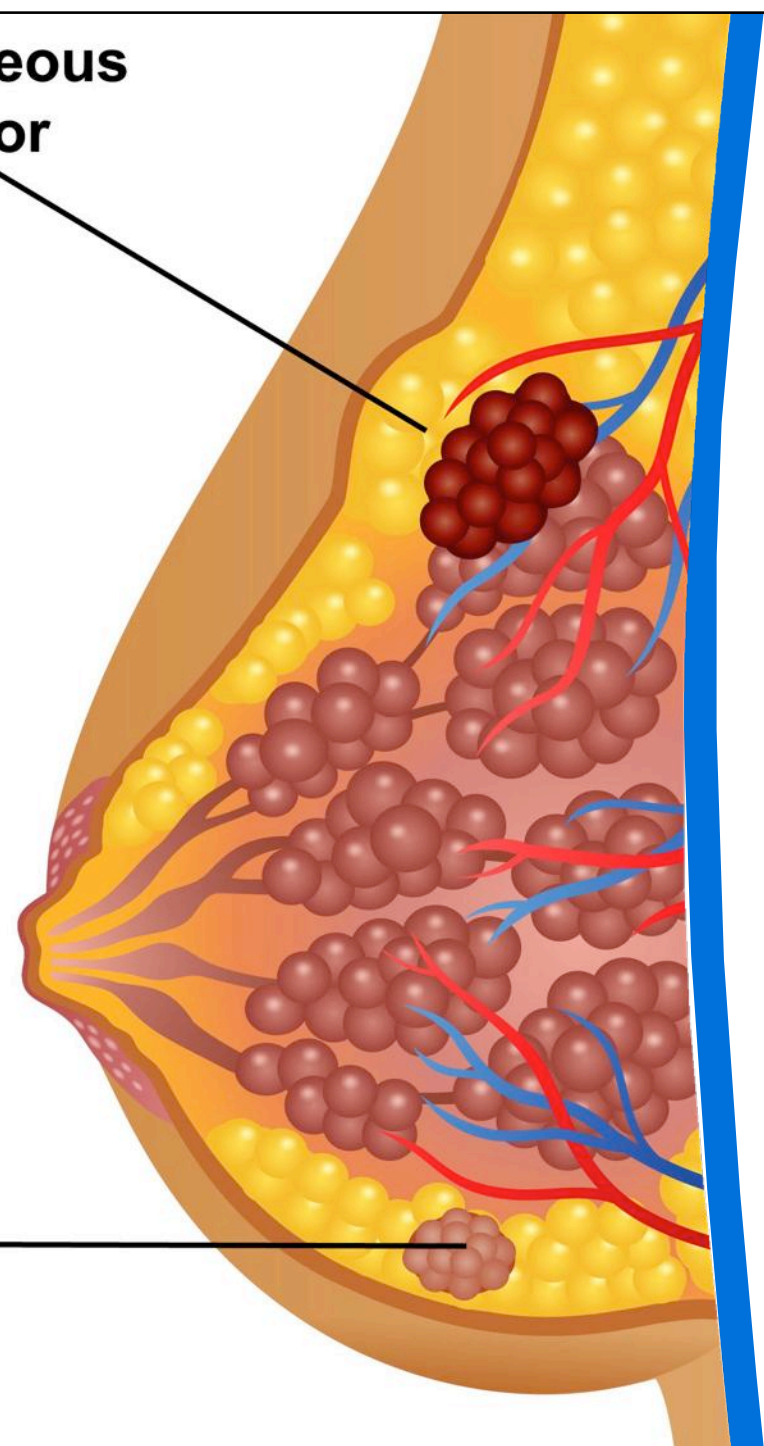
### Major Players

- 1 Zydus Cadila
- 2 Johnson and Johnson
- 3 Cipla
- 4 Pfizer Inc.
- 5 Sun Pharmaceutical Industries Ltd.



For personal use only

**ancereous  
Tumor**



# Breast cancer combination trial



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



**Uses optimal dosing and administration of Bisantrene**  
Historical breast cancer trials used sub-optimal dosing and administration of  
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 every year)  
POC trial to attract pharmaceutical partner for approval trials





# 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

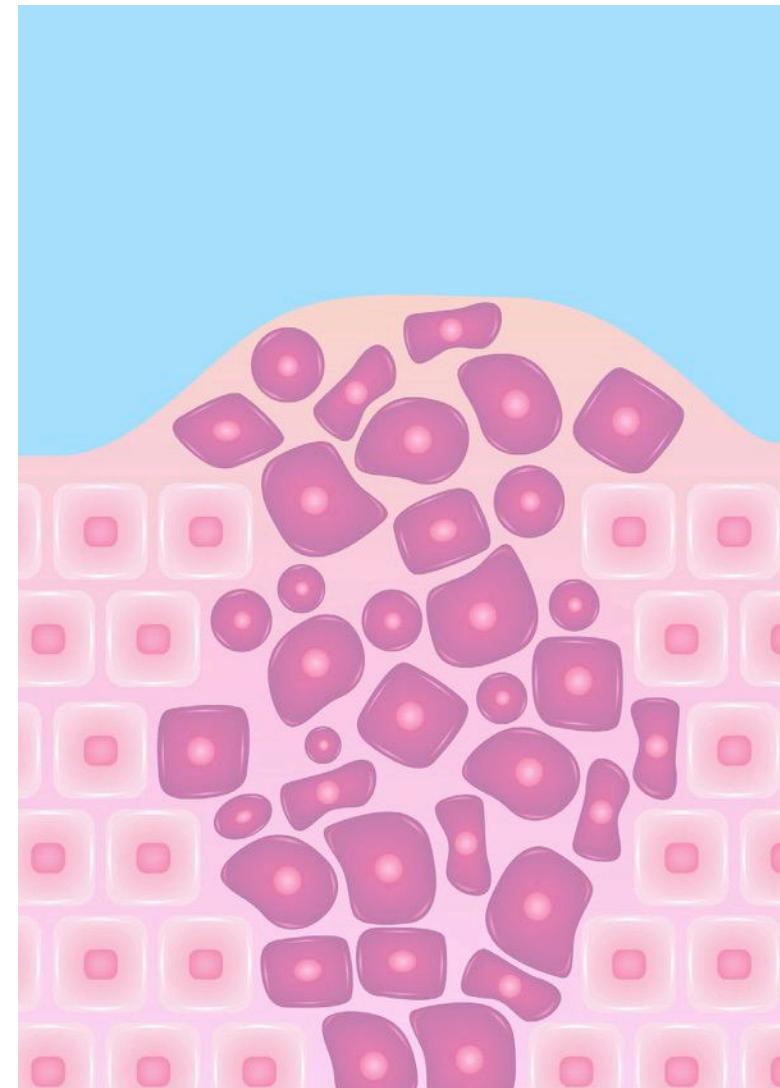
Does not require IND approval from FDA

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



# Case study

## ivosidenib

Approved by the FDA in May 2019 for newly diagnosed AML with a susceptible IDH1 mutation [1]

Early approval from a Phase I/II open label trial of 28 patients  
43% CR/CRi [2]

### Small Market

700 – 1100 patients in the USA per year

### Total Sales

US\$300 million per year [3]

1. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-first-line-treatment-aml-idh1-mutation>

2. <https://clinicaltrials.gov/ct2/show/NCT02074839>

3. <https://www.fiercebiotech.com/special-report/20-tibsovo>



# Case study

## gilteritinib

Approved by the FDA in November 2018 for relapsed or refractory AML with a FLT3 mutation [1]

Approval of gilteritinib based on an interim analysis of the ADMIRAL trial [2]

138 adult patients having a FLT3 ITD, D835, or I836 mutation  
CR/CRi ~21%

### Small Market

10% of all AML patients  
~1000 patients in USA per year

### Total Sales

Cost US\$400,000 per year per patient [3]

1. <https://www.fda.gov/drugs/fda-approves-gilteritinib-relapsed-or-refractory-acute-myeloid-leukemia-aml-flt3-mutation>

2. <https://clinicaltrials.gov/ct2/show/NCT02421939>

3. <https://www.drugs.com/price-guide/xospata>



# Benefits of the 5 Path plan



## RAC value driver

- Expands the market for Bisantrene by up to 20x
- Early approval potential
- Reduced binary risk
- Increased news-flow



## Partnering value

- Larger market expands pool of potential partners
- Bisantrene is more attractive to potential partners



## Clinical focus Australia

- Faster (early-stage) clinical outcomes without IND barriers
- Lower cost, especially at current x-rate
- R&D tax credits virtually halve trial costs again



# Expanded market potential for Bisantrene

## AML remains key market for Bisantrene

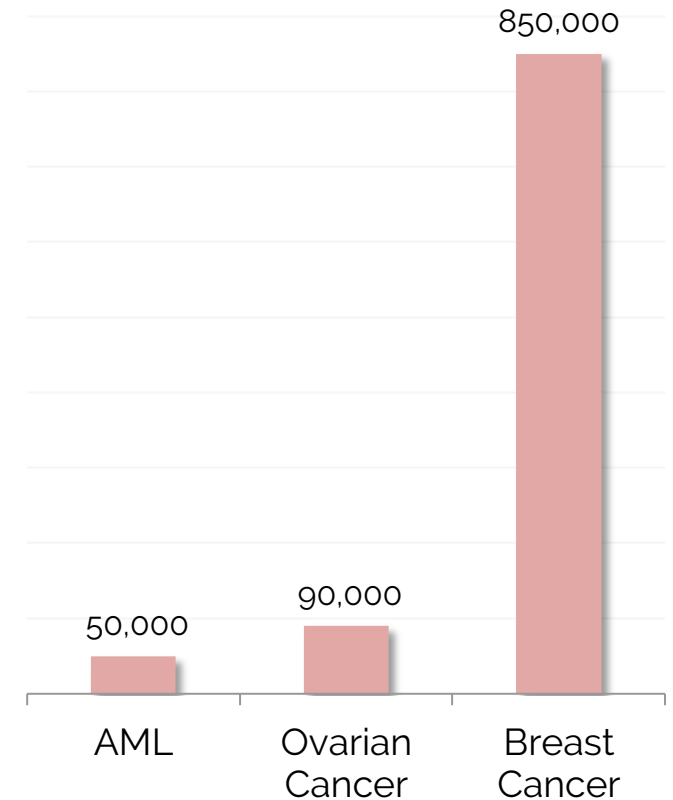
- Around 50,000 new cases p.a. and growing due to aging
- Now Bisantrene will target 3 AML segments

AML Segment	Annual Cases (US+EU)
Post-induction CR with MRD+	10,000-12,000
Adult R/R AML (combination)	15,000-20,000
Paediatric AML (combination)	1,800

## Bisantrene also targeted at much larger markets

- Combination potential in breast cancer, ovarian cancer and other significant cancer markets

Approx. Annual Cases US + EU





# Partnering is our long term goal

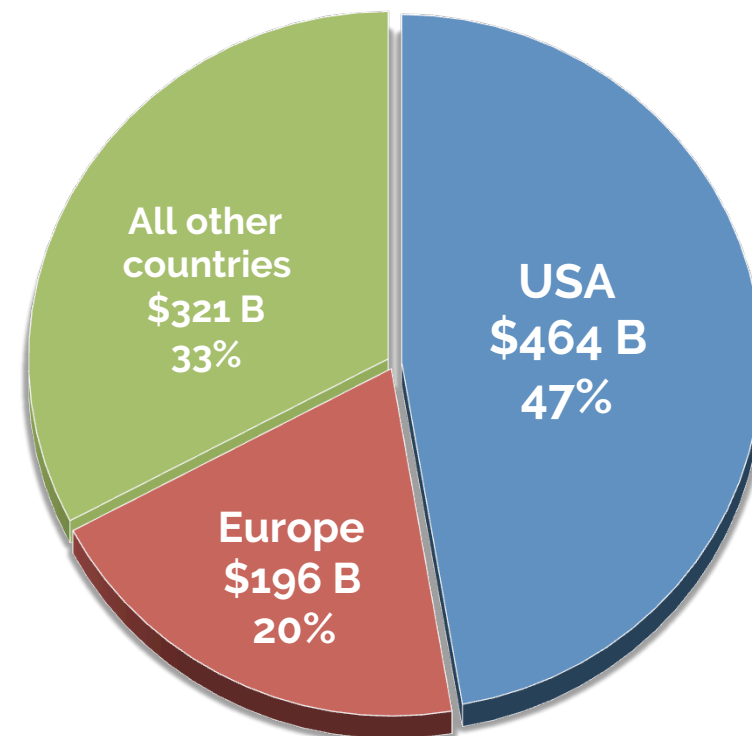
## US remains our key target market

- US has <5% of world population but 47% of global pharmaceutical sales, due to higher pricing (and consumption)
- Partnering deal values are driven by potential in US market

## Bisantrene is well-placed in US

- Three granted US patents covering use in a range of cancers and in combination; our patent portfolio is strong
- Orphan drug designation in AML == 7 years' exclusivity after approval
- Rare Pediatric Disease designation == valuable PRV
- Excellent KOL relationships, including Prof. Borje Andersson at MD Anderson Cancer Center in Houston Texas
- Bisantrene manufacturing based in San Diego CA

2018 Global Pharma Sales US\$





## 5 Path plan

Valuable, affordable, fundable

- Bisantrone's role in cancer has been enhanced and expanded
- Potential for early licensing deal and even early approval after in MRD or one of the proof-of-concept combination trials
- Race is seeking funding from US partners or US grants to support paediatric (PRV) study
- Four planned Australian studies to be part-funded by R&D tax credits (43.5%)



For personal use only



L40 140 William St, Melbourne, VIC 3000

[info@raceoncology.com](mailto:info@raceoncology.com)

+61 3 9098 8750