



INVESTOR PRESENTATION

August 2018

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Corporate Overview

Race Oncology is based in Melbourne Australia

- Listed on ASX July 2016 (RAC) at A\$0.20

Lead Drug Asset: Bisantrene

- Chemotherapy drug aimed at treating *Acute Myeloid Leukemia* (AML); valuable drug lost in pharma mergers in the 1990s
- Race rediscovered and now owns Bisantrene with US Orphan Drug designation (7 years exclusivity) and 2 granted US patents (2034 expiry)

Value Creation Strategy:

1. Generate revenues under a Named Patient Program (NPP) outside the US
2. Gain FDA approval for Bisantrene for adult AML creating a valuable, marketable asset
3. Use *Rare Pediatric Disease* designation to obtain a saleable Priority Review Voucher (PRV)

Corporate Snapshot

Shares on Issue (RAC)

Ordinary		77m
Performance Shares		10m
Options		35m

Market Capitalization (AUD)

Share price (27/7/18)		\$0.20
Market Capitalisation		\$15 m
Cash (30/6/18)		\$3.5 m

Major Shareholders

Update Pharma. Inc.	15 m	19%
Peter Molloy (CEO)	4 m	5%



The target disease: *AML (Acute Myeloid Leukemia)*

AML is a blood cancer caused by proliferation of myeloblasts and a shortage of white blood cells

Progenitor white blood cells (myeloblasts) fail to differentiate into white blood cells

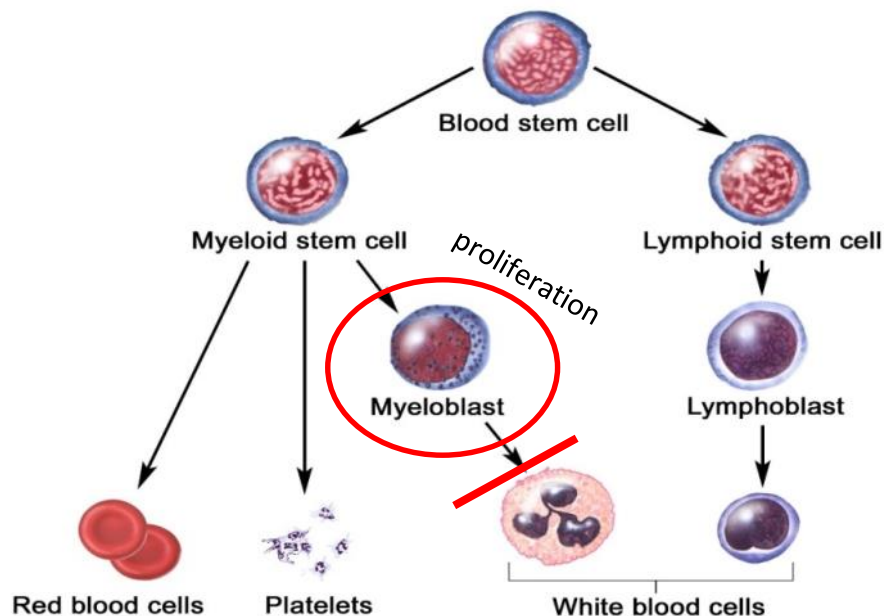
- They proliferate and build up in bone marrow and blood
- Shortage of crucial white blood cells

Rapidly progressive disease

- 74% die <5 years, mainly due to infections or treatment related mortality

Orphan disease

- 20,000 new patients a year in the US
- Disease mainly of the elderly: incidence growing as population ages



r/r AML: Unmet Medical Need

Treatment has not changed significantly in 30 years

- 1st line treatment is '7+3' chemotherapy: 7 days with cytarabine + 3 days with an anthracycline
- There is no approved 2nd line treatment, but multiple drugs in development
- Most treatments eventually fail and the patients relapse (disease returns) and AML becomes refractory (untreatable)

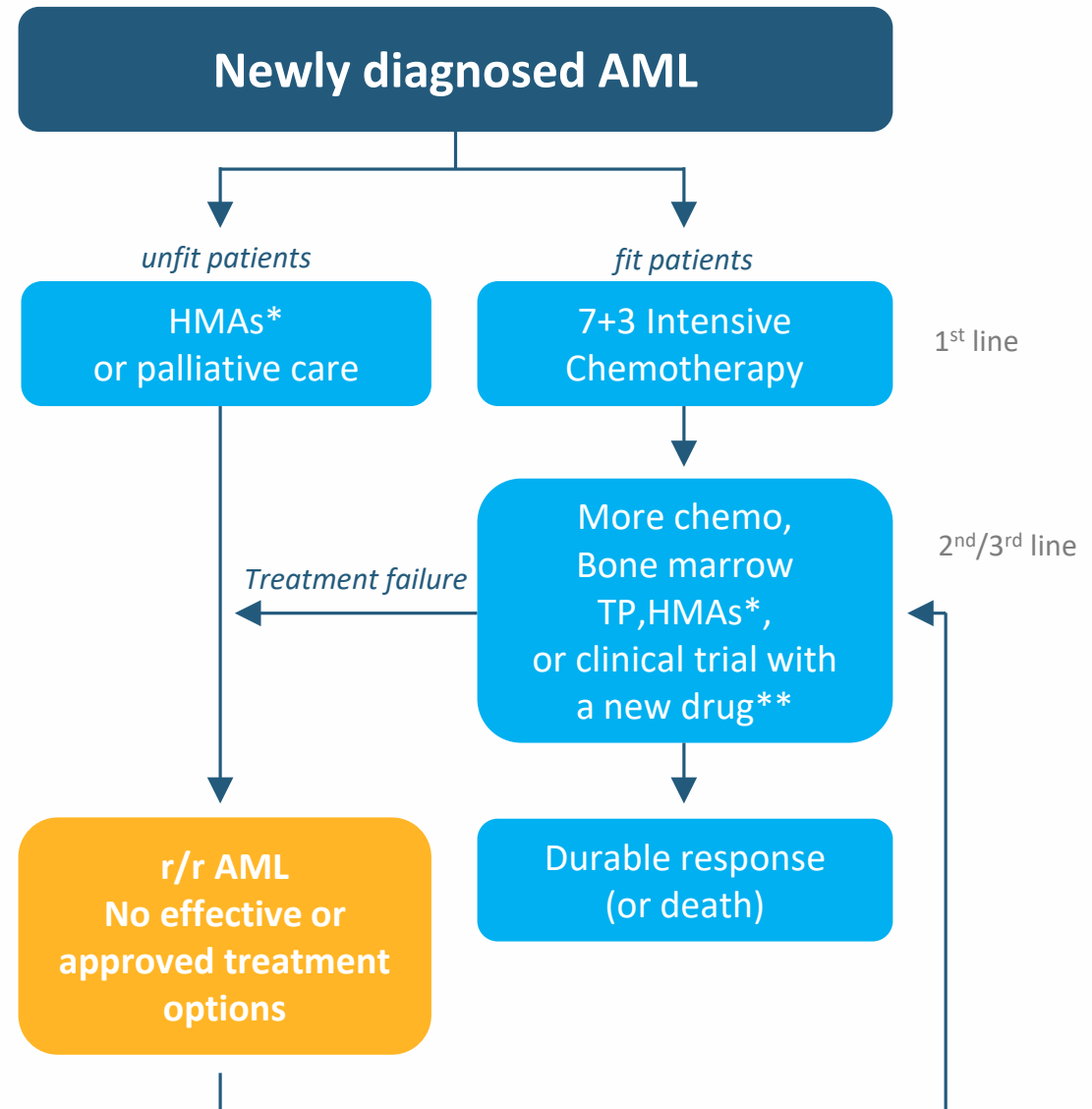
No effective treatment for relapsed/refractory (r/r) AML

- Up to 30% of all AML patients

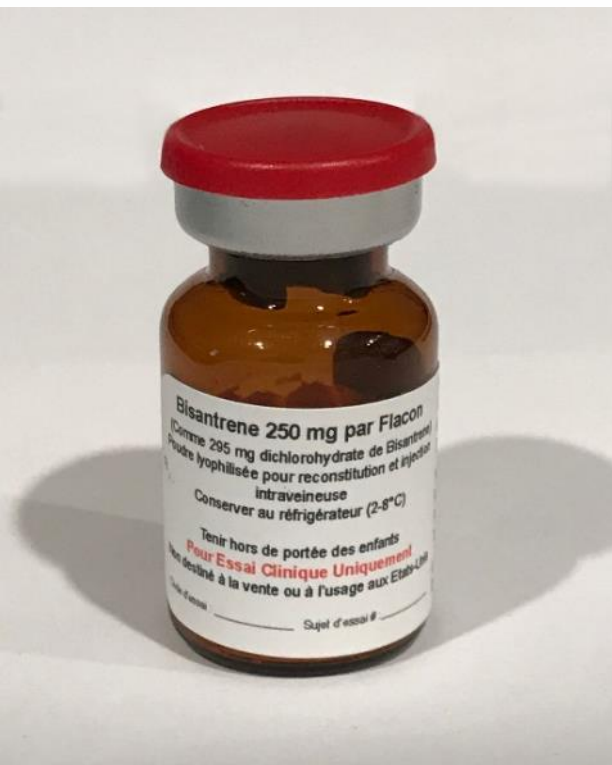
Bisantrene offers new hope for r/r AML

*Hypomethylating agents: azacytidine or decitabine

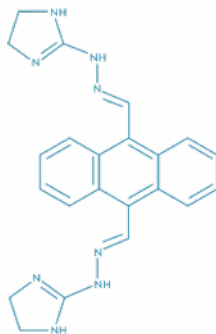
** Targeted drugs aimed at cytogenetic sub-populations



Bisantrene



Bisantrene Dihydrochloride
250mg lyophilised powder
for reconstitution &
infusion
via central venous line



Discovered in the 1970s by Lederle Laboratories (US)

- Small molecule chemotherapy drug similar to the anthracyclines
- Goal: anthracycline performance without the cardiac toxicity

Mode of action

- Cytotoxic (kills rapidly dividing cancer cells)
- Immune-stimulatory and other anti-cancer effects:
 - Activates macrophages to attack cancer cells
 - Binds to DNA displacing telomerase binding proteins, leading to apoptosis of cancer cells (programmed cell death)

Extensively tested during 1980s

- More than 40 phase 2 clinical studies completed by Lederle and the NCI (National Cancer Institute) against a range of cancers
- Bisantrene showed impressive activity in AML and was approved in France for treating r/r AML



Bisantrene in r/r AML

Average 48% remission rates in five AML studies (1987-1994)

- Patients were heavily pre-treated with up to 8 cycles of chemotherapy, i.e., relapsed/refractory

Bisantrene was approved in France in 1988 for treating AML

- But it was never commercialized and the approval was later withdrawn

Treatment of AML has not changed appreciably in more than 30 years

- Opportunity for Bisantrene in AML still exists today

Study	Phase	Number of AML Patients	Complete Response* Rate
Study 1, 1987	II	40	50%
Study 2, 1989	II	10	40%
Study 3, 1989	II	15	47%
Study 4, 1993	II	7	72%
Study 5, 1994	II	13	38%
Total/Average		85	48%

*Generally defined as no myeloblasts detected in the blood and less than 5% in bone marrow



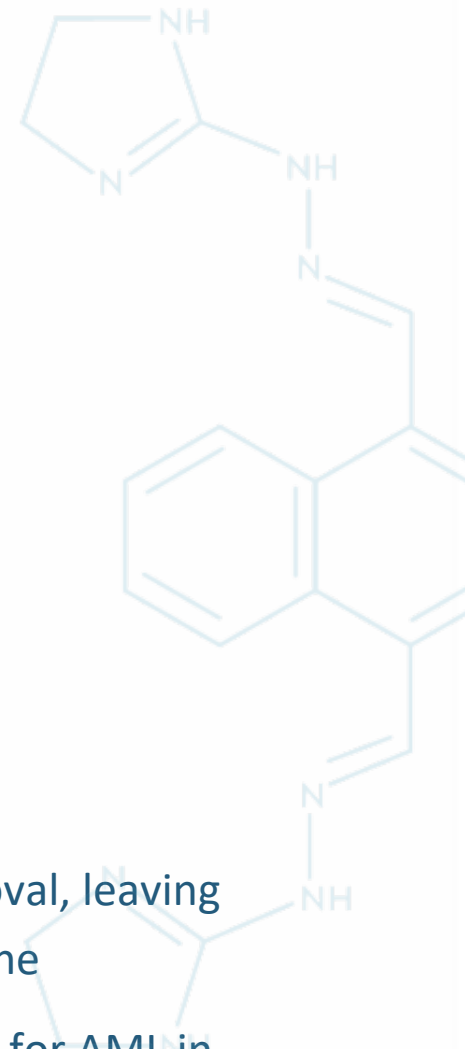
Bisantrene – a lost drug asset

Big pharma mergers in the 1990s

- Around the time of the French AML approval, Lederle's parent company (American Cyanamid) ran into financial problems
- American Cyanamid sold Lederle to Wyeth, which had no oncology franchise
- Wyeth was later sold to Pfizer, but by then the original patents had expired

Bisantrene disappeared for 25 years

- Eventually, the NCI closed their IND and Wyeth/Pfizer withdrew the French approval, leaving Bisantrene as an orphan – a unmarketed generic drug, effectively owned by no-one
- A drug with over 40 clinical trials, 70 peer reviewed publications, and an approval for AML in France, was lost for 25 years...until Race rediscovered it



Bisantrene's rebirth by Race

Commercial protection obtained

- Race obtained orphan drug designation (ODD) for Bisantrene in US, conferring 7 years exclusivity after FDA approval
- Race also filed two new patents that have now been granted in the US, extending Bisantrene's exclusivity out to 2034

GMP drug product successfully manufactured

- Race has manufactured enough GMP finished product to support clinical trials

Expedited approval pathway established

- FDA confirmed that Race can use the historical preclinical/clinical data (2,000 patient database) and not have to repeat the studies
- Race secured rights to the NCI IND data package
- Likely only need a single registration trial to gain FDA approval in adult AML

FDA approval of Bisantrene for the treatment of adult AML would generate a valuable asset that could be monetised in a pharmaceutical transaction



US FDA approval pathway for Bisantrene

Pre-IND meetings with FDA

- Target indication is r/r AML in adults
- Bisantrene qualifies for FDA review under 505(b)(2) expedited approval pathway – allows Race to use the historical phase II data on Bisantrene
- Bisantrene can be considered a phase 3 asset that could be approved after a single pivotal trial

Pivotal trial steps:

- Hire a CRO (contract clinical organisation) to run the trial ✓
- Hire a Chief Medical Officer to oversee the trial ✓
- Gain input from clinicians on a clinical protocol for the adult AML trial ✓
- Develop an international site plan to conduct the trial ✓
- **Next:** File an IND (*Investigational New Drug* application) and gain FDA agreement on the protocol
- Then run the trial and if successful, apply for FDA marketing approval





While completing steps
for FDA marketing approval
of Bisantrene, Race Oncology
plans to generate revenues under
Named Patient Programs outside US



Named Patient Program (NPP)

Early access schemes allow companies to supply an unlicensed (unapproved) drug if:

- Patients have a life-threatening disease with no approved treatment available (r/r AML)
- Patients are nominated by a doctor ('named patient')
- Supply must be unsolicited (no promotion)
- In some countries, it is possible to charge for drug supplied under NPP and generate revenues

Race is currently pursuing NPP supply for Bisantrane in several countries

- France, Italy, Korea and UK
- Each country has unique approval processes for NPP

Value of NPP

- Current clinical usage and experience with Bisantrane
- Revenues to support operational and clinical trial costs – first revenues expected soon





Latest news:
Bisantrene granted Rare
Pediatric Disease designation:
A new value creation pathway



Rare Paediatric Disease (RPD) Designation

16 July 2018: FDA grants RPD designation for Bisantrene

Means Bisantrene can receive a *Priority Review Voucher* (PRV) at the time of marketing approval for childhood AML

- PRV system incentivises companies to pursue rare diseases, such as childhood AML
- The voucher guarantees an accelerated review and can be sold to other companies
- Since 2016, PRVs have sold for US\$110-130 million (A\$150-175 million) each

Next steps: Develop and execute a paediatric clinical development plan

- Will be targeted at rare childhood AML
- Expected to be a much smaller, faster and less-costly trial than adult AML
- Voucher awarded at time of approval*; Race plans to sell the voucher

* Voucher is not guaranteed and subject to successful completion of a paediatric trial and other factors



Race Oncology Management Team



Peter Molloy *BSc MBA*
Managing Director & CEO

- ASX CEO who has delivered 10x market cap growth (Biota)
- 17 years big pharma marketing: Managing Director, Pharmacia
- Launched 23 products, 40 licensing deals
- Built profitable pharma businesses



Bill Garner *MD MPH*
Chairman

- US physician and entrepreneur
- Founder of numerous firms: Update Pharma, Urogen, Inverseon, Del Mar Pharmaceuticals, Isla Pharmaceuticals
- Co-inventor on Bisantrone patents



Race Oncology Management Team



Samar Al-Behaisi MD, PhD

Chief Medical Officer, Vice President Medical Affairs

- Oncologist, medical affairs expert
- 20 years industry experience: Takeda, GSK and Novartis
- Experience in oncology named patient programs in Europe



John Rothman PhD

Chief Scientific Officer

- Co-inventor on Bisantrene patents
- Director/Sr Dir at Roche; Exec VP at Advaxis
- Multiple drug approvals; outstanding pharmaceutical scientist



Summary

Race's goal is to create value for our investors in three ways:

1. Move Bisantrene towards FDA approval for adult AML, making it a valuable asset for potential acquirers >
2. Generate revenues through Named Patient Programs outside the US to support Race's operations >
3. Secure a tradable *Priority Review Voucher* through a targeted paediatric development program >

These represent largely independent pathways for value creation – Race intends to realise value on all three in the medium term

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