



## ASX RELEASE

# Race Oncology Update: Investor Presentation, JP Morgan Conference, Pre-IND Meeting with FDA

**11 January 2016, San Francisco CA:** Race Oncology Ltd (ASX: RAC) announced today that it had released an updated investor presentation that was shared with investors at a function this week in San Francisco, California, associated with the JP Morgan Healthcare Conference. The presentation is available on the company's website at [www.raceoncology.com](http://www.raceoncology.com).

"The JP Morgan conference is the premier annual conference for investors and a good opportunity to provide an update on Race to both investors and partners," said Race Oncology CEO, Peter Molloy. "Race has achieved all its stated goals in its first six months and we look forward to an exciting 2017 as we move closer to the first sales of Bisantrene in Europe under our Named Patient Program."

The JP Morgan conference is also a valuable meeting place for biotech and pharmaceutical companies from around the world. In addition to Mr Molloy, Race's chairman, Dr Bill Garner, and Race's Vice President for Europe, Gordon Beck, are attending the JP Morgan conference and meeting with partner companies and prospective licensees.

The Company also announced today that a pre-IND meeting had been scheduled between Race and the FDA for 10am on 14 February, 2017 US EST). At the meeting, the Company will review with the FDA its plans for further clinical development and regulatory approval of Bisantrene in the US, and seek assent from the FDA to proceed under the 505(b)(2) regime, which would allow Race to draw upon all the historical preclinical and clinical data for Bisantrene. Race CEO (Peter Molloy), Chairman (Dr Bill Garner) and Chief Scientific Officer (Dr John Rothman) will participate in the meeting, along with representatives from the Company's regulatory partner, Camargo Pharmaceutical Services.

### About Race Oncology

Race Oncology Ltd is a specialty pharmaceutical company, whose business model is to pursue later stage assets, principally in the cancer field. The Company's first important asset is a chemotherapy drug, called Bisantrene, which was the subject of more than 40 phase II clinical studies during the 1980s and 1990s. Race Oncology owns recent patent filings on Bisantrene and has secured Orphan Drug Designation in the US. The Company's goal is to complete final development of Bisantrene and bring this valuable cancer drug to market. Visit [raceoncology.com](http://raceoncology.com) for more information.

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*Specialty Pharma – Fast to Market Drugs*

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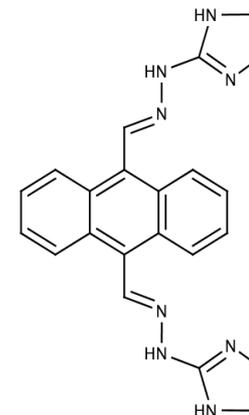
# Overview

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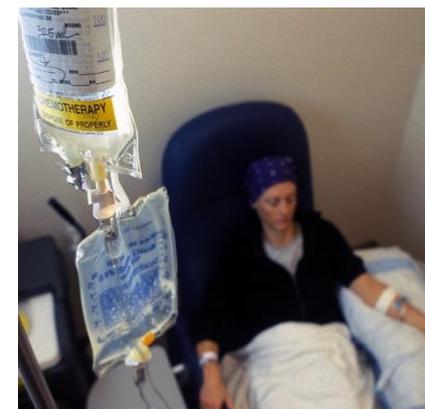
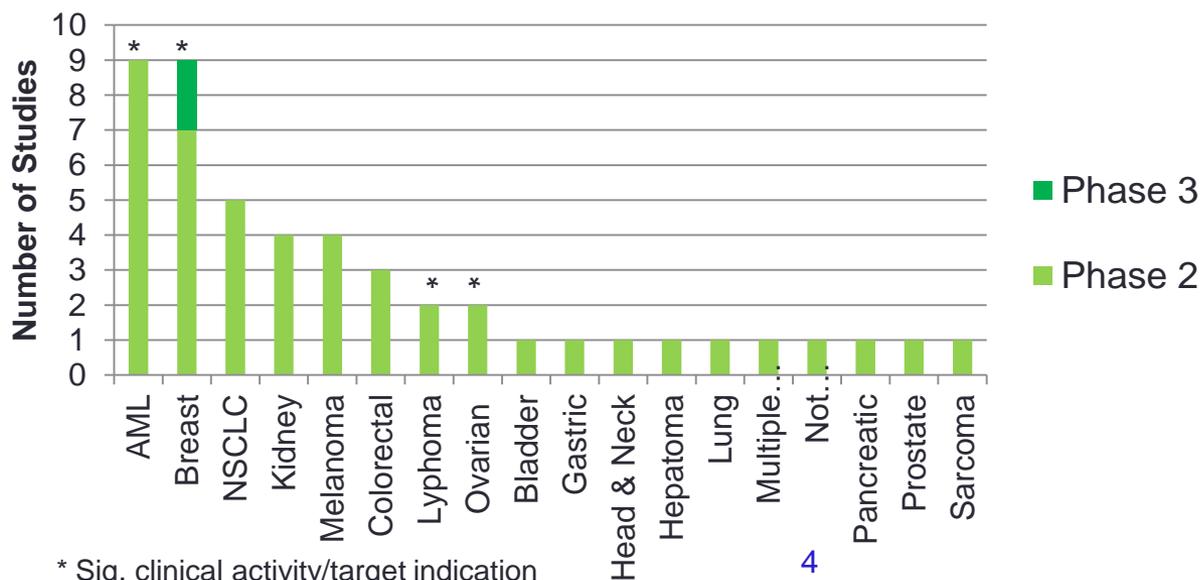
- Race Oncology (RAC) listed on the ASX in July 2016
- Our first drug is a cancer chemotherapy drug called “Bisantrene”
- We expect to see first sales of Bisantrene by end 2017 under a European Named Patient Program (NPP)
- Low valuation (~A\$11m) with significant upside from anticipated milestones in 2017

# Bisantrene

- Chemotherapy with reduced cardiotoxicity
  - Developed by Lederle in the 1980s, because of its reduced cardiac toxicity compared with the anthracyclines
  - Tested in >40 phase II clinical studies by Lederle and NCI (National Cancer Institute)



## Bisantrene Phase 2 and 3 Clinical Studies 1982-1995



# Bisantrene – lost and rediscovered

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- Impressive activity in relapsed/refractory AML
  - Average 48% CR in r/r AML in studies (1987-94)
  - In 1990, approved in France for treating AML
- Then the drug disappeared after a string of big pharma mergers during the 1990s:
  - Am. Cyanamid/Lederle → AHP/Wyeth → Pfizer
- 2013-2016: Bisantrene rediscovered
  - New patents filed, Orphan Drug Designation
  - Race Oncology formed to bring it to market

# Acute Myeloid Leukaemia (AML)

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- AML is a blood cancer (leukaemia)
  - Caused by proliferation of immature immune cells from bone marrow ('blasts')
- Orphan disease
  - Around 20,000 new patients a year in the US
- Disease mainly of the elderly
  - Incidence growing as pop. ages
  - AML progresses rapidly and has a poor long-term prognosis

# Treatment of AML

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- Standard of Care (SOC)
  - For younger/fitter patients: '7+3' chemotherapy
    - cytarabine x 7 days, daunorubicin (or epirubicin) x 3 days
  - 1<sup>st</sup> line SOC has not changed in 30 years
  - No effective 2<sup>nd</sup> line when SOC fails
- Unmet medical need
  - Most respond to SOC and then relapse
    - Relapsed/refractory(r/r) AML is extremely difficult to treat
  - Most elderly patients do not qualify for (cannot tolerate) 7+3
    - No effective treatment option for elderly/unfit patients
- *Bisantrene offers new hope for r/r and elderly/unfit AML*

# Bisantrene clinical studies in r/r AML

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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%

# Short term strategy: AML/NPP

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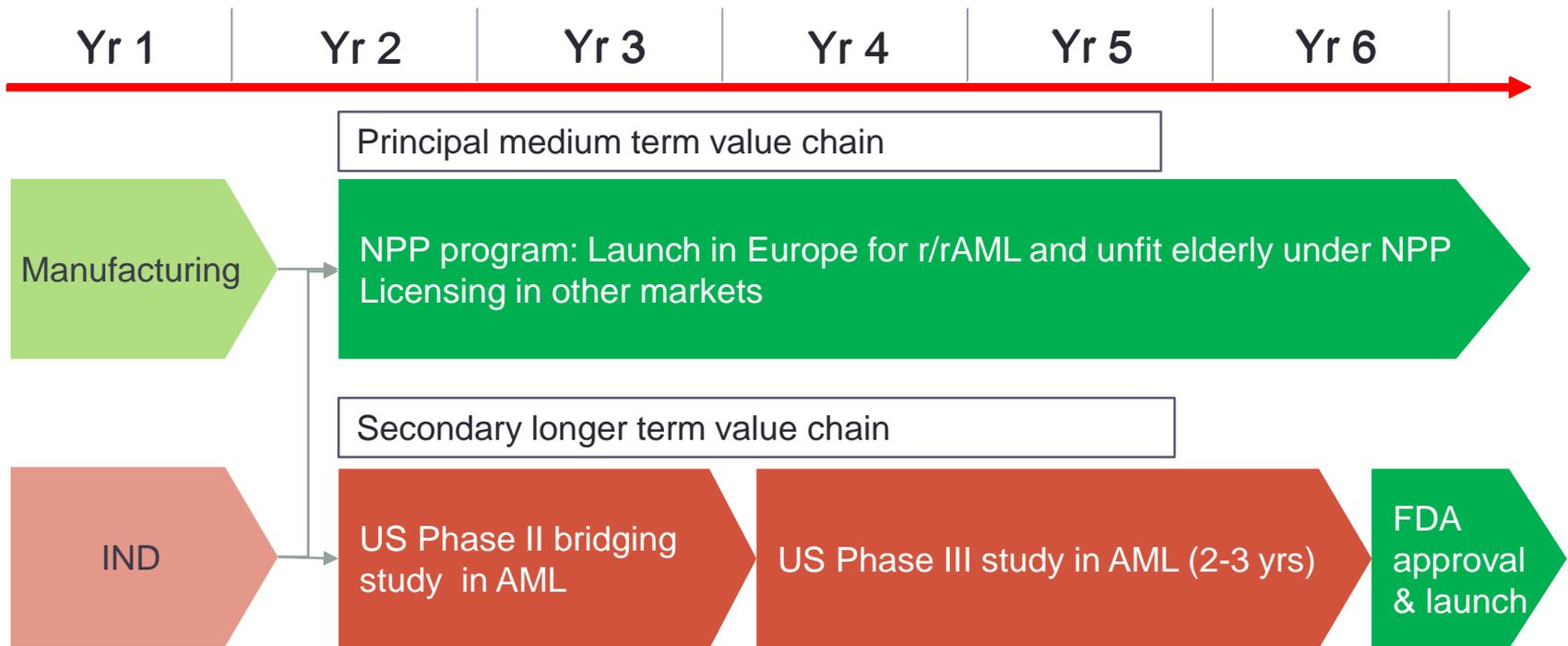
- During 2017, Race will apply to sell Bisantrene in France and some other EU countries where drugs can be sold under a Named Patient Program (NPP)
- We will also seek licensees for countries outside Europe, where profitable NPP sales can be made
- The product will be aimed at r/r AML and for newly diagnosed elderly AML patients unfit for 7+3 therapy
- May be used by oncologists as single agent or in combination with other drugs

# Long term market opportunity

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- The longer term opportunity is FDA approval of Bisantrene for general marketing
- Pathway to FDA approval
  - pre-IND meeting with FDA (Feb 2017)
  - IND filed
  - Complete clinical studies to meet FDA requirements
  - File for marketing approval in US
  - File for marketing approval in all other markets
- Opportunities beyond AML
  - Potential exists to expand indications to breast cancer (in combination with new drugs), lymphoma and ovarian cancer

# Two value creation pathways



*Timings shown are estimates only and subject to change*

# Year 1 Targets: Initiate NPP Sales

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- Completed or in-process
  - GMP manufacturing of Bisantrene API underway (Sai Life Sciences, India)
  - GMP drug product manufacturer appointed (IriSys, US)
  - Clinical protocol for US bridging study being developed (Camargo, US)
  - Pre-IND meeting with FDA set
  - NPP marketing partner in Europe appointed (CarthaGenetics, Switzerland)
  - Orphan Drug application in Europe filed
- Next steps
  - Pre-IND meeting with FDA (Feb 2017)
  - Complete and file IND (Q2 2017)
  - Apply for NPP sales authorisation in France (Q3 2017)
  - Prepare for launch of NPP sales (Q4 2017)

# Years 2-5

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- Expand NPP sales
  - Grow EU NPP sales
  - Continue licensing Bisantrene to marketing partners for all countries outside EU NPP markets
- FDA program
  - Conduct registration studies in US
  - Gain FDA and EMA approval
  - Launch under general marketing approval in all countries
- Expand clinical program in AML and to other cancers
  - Breast cancer, ovarian cancer and lymphoma

# Key management & board

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- CEO: Peter Molloy
  - CEO, Biota (antiviral drugs)
  - CEO, SLIL Biomedical (oncology)
  - VP Strategic Marketing, Pharmacia
  - Managing Director, Pharmacia Australia
- Chairman: Bill Garner MD MPH
  - US physician and entrepreneur
  - Founder/co-founder of several firms: Del Mar Pharmaceuticals, Urigen, Invion
  - Co-inventor on Bisantrone patents
- CSO: John Rothman PhD
  - Co-inventor on Bisantrone patents
  - Director/Senior Director at Roche; Exec VP for Science & Operations, Advaxis
  - Multiple drug approvals
- VP Europe: Gordon Beck
  - Roche: Global Business Team leader (oncology, ID, CVS, CNS)
  - BMS: Director, Cardiovascular Marketing and Business Development

# US Scientific Advisory Board

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- US Key Opinion Leaders:

- Martin Tallman MD
  - Memorial Sloan Kettering Cancer Center
- Roland Walter MD
  - Fred Hutchinson Cancer Research Center
- Doug Smith MD
  - Johns Hopkins University

- SAB members are advising Race on:

- Clinical positioning of Bisantrene
- Clinical trial protocols for ongoing development

# Share Price

Jul 15, 2016 - Jan 06, 2017 ● RAC



● Volume





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