



ASX Announcement

Race Oncology Phase II Bisantrene AML trial webinar

17 June 2020 – A group investor briefing will be held to discuss the significance of the trial results in more detail **on Wednesday 17 June 2020 at 10:30am Australian Eastern Time** (8:30am Western Australian/Hong Kong time; 8:30pm New York time and 5:30pm San Francisco time on Tuesday 16 June 2020).

Participants will need to pre-register for the call, using the following link:

https://us02web.zoom.us/webinar/register/WN_UZqeygRqSwq41YoH3PBWEw

- ENDS -

About Race Oncology (RAC: ASX)

Race Oncology (RAC) is a drug development biotech with a Phase II/III cancer drug called Bisantrene. RAC has compelling clinical data for Bisantrene in acute myeloid leukaemia (AML) as well as breast and ovarian cancer. RAC is pursuing an exciting '5-Path' clinical development strategy that involves parallel US and Australian clinical trials in AML, breast and ovarian with clinical trials to begin in 2020.

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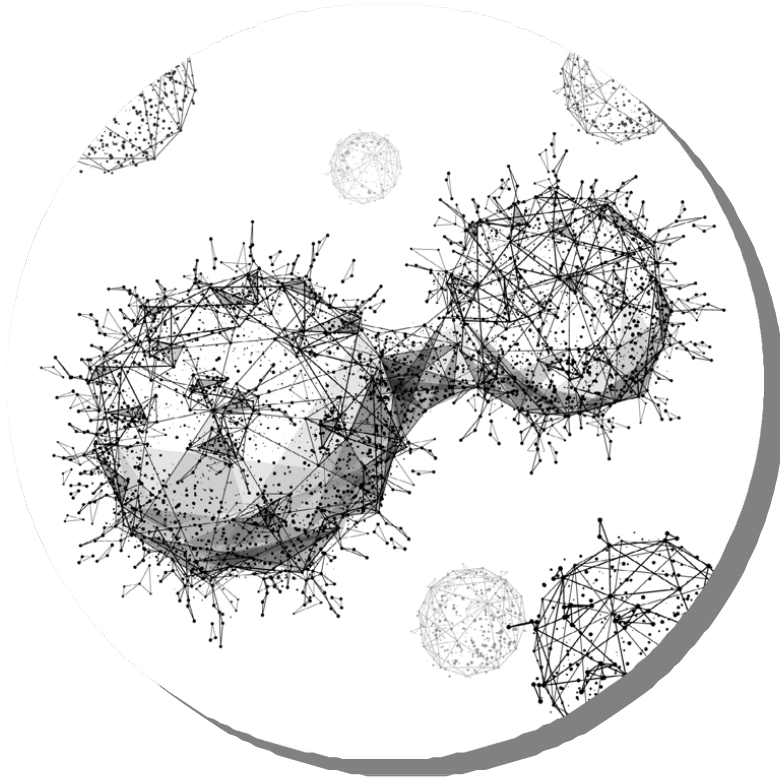
Bisantrene Phase II Data Presentation

June 2020



Trial highlights | Chair Clinical Advisory Board, Professor Borje Andersson

June 2020



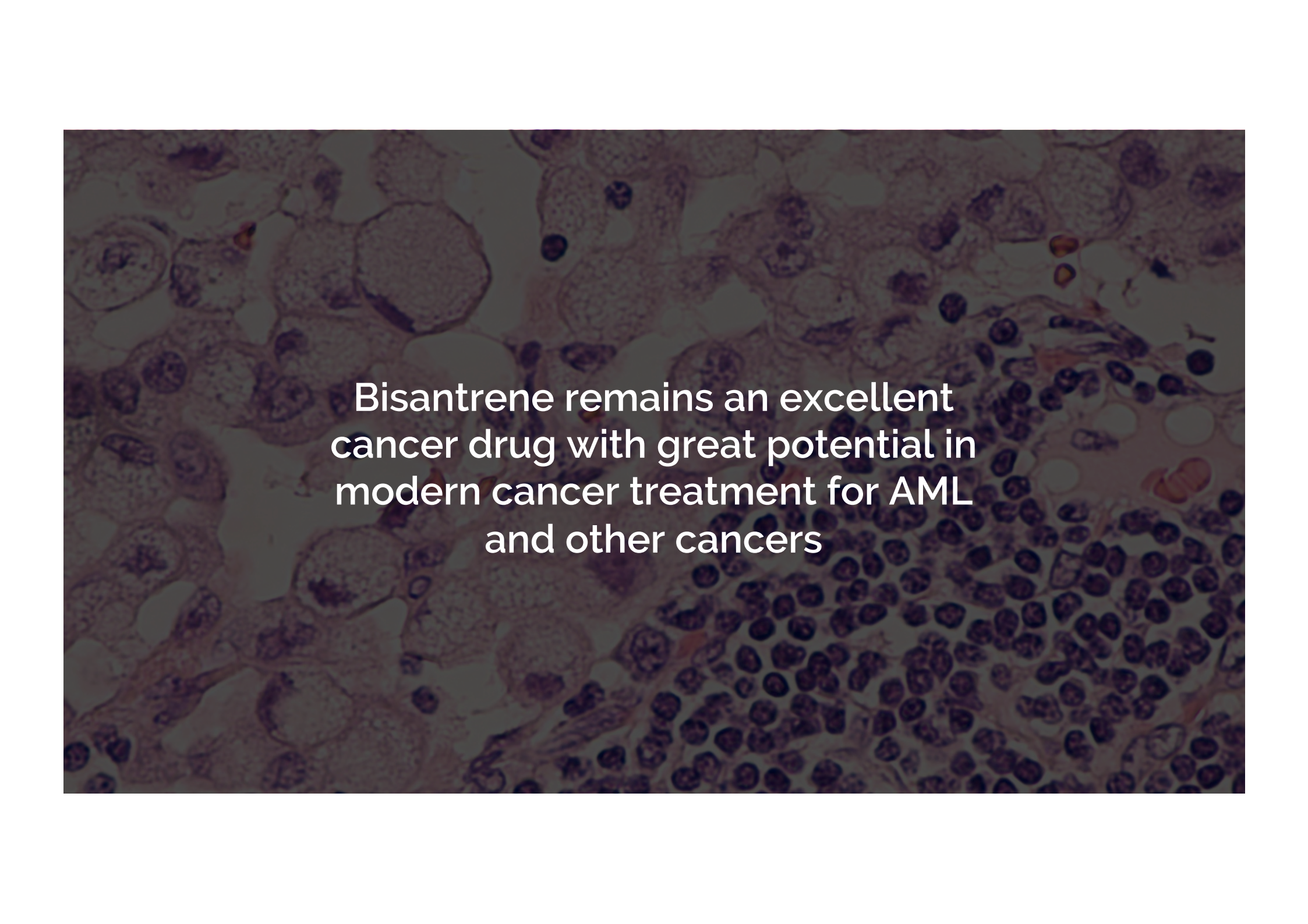
About Bisantrone

Bisantrone is a cancer chemotherapy that was previously approved for AML in France 1988 and then shelved. Race Oncology is returning this drug back into clinical development

Bisantrone ([Xantrene®](#)) is an anthracene with anthracycline-like activity and was shown in earlier clinical trials to be an effective salvage therapy in R/R AML with little or no discernible cardiotoxicity

Since then, Race:

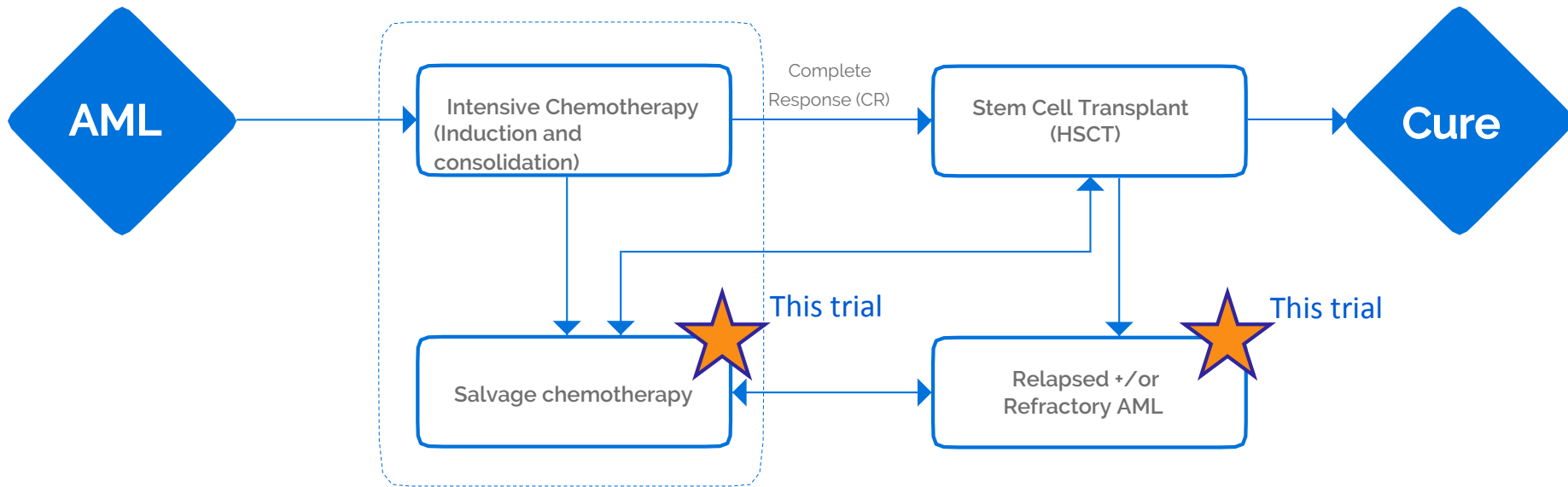
- Has successfully manufactured Bisantrone
- Built a strong patent position (3 granted US patents)
- US Orphan Drug designation (7 years exclusivity)
- Secured a Rare Paediatric Disease designation with the potential to receive a Priority Review Voucher (PRV)

A microscopic image showing a dense population of cells, likely cancer cells, with prominent nuclei and some cytoplasmic detail. The cells are stained, showing a range of purple and blue hues. The background is a light, slightly textured grey.

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

Current AML Treatment

Generalized overview



Bisantrene IV
250mg/m² x 7 days

Management of **R/R AML** represents a significant therapeutic challenge with **no established standard of care**

Phase II Bisantrene monotherapy in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML)



Bisantrene is active, safe and effective in Adult R/R AML after multiple prior therapies

Bisantrene

7 day (single IV course) treatment

10 patients enrolled

10 Evaluated for safety and efficacy

ORR = 40% (4/10 patients)

4 Responses reported (1 CR + 3 PR)

Favourable safety and tolerability

* 4/4 responses in high-risk extramed. disease



Study design

- Phase II open-label single arm single center study (NCT03820908)
- **Site.** Chaim Sheba Medical Center, Tel Aviv, Israel
- **Principal investigator.** Professor Arnon Nagler





Study design

Criteria

Key inclusion	Key exclusion
Patients with Relapsed/Refractory AML	Active pulmonary disease, diffusing capacity for carbon monoxide(DCFO) < 30%
Aged 18 years or older	Symptomatic heart failure (NYHA Grade 2 or above)
Eastern Cooperative Oncology Group (ECOG) performance score 0 or 1	Bilirubin > 3.0 mg/dl
Adequate cardiac function; left ventricular ejection fraction (LVEF) ≥ 40%	Transaminase levels more than three times the upper limit of normal (ULN)
Adequate birth control in potentially fertile patients	Creatinine > 2.0 mg/dl
	Active central nervous system (CNS) disease#
	Grade III-IV graft-versus-host disease (GVHD)

Two CNS patients enrolled with a waiver approved by local IRB; NYHA - New York Heart Association [NYHA] Class III to IV

Study design

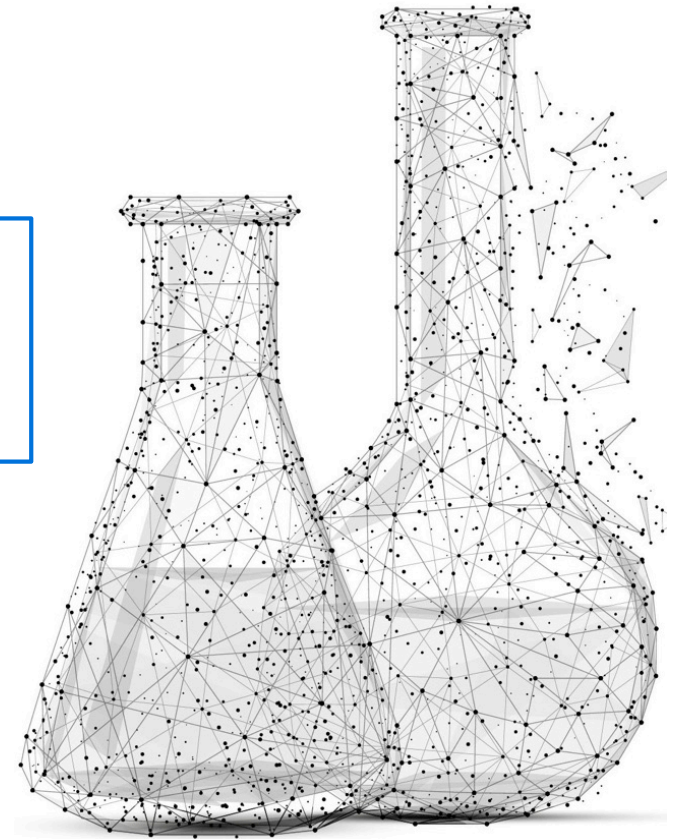
Treatments and assessments

Treatment

Bisantrene 250mg/m² over 2-hour, one infusion daily for 7 days
Salvage therapy - predominantly as 4th line therapy

Endpoints

- Primary** → composite of complete remission (CR) and complete remission with incomplete hematologic recovery (CRi)
- Secondary** →
- › survival (defined as the time from study entry to death from any cause)
 - › remission duration, type
 - › incidence and severity of AEs
 - › gene mutational analyses



Study design Assessments



Safety

- Vital signs & physical
- Clinical lab tests and bone marrow examination
- ECG
- Adverse Events per CTCAE v5.0

Evaluable patients: all that took one course of bisantrene (n=10)



Response

- Blast cells in bone marrow and in blood
- According to 2003 International Working Group (IWG) standardized response criteria for AML

Evaluable patients: all completed bisantrene treatment (n=10)



Disease mutations

- Next generation sequencing (NGS) studies on patient bone marrow samples pre-treatment

Evaluable patients: all that provided a sample (n=7)



Patient Demographics

Characteristic	N=10
Median age	
Years (range)	43 (22-80)
Gender	
Male	6
Female	4
ECOG performance status at screening	
0	9 (90%)
1	1 (10%)
Disease diagnosis	
Secondary disease (acute antecedent myeloid disorder)	3 (30%)
Extramedullary disease	4 (40%)
Prior system therapy regimens (lines)	
1	1 (10%)
2	3 (30%)
>3	6 (60%)
Prior allogenic transplant	7 (70%)

Characteristic	N=10
MRC Cytogenetic risk	
Favourable	0
Intermediate	7 (70%)
Advanced	3 (30%)
ELN 2017 risk category	
Favourable	2 (20%)
Intermediate	5 (50%)
Advanced	3 (30%)
NPM1 status	
<i>NPM1</i> ^{wt}	8 (80%)
<i>NPM1</i> ^{mut}	2 (20%)
FLT3-ITD status	
<i>FLT3</i> ^{wt}	6 (60%)
<i>FLT3</i> -ITD	4 (40%)

“Hard to treat” disease setting

Safety

Treatment Related Adverse Events (TRAEs) in 10 patients	Any grade	≥ Grade 3
Haematologic		
Anemia	1 (10%)	1 (10%)
Neutropenia	2 (20%)	2 (20%)
Thrombocytopenia	3 (30%)	3 (30%)
Non-Haematologic		
Fever	6 (60%)	
Headache	1 (10%)	
Chills	1 (10%)	
Dyspnea	1 (10%)	
Myocardial infarction	2 (20%)	2 (20%)
Mucositis	7 (70%)	6 (60%)
Acute Kidney Injury	1 (10%)	
Sepsis	3 (30%)	1 (10%)
Blood bilirubin increased	2 (20%)	2 (20%)
Confusion	1 (10%)	
Hypernatremia	1 (10%)	
Ejection fraction decreased	1 (10%)	1 (10%)
Atrial fibrillation	1 (10%)	1 (10%)
Abdominal pain	1 (10%)	0
Diarrhea	1 (10%)	
Vomiting	1 (10%)	
Rash	1 (10%)	
Upper gastrointestinal bleeding	1 (10%)	1 (10%)
Death (unrelated)		
Cardiac arrest [#]		1 (10%)

Most frequently reported serious adverse events:

- thrombocytopenia (low blood platelets)
- mucositis (mouth ulcers)

Both of these are expected side effects with chemotherapeutics of this kind.

[#]Deemed due to pre-transplant chemotherapy conditioning regimen

Outcomes

- Of the 10 patients, one patient (10%) achieved a complete remission and three patients achieved a partial remission → **Overall Response Rate of 40%**
- All 4 **responders** had **high-risk extramedullary disease**:
 - Patient with leukaemia cutis (skin) achieved CR and bridged to allogeneic stem cell transplantation
 - Patient with breast chloromas achieved high reduction in sites of disease deemed as partial response
 - Patients with CNS disease both achieved transient clearance of peripheral blood blasts with one resulting in partial remission of ocular disease and other partial response of CNS disease





Conclusion

Established safety and tolerability of current Bisantrene formulation
Confirmed previous anti-leukeamic activity
Dose of (250mg/m²) maintains effectiveness in R/R AML



Bisantrene is safe and its effectiveness maintained.
Positioned to be investigated with complementary anti-leukemic therapy
to re-enter the modern AML therapy landscape

So Where, Henceforth





Other Activities | CSO Daniel Tillett

June 2020

The MRD opportunity

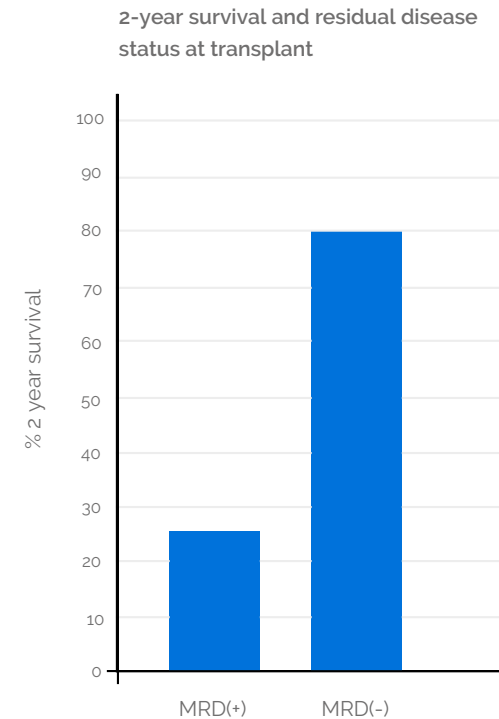
Up to 80% of AML patients who are fit enough for induction chemotherapy (3+7) will enter remission (CR) and may then be candidates for a human stem cell transplant (HSCT)

Whether the transplant results in long term survival 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!

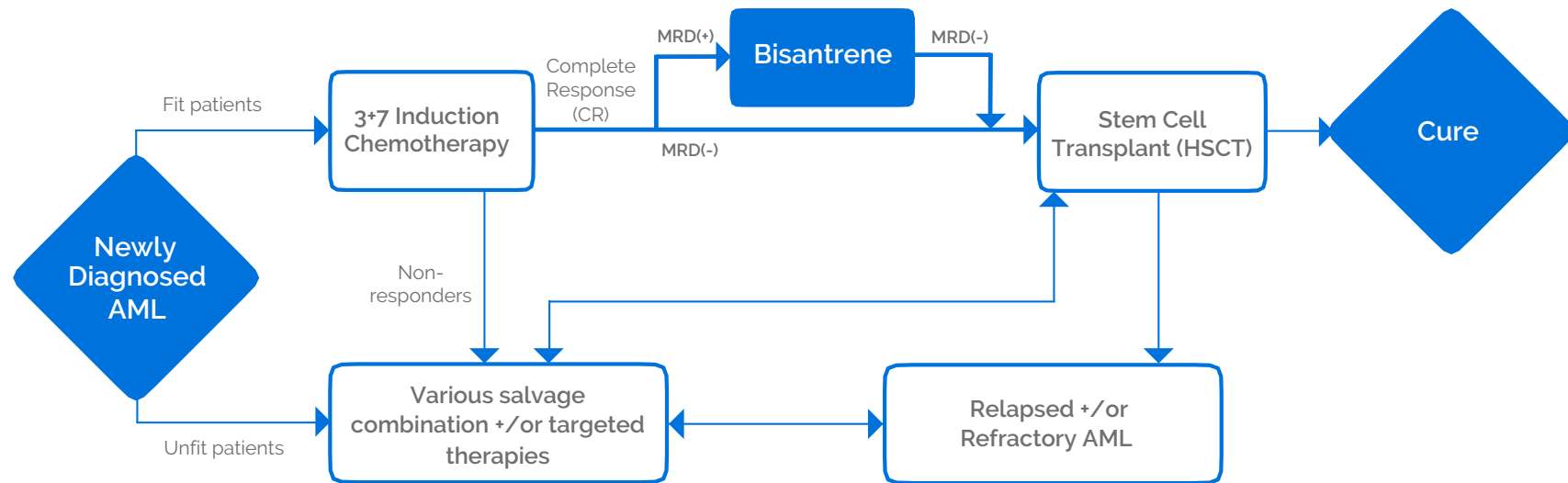
As yet, there are no approved treatments that can change MRD status from (+) to (-) for AML

- Bisantrene is potentially the answer



Bisantrene in AML treatment for MRD

Bisantrene could transform cure rates by changing MRD status



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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 and/or Israel in partnership with a leading US cancer center



Eligibility

Transplant eligible MRD(+) patients in CR after induction chemotherapy – potential for paediatric study too



Study Design

Open label 7-day Bisantrene 250mg/m²/day treatment in 28 MRD(+) patients



Endpoints

MRD status post-Bisantrene

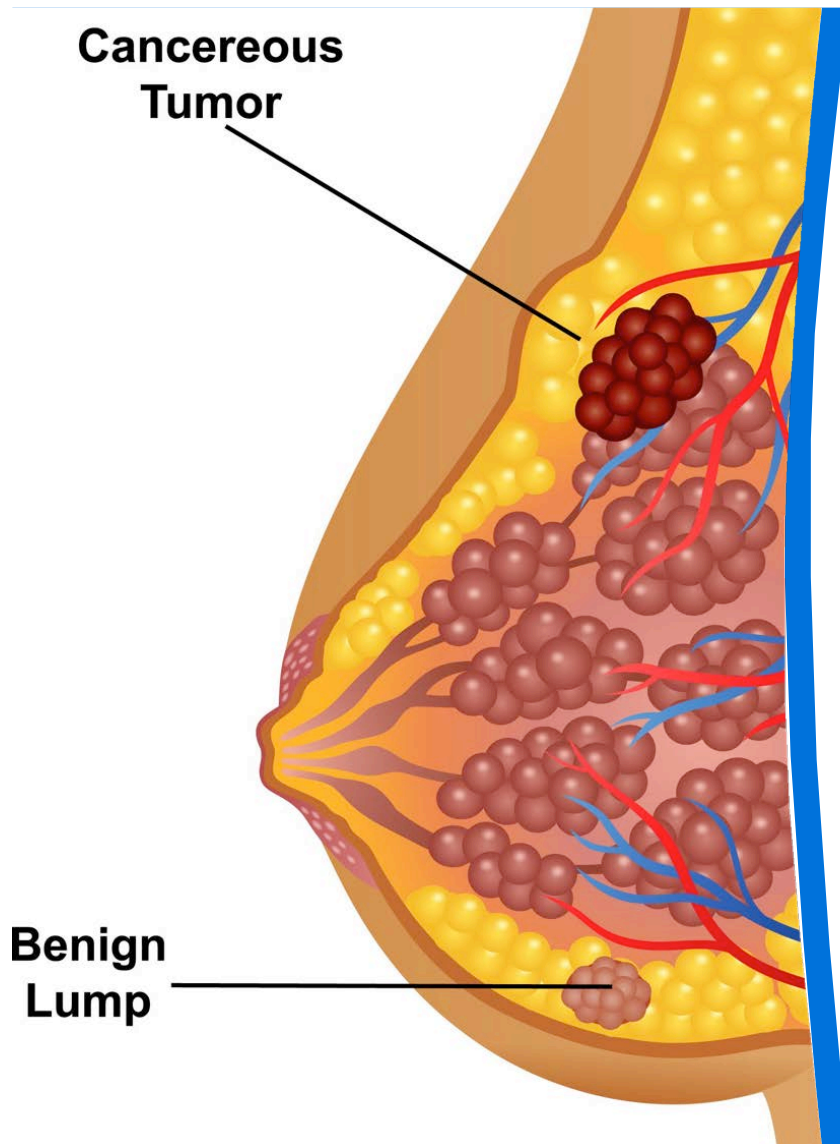
Treatment post-transplant survival



Goal

Early FDA approval of Bisantrene for MRD(+) patients





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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 (preclinical studies underway with U. Newcastle)



Use optimal dosing, administration and combination of Bisantrene

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



Goal

Opens up much larger cancer market than AML
(2 million cases each year)

Show equivalent efficacy to existing treatments but with fewer serious side effects (less damage to the heart)

Displace current anthracyclines used in breast cancer treatment

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Ovarian cancer combination 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



Use optimal dosing, administration & combinations of Bisantrene

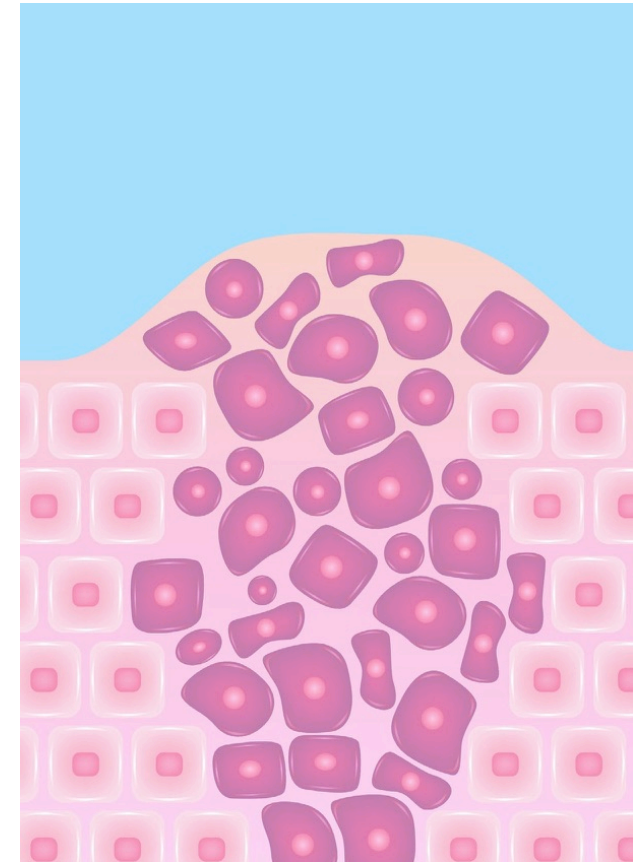
Historical non-AML cancer trials all used sub-optimal dosing and did not use combinations, but still showed activity for Bisantrene



Goal

Open up much larger cancer market than AML (200,000 cases each year)

POC trial to attract pharmaceutical partner for approval trials





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