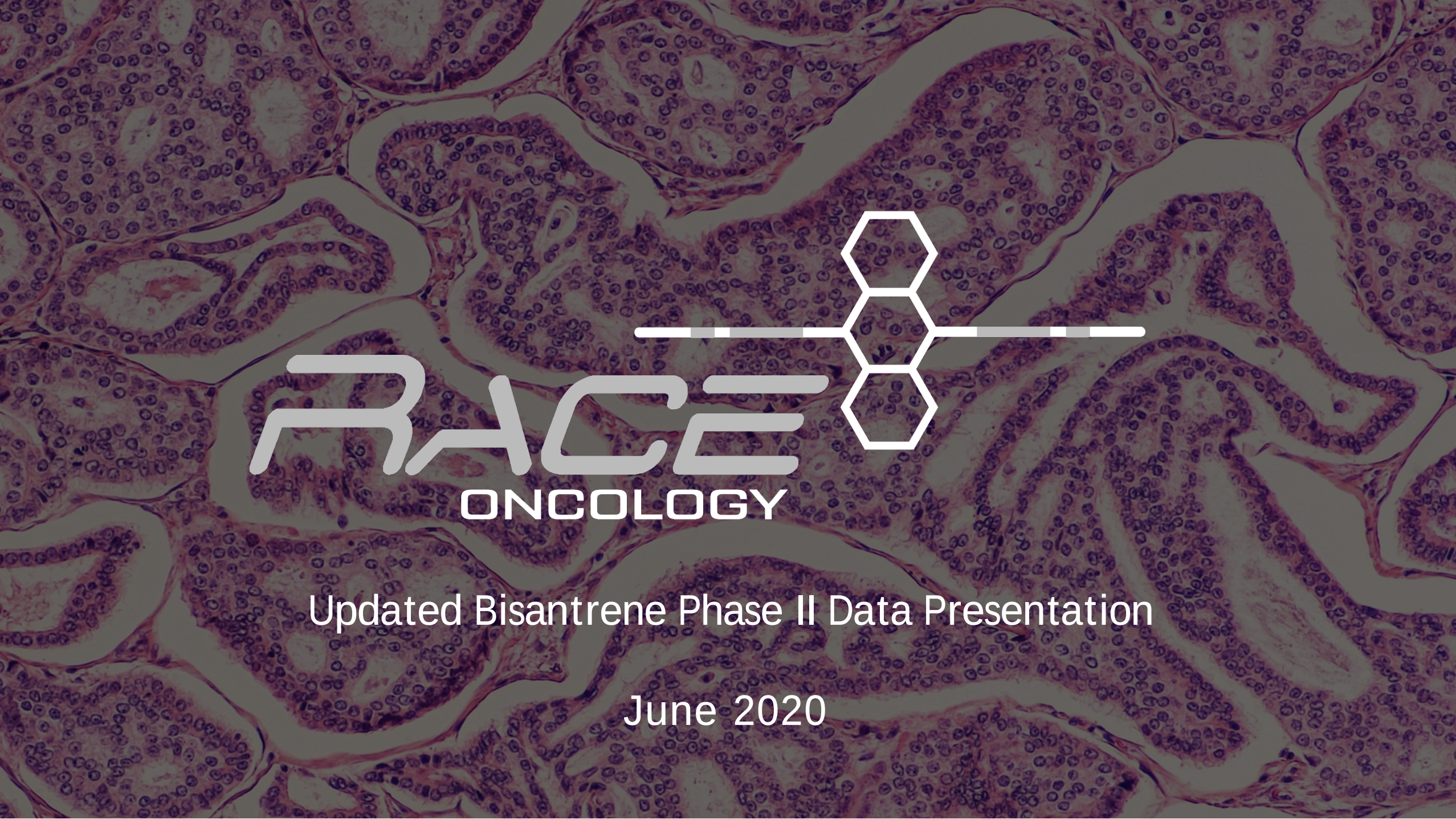


RACE ONCOLOGY

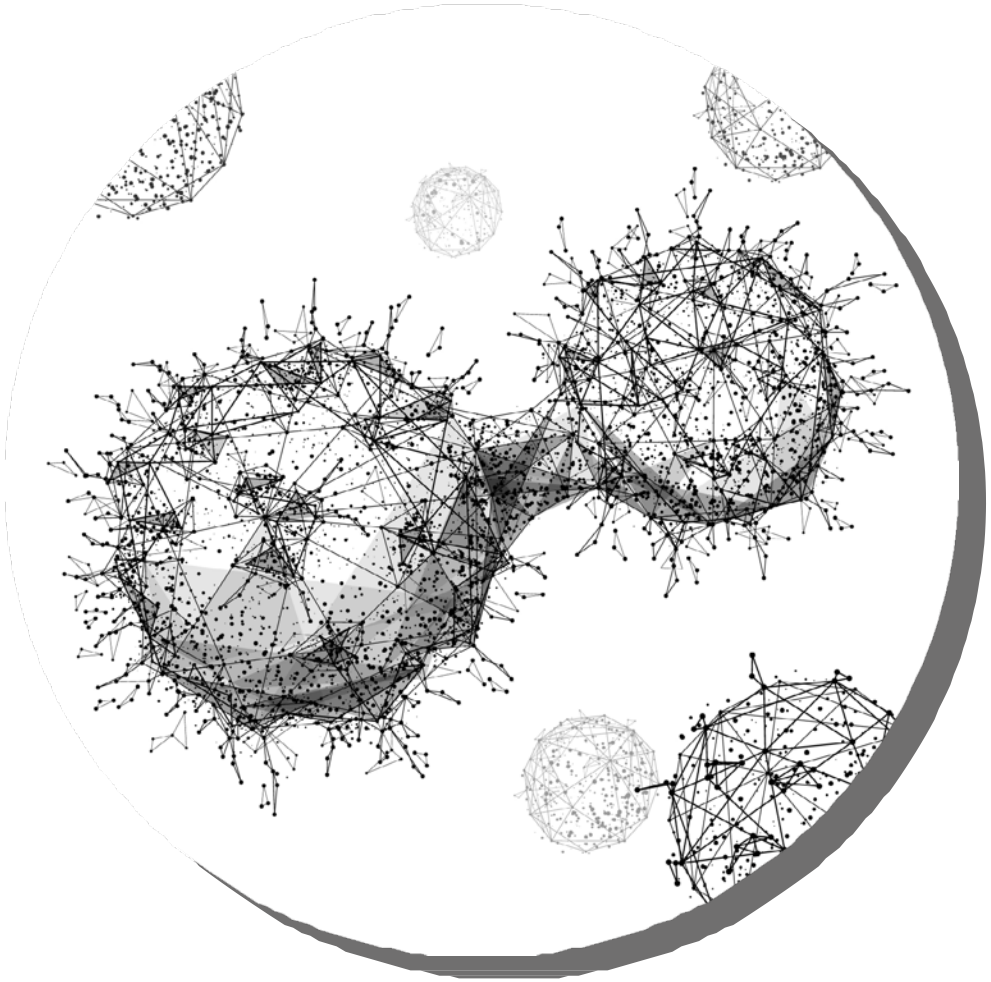
Updated Bisantrene Phase II Data Presentation

June 2020

RACE ONCOLOGY

Trial highlights | Chair Clinical Advisory Board, Professor Borje Andersson

June 2020



About
Bisantrene

Bisantrene 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

Bisantrene (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

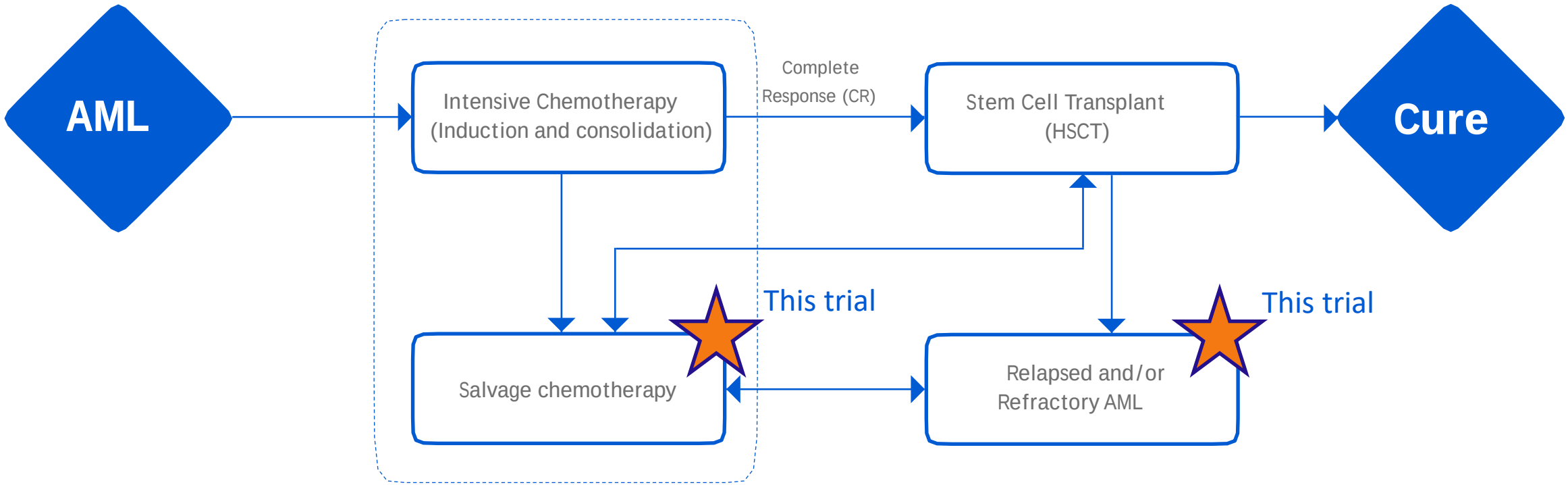
Since then, Race:

- Has successfully manufactured Bisantrene
- 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)


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

Current AML Treatment

General 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 extramedullary 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

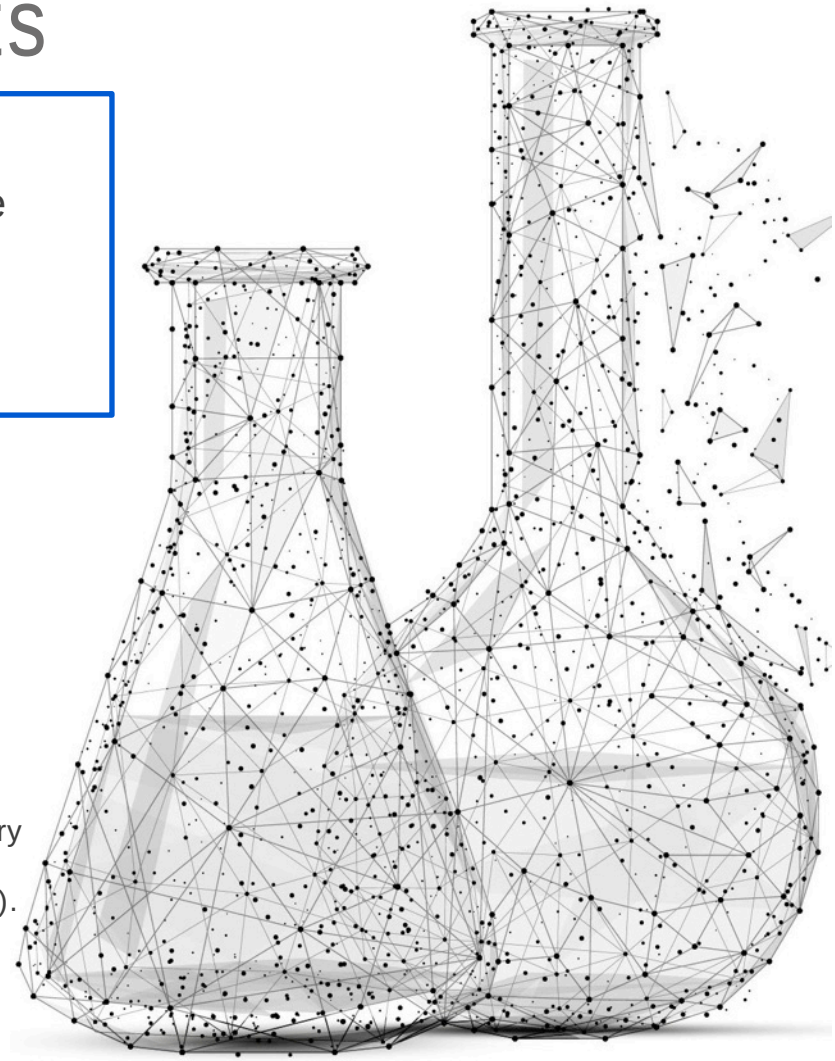
Inclusion Criteria	Exclusion Criteria
Patients with Relapsed/Refractory AML	Active pulmonary disease, diffusing capacity for carbon monoxide(DCFO) < 30%
Aged 18 years or older	Symptomatic heart failure (NYHA Grade 2 or higher)
Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2	Bilirubin =/≥ 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#
	Active Grade III-IV graft-versus-host disease (GVHD) after previous allogeneic stem cell transplant.

 # 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/m^2 over 2-hour, one infusion daily for 7 days, one course only. Patients achieving CR may receive one 3-day consolidation course with the same daily dose and schedule.
Salvage therapy - predominantly as 4th line therapy



Trial Endpoints

Primary →

1. Overall survival [Time Frame: 24 months]
Overall survival will be calculated from the day of bisantrene administration until death or last follow-up.

2. Leukemia-free survival [Time Frame: 24 months]
Leukemia-free survival will be calculated from the day of bisantrene administration until relapse, death of any cause, or last follow-up.

Secondary →

1. To determine the safety and toxicity of bisantrene in relapsed (Rel)/refractory (Ref) AML including post allogeneic stem cell transplantation (alloSCT)
2. To determine achievement of cytogenetic or molecular remission (if relevant).
3. To evaluate the Relapse rate.
4. To determine Leukemia Free Survival (LFS).
5. To determine Overall Survival (OS).
6. To evaluate the number of hospitalization days including days of antibiotic therapy
7. To determine the Incidence of infection episodes (bacterial and fungal).
8. To describe the Safety and toxicity of bisantrene treatment. Patients will be evaluated for toxicity according to CTC and infectious complications.

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 received 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 Female	6 4
ECOG performance status at screening	
0 1	9 (90%) 1 (10%)
Disease diagnosis	
Antecedent myeloid disorder Extramedullary disease	3 (30%) 4 (40%)
Prior system therapy regimens (lines)	
1 2 >3	1 (10%) 3 (30%) 6 (60%)
Prior allogenic transplant	7 (70%)

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

"Hard to treat" disease setting

Safety

	All-cause adverse events				Adverse events attributed to bisantrene		
	Grade 1-2	Grade 3	Grade 4	Grade 5	Grade 1-2	Grade 3	Grade 4
Anemia	1 (10%)	1 (10%)			1 (10%)	1 (10%)	
Neutropenia		2 (20%)	2 (20%)			2 (20%)	2 (20%)
Thrombocytopenia		4 (40%)	2 (20%)			4 (40%)	2 (20%)
Fever	6 (60%)				6 (60%)		
Headache	1 (10%)				1 (10%)		
Chills	1 (10%)				1 (10%)		
Dyspnea	1 (10%)				1 (10%)		
Myocardial infarction		1 (10%)	1 (10%)			1 (10%)	1 (10%)
Mucositis	1 (10%)	4 (40%)	2 (20%)		1 (10%)	4 (40%)	2 (20%)
Acute kidney injury	1 (10%)				1 (10%)		
Sepsis	2 (20%)		1 (10%)		2 (20%)		1 (10%)
Blood bilirubin increased		2 (20%)				2 (20%)	
Confusion	1 (10%)				1 (10%)		
Hypernatremia	1 (10%)				1 (10%)		
Ejection fraction decreased		1 (10%)				1 (10%)	
Cardiac arrest [#]				1 (10%)			
Atrial fibrillation		1 (10%)				1 (10%)	
Abdominal pain	1 (10%)				1 (10%)		
Diarrhea	1 (10%)				1 (10%)		
Vomiting	1 (10%)				1 (10%)		
Rash	1 (10%)				1 (10%)		
Upper gastrointestinal bleeding		1 (10%)				1 (10%)	

Most frequently reported serious adverse events:

- thrombocytopaenia (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 was bridged to allogeneic stem cell transplantation
  - Patient with breast chloromas achieved high reduction in sites of disease deemed as partial response based on serial PET-scans.
  - Two patients with CNS disease achieved transient clearance of peripheral blood blasts with one resulting in partial remission of ocular disease involvement and the other had a partial response of CNS (leptomeningeal) disease

Conclusion

Established safety and tolerability of current Bisantrene formulation
Confirmed previously recorded anti-leukeamic activity
The Dose and Schedule (250mg/m^2 once daily for 7 days) maintains effectiveness in R/R AML

Bisantrene is safe and its efficacy confirmed in the dose and schedule used.
Positioned to be investigated with complementary anti-leukemic therapy to re-enter the modern AML therapy landscape.


So where, henceforth ……..

RACE ONCOLOGY

Other Activities | CSO Daniel Tillett

June 2020

The MRD opportunity

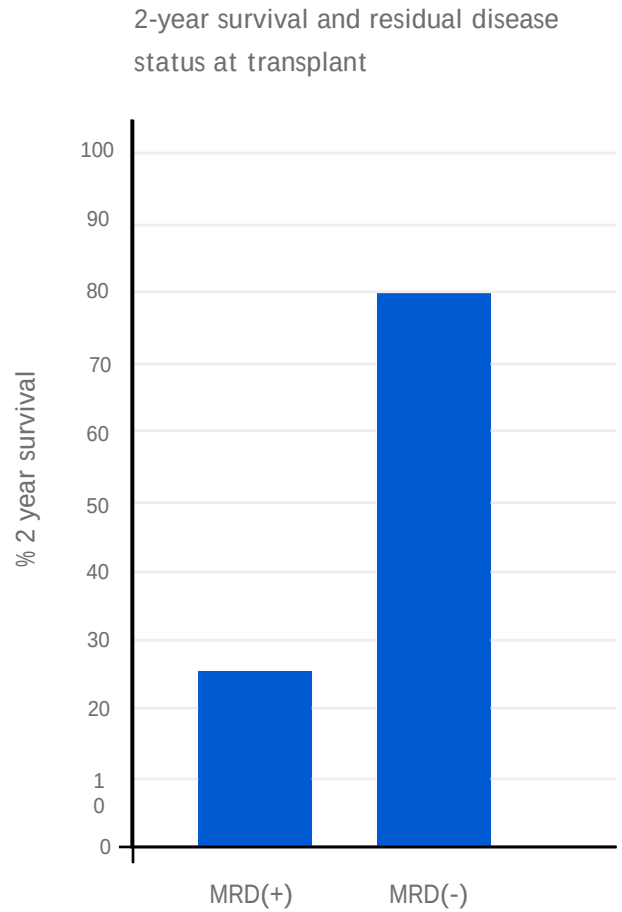
Up to 80% of AML patients who are fit enough for induction chemotherapy (3+7) with enter remission (CR) and may then be candidates for a human stem cell transplant (HSCT)

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!

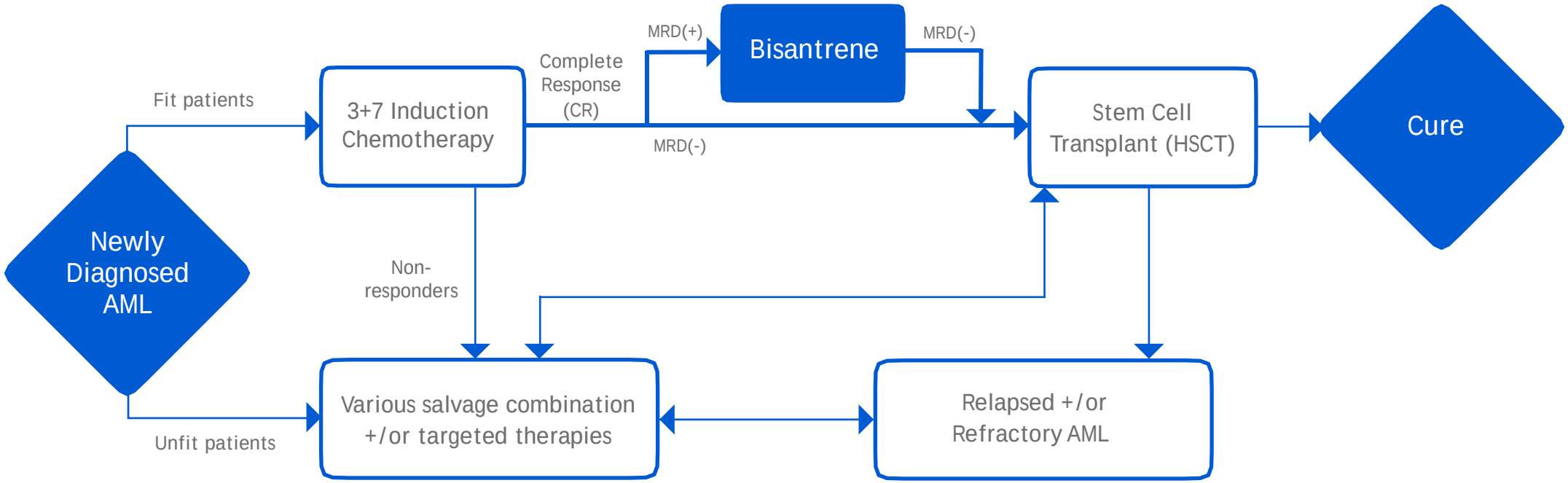
As yet, there are no approved treatments that can change MRD status from (+) to (-) for AML

- Bisantrene is potentially the answer



Bisantrene in AML treatment for MRD

Bisantrene could transform cure rates by changing MRD status



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 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/m^2/day treatment in 28 MRD(+) patients

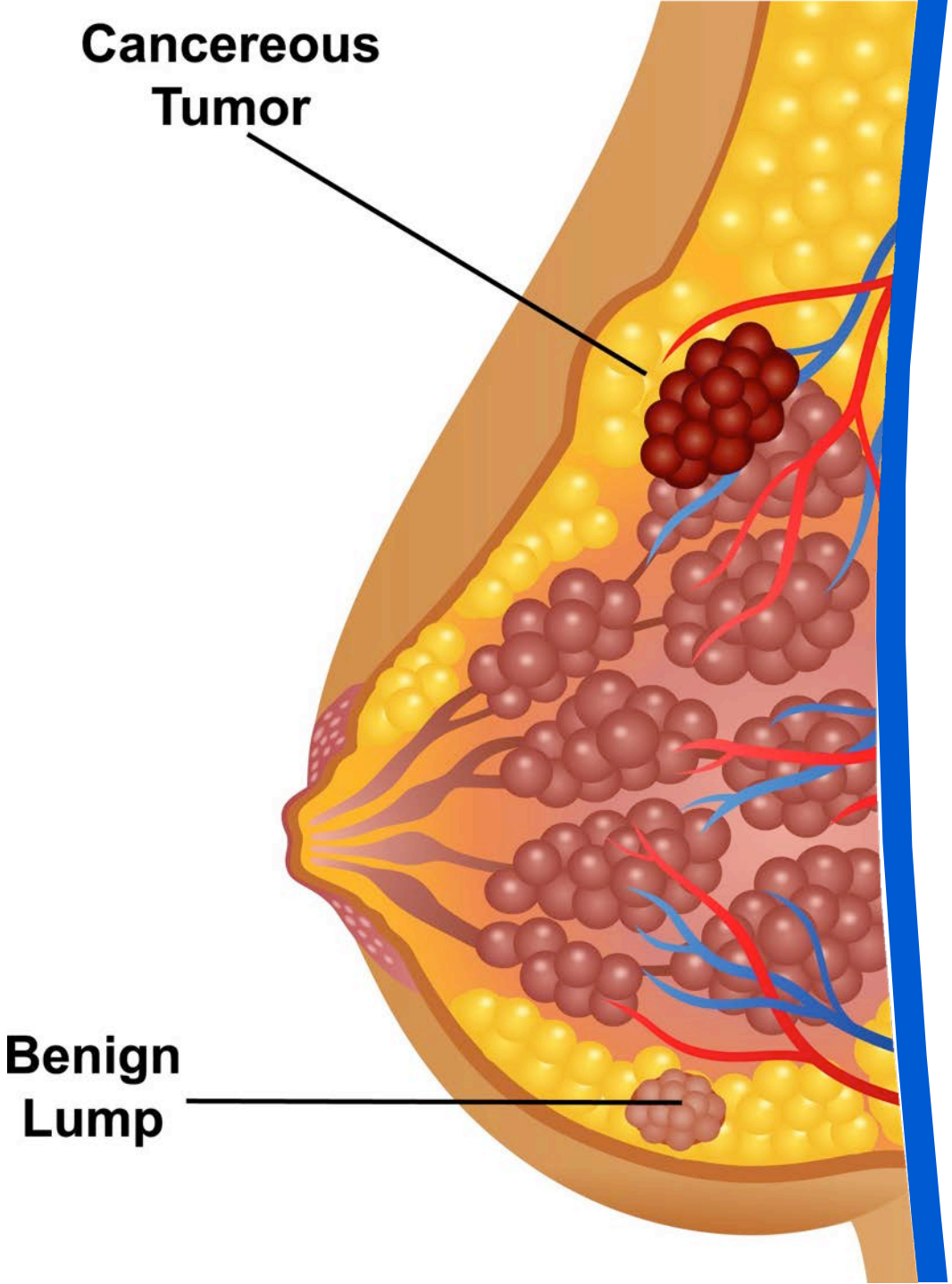
Endpoints

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!)

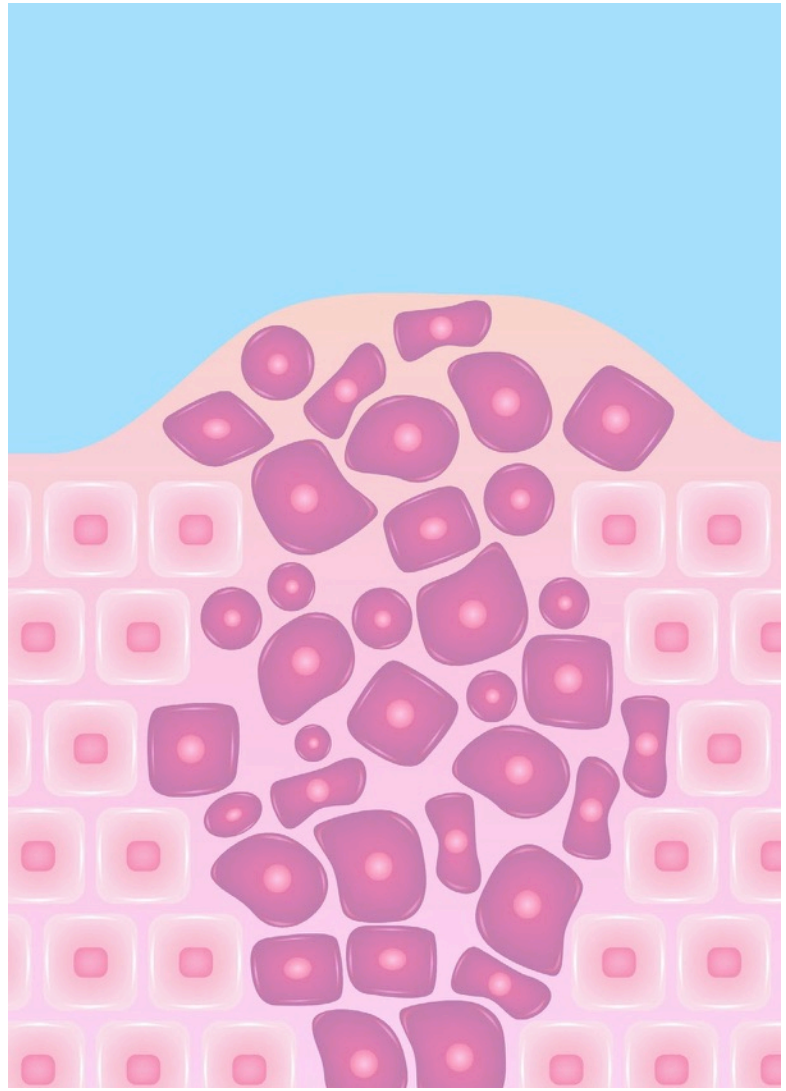
Goal
Opens up much larger cancer market than AML
(2 million cases each year)
Show equivalent efficacy to existing treatments but with fewer serious side effects (less damage to the heart)
Displace current anthracyclines used in breast cancer treatment

5 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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