



NOVEL RNA-DIRECTED THERAPEUTICS TO TREAT CANCER AND PROTECT THE HEART

Annual General Meeting
November 2022

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COMPANY SNAPSHOT



Clinical stage m⁶A RNA focused company targeting multiple cancer indications



Zantrene[®] first in class, best in class, most clinically advanced FTO inhibitor



Cardioprotection, an opportunity with significant commercial potential

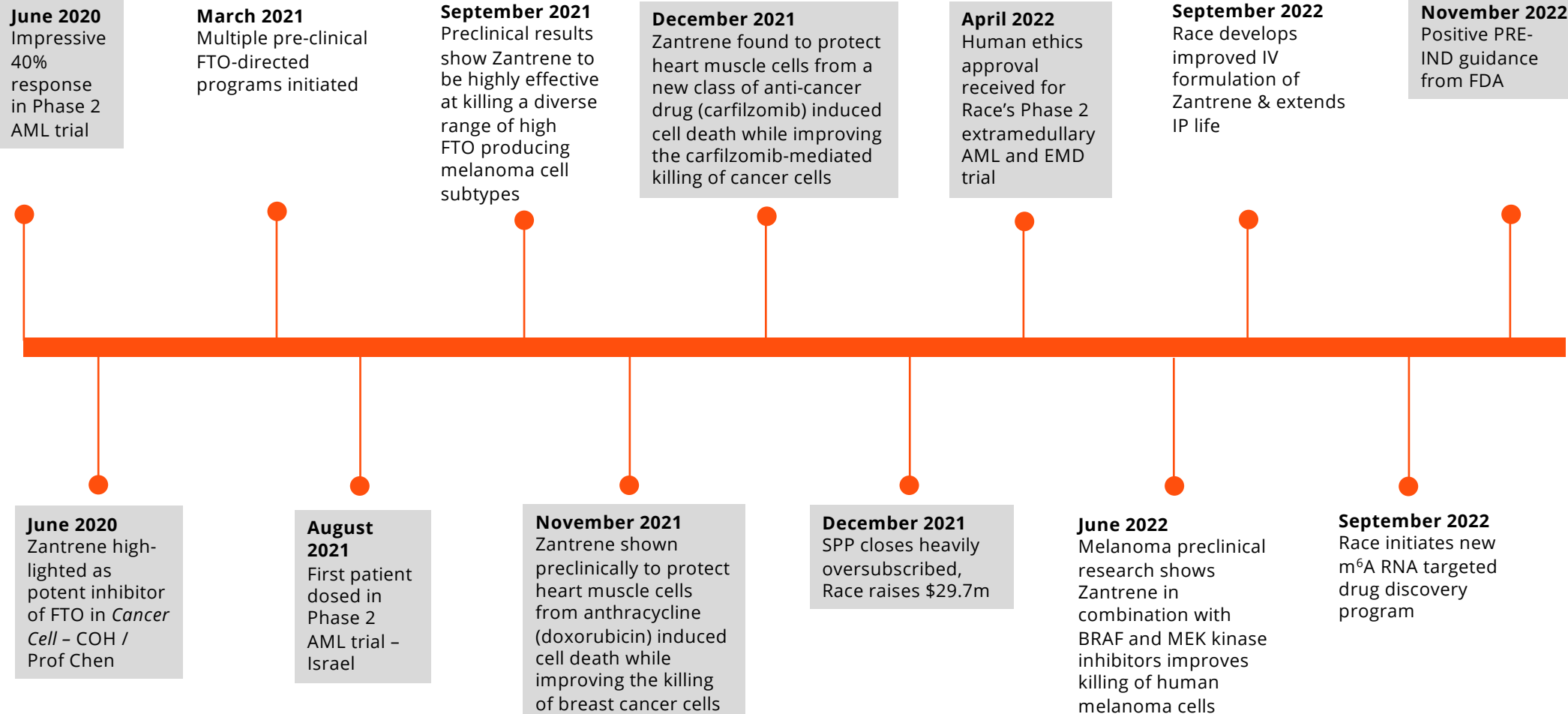


New formulation extends Zantrene[®] utility and value



Multiple short-to-medium term, high-impact inflection points

2020-2022 A PIVOTAL PERIOD FOR ZANTRENE



SIGNIFICANT COMMERCIAL OPPORTUNITIES



Multi-billion addressable market for AML & solid tumours

Significant revenue potential from FTO-driven cancers



Existing market with millions of patients given anthracyclines each year

Multi-billion dollar addressable market

Potential of similar magnitude to the FTO opportunity



Expanded opportunities in oncology, diabetes, cardiology and other diseases



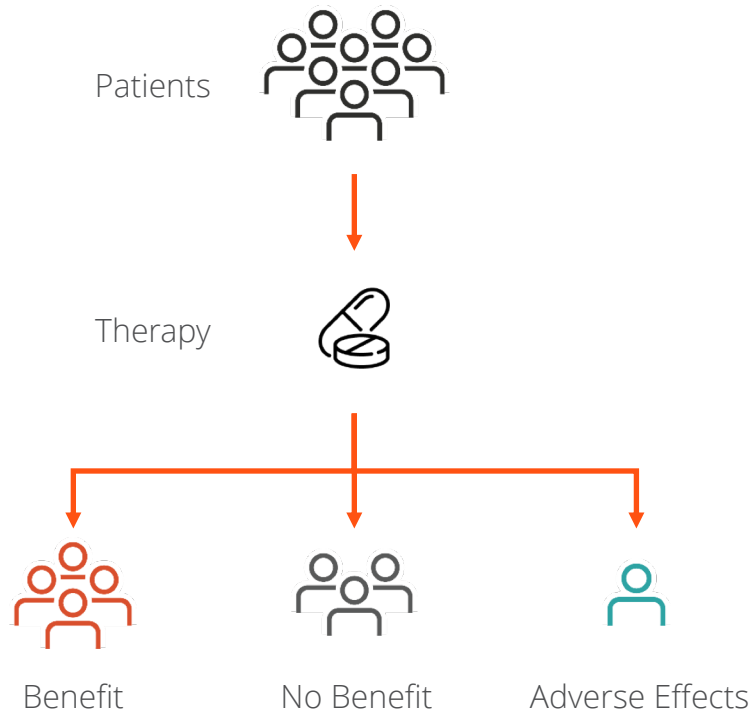
MARKET RATIONALE

PRECISION THERAPY. A FUNDAMENTAL CHANGE IN THE TREATMENT OF CANCER AND OTHER DISEASES



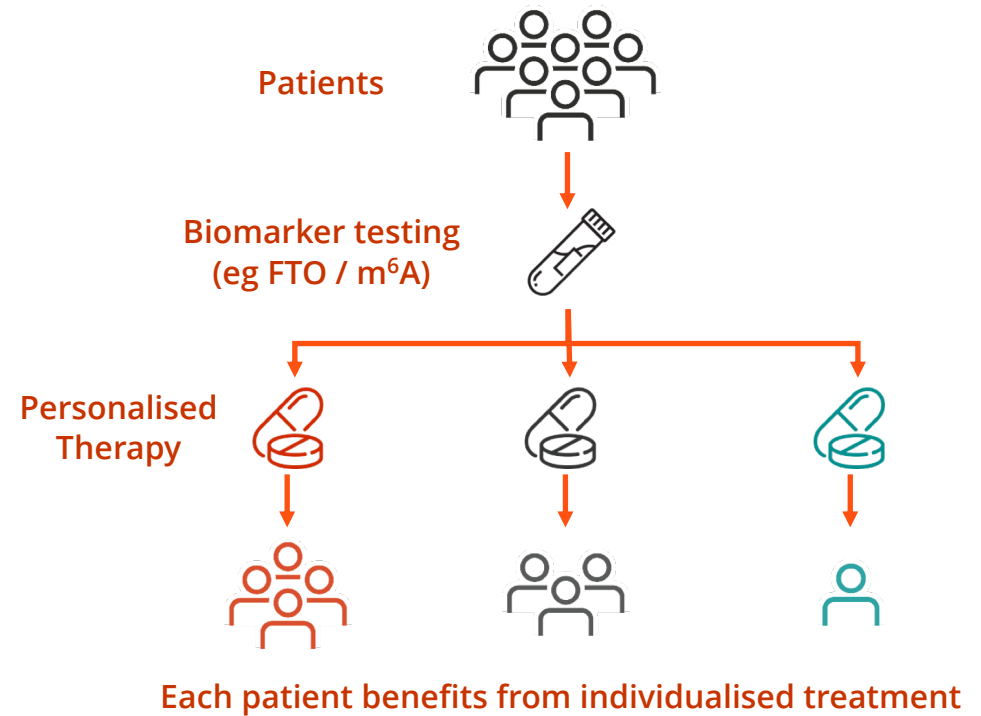
STANDARDISED MEDICINE

Some benefit, some do not

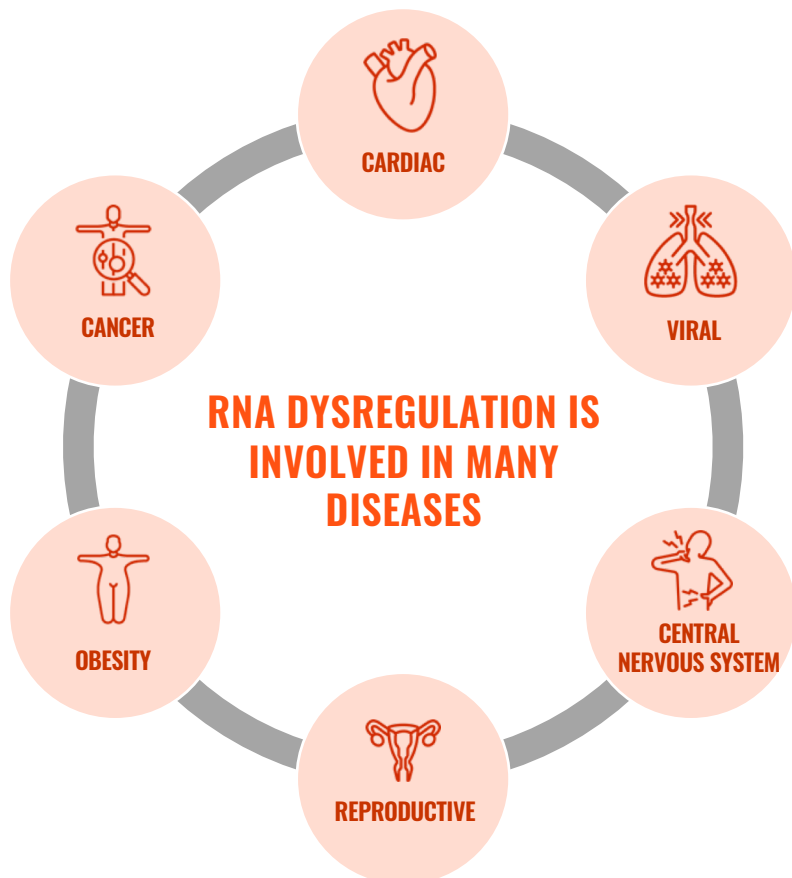


PERSONALISED MEDICINE

Each patient receives the right medicine for them



m⁶A RNA. DYSREGULATION UNDERLIES MANY DISEASES



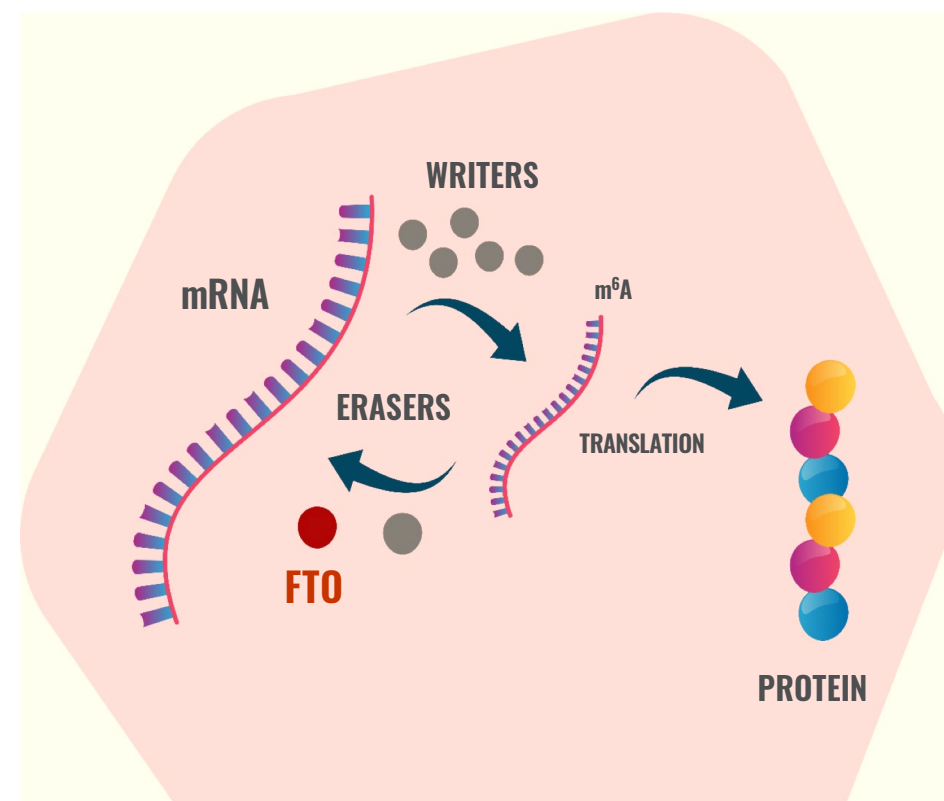
FTO. AN IMPORTANT m⁶A RNA DEMETHYLASE REGULATOR

FTO is a key m⁶A RNA demethylase that is dysregulated in many cancers and other diseases^{1,2}

Zantrene[®] has been independently confirmed as the first-in-class, best-in-class FTO inhibitor³

Race is advancing Zantrene[®] as the lead FTO targeted therapy in the clinic

Race is developing new m⁶A RNA targeted drugs to complement Zantrene[®]



1. Deng, X., Su, R., Stanford, S., & Chen, J. (2018). Critical Enzymatic Functions of FTO in Obesity and Cancer. *Frontiers in Endocrinology*, 9, 724–7
2. Huang, H., Weng, H., & Chen, J. (2020). m⁶A Modification in Coding and Non-coding RNAs: Roles and Therapeutic Implications in Cancer. *Cancer Cell*, 37(3), 270–28
3. Su, R. et al. Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion. (2020) *Cancer Cell* 38, 79-96.e11.



CORPORATE STRATEGY & GROWTH PLAN

CORPORATE SNAPSHOT



ISSUED CAPITAL

Shares ¹	161.2m
Options ¹	11.1m
Shareholders ²	9,168

MARKET CAPITALISATION

Share price ¹	\$2.26
Market value ¹	\$364m
Cash ²	\$29.4m
Enterprise value	\$334.9m

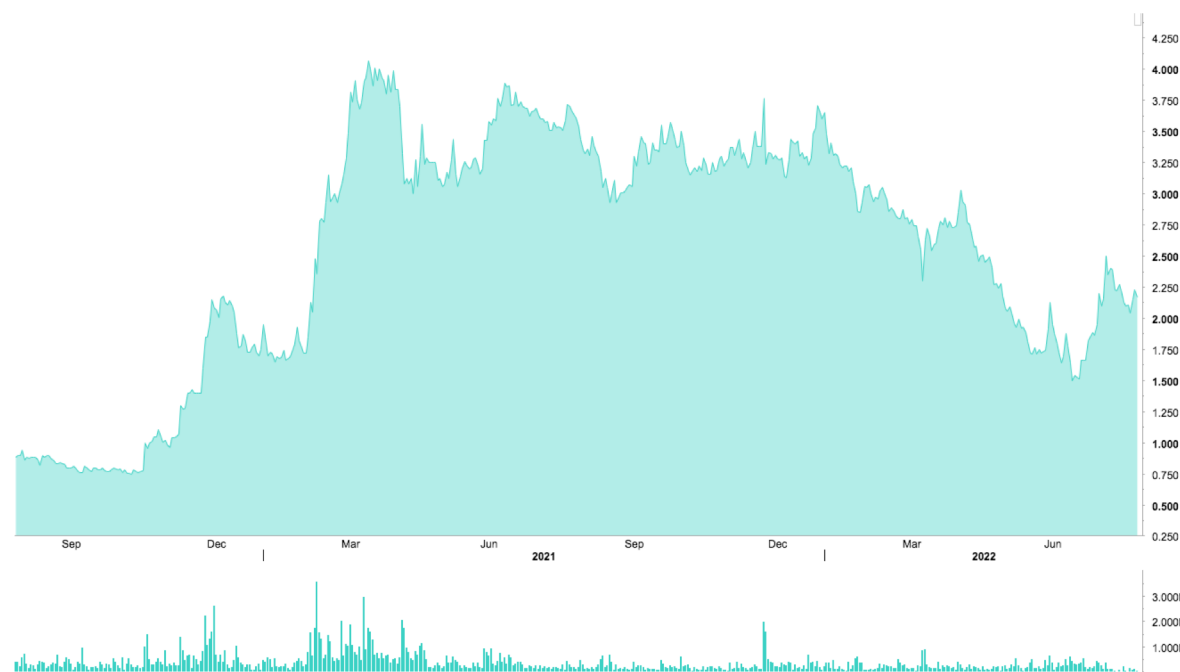
SIGNIFICANT SHAREHOLDERS

Dr Daniel Tillett (Director & CSO)	9.9%
Dr John Cullity (Chairman)	5.0%
Merchant Opportunities Fund	4.8%

1. As at 22 November 2022

2. As at 30 September 2022

ASX 24 MONTH PERFORMANCE



THREE PILLAR STRATEGY OPTIMISED BUILDING SHAREHOLDER VALUE



Capitalising on RNA regulation leadership credentials across all 3 Pillars

1 **ZANTRENE®**

Maximising Current Zantrene® Formulation

- Extramedullary AML provides pathway to regulatory approval
- Proof-of-principle FTO program
- US IND optionality in 2023

2 **ZANTRENE® OPTIMISED**

Enhancing Zantrene® Utility With New Formulations

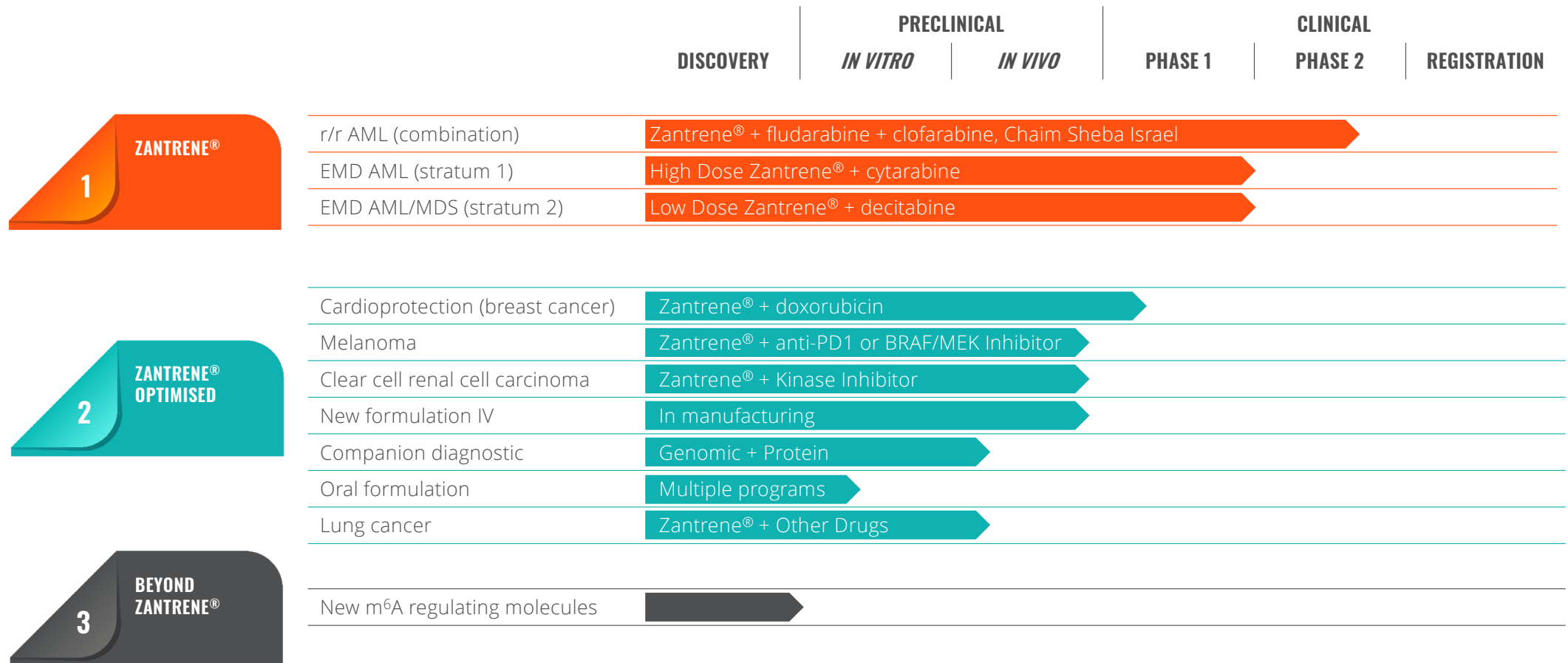
- Improved IV formulation(s) for FTO-targeting solid tumours and Cardioprotection
- Potential oral formulation
- New IP to support commercial value and partnering

3 **BEYOND ZANTRENE®**

Pursuing New m⁶A RNA-Targeting Drugs

- Internal development, partnership and/or acquisitions
- Monash fragment screening project underway

EXPANDED PIPELINE TARGETING FTO & m⁶A RNA METHYLATION



2023 PLANS



EMD AML. FTO CLINICAL PROOF-OF-CONCEPT



WHY EXTRAMEDULLARY (EMD) AML?

High unmet medical need with no stand-of-care therapy

EMD prevalence > 25% AML patients¹ with poor prognosis

Small number of patients needed for registrational trial



PHASE 2 TRIAL WITH TWO STRATA (ARMS)

Stratum 1 – traditional use: high dose Zantrene® + cytarabine

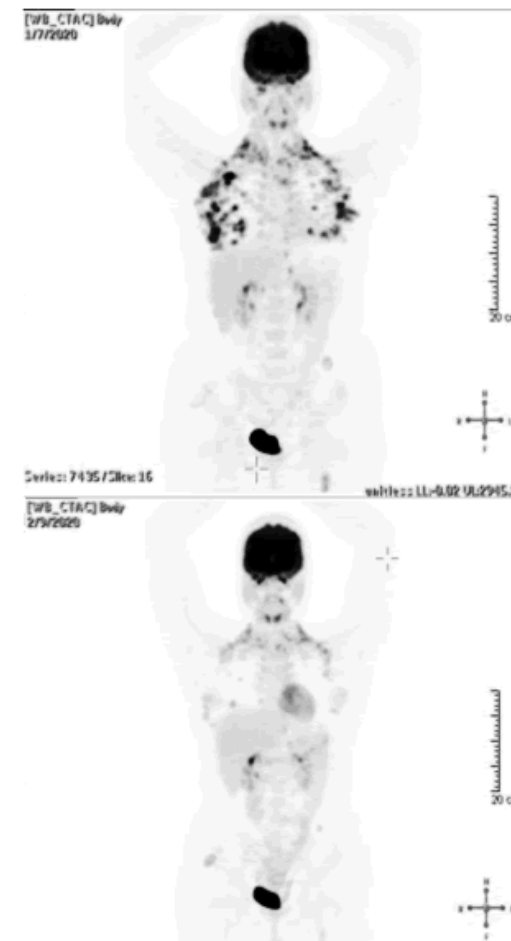
Stratum 2 – FTO targeting: low dose Zantrene® plus oral decitabine

Decitabine upregulates FTO expression² + synergy

Designed for AML & MDS patients that can not tolerate high intensity chemotherapy

Aim: RAC-006 x 10 sites - Australia + Europe

Challenge: Slow patient recruitment – why?



1. Stölzel, F., Lühr, T., Löck, S., Parmentier, S., Kuithan, F., Kramer, M., et al. (2020). The prevalence of extramedullary acute myeloid leukemia detected by 18FDG-PET/CT: final results from the prospective PETAML trial. *Haematologica*, 105(6), 1552–1558.
2. Su, R. et al. Targeting FTO Suppresses Cancer Stem Cell Maintenance and Immune Evasion. (2020) *Cancer Cell* 38, 79-96.e11



WHY HAS EMD AML PATIENT RECRUITMENT BEEN SO SLOW?



- EMD AML is a rare subtype of a rare disease
- Trial competition for AML patients
- Lack of capacity & clinical trial personnel
 - Massive growth of clinical trials in Australia in 2020
 - COVID-19 caused chaos in Australian public hospitals – no ability or people to start new trials
- Difficult to schedule AML patients into PET screening quickly – not standard-of-care in AML
- Clinicians not willing to PET screen patients for EMD unless they think the patient has EMD, but they can't diagnose EMD in most patients unless PET is used – the classic chicken & the egg problem!





EMD AML TRIAL. SOLUTIONS



Increase the number of trial sites in Australia & Europe

- 3 new sites in Australia interested now that COVID-19 pressure has reduced
- 6 sites in Italy & Spain on-board

Modify the Trial Design

- PET screen to be made a non-interventional sub-study (Study 1) looking at the rate of EMD in AML - can be performed at any time and not be linked to treatment (Study 2)
- Clinicians can enrol their patients just in Study 1 – low risk and easy to schedule



Study 1: Rate of EMD



Fit

Study 2: Treatment of EMD AML

Stratum 1: High Dose Zantrene®

Low risk of failure

Unfit

Stratum 2: Low Dose Zantrene®

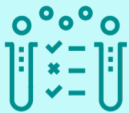
FTO proof-of-concept

IMPROVED IV FORMULATION EXTENDING AND ENHANCING ZANTRENE®



Original Zantrene® formulation requires a two hour central line IV infusion due to crystallisation in the blood

Not optimal for use in patients with solid tumours or cardioprotection (most cancers)



Race has developed a new Zantrene® peripheral IV formulation (RC220) that can be given over a shorter time

Allows the use of an arm or leg vein in an outpatient or home setting – much greater market potential

New IP with patent life to 2043 – resets the patent clock



IMPROVES ZANTRENE'S UTILITY, IP PROTECTION, PATIENT CONVENIENCE AND COMMERCIAL OPPORTUNITY



CARDIOPROTECTION OVERVIEW



High unmet patient need

Heart damage from cancer therapies is a major and increasing issue as cancer patients live longer

Anthracyclines and other anti-cancer drugs can cause permanent damage to the heart

New & emerging field of cardio-oncology

Limited range of effective therapies



Differentiated by cardio and cancer efficacy

Zantrene® known to have lower cardiotoxicity

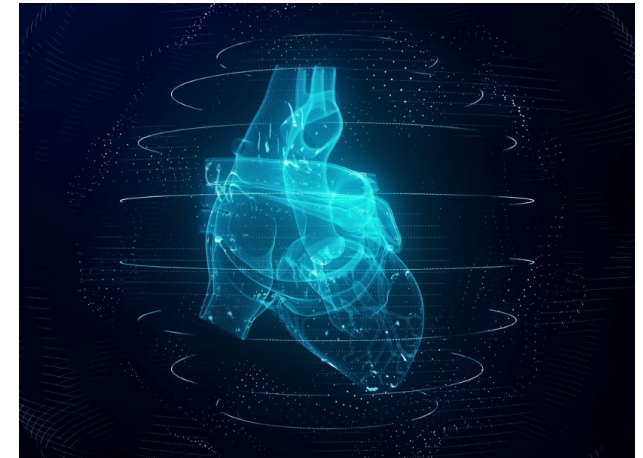
Zantrene® found to protect from anthracycline induced cardiac damage while providing anti-cancer synergy^{1,2}

Effect independent of FTO inhibition!



MULTI-BILLION DOLLAR ADDRESSABLE MARKET

**The Role of Anthracyclines – today's Cancer Patients
Are tomorrow's Cardiac Patients**



1. ASX Release: 21 November 2021; 2. 30 June 2022

Population: breast cancer patients with ≥ 2 cardiac risk factors to be treated with doxorubicin + cyclophosphamide (AC)

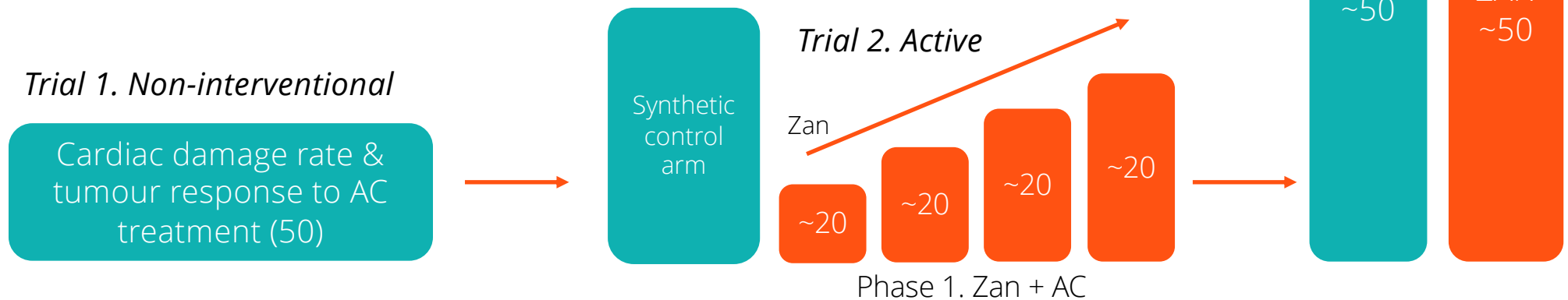
Split Two Trial Design

Trial 1. Non-interventional

- observation of cardiac damage and tumour response to AC treatment

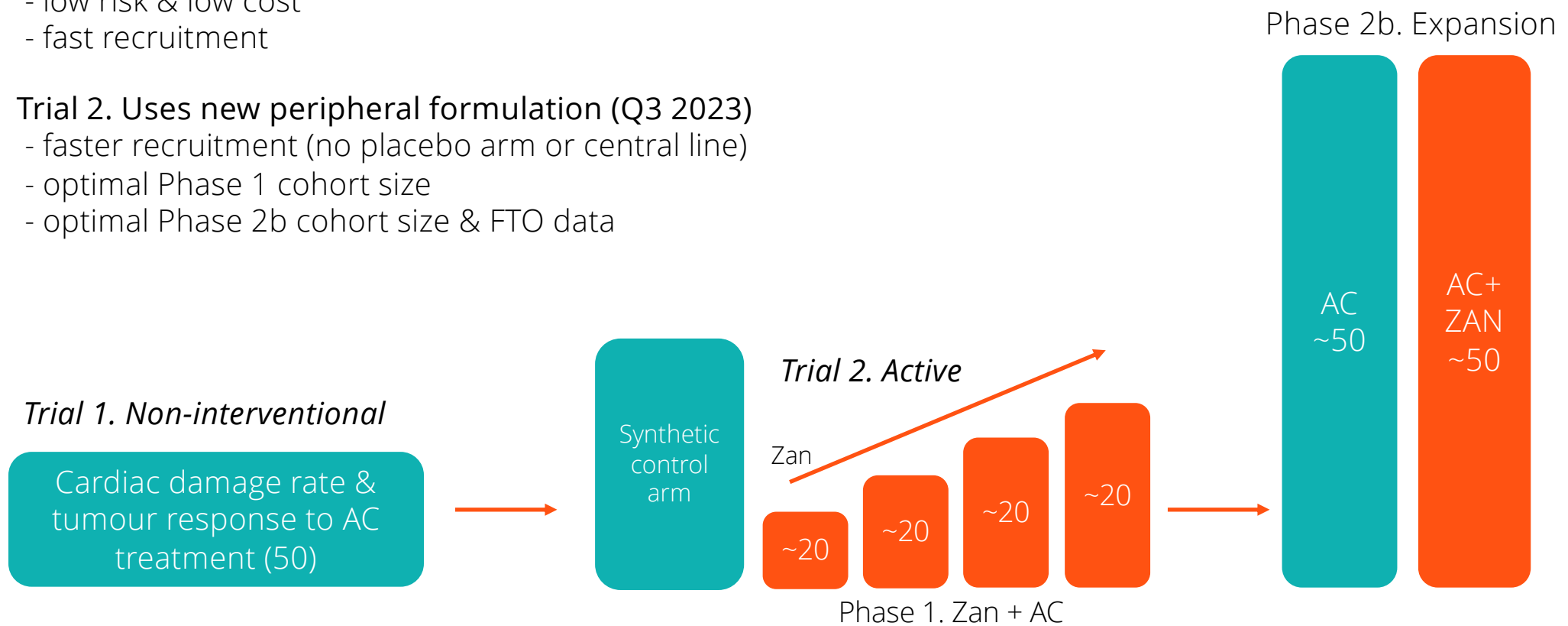
Trial 2. Phase 1/2b Active

- *Phase 1:* Dose escalation to MTD using cohort sizes determined from Trial 1
- *Phase 2:* Dose expansion using optimal dose determined from Phase 1



CARDIOPROTECTION. TRIAL DESIGN ADVANTAGES

- Trial 1. Early start (Q1 2023)
 - protocol written and ethics submission imminent (30 Nov 2022)
 - low risk & low cost
 - fast recruitment
- Trial 2. Uses new peripheral formulation (Q3 2023)
 - faster recruitment (no placebo arm or central line)
 - optimal Phase 1 cohort size
 - optimal Phase 2b cohort size & FTO data



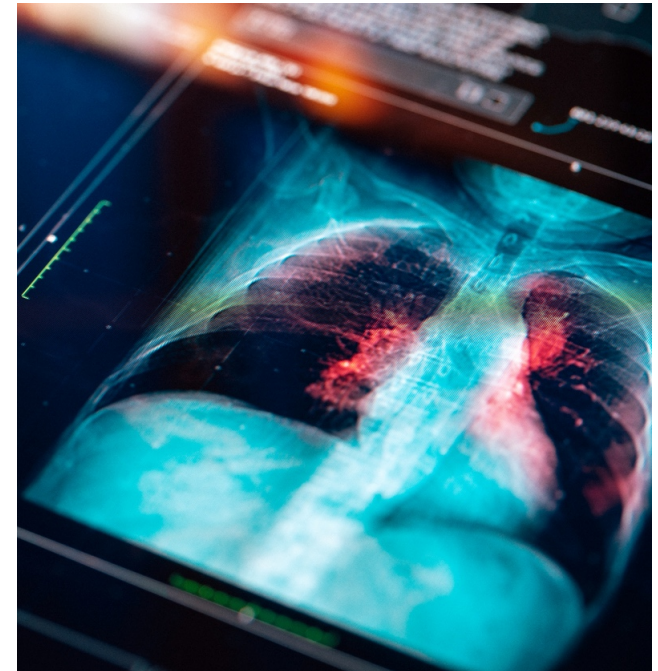
FTO. SOLID TUMOUR OPPORTUNITY



- FTO found to be important in almost all cancer types
- Kidney cancer and melanoma current lead indications based on preclinical and clinical data
- Many other options, both in cancer type and drug combinations

SOLID TUMOUR PLAN

- Delay trial start until RC220 available (Q3 2023); faster recruitment and avoids having to repeat trial with new formulation (large cost and resources savings)
- Use time window to preclinically screen across all tumour types and drug combinations; unbiased & optimal
- Best FTO opportunity carefully identified

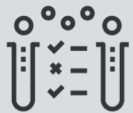


RIGHT TRIAL, RIGHT FORMULATION & RIGHT CANCER = OPTIMAL COMMERCIAL RESULT

NEW m⁶A RNA TARGETING DRUGS



Recent scientific and clinical discoveries implicate m⁶A RNA methylation in many disease areas including cancer



- Initiated NMR based drug screen program in collaboration with the Monash Fragment Platform
- Targeting FTO and other m⁶A RNA regulatory proteins
- Addresses cancer and non-cancer indications
- Builds Race beyond Zantrene®



PROVIDE NEW IP AND EXTEND APPLICATIONS AND COMMERCIAL OPPORTUNITY BEYOND ZANTRENE®



PUTTING ALL THE PIECES TOGETHER



We are pursuing the m⁶A RNA and cardioprotection pathway via:

1. EMD AML trial (Stratum 2 targeting FTO)
2. Breast Cancer (cardioprotection + FTO)
3. Other solid tumours
4. Improved Zantrene[®] formulation with novel IP
5. Discovery of new molecules which target the m⁶A RNA regulatory system (Monash)
6. Companion diagnostics that support the targeted use of Zantrene[®] and other future molecules as precision oncology agents

Race Oncology has the only m⁶A RNA-targeting drug in the clinic

MULTIPLE VALUE-DRIVING INFLECTION POINTS IN 2023



- Initiation of Phase 1/2b cardioprotection clinical trial (Australia)
- First patient dosed in Phase 1/2 EMD AML (FTO PoC) trial (Australia)
- Initiating European sites for Phase 1/2 EMD AML trial (Spain and Italy)
- Solid tumour FTO trial selection and initiation (Australia)
- Phase 2 data from combination AML trial (Israel)
- Delivery of new IV peripheral formulation (RC220)
- Update on new molecule program
- Update on companion diagnostic program
- Formal initiation of partnership and commercialisation campaign



Contact us

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