



# KINTARA

Therapeutics

*Developing Advanced Oncology Therapies for Rare Unmet Medical Needs*

## Corporate Presentation

June 2022

# Forward Looking Statements

This presentation contains forward-looking statements based upon Kintara’s current expectations. This communication contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by terminology such as “may,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar words. These statements are only predictions. Kintara has based these forward-looking statements largely on its then-current expectations and projections about future events, as well as the beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Kintara’s control, and actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to: (i) risks associated with the impact of the COVID-19 pandemic; (ii) risks and uncertainties relating to Kintara’s ability to develop, market and sell products based on its technology; the expected benefits and efficacy of Kintara’s products and technology; the availability of substantial additional funding for Kintara to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, Kintara’s business, research, product development, regulatory approval, marketing and distribution plans and strategies, and (iii) those risks detailed in Kintara’s most recent Annual Report on Form 10-K and subsequent reports filed with the SEC, as well as other documents that may be filed by Kintara from time to time with the SEC. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Kintara cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this communication relate only to events as of the date on which the statements are made. Except as required by applicable law or regulation, Kintara undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. Investors should not assume that any lack of update to a previously issued “forward-looking statement” constitutes a reaffirmation of that statement.

# Late-stage Oncology Company with Two De-Risked Product Candidates

## **VAL-083: A first-in-class small molecule with unique MOA (MW = 146)**

- Pivotal, pre-eminent GBM AGILE International registrational study for three GBM patient subtypes initiated January 2021
- ~\$1B<sup>1</sup> market opportunity in lead program: Glioblastoma Multiforme (GBM)
  - Multiple shots on goal via parallel enrollment of three GBM patient subtypes
  - Over 1,200 patient safety database via ~40 prior studies

## **REM-001: 2nd generation photodynamic therapy platform**

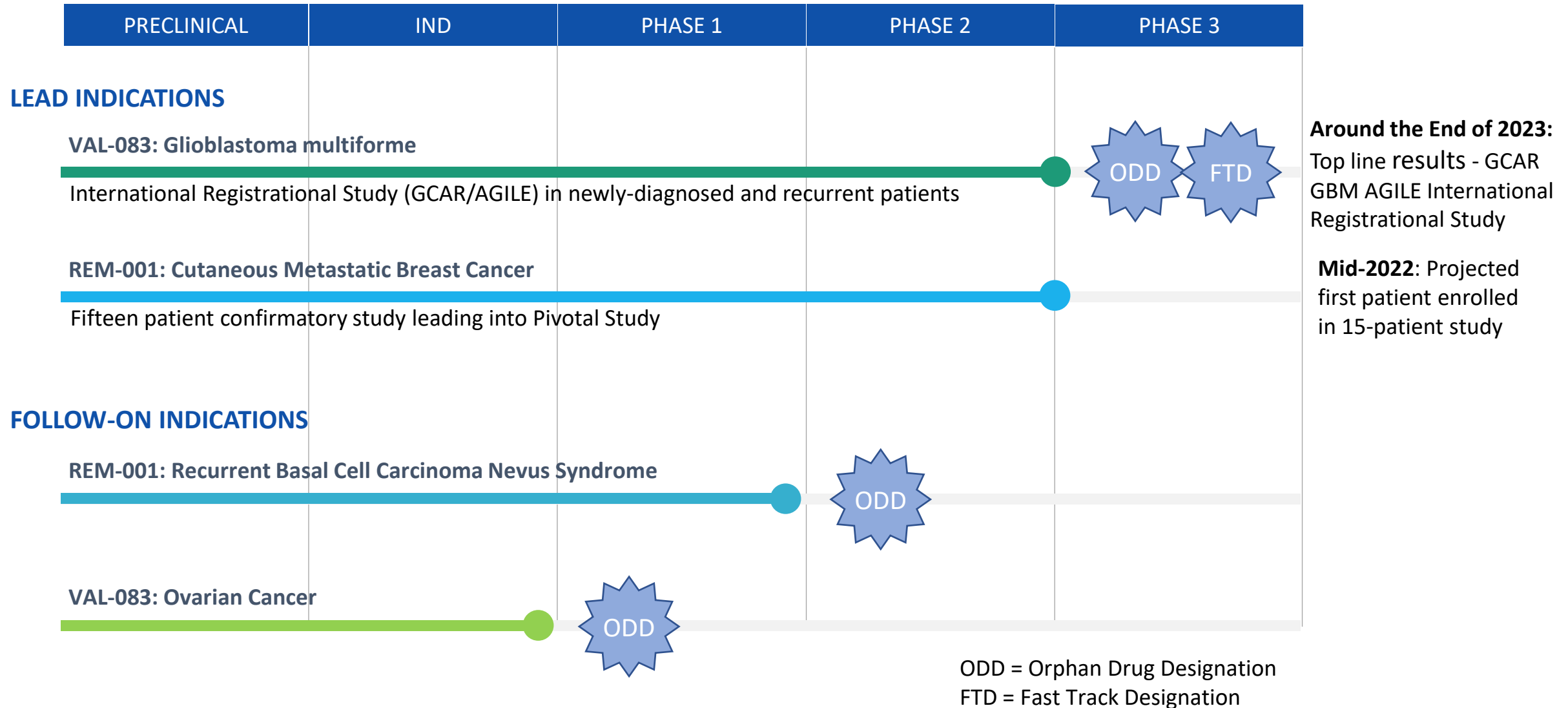
- 15-patient confirmatory study initiation planned for Mid-2022, prior to Phase 3 trial
- ~\$500M<sup>2</sup> market in lead program: Cutaneous Metastatic Breast Cancer
  - Extensive Phase 2/Phase 3 efficacy data (80% complete responses across four trials)
  - Over 1,100 patient safety database

## **Multiple follow-on indications with existing orphan designations and/or approved INDs**

<sup>1</sup>GlobalData November 2018

<sup>2</sup>Charles River Associates April 2018

# Kintara Product Pipeline – Multiple Shots on Goal



# VAL-083: GBM Opportunity

“Survival rates for patients with GBM have shown no notable improvement in population statistics in the last three decades.”

Tamimi AF, Juweid M. Epidemiology and Outcome of Glioblastoma. In: De Vleeschouwer S, editor. Glioblastoma [Internet]. Brisbane (AU): Codon Publications; 2017 Sep 27. Chapter 8. PMID: 29251870.

“No new systemic therapy has been approved for use against glioblastoma in almost two decades.”

Lyne SB, Yamini B. An Alternative Pipeline for Glioblastoma Therapeutics: A Systematic Review of Drug Repurposing in Glioblastoma. *Cancers (Basel)*. 2021;13(8):1953. Published 2021 Apr 18. doi:10.3390/cancers13081953

>\$800M market growing to \$1.4B in 2027<sup>1</sup>

- ~30,000 newly-diagnosed patients in US/EU
- ~14,000 recurrent patients in US/EU

GBM AGILE Phase 2/Phase 3 international registration study:

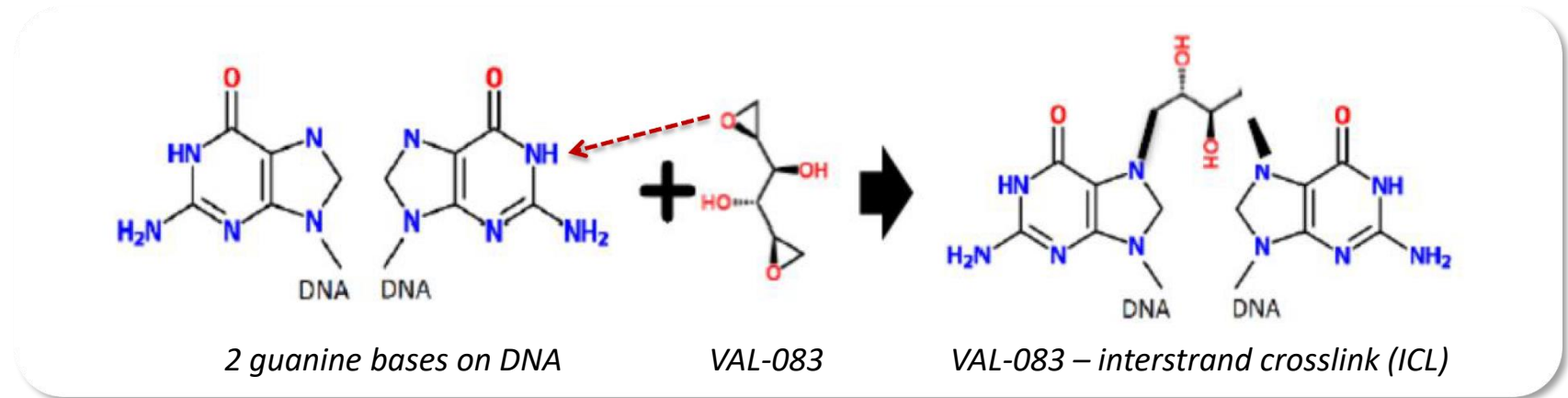
- FDA approved & strongly endorsed adaptive design
- Involvement from numerous KOLs
- Partnership with Global Coalition for Adaptive Research (GCAR)

Kintara is enrolling in all three GBM AGILE patient subtypes:

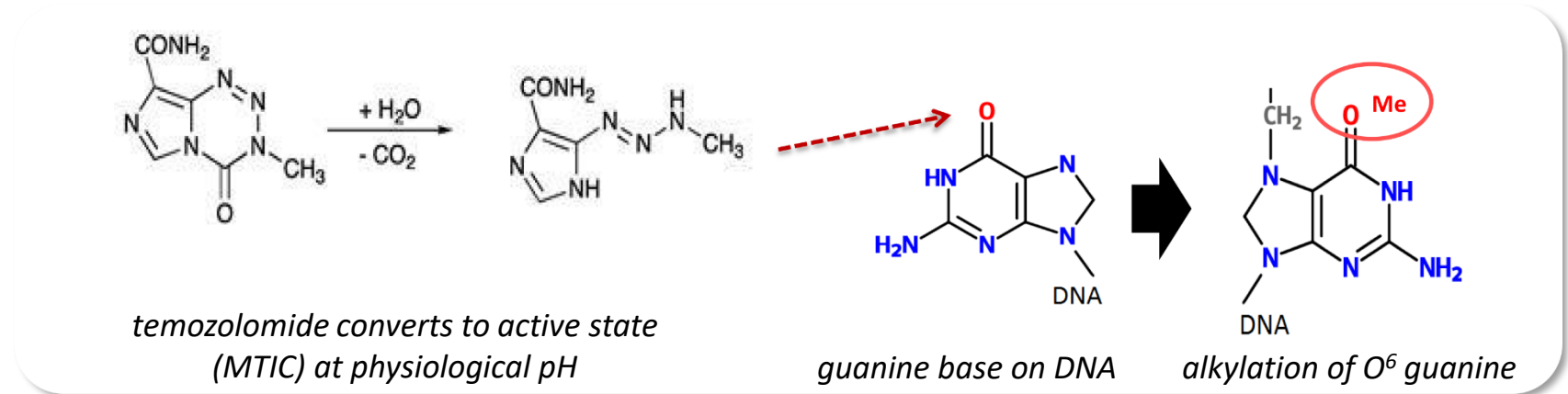
- Newly-Diagnosed Unmethylated (>60% of GBM patients)
- Newly-Diagnosed Methylated (<40% of GBM patients)
- Recurrent

# VAL-083 Mechanism of Action

VAL-083's unique mechanism of action creates inter-strand DNA cross-links at the N<sup>7</sup> position of guanine, resulting in double-strand DNA breaks and cancer cell death via apoptosis



Mechanism of VAL-083 via crosslinks at N<sup>7</sup> of guanine



Mechanism of temozolomide (TMZ) via alkylation at O<sup>6</sup> of guanine

VAL-083's unique DNA targeting mechanism circumvents MGMT-mediated chemoresistance and differentiates it from other therapies used in the treatment of GBM, including TMZ.

# VAL-083 vs Standard-of-Care TMZ

VAL-083	TMZ
Bifunctional DNA alkylating agent	Monofunctional
Induces DNA interstrand crosslinks	Does not induce DNA interstrand crosslinks
Induces double strand DNA breaks (DSB): non-repairable and lethal to tumor cells	Induces single strand DNA breaks (SSB): tumor cells can repair
Administered IV with very reproducible pharmacokinetics	An oral prodrug with varying bioavailability
Achieves peak brain concentrations that are ~20% higher than corresponding plasma levels	Achieves peak brain concentrations ~80% lower than peak plasma levels
Activity similar in both methylated and unmethylated MGMT GBM cells	Unmethylated MGMT GBM cells very resistant to TMZ
Twice as potent as TMZ for methylated MGMT GBM cells	Half as potent as VAL-083 for methylated MGMT GBM cells

# VAL-083: Clinical Data - Phase 2 Studies Top Line Results

Newly-Diagnosed Patients (MGMT-unmethylated)	Evaluable 30 mg Patients	Median Progression Free Survival	Median Overall Survival
<i>TMZ Historical Comparator</i>		<i>5.0-6.9 months<sup>1,2,3</sup></i>	<i>12.7-16.0 months<sup>1,2,3</sup></i>
SYSUCC Newly-Diagnosed [First Line]	n=25	8.7 months	19.1 months
MDACC Newly-Diagnosed [Adjuvant]	n=36	9.5 months	16.5 months

Recurrent Patients (MGMT-unmethylated)	Evaluable 30 mg Patients	Median Overall Survival
<i>Lomustine Historical Comparator</i>		<i>7.2 months<sup>4</sup></i>
MDACC Recurrent	n=48	8.0 months

<sup>1</sup>Hegi et al N Eng J Med (2005)

<sup>2</sup>Tanguturi et al. NeuroOncol (2017)

<sup>3</sup>Alnahhas et al. Neurooncol Adv (2020)

<sup>4</sup>Wick et al N.Eng.J.Med (2017)

*Open label Phase 2 studies in unmethylated patients;  
treatment dose for GCAR GBM AGILE Study;*



# VAL-083: FDA Approved Expedited Development and Registration Pathway

## Collaboration with the Global Coalition for Adaptive Research (GCAR)

- Founded in 2017 by world’s foremost clinical, translational, basic science investigators, and health authorities
- Sponsor of innovative and complex platform trials utilizing adaptive design
- Prior success via I-SPY with similar design for breast cancer

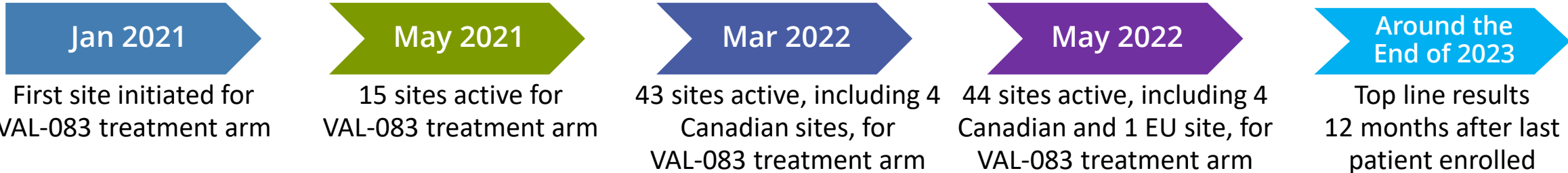
## GBM Adaptive Global Innovative Learning Environment (AGILE) Study

- International effort in newly-diagnosed and recurrent glioblastoma
- Master Protocol with three or more experimental arms versus a common control
- Primary endpoint: overall survival
- “Seamless” transition to Stage 2, with Stage 1 patients included in final analysis
- Final analysis 12 months after last patient randomized

## 150 to 200 Patients Maximum Stratified by Three Subtypes

- Newly-diagnosed methylated
- Newly-diagnosed unmethylated<sup>1</sup>
- Recurrent<sup>2</sup>

<sup>1</sup>Comparable to MDACC Phase 2 trial – adjuvant cohort  
<sup>2</sup>Comparable to MDACC Phase 2 Trial – recurrent cohort



# GCAR/GBM AGILE Advantages

**Utilized non-profit funding to design and initiate GBM trial (1<sup>st</sup> patient enrolled: June 2019)**

**Principals successful in platform and adaptive design paradigm per highly successful breast cancer trial**

- (I-Spy): 10-year trial, 16 compounds tested, three received FDA accelerated approval

**Regulatory buy-in at highest level with strong FDA support**

**Rapid study startup and patient enrollment**

- Turn-key solution
- 44 sites currently enrolling Kintara arm:
  - Includes four sites in Canada and one site in Europe
- Expanding into additional sites in the EU in the near future
- Shared control group:
  - Contains costs and accelerates speed of study
  - Has been enrolling for over two years
- Provides significant time and cost savings vs. multiple trials
- Avoids company scale up of fixed expenses for trial execution



**GLOBAL COALITION  
FOR ADAPTIVE RESEARCH™**

*"Platform trials can accelerate the time from discovery in the laboratory to implementation in the clinic. **GBM AGILE will raise the bar for all clinical trials.**"*

Janet Woodcock, M.D.  
Director of the Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

<https://www.businesswire.com/news/home/20190619005230/en/Global-Coalition-Adaptive-Researchs-Innovative-Clinical-Trial>

# GCAR: GBM AGILE Major Clinical Sites/Investigators

## Principal Investigators of Kintara's arm of the GBM AGILE study:



Dr. John de Groot  
Division Chief Neuro Oncology Division  
Department of Neurological Surgery  
University of California San Francisco



Dr. James Perry  
Professor of Neurology  
University of Toronto  
Sunnybrook Research Institute

## With 40 sites enrolling, GBM AGILE includes Key Opinion Leaders and leading clinical sites:



Henry Ford Health System - Detroit



Dana Farber Cancer Institute - Boston



Memorial Sloan Kettering Center - New York



Mount Sinai - New York



MD Anderson Cancer Center - Houston



Cleveland Clinic - Cleveland



Mayo Clinic Cancer Center - Jacksonville



Duke University Medical Center - Durham

“GBM AGILE is an innovative clinical trial approach that enables us to simultaneously and dynamically study the effects of multiple new drug candidates. With the inclusion of paxalisib and VAL-083 for newly-diagnosed unmethylated and recurrent GBM patients, as well as VAL-083 for the additional methylated GBM patient group, we are excited to offer all GBM patients access to these latest therapies.”

- Dr. James Perry

# VAL-083: FDA Approved Expedited Development and Registration Pathway

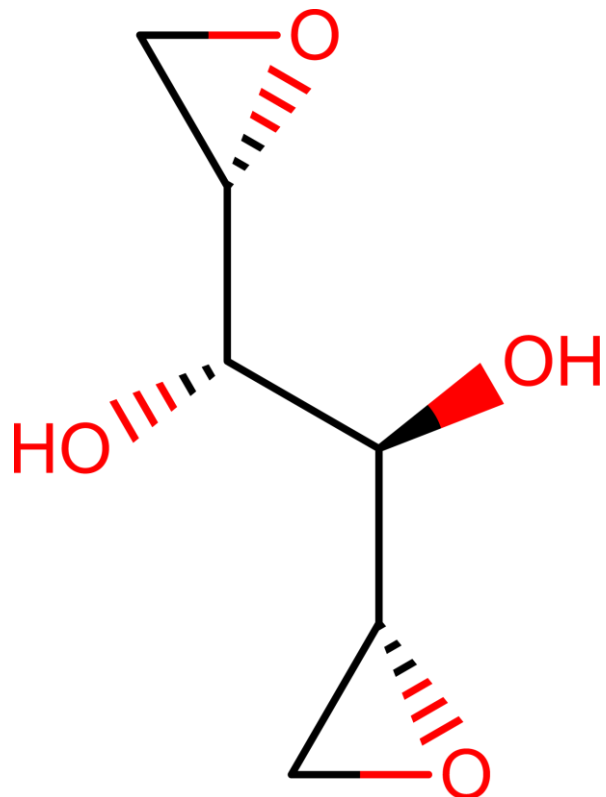
## Current Clinical Status

### January 2021:

- Kintara jumps on “a fast-moving train” with GBM AGILE
- Current patient enrollment better than initially anticipated
- Over 1,000 patients screened

### Kintara’s VAL-083 is participating in all three patient subtypes:

- Newly-diagnosed MGMT-unmethylated (>60% of GBM patients)
- Newly-diagnosed methylated (<40% of GBM patients) — Kintara / VAL-083 only
- Recurrent



# REM-001: 2<sup>nd</sup> Generation Photodynamic Cancer Therapy

## CMBC Overview

Cutaneous Metastatic Breast Cancer is a major unmet medical need

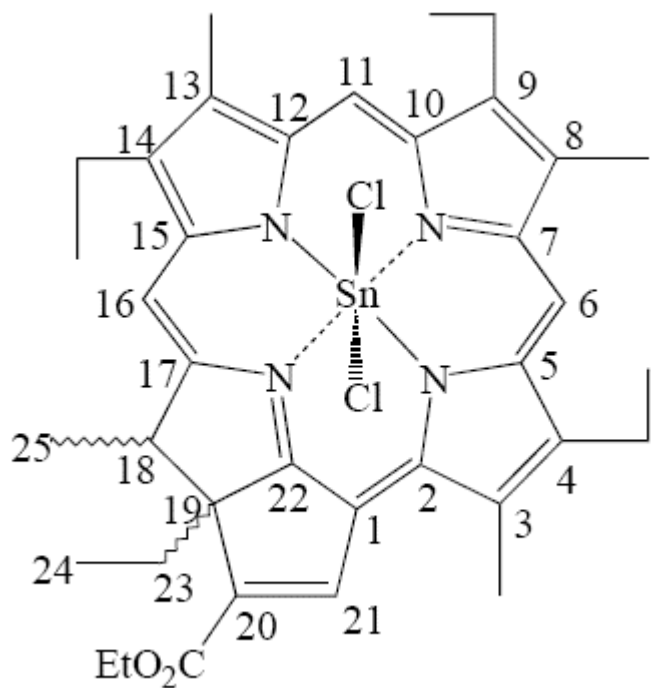
Up to 40,000 patients in the U.S.<sup>1</sup>, representing \$500M market opportunity<sup>2</sup>

Clinical aspects: Highly morbid form of breast cancer

- Bleeding, infectious and malodorous lesions on chest wall, neck and back
- Narcotics for pain control

Limited current therapies

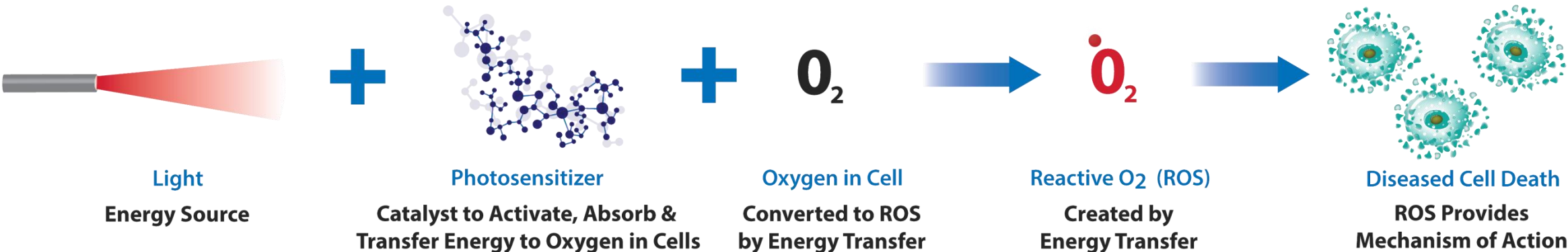
- Chemotherapy: generally non-responsive
- Radiation: dose limiting toxicities, lesions are often refractory to radiation



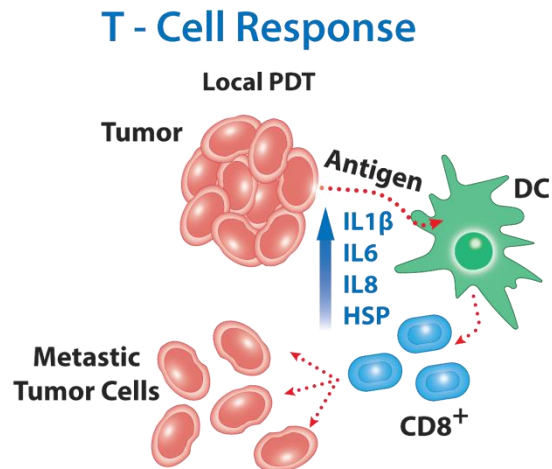
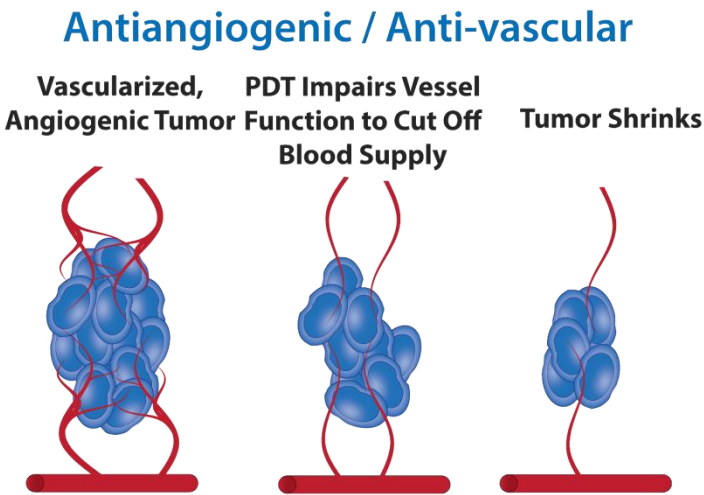
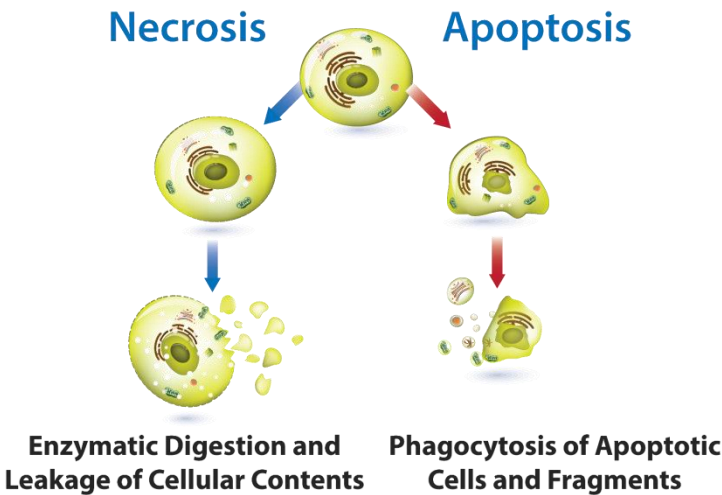
<sup>1</sup>Source (a): Saika et al, 2009; Kamaraju et al, 2016; Vano-Galvan et al, 2009; GlobalData Report on Metastatic Breast Cancer; Schoenlaub et al, 2001

<sup>2</sup>Charles River Report April 2018

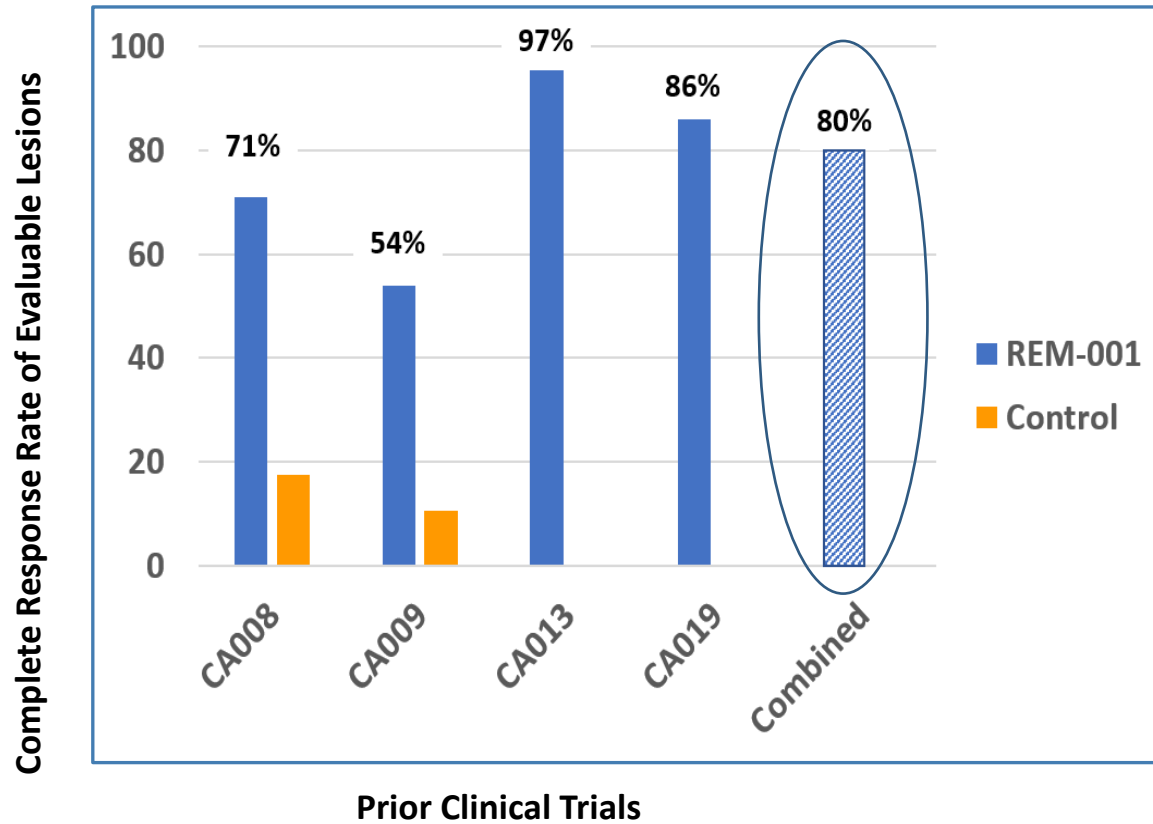
# Photodynamic Therapy Mechanisms of Action



PDT induces elimination of diseased cells by immune response, apoptosis, antiangiogenesis and necrosis



# REM-001: High Response Rates in CMBC



## Second Generation Photodynamic Therapy

- Light activated cancer therapy

## Extensive data from prior Phase 2/Phase 3 clinical trials

- 149 patients treated in 4 trials
  - 80% complete response rate in 674 evaluable lesions

## Localized Outpatient Treatment

- IV drug infusion accumulates in tumors
- Activated by simple red light

Safety database ~1,100 patients

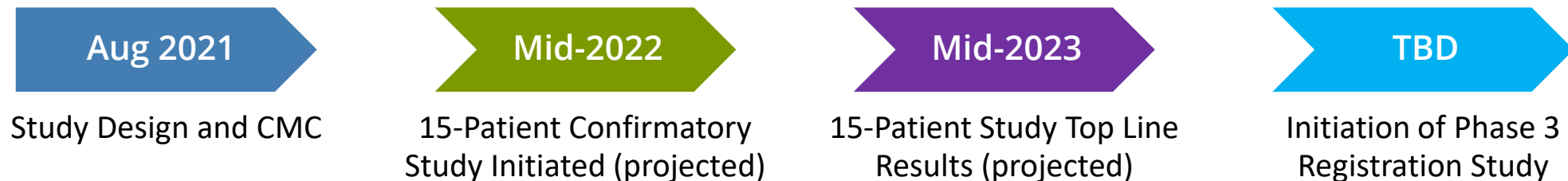
Previous trial experience used to optimize current trial design

# REM-001: CMBC Development Plan

## Development plan optimized for success while minimizing cost

- Phase 3 ready
- Initial open-label, 15-patient study to confirm lower dose and optimize trial design
- Leverages prior data indicating lower dose can improve outcome
  - Faster healing
  - Less photosensitivity
- De-risks full Phase 3 study

## Anticipated study start in Mid-2022





# Indication Expansion Opportunities

## VAL-083

- Platinum resistant Ovarian Cancer<sup>1</sup>
- Non-Small Cell Lung Cancer<sup>1</sup>
- Other Solid Tumors, including pediatric indications

## REM-001

- Other Cutaneous Metastatic Cancers
- Recurrent Basal Cell Carcinoma Nevus Syndrome<sup>2</sup>
- Locally Advanced Basal Cell Carcinoma (laBCC)
- Peripheral Lung Cancer
- Hemodialysis Arteriovenous (AV) Access

<sup>1</sup>Prior Phase 1 and Phase 2 studies completed by NCI

<sup>2</sup>Demonstrated positive results in prior sponsor's Phase 2 study

# Barriers to Competition

## VAL-083

GBM Orphan drug designation in US and EU

- Seven years market exclusivity after approval in US
- 10 years market exclusivity after approval in Europe

Fourteen patent families

- Claims to methods of use, dosing and administration, combinations, manufacturing, analytical methods, and methods of synthesis

Fourteen US granted patents and forty-five patents granted worldwide

- Expiry dates range from 2031 to 2038

Ovarian Cancer Orphan Drug Designation in US

## REM-001

New Chemical Entity

- Five years data exclusivity after approval in US
- 8+2+1 Regime in Europe

Combination Product Regulatory Pathway

- REM-001 and Laser Device

Follow-on Indication Orphan Drug Designations in US

- Basal cell carcinoma nevus syndrome (BCCNS)
- Hemodialysis access grafts

# Upcoming Milestones/Value Inflection Events

## Q1 2021

- Commence Enrollment - GCAR GBM AGILE International Registrational Study ✓

## Q2 2021

- AACR Posters – Data updates for Phase 2 GBM Studies ✓
- Top Line Results - Phase 2 Recurrent GBM Study ✓

## Q3 2021

- Top Line Results - Phase 2 Newly Diagnosed Adjuvant GBM Study ✓

## Q4 2021

- First site in Canada – GCAR GBM AGILE International Registrational Study ✓

## Q2 2022

- First site in the EU – GCAR GBM AGILE International Registrational Study ✓

## Mid-2022

- Initiate 15-patient CMBC confirmatory trial

## Mid-2023

- Top line results from 15-patient CMBC confirmatory trial

## Around the End of 2023

- Top line results 12 months after last patient randomized - GCAR GBM AGILE International Registrational Study



# Seasoned Biopharma Leadership Team

## **Robert Hoffman**

President and CEO  
Chair, Board of Directors

CEO of Kintara from November 2021, Chair of Board from June 2018; Board member of ASLAN Pharmaceuticals and Antibe Therapeutics; previously served as Senior Vice President and Chief Financial Officer of Heron Therapeutics from April 2017 to October 2020; part of the founding management team of Arena Pharmaceuticals in 1997, serving in various roles until 2015, including Senior Vice President, Finance and Chief Financial Officer

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## **Greg Johnson**

(Acting) Head of Operations

Acting head of operations since January 2018; 29 years of international clinical research and drug development experience; 10 years at MedGenesis Therapeutix Inc. initially as COO, then President and CFO; 15 years at PRA International (now ICON) in a variety of senior roles in four different countries; M.Sc. in Clinical Research; Fellow of the Institute of Clinical Research (FICR)

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## **Scott Prail**

CFO

CFO of Kintara since January 2013; previously consulted with multiple companies including Kintara; served as Director of Finance for Inflazyme Pharmaceuticals; worked at PricewaterhouseCoopers LLP for four years and completed a CPA in 1996

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## **Dennis Brown**

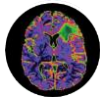
CSO

Kintara founder, and Chief Scientific Officer since January 2013; served as a member of Board of Directors from February 2013 to April 2018; more than 30 years of successful drug discovery and development experience; B.A. in Biology and Chemistry, M.S. in Cell Biology, Ph.D. in Radiation and Cancer Biology

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# Scientific Advisory Boards

## GBM Scientific Advisory Board



**Dr. John de Groot (PI for Kintara/VAL-083 in GBM AGILE)**  
**University of California San Francisco**  
Division Chief Neuro Oncology Division, Department of Neurological Surgery



**Dr. Timothy Cloughesy (Overall PI for GBM AGILE)**  
**David Geffen School of Medicine (UCLA)**  
Professor of Neurology



**UCLA Brain Research Institute and Jonsson Comprehensive Cancer Center**  
Member



**Dr. Napoleone Ferrara**  
**University of California, San Diego**  
World renowned scientist and Distinguished Professor of Pathology and a Distinguished Adjunct Professor of Ophthalmology and Pharmacology



**Dr. David Reardon**  
**Dana-Farber Cancer Institute**  
Clinical Director of the Center for Neuro-Oncology



**Harvard Medical School**  
Professor of Medicine



**Dr. Nicholas Butowski**  
**UCSF Medical Center**  
Neuro-oncologist



**Brain Tumor Center**  
Director of Translational Research in Neuro-Oncology and Researcher

## CMBC Scientific Advisory Board



**Mario Lacouture, MD**  
**Memorial Sloan Kettering Cancer Center**  
Director, Oncodermatology Program  
Leading expert in treatment of cutaneous metastases in cancer



**Thomas S. Mang, PhD**  
**University at Buffalo (UB) School of Dental Medicine\***  
Director of Research for Oral and Maxillofacial Surgery Department  
Recognized PDT expert and prior clinical work with REM-001 Therapy



**Stephen B. Solomon, MD**  
**Memorial Sloan Kettering Hospital**  
Chairman, Interventional Radiology and Co-Director, Image-Guided Intervention  
Specializes in image-guided interventions in cancer



**Leonard A. Farber, MD**  
**Weill Cornell Hospital\***  
Radiation Oncologist  
Specialties include adult radiation oncology for breast cancer patients  
Experience in treating CMBC and recurrent basal cell carcinoma

*\*Prior affiliations*

# Investment Highlights

- Late-stage oncology company with two highly de-risked assets for underserved indications
- VAL-083
  - Initiated GBM AGILE International Registrational Study: January 2021 with VAL-083 enrolling all three GBM AGILE patient subtypes
  - Accelerated clinical pathway with strong regulatory support and 44 sites enrolling in Kintara arm
  - >\$1B market opportunity<sup>1</sup>
- REM-001 — Light activated cancer therapy diversifies late-stage oncology pipeline
  - 80% complete responses across four clinical trials to date in CMBC
  - 15-Patient confirmatory study initiation planned for Mid-2022, prior to Phase 3 trial
  - \$500M market opportunity<sup>2</sup>
- Significant upcoming milestones/value inflection events
  - Mid-2022: Initiate 15-patient CMBC confirmatory trial
  - Mid-2023: Top line results from 15-patient CMBC confirmatory trial
  - Around the End of 2023: Top line results from GCAR GBM AGILE Study 12 months after last patient randomized

<sup>1</sup>GlobalData November 2018

<sup>2</sup>Charles River Associates April 2018