

# **Forward Looking Statements**

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# 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. A total of 45 sites across US, Canada and Europe.
- ~\$1B¹ 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**

- National Institutes of Health grant awarded June 2023
- 15-patient confirmatory study to start this quarter (3Q 2023)
- ~\$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

# Kintara Product Pipeline – Multiple Shots on Goal

|   |     |                              |                    |         | Orphan Drug<br>Designation | Fast Track<br>Designation |
|---|-----|------------------------------|--------------------|---------|----------------------------|---------------------------|
| PRECLINICAL   | IND | PHASE 1                      | PHASE 2            | PHASE 3 |                            |                           |
| LEAD INDICATIONS  |     |                              |                    |         |                            |                           |
| VAL-083: Glioblastoma multiforme  |     | Newly-Diagnosed Unmethylated |                    |         | Malignant Gliomas          | <b>~</b>                  |
| VAL-083: Glioblastoma multiforme  |     | Newly-Diagnosed Methylated   |                    |         | Medulloblastoma            |                           |
| VAL-083: Glioblastoma multiforme  |     | Recurrent                    |                    |         | Glioma                     | <b>✓</b>                  |
| International Registrational Study (GCAR/AGILE) in Top line results expected before the end of 2023 |     |                              | recurrent patients |         | )                          |                           |
| REM-001: Cutaneous Metastatic Breast Cancer   |     |                              |                    |         |                            | <b>~</b>                  |
| Fifteen-patient study leading into Pivotal Study Program awarded National Institutes of Health Gra  |     | irant                        |                    |         |                            |                           |
| FOLLOW-ON INDICATION  | ONS |                              |                    |         | `                          |                           |
| REM-001: Recurrent Basal Cell Carcinoma Nevu  |     | s Syndrome                   |                    |         | BCCNS                      |                           |
| VAL-083: Ovarian Cance  | er  |                              |                    |         | Ovarian Cancer             |                           |

# VAL-083: GBM Opportunity

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 >\$1.0B 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 arms in all three GBM AGILE patient subtypes:

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

# VAL-083's unique DNA targeting mechanism circumvents MGMT-mediated chemoresistance and differentiates it from other therapies used in

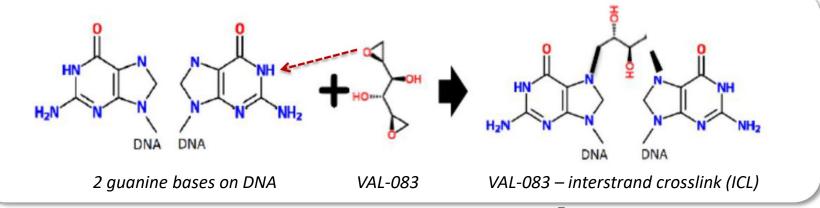
the treatment of

GBM, including

TMZ.

# VAL-083 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

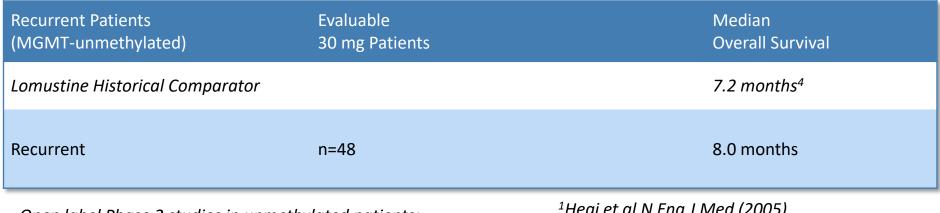
Mechanism of temozolomide (TMZ) via alkylation at O<sup>6</sup> of guanine

# VAL-083 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<br>30 mg Patients | Median Progression Free Survival                            | Median<br>Overall Survival                                     |
|--------------------------------------|--|-----------------------------|---|--|
|                                      | TMZ Historical Comparator                    |                             | 5.3 <sup>1</sup> /6.9 <sup>2</sup> /5.0 <sup>3</sup> months | 12.7 <sup>1</sup> /16.0 <sup>2</sup> /14.1 <sup>3</sup> months |
| Sun Yat-sen University Cancer Center | Newly-Diagnosed<br>[First Line]              | n=25                        | 8.7 months  | 19.1 months  |
| MDAnderson<br>Cancer Center          | Newly-Diagnosed<br>[Adjuvant]                | n=36                        | 9.5 months  | 16.5 months  |



**MDAnderson** Cancer Center

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

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

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

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

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

# 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 <u>newly-diagnosed and recurrent glioblastoma</u>
- Master Protocol with three or more experimental arms versus a common control
- Primary endpoint: overall survival
- 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

Jan 2021

First site initiated for VAL-083 treatment arm

May 2021

15 sites active for VAL-083 treatment arm

Mar 2022

43 sites active, including 4
Canadian sites, for
VAL-083 treatment arm

August 2022

45 sites active, including 4 Canadian and 2 EU sites, for VAL-083 treatment arm Before the End of 2023

Top line results
12 months after last
patient enrolled

# **GCAR/GBM AGILE Advantages**

Utilized non-profit funding to design and initiate GBM trial (1st 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
- 45 sites open to Kintara arm:
  - Includes four sites in Canada and two sites in Europe
- Shared control group:
  - Contains costs and accelerates speed of study
  - Has been enrolling for over three years
- Provides significant time and cost savings vs. multiple trials
- Avoids company scale up of fixed expenses for trial execution



"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**."

FOR ADAPTIVE RESEARCH

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

## **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

- Dr. James Perry

"GBM AGILE is an innovative

enables us to simultaneously

clinical trial approach that

and dynamically study the

newly-diagnosed

083 for the additional

methylated GBM patient

all GBM patients access to these latest therapies."

effects of multiple new drug candidates. With the inclusion of paxalisib and VAL-083 for

unmethylated and recurrent

GBM patients, as well as VAL-

group, we are excited to offer



Mayo Clinic Cancer Center - Jacksonville



Duke University Medical Center - Durham

# **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



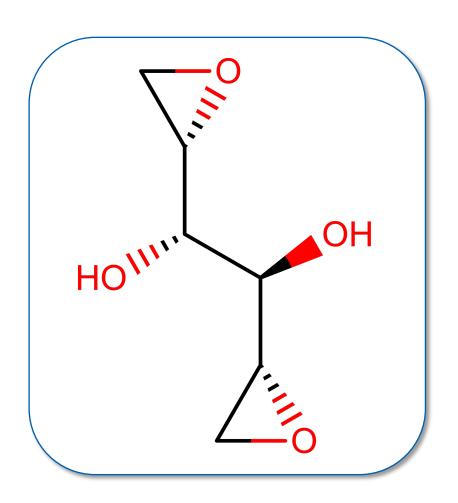
Dr. David Reardon
Dana-Farber Cancer Institute
Clinical Director of the Center for Neuro-Oncology
Harvard Medical School
Professor of Medicine





Dr. Nicholas Butowski
UCSF Medical Center
Neuro-oncologist
UCSF Brain Tumor Center
Director of Translational Research in Neuro-Oncology
and Researcher

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



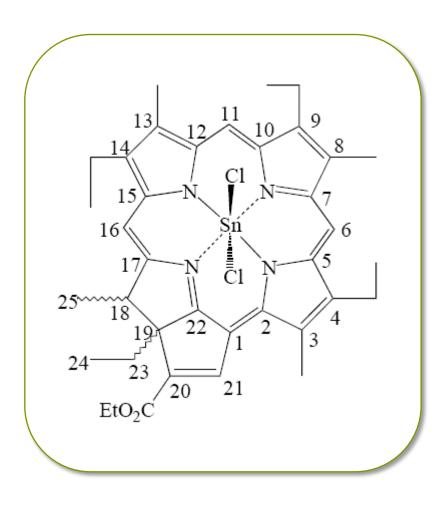
## **Current Clinical Status**

- Kintara jumps on "a fast-moving train" with GBM AGILE with first patient screened in January 2021
- Patient enrollment has been better than initially anticipated

## 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 National Institutes of Health Grant awarded in June 2023

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

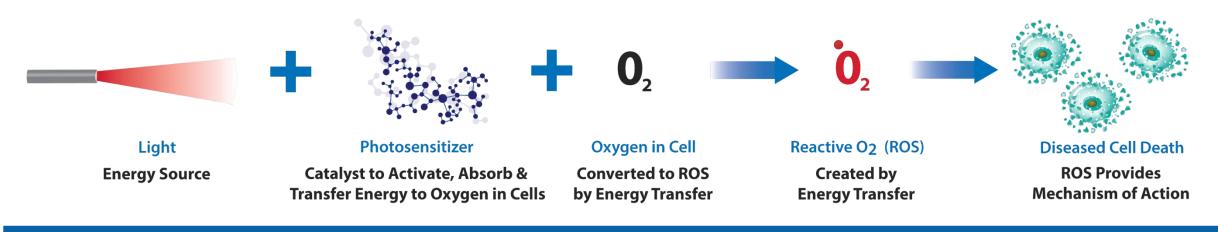
- Bleeding, infectious and malodorous lesions on chest wall, neck and back
- Narcotics for pain control

Limited current therapies

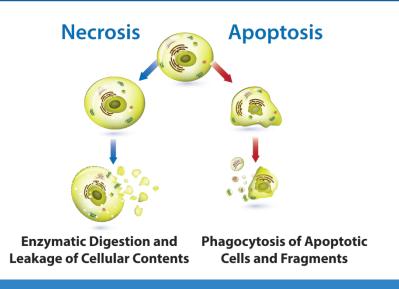
- Chemotherapy: generally non-responsive
- Radiation: dose limiting toxicities, lesions are often refractory to radiation

<sup>&</sup>lt;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

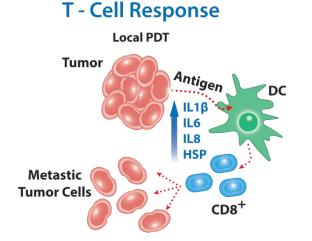
# Photodynamic Therapy Mechanisms of Action



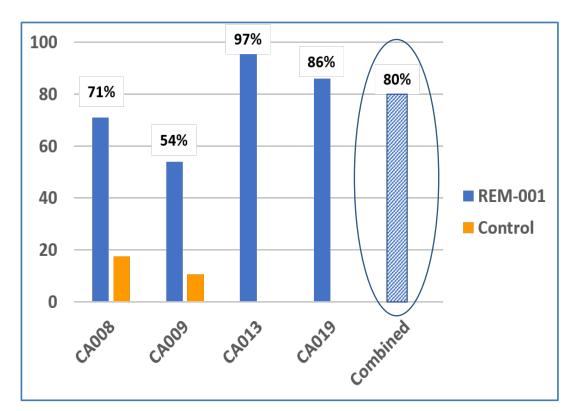
# PDT induces elimination of diseased cells by immune response, apoptosis, antiangiogenesis and necrosis



# Antiangiogenic / Anti-vascular Vascularized, PDT Impairs Vessel Angiogenic Tumor Function to Cut Off Blood Supply Tumor Shrinks



# REM-001: High Response Rates in CMBC



**Prior Clinical Trials** 

**Complete Response Rate of Evaluable Lesions** 

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

**IND reactivated August 2022** 

Fast Track designation received from the FDA in November 2022

**National Institutes of Health Grant awarded June 2023** 

# **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

# 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
- Fast Track Designation from FDA for VAL-083 in Newly Diagnosed Unmethylated GBM Patients

## Mid-2022

• Reactivate IND for REM-001 in CMBC

## 4Q 2022

- Fast Track Designation from FDA for REM-001 in CMBC Patients
- Orphan Drug Designation from FDA for VAL-083 in Diffuse Intrinsic Pontine Glioma (DIPG)

## 2Q2023

• National Institutes of Health grant awarded for REM-001 in CMBC

## Before 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 |
|--|---|
| <b>Greg Johnson</b> (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)   |
| Dennis Brown<br>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   |

# **Investment Highlights**

- Late-stage oncology company with two highly de-risked assets for underserved indications
- VAL-083
  - Initiated GBM AGILE International <u>Registrational Study:</u> January 2021 with VAL-083 enrolling all three GBM AGILE patient subtypes
  - Accelerated clinical pathway with strong regulatory support and 44 sites enrolled 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
  - National Institutes of Health grant awarded to support 15-Patient study
  - \$500M market opportunity<sup>2</sup>
- Significant upcoming milestone/value inflection event
  - Before the end of 2023: Top line results from GCAR GBM AGILE Study 12 months after last patient randomized