# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of**
**the Securities Exchange Act of 1934**
**Date of Report (Date of earliest event reported): December 5, 2022**

# KINTARA THERAPEUTICS, INC.
**(Exact name of Registrant as Specified in Its Charter)**

| Nevada | 001-37823 | 99-0360497 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**9920 Pacific Heights Blvd, Suite 150**
**San Diego, CA 92121**
**(Address of principal executive offices)**

**Registrant's Telephone Number, Including Area Code: (858) 350-4364**

**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4©)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock** | **KTRA** | **The Nasdaq Capital Market** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition.**

As previously disclosed, Kintara Therapeutics, Inc. (the "Company") paused its REM-001 program in Cutaneous Metastatic Breast Cancer to conserve cash which will be used to support the funding of the Company's ongoing international registrational study for VAL-083 in glioblastoma. The Company anticipates announcing topline data around the end of calendar year 2023. By pausing the REM-001 program, the Company expects to save approximately $3.0 million through calendar year 2023. Additionally, the Company recently reviewed and reduced expenses in other areas. As a result, and based on current operating plans, the Company expects that its cash and cash equivalents as of September 30, 2022 are sufficient to finance its anticipated cash requirements into the third quarter of calendar year 2023 and reduced cash required to enter calendar year 2024 to approximately $3.0 million.

**Item 7.01 Regulation FD Disclosure.**

See "Item 2.02 Results of Operations and Financial Condition" above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01 is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by a specific reference in such filing.

**Item 8.01 Other Events.**

The Company has prepared presentation materials (the "Investor Presentation") in connection with management presentations to describe its business. A copy of the Investor Presentation has been posted to the Company's website and is attached as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Investor Presentation |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**KINTARA THERAPEUTICS, INC.**

Date: December 5, 2022

By: */s/ Scott Praill*
Name: Scott Praill
Title: Chief Financial Officer

**Exhibit 99.1**


KINTARA
Therapeutics
Developing Advanced Oncology Therapies for Rare Unmet Medical Needs
Corporate Presentation
December 2022
CONFIDENTIAL
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# 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. A total of 45 sites across US, Canada and Europe.
- ~$1B[1] 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

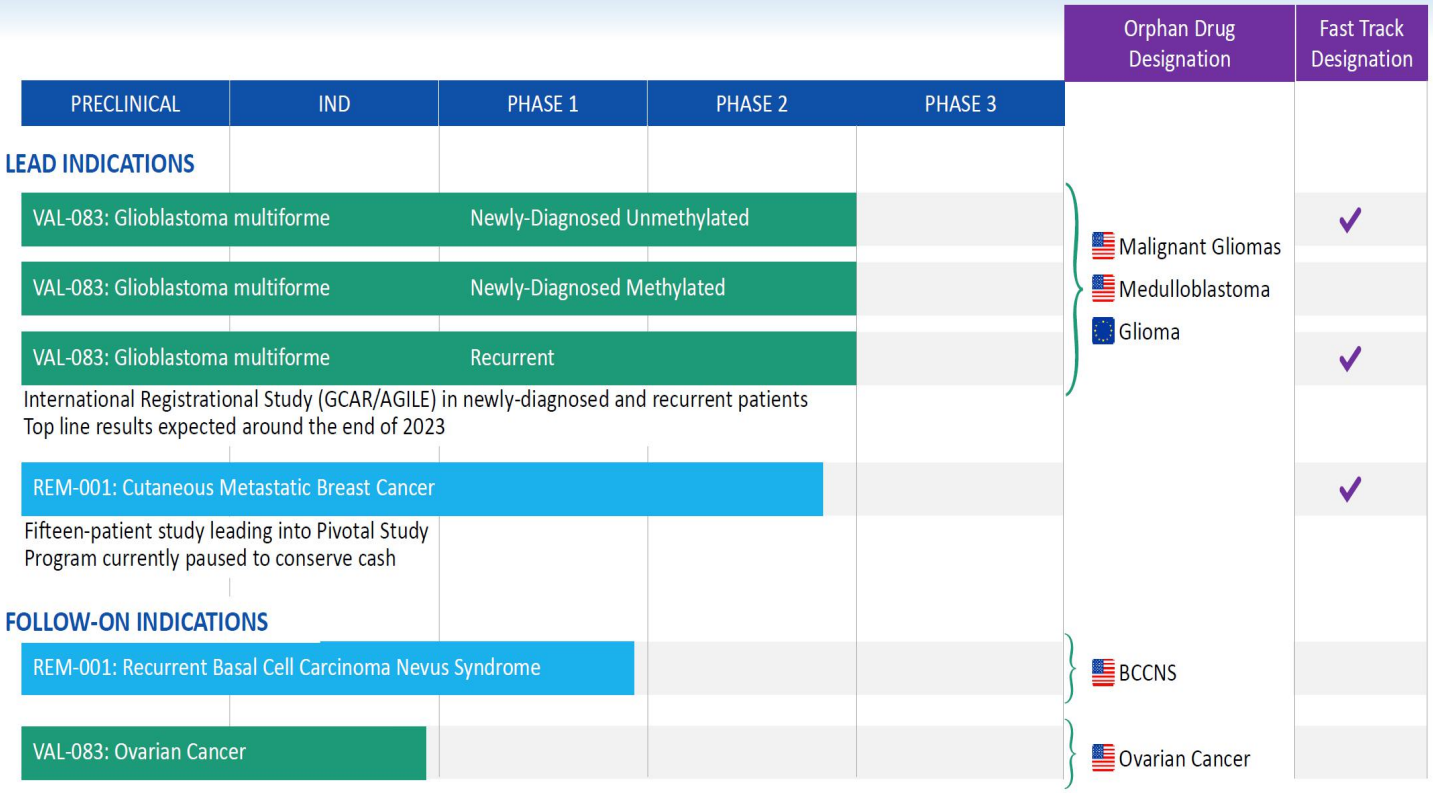
**REM-001: 2nd generation photodynamic therapy platform**

- 15-patient confirmatory study start has been paused to conserve cash
- ~$500M[2] 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**

*[1]GlobalData November 2018*
*[2]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[1]

- ~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:

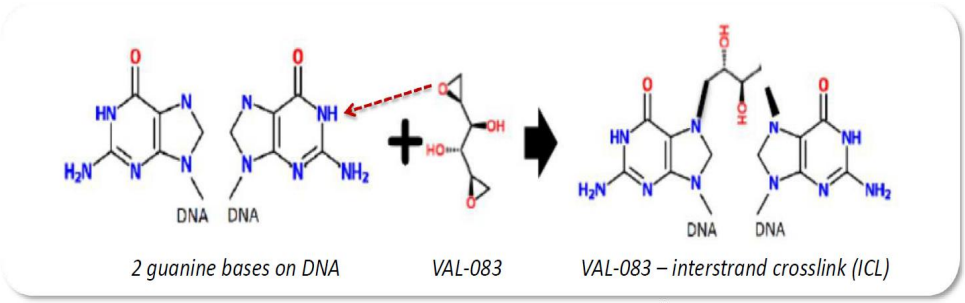
- Newly-Diagnosed Unmethylated (>60% of GBM patients)
- Newly-Diagnosed Methylated (<40% of GBM patients)
- Recurrent

*[1]GlobalData November 2018*

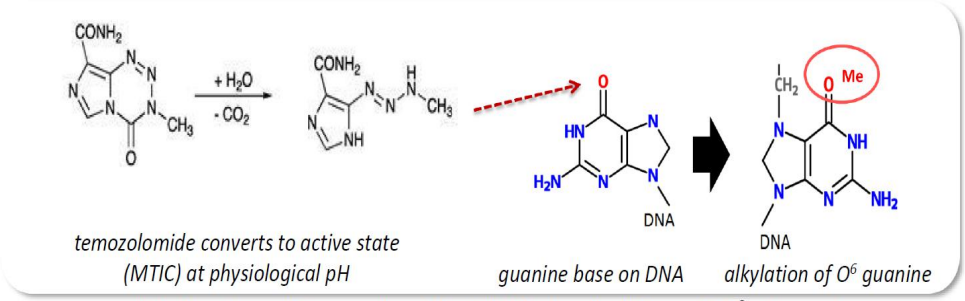
# VAL-083 Mechanism of Action

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's unique mechanism of action creates inter-strand DNA cross-links at the $N^7$ position of guanine, resulting in double-strand DNA breaks and cancer cell death via apoptosis




Mechanism of VAL-083 via crosslinks at $N^7$ of guanine




Mechanism of temozolomide (TMZ) via alkylation at $O^6$ 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 30 mg Patients | Median Progression Free Survival | Median Overall Survival |
|---|---|---|---|
| *TMZ Historical Comparator* | | *5.3[1]/6.9[2]/5.0[3] months* | *12.7[1]/16.0[2]/14.1[3] months* |
| Newly-Diagnosed [First Line] | n=25 | 8.7 months | 19.1 months |
| Newly-Diagnosed [Adjuvant] | n=36 | 9.5 months | 16.5 months |

| Recurrent Patients (MGMT-unmethylated) | Evaluable 30 mg Patients | Median Overall Survival |
|---|---|---|
| *Lomustine Historical Comparator* | | *7.2 months[4]* |
| Recurrent | n=48 | 8.0 months |

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


[1]*Hegi et al N Eng J Med (2005)*
[2]*Tanguturi et al. NeuroOncol (2017)*
[3]*Alnahhas et al. Neurooncol Adv (2020)*
[4]*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 newly-diagnosed and recurrent glioblastoma
- 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[1]
- Recurrent[2]

*[1]Comparable to MDACC Phase 2 trial – adjuvant cohort*
*[2]Comparable to MDACC Phase 2 Trial – recurrent cohort*

| Jan 2021 | May 2021 | Mar 2022 | August 2022 | Around the End of 2023 |
|---|---|---|---|---|
| First site initiated for VAL-083 treatment arm | 15 sites active for VAL-083 treatment arm | 43 sites active, including 4 Canadian sites, for VAL-083 treatment arm | 45 sites active, including 4 Canadian and 2 EU sites, for VAL-083 treatment arm | 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

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

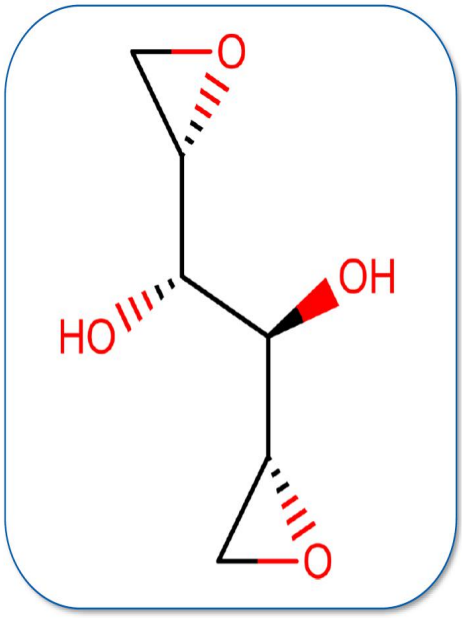
# GBM Scientific Advisory Board

**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



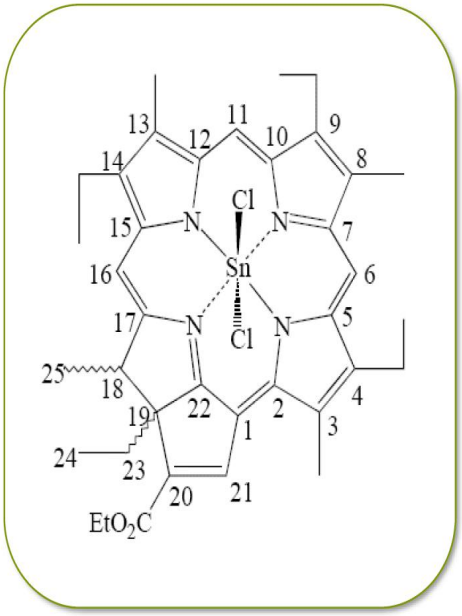

## Current Clinical Status

- 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
- 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: 2nd 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.[1], representing $500M market opportunity[2]

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

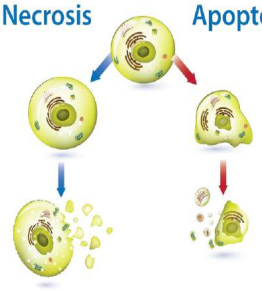
*[1]Source (a): Saika et al, 2009; Kamaraju et al, 2016; Vano-Galvan et al, 2009; GlobalData Report on Metastatic Breast Cancer; Schoenlaub et al, 2001*
*[2]Charles River Report April 2018*

# Photodynamic Therapy Mechanisms of Action


| Light | Photosensitizer | Oxygen in Cell | Reactive $O_2$ (ROS) | Diseased Cell Death |
|---|---|---|---|---|
| Energy Source | Catalyst to Activate, Absorb & Transfer Energy to Oxygen in Cells | Converted to ROS by Energy Transfer | Created by Energy Transfer | ROS Provides Mechanism of Action |

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

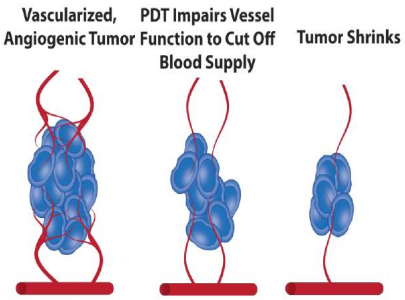
## Necrosis Apoptosis



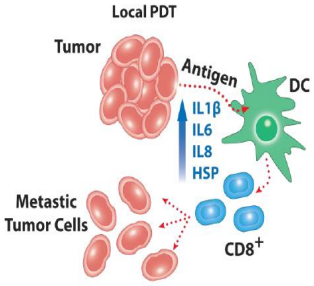
Enzymatic Digestion and Leakage of Cellular Contents

Phagocytosis of Apoptotic Cells and Fragments

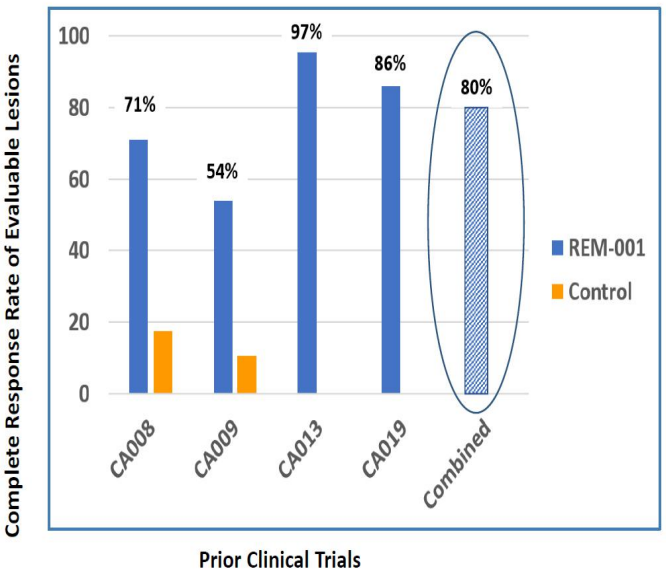
## Antiangiogenic / Anti-vascular




## T - Cell Response



# 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

**IND reactivated August 2022**

**Fast Track designation received from the FDA in November 2022**

**Program paused to conserve cash**

# Indication Expansion Opportunities

**VAL-083**

- Platinum resistant Ovarian Cancer[1]
- Non-Small Cell Lung Cancer[1]
- Other Solid Tumors, including pediatric indications

**REM-001**

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

[1]*Prior Phase 1 and Phase 2 studies completed by NCI*

[2]*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 ✓
- Fast Track Designation from FDA for VAL-083 in Newly Diagnosed Unmethylated GBM Patients ✓

**Mid-2022**

- Reactivate IND for REM-001 in CMBC ✓

**Q4 2022**

- Fast Track Designation from FDA for REM-001 in CMBC Patients ✓

**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**<br>President and CEO<br>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 |
| **Greg Johnson**<br>(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) |
| **Scott Praill**<br>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 |
| **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 Registrational Study: 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[1]

- 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 start paused to conserve cash
  - $500M market opportunity[2]

- Significant upcoming milestone/value inflection event
  - Around the end of 2023: Top line results from GCAR GBM AGILE Study 12 months after last patient randomized

*[1]GlobalData November 2018*
*[2]Charles River Associates April 2018*