



**Breakthrough Cancer Therapeutics**

OTCQX: DMPI

[www.delmarpharma.com](http://www.delmarpharma.com)

Business Update Conference Call  
September 4, 2015

# Forward-Looking Statements

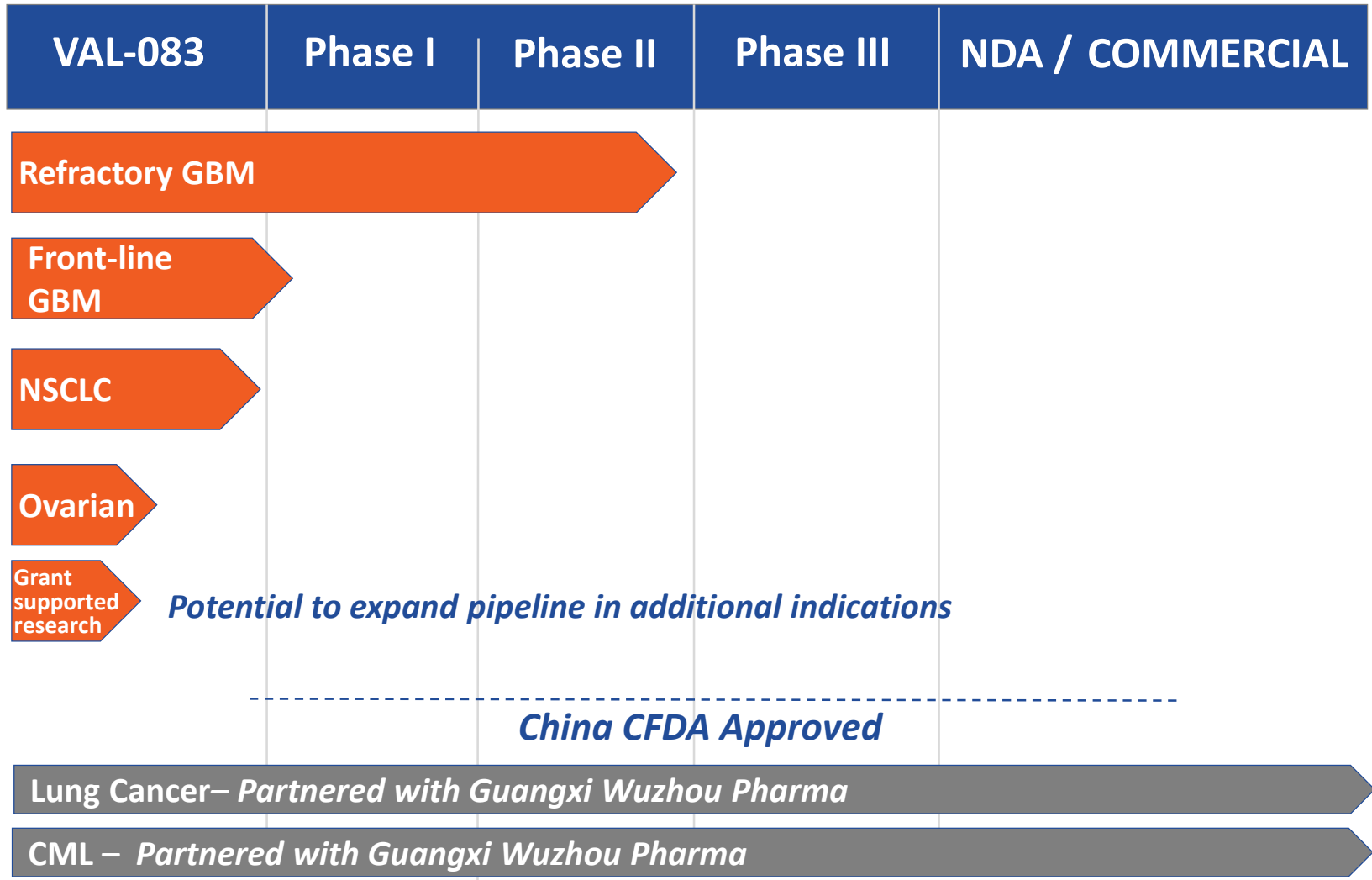


Any statements contained in this presentation that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. Any forward-looking statements contained herein or made in the course of the presentation are based on current expectations, but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC and the British Columbia Securities Commission, including our current reports on Form 8-K's, Form 10-Q's and most recent Form 10-K. We do not undertake to update these forward-looking statements made by us.



- Significant clinical and research progress with VAL-083
- Raised \$2.6 million gross proceeds in a registered direct offering
- Announced additional non-dilutive funding increase of up to CDN\$287,000 from the National Research Council of Canada Industrial Research Assistance Program for continued support of our non-clinical research programs
- Continued to take steps toward listing our common shares on a National Exchange including:
  - Reducing the derivative liability component of our balance sheet
  - Appointing new independent directors and establishing required corporate governance structures and policies

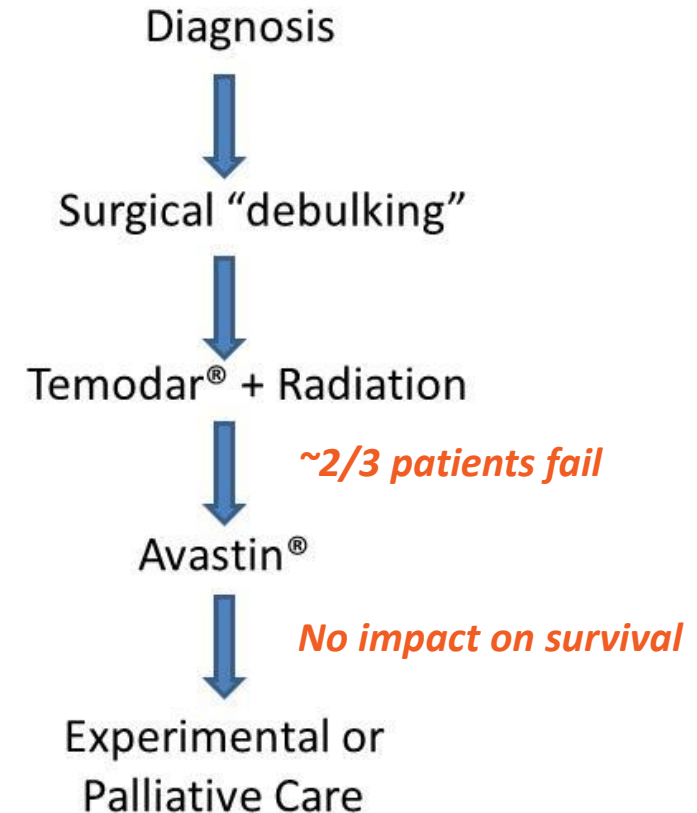
# VAL-083: Building a Pipeline to Address Major Unmet Medical Needs in Oncology



# Glioblastoma Multiforme

## First Target Market for VAL-083

- Glioblastoma Multiforme (GBM):
  - *The most common and aggressive form of brain cancer*
- Large market opportunity:
  - *>\$1 billion annual sales<sup>(a)</sup>*
- Significant unmet need:
  - *Affects approx. 15,000 adults each year in United States<sup>(b)</sup>*
  - *Median survival without treatment = 4 ½ months<sup>(c)</sup>*
  - *Approximately half of patients' tumors fail all other treatment<sup>(c)</sup>*
  - *5 year survival <3%<sup>(c)</sup>*



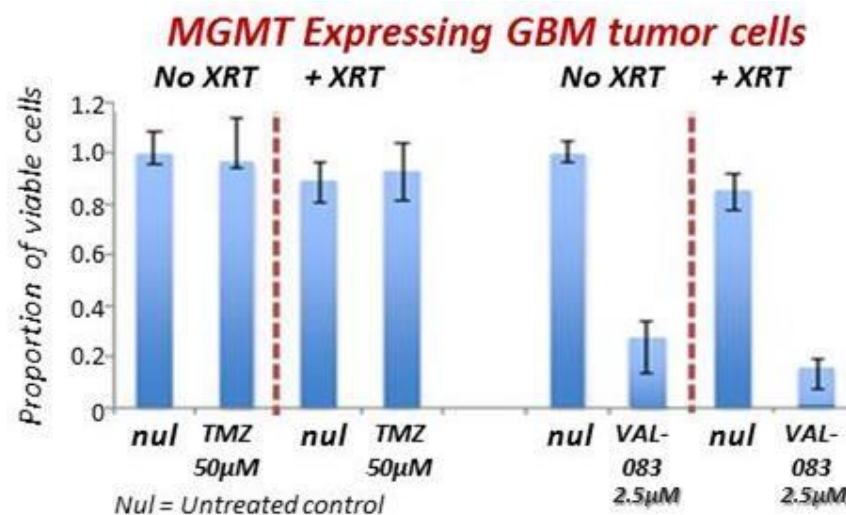
<sup>(a)</sup>Evaluate Pharma reports

<sup>(b)</sup>Ostrom QT, Gittleman H, Liao P, et al. CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2007-2011. *Neuro Oncol.* 2014

<sup>(c)</sup>Johnson, Derek R.; O'Neill, Brian Patrick (2011). "Glioblastoma survival in the United States before and during the temozolomide era". *Journal of Neuro-Oncology* **107** (2): 359–64

# VAL-083's First Opportunity: GBM

- **2/3 of newly diagnosed patients have unmethylated MGMT promoter & are resistant to front-line therapy**
  - MGMT expression correlates with resistance to front-line Temodar + radiotherapy and poor patient outcomes
  - Published NCI-clinical trials support VAL-083 activity in GBM
  - VAL-083 is active independent of MGMT-mediated resistance



**VAL-083 represents a potential paradigm shift in the treatment of GBM**

# VAL-083 Refractory GBM

## Phase I/II Clinical Trial Overview



Clinicaltrials.gov Identifier: NCT01478178



Design	<ul style="list-style-type: none"> <li>• Single-arm, open label</li> </ul>
Intervention	<ul style="list-style-type: none"> <li>• Treatment : VAL-083 (single agent)</li> <li>• Dosing: i.v. 3 consecutive days every 21 days; escalating cohorts from 1.5mg/m<sup>2</sup>/day in 3+3 design</li> <li>• Patients undergo a single treatment cycle unless stable disease or tumor regression is observed</li> </ul>
Summary Inclusion Criteria	<ul style="list-style-type: none"> <li>• Histologically confirmed GBM, now recurrent</li> <li>• Previously treated with surgery &amp; radiation; failed Temodar® (temozolomide) and Avastin® (bevacizumab)</li> <li>• Wash-out period from prior therapy</li> <li>• Karnofsky performance status &gt;50%</li> </ul>
Outcome Measures	<ul style="list-style-type: none"> <li>• Determination of maximum tolerated dose (MTD)</li> <li>• Tumor response by MRI</li> <li>• Pharmacokinetic analysis</li> <li>• MGMT assessment (optional)</li> </ul>
Anticipated Enrollment	<ul style="list-style-type: none"> <li>• Phase 1: up to 40 patients</li> <li>• Phase 2: 14 patients</li> </ul>
Five Current Sites	<ul style="list-style-type: none"> <li>• UC San Francisco</li> <li>• Mayo Clinic (Rochester, MN)</li> <li>• Sarah Cannon Cancer Research Institute (Nashville; Denver; Sarasota)</li> </ul>

**Goal: Determine dose for advancement to registration-directed Phase II/III registration trial**



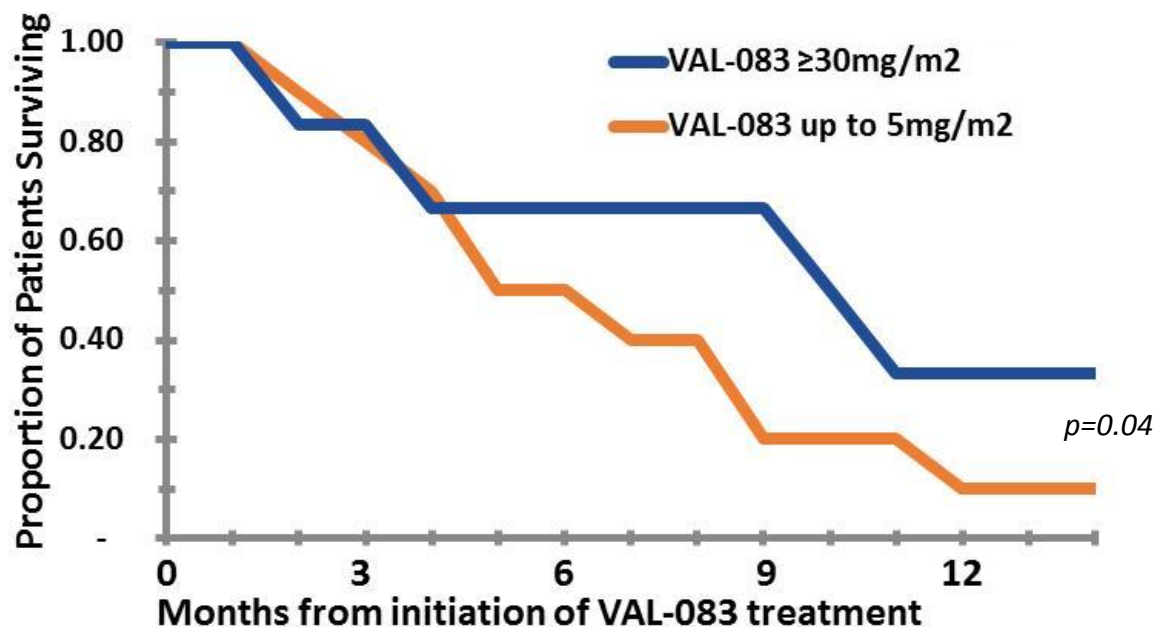
## VAL-083 (dianhydrogalactitol), for the treatment of refractory glioblastoma multiforme (GBM)

- Completed Phase I dose-escalation in the clinical trial
- Presented data supporting a dose response trend
- Initiated a Phase II expansion cohort
- Continued preparation for advancement into registration-directed Phase II/III clinical trials
- Presented additional data on the activity of VAL-083 against temozolomide-resistant GBM
- Added the fourth and fifth Phase I/II clinical trial sites





## Interim Analysis of Phase I/II Study Supports a Promising Dose-response Trend



Dose Cohort Subgroups	6 months	9 months	12 months	Median
High (30 & 40 mg/m <sup>2</sup> n=6)	67%	67%	33%	9.2 months
Low (up to 5mg/m <sup>2</sup> n=10)	44%	33%	22%	5.1 months



- Pharmacokinetic observations are consistent with dose-response trend

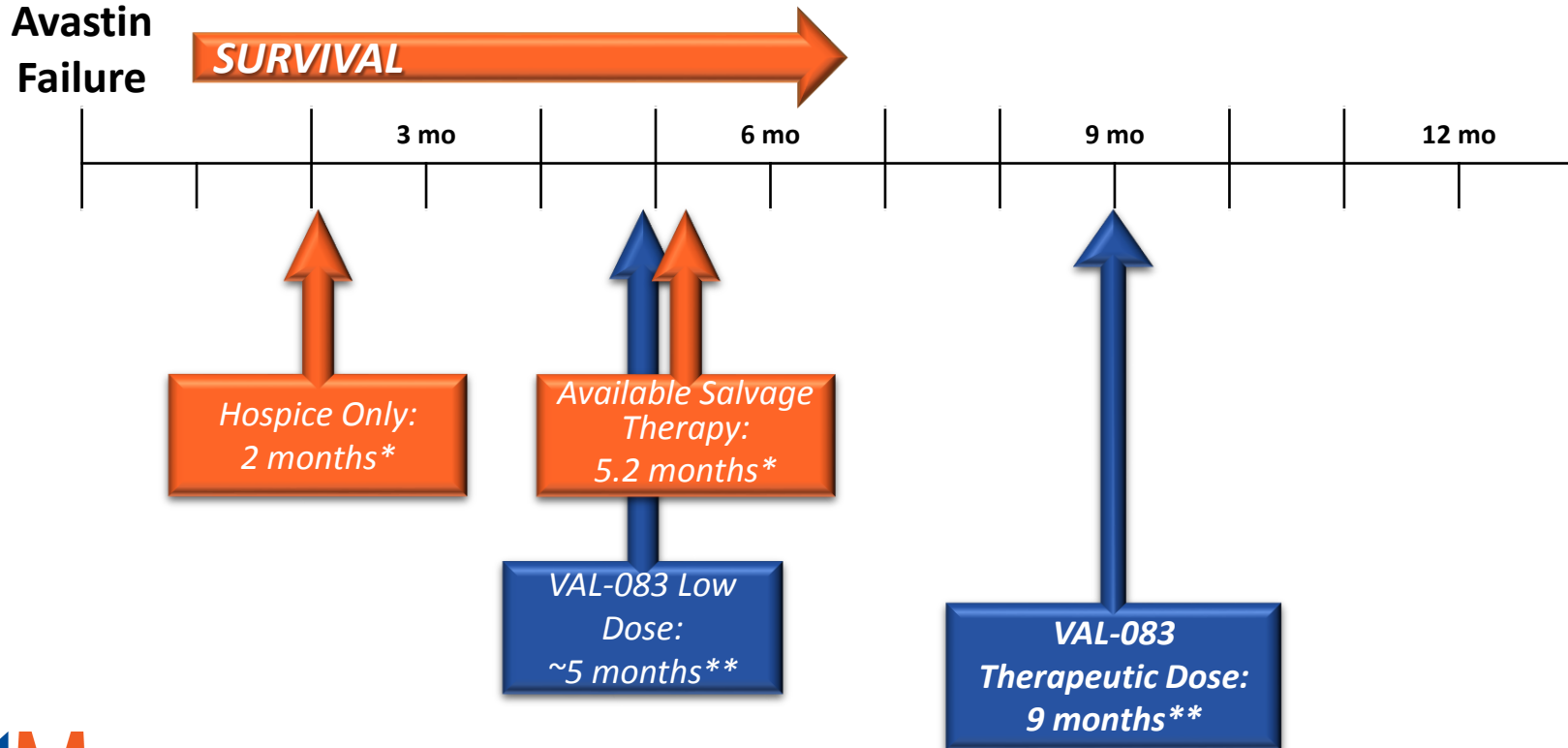
Dose x 3 days	Plasma Cmax @ day 3	Calculated Brain Tumor Tissue Concentration	IC <sub>50</sub> in GBM Cell Lines	Expected Activity?
5mg/m <sup>2</sup>	0.08 µg/mL	0.4 µM	2 – 4 µM	no
40mg/m <sup>2</sup>	0.78 µg/mL	3.9 µM		<b>YES</b>

- VAL-083 well tolerated at doses up to 40mg/m<sup>2</sup>
  - Dose limiting toxicity (DLT) observed at 50mg/m<sup>2</sup>
    - Grade 4 thrombocytopenia, consistent with published literature
    - DLT resolved rapidly and spontaneously, consistent with published literature



## *Interim Observations in Clinical Context*

- VAL-083 Therapeutic Dose: Survival of 9 months offers clinically meaningful benefit with well-tolerated therapy





- Phase II expansion initiated at 40mg/m<sup>2</sup>
  - Planned enrollment: ~14 patients
  - Data will guide design of registration-directed Phase II/III trial
- Parallel 45mg/m<sup>2</sup> exploratory cohort to explore therapeutic window

## ENROLLMENT STATUS 3-Sept/2014

*Screening & Enrollment Ongoing*

Patients Screened	19	
Ineligible	<u>8</u>	
Eligible	11	
	<b>Phase II Expansion (40mg/m<sup>2</sup>)</b>	<b>Exploratory Cohort (45mg/m<sup>2</sup>)</b>
On Study (undergoing treatment)	<b>6</b>	<b>3</b>
Treatment pending washout of prior therapy	<b>2</b>	<i>Cohort full</i>

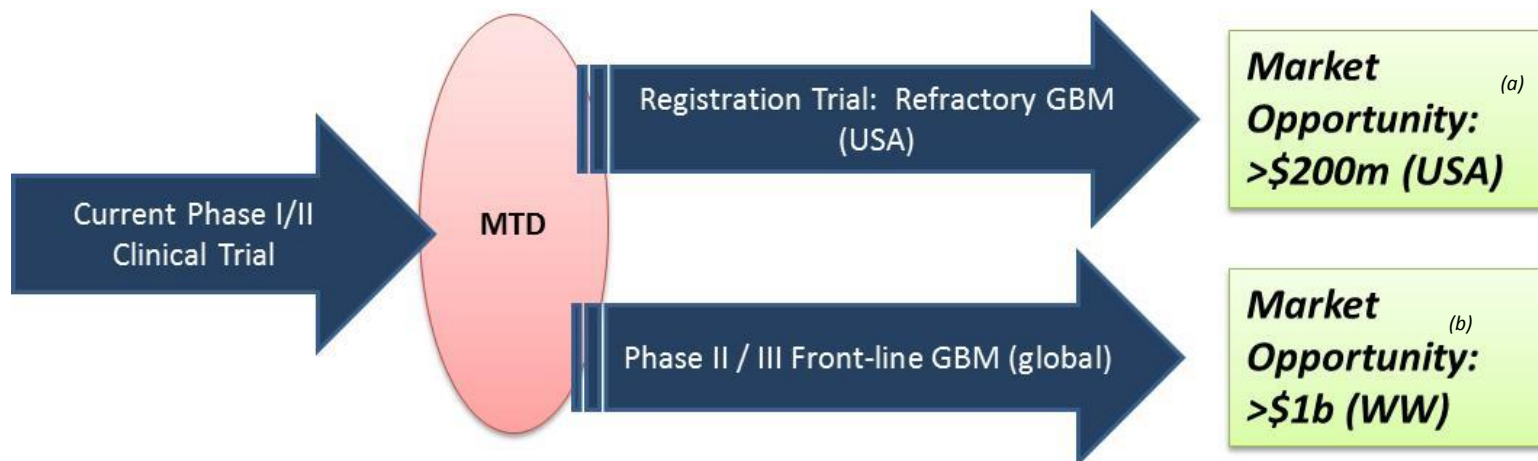
- Expansion cohort may be continued at 45mg/m<sup>2</sup> if safety data warrants

# VAL-083 Clinical Trial: Next Steps Refractory GBM – Target Timelines

KEY MILESTONES	2015	2016	2017
Phase I: Define MTD	✓ COMPLETED		
Phase II Enrollment		ONGOING	
<u>Registration Directed Activities: Target Timelines</u>			
• Complete Phase II enrollment		H2 2015	
• Interim Data presentation: GBM 2015 & SNO		Q3 & Q4 2015	
• Request FDA Guidance Meeting		H2 2015	
• Phase II/III Registration Trial		Within 12 months	
• FILE NDA		2017	
○ Orphan designation allows for fast-track status			
○ Potential break-through therapy to be considered at end of current Phase II and during Phase II/III			



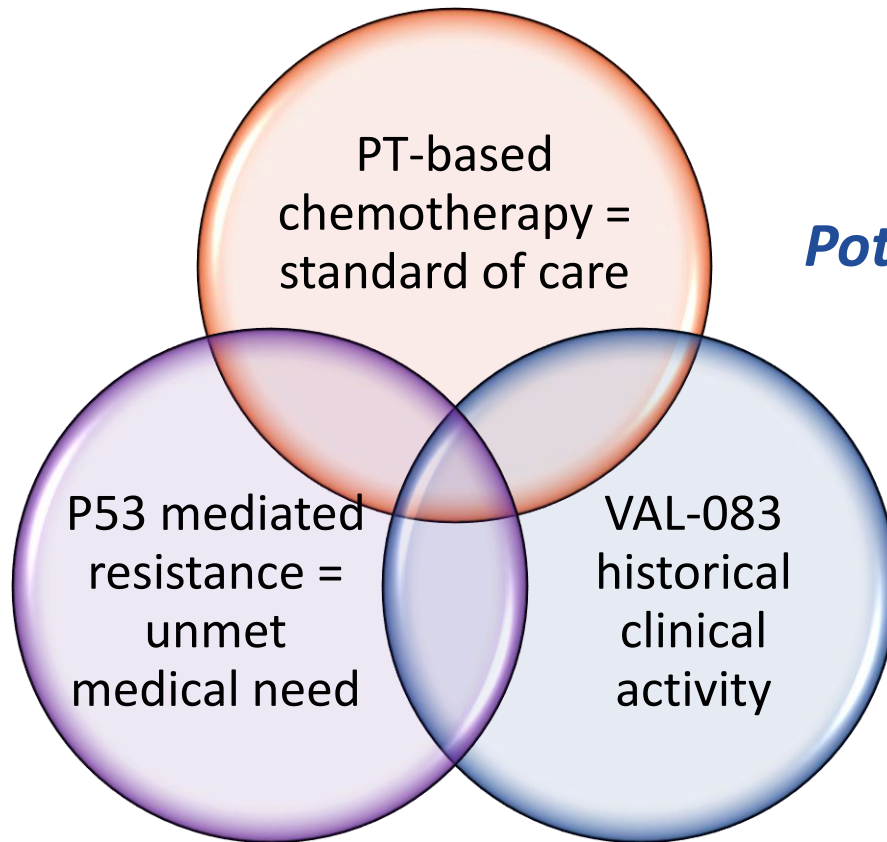
**Current Phase I/II clinical trial in USA unlocks global development programs for VAL-083 to address \$1+ billion market opportunity in front-line GBM**





## DelMar Non-clinical Data Supports Differentiation from Standard-of-Care Platinum-based Chemotherapy

- **Cytotoxic mechanism is distinct from platinum-based chemotherapy**
  - Not dependent on p53 activation *in vitro*
- **Active against both platinum-resistant and TKI-resistant NSCLC strains *in vitro* and *in vivo***
- **More potent vs. platinum-based chemotherapy on an equimolar basis *in vivo***
- **Synergy with platinum-based chemotherapy**
  - No evidence of over-lapping toxicity *in vivo*



## ***Potential Target Cancers for VAL-083***

- ✓ Lung Cancer
- ✓ Ovarian Cancer
- ✓ Cervical Cancer
- ✓ Other Solid Tumors





- Lung cancer is the leading cause of cancer death world-wide
- Non-small cell lung cancer (NSCLC)
  - Current drugs represent >\$6 billion in world wide annual sales<sup>(a)</sup>
  - Overall 5 year NSCLC survival rate: 15%
  - CNS metastases – a leading cause of NSCLC mortality
- Existing and new data support potential of VAL-083 in NSCLC
- VAL-083 is approved in China for the treatment of lung cancer
- Confirmatory Phase IV NSCLC trial to be initiated in 2015
  - Post-market study under existing CFDA approval
  - Funded through collaboration with Guangxi Wuzhou Pharma
  - Results will also establish Global Phase II proof-of-concept
- Potential global partnering opportunity



- Pre-clinical and historical clinical data support potential of VAL-083 in Ovarian Cancer
  - *Data to be presented at AACR Advances in Ovarian Cancer*
- Plans for clinical strategy under development
- Potential global partnering opportunity



- \$1,754,433 million cash as of June 30, 2015
- Completed Registered Direct placement in August 2015: Gross Proceeds \$2.6 million
- Operating funds into Q3'2016

## Pro Forma at June 30, 2015 (unaudited)

<b>Shares Outstanding</b>	
DMPI Shares	<b>35.2 m</b>
ExchangeCo	<b><u>4.2 m</u></b>
<b>Total outstanding</b>	<b>39.4 m</b>
<b>Warrants*</b>	<b>13.5 m</b>
<b>Options</b>	<b><u>3.6 m</u></b>
<b>Fully Diluted</b>	<b><u>56.5 m</u></b>

*\*4.3 million investor warrants can be called at \$0.786/share if stock is >\$1.60/share for 20 consecutive trading days*



- Complete enrollment of the Phase II expansion study in refractory GBM
- Advance VAL-083 into registration-directed Phase II/III clinical trials
- Maximize value of VAL-083 through clinical trials in new indications
  - *Supported by our collaboration with Guangxi Wuzhou Pharmaceutical (Group) Co. Ltd.*
- Continue to actively communicate our progress to the investment and medical communities through peer-reviewed presentations and publications
- Continue to build our intellectual property portfolio
- Implement strategies to enable DelMar to meet qualifications to list its shares on a national stock exchange



- Refractory GBM – Advancing into Phase II/III
  - Clinical plan being implemented
  - Can be developed and launched by DelMar
- NSCLC – Planned Phase IV (China) / Phase IIa (ROW)
  - Clinical plan being implemented (funded by Guangxi Wuzhou)
  - Potential partnering opportunity
- Front line GBM – Planned Phase II
  - Clinical plan being implemented (funded by Guangxi Wuzhou)
  - Potential for partnering opportunity
- Ovarian cancer
  - Clinical plan being developed
  - Potential for partnering opportunity



- WCLC 2015 - September 6-9, 2015
  - Poster Session September 8 from 9:30 a.m. - 4:30 pm
- Rodman & Renshaw - September 8-10, 2015
  - Presentation/Webcast September 9 from 3:50 to 4:15 pm
- GBM 2015 - September 9-12, 2015
- AACR-Advances in Ovarian Cancer - October 17-20, 2015
- BIO Investor Forum – October 20-21, 2015
- AARC-NCI-EORTC– November 5-9, 2015
- Society for Neuro-Oncology Data – November 19-22, 2015
- LD Micro - December 2-3, 2015



## ✓ VAL-083

- A "first-in-class" small molecule therapeutic with a unique mechanism of action
- Anti-cancer activity demonstrated across a range of cancers in prior US National Cancer Institute (NCI)-sponsored clinical trials
- DelMar reported promising interim outcomes data from ongoing Phase I/II trial of VAL-083 in refractory GBM at ASCO 2015
  - Phase II/III registration trial of VAL-083 in refractory GBM in 2016
- Orphan drug designation in USA and EU
- Newly allowed patent claims provide intellectual property protection through 2032
- Pipeline expansion opportunities in high value oncology markets

## ✓ Experienced Team with History of Success

## ✓ Proven Business Model



## QUESTIONS





**Breakthrough Cancer Therapeutics**

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