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): November 22, 2019

DELMAR PHARMACEUTICALS, 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.)*

12707 High Bluff Dr., Suite 200
San Diego, CA 92130
(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: **(858) 350-4364**

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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(c))

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	DMPI	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 8.01 Other Events.

Presentation Posters

On November 22, 2019, DelMar Pharmaceuticals, Inc. (the "Company") presented two posters at the Society for Neuro-Oncology annual meeting in Phoenix, Arizona. Copies of the posters are attached as Exhibits 99.1 and 99.2 hereto.

Post-Effective Amendments

As previously disclosed, on June 25, 2019, the Company filed a registration statement with the Securities and Exchange Commission (the "SEC") on Form S-1 (File No. 333-232332) (as amended, the "Resale Registration Statement") covering the resale of 760,500 shares of its common stock, par value $0.001 per share (the "Common Stock"), issuable upon the exercise of common warrants by certain selling stockholders. The Resale Registration Statement was originally declared effective by the SEC on July 16, 2019.

Also as previously disclosed, on August 1, 2019, the Company filed a registration statement with the SEC on Form S-1 (File No. 333-232931) (as amended, the "Primary Registration Statement" and, together with the Resale Registration Statement, the "Registration Statements"). The Primary Registration Statement was originally declared effective by the SEC on August 14, 2019. The Primary Registration Statement originally covered a primary offering of (i) 4,095,000 shares of Common Stock, pre-funded warrants to purchase an aggregate of 2,655,000 shares of Common Stock and (ii) common warrants to purchase an aggregate of 6,750,000 shares of Common Stock. On August 16, 2019, the Company closed on the sale of (i) 4,895,000 shares of Common Stock, (ii) pre-funded warrants to purchase an aggregate of 2,655,000 shares of Common Stock and (iii) common warrants to purchase an aggregate of 7,762,500 shares of Common Stock, including 800,000 shares of Common Stock and warrants to purchase an aggregate of 1,012,500 shares of Common Stock sold pursuant to a partial exercise by the underwriters of the underwriters' option to purchase additional securities.

On November 15, 2019, the Company filed a Post-Effective Amendment No. 1 to the Resale Registration Statement (the "Resale Post-Effective Amendment") and a Post-Effective Amendment No. 2 to the Primary Registration Statement (the "Primary Post-Effective Amendment" and, together with the Resale Post-Effective Amendment, the "Post-Effective Amendments") in order to incorporate by reference the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2019 that was filed with the SEC on September 9, 2019 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 that was filed with the SEC on November 13, 2019 and to make certain corresponding changes in each Registration Statement.

No additional securities are being registered under the Post-Effective Amendments. The Post-Effective Amendments were declared effective by the SEC on November 20, 2019.

At September 30, 2019, the Company had cash and cash equivalents on hand of approximately $8.06 million, which are expected to be sufficient to fund the Company's planned operations into the fourth quarter of calendar year 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Poster
99.2	Poster

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.

DELMAR PHARMACEUTICALS, INC.

Date: November 22, 2019

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

Phase 2 study of dianhydrogalactitol (VAL-083) in patients with MGMT-unmethylated, bevacizumab-naïve glioblastoma in the recurrent and adjuvant setting

Barbara O'Brien[1], Marta Penas-Prado[4], Carlos Kamiya-Matsuoka[1], Shiao-Pei Weathers[1], Alfred Yung[1], Monica Loghin[1], Rebecca Harrison[1], Nazanin Majd[1], Jeffrey Bacha[3], Dennis Brown[2], Gregory Johnson[2], John Langlands[2], Richard Schwartz[2], Sarath Kanekal[2], Lorena Lopez[2], John DeGroot[1]

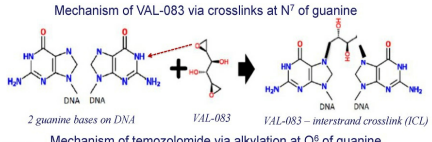
[1]Department of Neuro-Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [2]DelMar Pharmaceuticals, Inc., Vancouver, Canada and Menlo Park, California, USA; [3]Formerly affiliated with DelMar Pharmaceuticals, Inc., no longer involved with the company or this clinical trial; [4]Neuro-Oncology Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD, USA

ABSTRACT #ACTR-12

Current standard-of-care for glioblastoma (GBM) includes surgery followed by concurrent therapy with radiation and temozolomide (TMZ) followed by adjuvant TMZ (days 1-5 every 28 days). Almost all GBM patients experience recurrent/progressive disease, with a median survival after recurrence of 3-9 months. Second-line treatment for recurrent GBM with bevacizumab (BEV) has not improved survival, and effective therapies for GBM are lacking. Unmethylated promoter for O^6-methylguanine-DNA-methyltransferase (MGMT) is a validated biomarker for TMZ-resistance and is correlated with poor patient prognosis. VAL-083 is a bi-functional DNA-targeting agent which rapidly induces interstrand DNA cross-links at N^7-guanine, induces double-strand breaks and acts independent of MGMT DNA repair. The current ongoing trial is a biomarker-driven Phase 2 study in MGMT-unmethylated BEV-naïve adult GBM. The primary objective of this study is to determine the effect of VAL-083 on median overall survival (mOS) for MGMT-unmethylated GBM patients compared to historical control. Secondary efficacy endpoints include progression-free survival (PFS), overall response rate (ORR), duration of response (DOR), and quality-of-life. Thirty-five (35) subjects with recurrent GBM have received 40 mg/m^2/day VAL-083 on days 1, 2, 3 of a 21-day cycle as the starting dose. Myelosuppression is the most common adverse event and a higher potential for this toxicity correlated with those patients who received a higher number of cycles of prior TMZ maintenance therapy, (>5 cycles vs. ≤5 cycles, p< 0.05). To minimize the potential for hematological toxicity in rGBM, subsequent subjects initiated treatment at 30 mg/m^2/d VAL-083 x 3 consecutive days every 21 days. In addition, since TMZ is of limited value in the MGMT-unmethylated setting, a second arm in newly diagnosed GBM has been included to explore whether substituting TMZ with VAL-083 offers clinical benefit and extends the time to recurrence. Enrollment, safety data and study updates will be presented at the meeting. Clinicaltrials.gov identifier: NCT02717962.

BACKGROUND

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



Mechanism of temozolomide via alkylation at O^6 of guanine

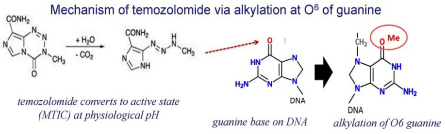


FIGURE 1. *The N^7-targeting mechanism of action of VAL-083 differs from those of O^6-alkylating agents like temozolomide and nitrosoureas.*

VAL-083 is a novel bi-functional DNA targeting agent that rapidly induces interstrand cross-links at N^7-guanine, leading to DNA double-strand breaks (DSBs) and ultimately cell death.[1] VAL-083's unique cytotoxic mechanism circumvents MGMT-mediated chemoresistance and maintains cytotoxic activity in cancer cells deficient in DNA mismatch repair (MMR).[2,3] The N^7-targeting mechanism differs from temozolomide (TMZ) and nitrosoureas, enabling VAL-083 to overcome MGMT-mediated chemoresistance. This distinct mechanism of action of VAL-083 suggests that VAL-083 may offer a treatment alternative against tumors with MMR-, or MGMT-mediated resistance to chemotherapeutic agents, including temozolomide and nitrosoureas.[1,2,3]

STUDY UPDATE

As of November 15th, 2019:

- Recurrent Arm (Group 1) - total 83 subjects planned
  - 35 subjects enrolled with starting dose of 40 mg/m^2/day x 3 days every 21 days
  - 27 (of 48 planned) subjects enrolled with starting dose of 30 mg/m^2/day x 3 days every 21 days
- Adjuvant Arm (Group 2) - total 24 subjects planned
  - 5 subjects enrolled with a starting dose of 30 mg/m^2/day x 3 days every 21 days

The data presented provide assessments for the subjects who had completed at least 1 cycle of VAL-083 as of November 15th, 2019.

Lowering of starting dose from 40 to 30 mg/m^2/day

- A higher potential for myelosuppression with 40 mg/m^2/day VAL-083 in recurrent GBM subjects (Group 1) appeared to be correlated with the number of cycles of prior TMZ maintenance therapy, e.g. > 5 cycles
- Dose reduction was aimed at lowering the potential for myelosuppression and may increase the number of cycles of VAL-083 treatment a patient may receive and thus the potential efficacy of VAL-083 treatment

SAFETY

GROUP 1 (RECURRENT)

- Sixty (60) subjects have completed at least 1 cycle of treatment
- Similarly to prior experience with VAL-083, myelosuppression has been the most common adverse event observed
- Decreases in platelet and neutrophil counts generally resolved spontaneously
- 7/35 (20.0%) subjects experienced SAE possibly related to VAL-083 at a starting dose of 40 mg/m^2/day
- 4/25 (16.0%) subjects experienced SAE possibly related to VAL-083 at a starting dose of 30 mg/m^2/day
- Fewer subjects experienced a dose-limiting toxicity (DLT) at cycle 1 at 30 mg/m^2/day (Table 1)

Table 1. Dose-Limiting Toxicities during cycle 1 in Group 1 (Recurrent). All subjects completed at least 1 cycle. (Data cut-off November 15th, 2019)

Number and Percent of Subjects with DLT, as defined below	40 mg/m^2/d (n=35)	30 mg/m^2/d (n=25)	All (n=60)
Number of subjects with DLT*	8 (22.9%)	3 (12.0%)	11 (18.3%)
Grade 3 decreased platelet count with hemorrhage	0 (0%)	0 (0%)	0 (0%)
Grade 4 decreased platelet count	5 (14.3%)	1 (4.0%)	6 (10.0%)
Grade 3 decreased ANC (<500 µL) with fever (febrile neutropenia)	0 (0%)	0 (0%)	0 (0%)
Grade 3 decreased platelet count lasting more than 5 days	5 (14.3%)	2 (8.0%)	6 (10.0%)
Treatment delay >3 weeks (due to decrease platelet or ANC)	8 (22.9%)	2 (8.0%)	10 (16.6%)
Non-hematol. Grade 3/4 toxicity	1 (2.8%)	1 (4.0%)	2 (3.3%)
Dose reduction (Cycle 2)	9 (25.7%)#	2 (8.0%)##	11 (18.3%)

*Subjects may have experienced more than one DLT (listed above)
Dose reduction from 40 to 30 mg/m^2/day; ## Dose reduction from 30 to 20 mg/m^2/day

GROUP 2 (ADJUVANT)

- All 5 subjects have completed at least 1 cycle of treatment
- No SAEs, dose limiting toxicities or dose reductions (Cycle 2) have been recorded for this group

Tumor Response

- Tumor Assessment by MRI at the end of cycle 2 and every 42 days (every other cycle)
- Best Overall Response based on Investigator's clinical and radiologic assessment according to RANO criteria

GROUP 1 (RECURRENT)

Table 2. Best Tumor Response Measurement in Group 1 (Recurrent). All subjects completed at least 1 cycle. (Data cut-off November 15th, 2019)

Number of subjects completed first MRI assessment (Pre-Cycle3)	40 mg/m^2/d (n=35)	30 mg/m^2/d (n=23)	All (n=58)
Stable Disease	9 (25.7%)	6 (26.1%)	15 (25.9%)

No subjects demonstrated a partial response (PR) or complete response (CR)

GROUP 2 (ADJUVANT)

First subject reached first MRI assessment at the end of cycle 2, with best overall response of stable disease (SD).

Overall Survival (Snapshot)

GROUP 1 (RECURRENT)

- Of the subjects who had completed at least 1 cycle of treatment, 31/35 subjects at 40 mg/m^2/day and 8/25 subjects at 30 mg/m^2/day had died.
- Median OS (mOS) snapshot (censored at last known date alive):
  - All subjects: 7.5 (CI 6.0-11.5) months
  - 40 mg/m^2/day dose: 6.5 (CI 4.4-9.0) months
  - 30 mg/m^2/day dose: 10.6 (CI 5.8 to 10.6) months; dose group enrollment and treatment ongoing

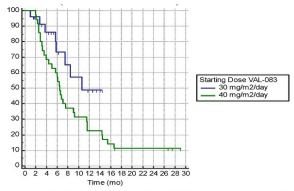


Figure 2. *Kaplan-Meier Survival Analysis of subjects receiving 30 or 40 mg/m^2/day VAL-083. Censored at last known date alive. Snapshot at data cut-off November 15th, 2019.*

GROUP 2 (ADJUVANT)

- As of November 15th 2019, all 5 subjects were continuing treatment.

CONCLUSIONS – FUTURE PLANS

- In the recurrent setting, 30 mg/m^2/day VAL-083 is better tolerated than 40 mg/m^2/day with fewer dose limiting toxicities
- To date VAL-083 is well tolerated as an alternative adjuvant treatment in unmethylated GBM to TMZ (which is of limited value in this setting[7]), and may offer a broader therapeutic window for VAL-083 and an opportunity to provide early intervention for these patients
- We continue to evaluate the efficacy of VAL-083 at the 30 mg/m^2/day dose which offers a potentially less toxic treatment in patients for treating recurrent disease

STUDY DESIGN

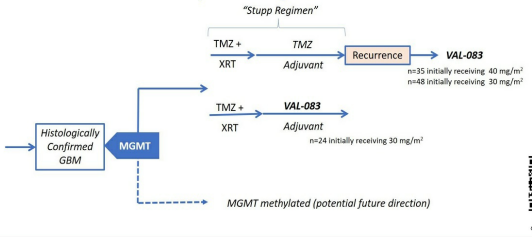
An open label, single-arm, biomarker-driven, Phase 2 study of VAL-083 treatment for MGMT unmethylated bevacizumab-naïve glioblastoma in the recurrent or adjuvant setting *(Clinicaltrials.gov Identifier: NCT02717962).*

Group 1:

- To determine if treatment with VAL-083 improves overall survival (OS) in patients with *MGMT*-unmethylated recurrent GBM
- Comparison of survival will be made to historical control for lomustine of median OS = 7.2 months (EORTC 26101, for patients with recurrent *MGMT*-unmethylated GBM treated with lomustine alone)
- Up to 83 patients with recurrent/progressive GBM will be enrolled. This will include 35 patients initially treated at 40 mg/m^2/day and up to 48 patients initially treated at 30 mg/m^2/day

Group 2:

- To determine if treatment with VAL-083 in *MGMT*-unmethylated GBM improves progression-free survival (PFS) in newly diagnosed patients when given as adjuvant therapy post chemoradiation with TMZ
- Median PFS will be compared to historical control, temozolomide (6.9 months) (Tanguturi, et al. 2017)[8]
- Up to 24 newly diagnosed GBM patients who have completed chemoradiation treatment with TMZ and received no subsequent adjuvant TMZ will be enrolled



References:
1. Zhai B, et al. *Cell Death and Disease. (2018)9:1016;* ***2. Zhai B, et al.*** *Cancer Res. July 2017: 77(13), abstract #2483;* ***3. Fouse S, et al.*** *Neuro Oncol. (2014). v16(Suppl 5), ET-18;* ***4. Stupp R, et al.*** *N Engl J Med. 2005; 352(10):997-1003;* ***5. Weathers SP, et al.*** *J Neurooncol.129(3): 487-94 (2016);* ***6. Shih K, et al.*** *J Clin Onc. 34, 15 (suppl.) 2016, 2063-2063;* ***7. NCCN guidelines*** *(CNS cancers, 2017);* ***8. Tanguturi SK, et al.*** *NeuroOncol.19(7):908-917 (2017).*

Clinical Trial of VAL-083 in Newly Diagnosed MGMT-unmethylated GBM: Half-Way Report

Zhong-ping Chen[1], Chengcheng Guo[1], Qun-ying Yang[1], Jia-wei Li[1], Shao-xiong Wu[1], Jeffrey Bacha[2], Gregory Johnson[3], John Langlands[3], Claire Kwan[3], Sarath Kanekal[3], Richard Schwartz[3], Lorena M. Lopez[3], Dennis Brown[3]

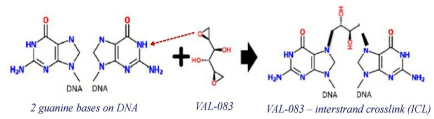
[1]Sun Yat-sen University, Guangzhou, China; [2]Formerly affiliated with DelMar Pharmaceuticals, Inc., no longer involved with the company or this clinical trial; [3]DelMar Pharmaceuticals, Inc., Vancouver, Canada and Menlo Park, California, USA;

ABSTRACT #ACTR-06

Approximately 60% of glioblastoma multiforme (GBM) patients possess an unmethylated methylguanine DNA-methyltransferase (MGMT) gene, which confers a limited response to standard of care treatment with temozolomide (TMZ) resulting in a lower survival. VAL-083 is a novel bi-functional DNA targeting agent that induces interstrand cross-links at N7-guanine, leading to DNA double-strand breaks and ultimately cell death. VAL-083 circumvents MGMT-mediated repair of the O6 guanine alkylator TMZ. A Phase 2 study has been initiated for VAL-083 in newly diagnosed MGMT unmethylated GBM. The study has 2 stages: Stage 1 is a dose-escalation and induction format to confirm the recommended dose of VAL-083 when administered concurrently with radiation therapy (RT) based on safety and tolerability. The subjects received VAL-083 at 20, 30, or 40 mg/m²/day x 3 days every 21 days along with standard radiation treatment. Stage 2 comprises an expansion phase to enroll up to 30 patients. The dose escalation stage is complete, and 30 mg/m²/day of VAL-083 in combination with RT was generally safe and well-tolerated. As of 17th May, 2019, 18 patients have been enrolled. Fifteen patients have completed their prospectively planned MRI scans and had their initial assessment for tumor progression. Of these 15 patients, seven were assessed as a complete response (CR), and eight patients as having stable disease (SD). Of the remaining three patients, one died prior to their post-cycle 3 MRI and two have not been on study long enough to reach their planned post-cycle 3 MRI. As of the data cutoff, 14 of the 18 patients were still alive. Consistent with our prior experience, myelosuppression was the most common adverse event. Three dose-limiting toxicities have been reported - one at the 40 mg/m²/day and two at the 30 mg/m²/day dose. Further enrollment, safety & study updates will be presented at the meeting. Clinicaltrials.gov identifier: NCT03050736.

BACKGROUND

Mechanism of VAL-083 via crosslinks at N7 of guanine



Mechanism of temozolomide (TMZ) via alkylation at O6 of guanine

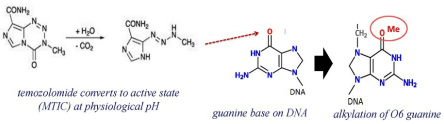


Figure 1. *The N7-targeting mechanism of action of VAL-083 differs from those of O6-alkylating agents like temozolomide and nitrosoureas.*

VAL-083 overcomes MGMT-mediated chemoresistance

VAL-083 is a novel bi-functional DNA targeting agent that rapidly induces interstrand cross-links at N7-guanine, leading to DNA double-strand breaks (DSBs) and ultimately cell death.[1] VAL-083's unique cytotoxic mechanism circumvents MGMT-mediated chemoresistance and differentiates it from other therapies used in the treatment of GBM, including TMZ.[2,3] VAL-083 is able to overcome TMZ-resistance in GBM, *in vitro* and *in vivo* and it acts as a radio-sensitizer against GBM cancer stem cells *in vitro*.[3]

Reported median survival in combination with radiotherapy, and the benefit versus radiotherapy (XRT) alone is similar or superior to other DNA-targeting agents (see Table 1).

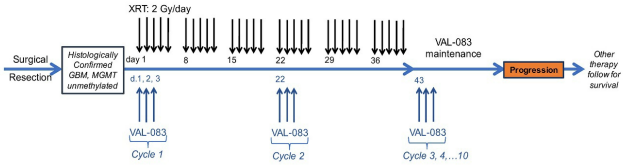
Table 1. **Historical data comparing randomized clinical trials of VAL-083 versus other chemotherapies used in the treatment of high-grade gliomas**

		Nitrosourea therapy			
XRT +	VAL-083[4]	TMZ[5]	BCNU[6]	CCNU[7]	ACNU[8]
Median survival (months)	16.8	14.6	12.5	13.0	8.8
Benefit vs. XRT alone	***8.4***	*2.5*	*2.5*	*1.2*	*n/a*

This distinct mechanism of action of VAL-083 combined with results from historical clinical trials suggests that VAL-083 in combination with radiation therapy may offer a treatment alternative against GBM tumors with MGMT-mediated resistance to chemotherapeutic agents, including TMZ and nitrosoureas.

STUDY DESIGN

An open label, single-arm, biomarker-driven, Phase 2 study of VAL-083 and radiation therapy in patients with newly diagnosed MGMT-unmethylated GBM. Currently enrolling at Sun Yat-sen University Cancer Center *(Clinicaltrials.gov identifier NCT03050736).*



Newly diagnosed GBM with unmethylated-MGMT are treated with VAL-083 IV on days 1,2,3 of a 21-day cycle combined with radiotherapy (2Gy/day x 5 days) for 6 weeks followed by up to 8 cycles of VAL-083 maintenance therapy:

- Dose-escalation Phase : VAL-083 in cohorts (20, 30 and 40 mg/m²/day IV) to assess safety and activity when administered concurrently with XRT to confirm the maximum tolerated dose (MTD)
- Expansion Phase: VAL-083 is being studied in up to 20 additional patients at the determined maximum tolerated dose of 30 mg/m²/day VAL-083 administered concurrently with XRT. Primary endpoint will be progression free survival (PFS) compared to historical control of TMZ at 6.9 months (Tanguturi et al, 2017)[9]. Tumor response will be assessed by MRI, according to RANO criteria
- Secondary endpoints include overall survival (OS), pharmacokinetic assessments of plasma and CSF samples (when available), and safety and tolerability evaluations of VAL-083 in combination with a standard-of-care radiation regimen

STUDY UPDATE

As of November 2nd, 2019:

- ❖ Dose escalation cohorts evaluating doses of 20, 30 and 40 mg/m²/day on days 1, 2 and 3 of a 21-day cycle have been completed
- ❖ As myelosuppression was observed at 40 mg/m²/day, the dose of VAL-083 was reduced to 30 mg/m²/day on days 1, 2 and 3 every 21 days, administered concurrently with radiation therapy
- ❖ A total of 23 subjects have been treated in the study
- ❖ 14 subjects have been treated in the Expansion Phase with a starting dose of 30 mg/m²/day
- ❖ Overall, 7/23 (30.4%) of subjects have died

Safety

- Consistent with prior studies, myelosuppression has been the most common adverse event
- Hematological adverse events generally resolved spontaneously
- Serious adverse events possibly related to VAL-083 have been reported in 4/23 (17.4%) of subjects
- Three DLTs have been reported in subjects who completed the first 2 cycles of treatment:

Table 2. Subjects with Dose-Limiting Toxicities (DLTs) during the first 42 days (2 cycles of treatment)

VAL-083 Dose (mg/m²/day)	Number of Subjects Completed 42 Days Treatment (2 cycles)	Number of Subjects with Dose Limiting Toxicities
20	1	0 (0%)
30	18	2 (11.1%)
40	3	1 (33.3%)

Pharmacokinetics

- Pharmacokinetic profiles are being determined on day 1 of cycle 1 for each subject
- Cmax and AUC are broadly linear with respect to dose; T1/2 = 0.8 hr
- Preliminary data indicate that overall the concentration of VAL-083 is as high in CSF as in plasma at 2 hours post-infusion

Table 3: Concentration of VAL-083 in Plasma and CSF

		Mean VAL-083 (SD) Conc. (ng/mL)			
Dose (mg/m²/d)	N	Plasma C_{max}	Plasma 2 hr post dose	CSF 2 hr post dose	Ratio @ 2 hr CSF/Plasma
20	1	481.0	110.0	154	1.40
30	6	574.9 (261.5)	97.2 (20.9)	123.0 (27.8)	1.19 (0.37)
40	3	898.7 (69.6)	169.7 (41.9)	189.7 (69.9)	1.13 (0.41)

Progression Free Survival

As of the cut-off date of November 2nd, 2019:

- For all subjects (completed and active treatment), the median number of cycles of VAL-083 received was 8; 9 subjects have received ≥ 10 cycles
- For the 22 subjects who had completed at least their first assessment, 12 had been assessed with disease progression
- Median progression free survival (PFS) (censored at last date alive):
  - All subjects: 9.9 (CI 7.3 – 12.0) months; 12/22 (54.6%) progressed
  - 20 mg/m²/day: 3.0 months; 1/1 (100%) progressed
  - 30 mg/m²/day: 10.4 (CI 6.0-12.0) months; 9/18 (50.0%) progressed
  - 40 mg/m²/day: 9.9 (CI 9.3 to 9.9) months; 2/3 (66.6%) progressed
  - TMZ historical comparator 6.9 months

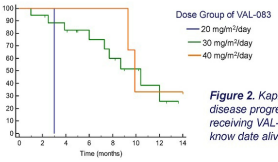


Figure 2. *Kaplan-Meier analysis of disease progression in subjects receiving VAL-083. Censored at last know date alive.*

Tumor Response

Best Response has been determined for subjects who completed their first planned assessment prior to cycle 4 (PreC4).

At November 2nd, 2019, 19 subjects had received at least one assessment prior to initiating C4 and beyond.

- 9/19 (47.4%) assessed as Complete Response
- 8/19 (42.1%) assessed as Stable Disease
- 2/19 (10.5%) assessed as Disease Progression

Two subjects not yet reached preC4 assessment; two subjects discontinued/died before first planned assessment time point (preC4).

CONCLUSIONS

- ➢ VAL-083 at 30 mg/m²/day in combination with radiation therapy is generally safe and well-tolerated, and multiple treatment cycles in the adjuvant setting have been achieved
- ➢ Adverse events have been consistent with prior studies
- ➢ Levels of VAL-083 measured in the CSF at 2 hrs post-infusion were as high as those measured in plasma demonstrating significant penetration to the brain
- ➢ VAL-083 at 30 mg/m²/day in combination with radiotherapy has demonstrated benefit with respect to disease progression over standard of care TMZ (6.9 months – Tanguturi et al, 2017)[9] in the same setting.

References

1. **Zhai B, et al.** *Cell Death and Disease. 9:1016 (2018)*
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