Calculated Objective Response Rate (ORR) of 97% from Post-Hoc Analysis of a Phase 2 Multicenter Study to Evaluate the Efficacy of VP-315, an Investigational therapy for Basal Cell Carcinoma (BCC)

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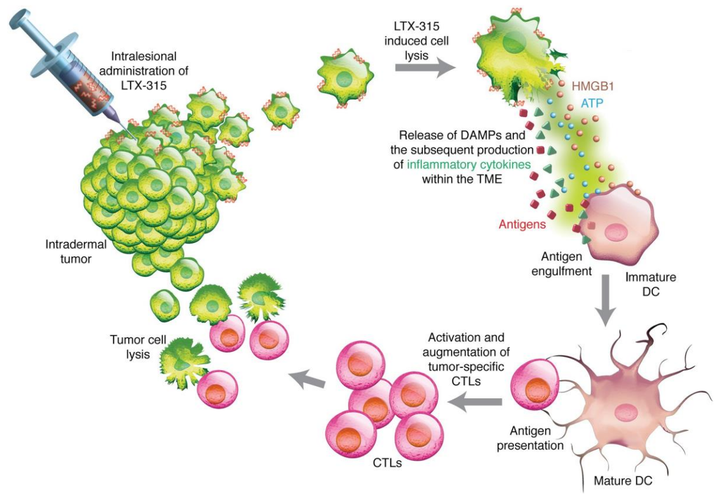
INTRODUCTION

VP-315 is an intratumorally injected, chemotherapeutic oncolytic peptide in development as a non-surgical immunotherapeutic agent to be utilized as first line therapy in a primary or neoadjuvant setting for patients with basal cell carcinoma (BCC).

Intratumoral injection of VP-315 induces lysis and tumor cell death releasing a repertoire of potent tumor antigens that then activatate the adaptive immune system.



Objective response rate (ORR) is a key measure used in clinical trials to evaluate potential efficacy for treatments in oncology. It refers to the percentage of patients who experience a predefined level of tumor reduction along with partial or complete response following treatment. ORR can assess tumor burden in patients with solid tumors, including BCC.

Complete response is when all detectable tumors resolve, while a partial response shows a significant reduction in tumor size. ORR is commonly used as either a primary or secondary endpoint in clinical trials to assess tumor burden and to assess how well a therapy works at reducing the size of the tumor or eliminating the tumor.

ORR provides valuable insights into the efficacy of a treatment, helping to inform decision-making for further development and approval of new drugs or therapies.

In this study, a post-hoc analysis was performed exploring ORR as a potential primary endpoint for future studies evaluating the efficacy of VP-315, an intratumorally injected, chemotherapeutic oncolytic peptide.

OBJECTIVE

To evaluate the effect of various VP-315 8 mg dosing regimens on antitumor response in subjects with BCC.

METHODS

- Eighty-two (82) subjects with up to 2 target BCC tumors were treated intratumorally with VP-315 for up to 2 weeks. Cohort 3 was not enrolled based on results from Cohorts 1-2. Each 7-day treatment week was comprised of 2 or 3 consecutive treatment days followed by a no-treatment period of at least 4 days. In Cohort 4, each BCC was treated for 2 consecutive days. In Cohort 5, each BCC was treated for 3 consecutive days. A subject could have up to two target (treated) tumors.
- Post-hoc evaluation by ORR was based on response defined a priori as absence of disease progression and ≥30% reduction in lesion size from baseline, or complete resolution of ulceration in all target lesions. Complete response was based upon objective response with no residual BCC on post-treatment excisional biopsy. Partial response was objective response with presence of residual BCC.

Table 1. VP-315 Study Design – Part 2

Cohorts	W1D1	W1D2	W1D3	W1D4	W2D1	W2D2	W2D3	W2D4*
Cohort 1 Loading Dose (n=6)	4 mg loading	8 mg	8 mg	Safety	8 mg	8 mg	8 mg	Safety
Cohort 2 No Loading Dose (n=3)	W1D1	W1D2	W1D3	W1D4	W2D1	W2D2	W2D3	W2D4
	8 mg	8 mg	8 mg	Safety	8 mg	8 mg	8 mg	Safety
Cohort 4 2-day Dosing Regimen (n=36)**	Lesion #1 Treatment				Lesion #2 Treatment			
	W1D1	W1D2	W1D3	W2D1	W2D1	W2D2	W2D3	W3D1
	30/70 8 mg	30/70 8 mg	Safety	Limited Safety	30/70 8 mg	30/70 8mg	Safety	Limited Safety
Cohort 5 3-day Dosing Regimen (n=37)**	Lesion #1 Treatment					Lesion #2 Treatment				
	W1D1	W1D2	W1D3	W1D4	W2D1	W2D1	W2D2	W2D3	W2D4	W3D1
	30/70 8 mg	30/70 8 mg	30/70 8 mg	Safety	Limited Safety	30/70 8 mg	30/70 8 mg	30/70 8 mg	Safety	Limited Safety

** Cohort 3 was not enrolled based on results from Cohorts 1-2.*
*** 8 mg total dose split into 2 injections, 30% given initially followed 15-30 minutes later (70%).*

RESULTS

Eighty-two subjects (n=92 tumors) treated with VP-315 had a calculated ORR of 97%. Response rates were: 52% complete response (CR) and 45% partial response (PR). No TRSAEs were reported. TRAEs were mostly mild to moderate.

Table 2. Post-Hoc Analysis of ORR, CR, and PR

Tumors per Cohort	ORR	CR	PR
Cohort 1 (n=7)	**100%**	**71%**	**29%**
Cohort 2 (n=3)	**100%**	**33%**	**67%**
Cohort 4 (n=38)	**97%**	**53%**	**44%**
Cohort 5 (n=44)	**95%**	**48%**	**47%**
Total (n=92)	**97%**	**52%**	**45%**

CONCLUSIONS

These results support further investigation of ORR as a reliable endpoint for VP-315 in future BCC studies. Additional research using VP-315 as a potential non-surgical immunotherapy for BCC as a first line therapy in a primary or neoadjuvant setting is warranted.

References

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Disclosures

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This study was sponsored by Verrica Pharmaceuticals Inc.