Survival Outcomes of *Bria-IMT*: an Allogeneic Whole Cell Cancer Vaccine

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BACKGROUND

Bria-IMT™ is a combination immunotherapy comprising the allogeneic whole-cell vaccine SV-BR-1-GM, administered with low-dose cyclophosphamide (CTX), pegylated interferon alpha (IFNα), and an immune checkpoint inhibitor (CPI). SV-BR-1-GM breast cancer cells are engineered to express both class I and II HLA molecules, secrete GM-CSF to enhance dendritic cell activation, and present tumor-associated antigens such as HER2 and PRAME. Functioning as antigen-presenting cells, these cells serve as a reservoir of shared tumor antigens capable of activating anti-tumor immune responses. Subsequent enhancements to SV-BR-1-GM have improved in vitro immunologic characteristics (Lopez-Lago, SABC 2023). The addition of CPI is intended to potentiate SV-BR-1-GM–induced immune activation by overcoming tumor-induced immune suppression. We present updated findings from prospective randomized and post hoc exploratory analyses in patients with advanced metastatic breast cancer (aMBC) treated with the Bria-IMT regimen.

METHODS

This is an ongoing, prospective, phase 1–2 study with a randomized phase 2 cohort (NCT03328026; initiated in 2018), evaluating the Bria-IMT regimen in combination with an anti–PD-1 checkpoint inhibitor (CPI). Treatment cycles are administered every 3 weeks. To date, 54 patients have received at least one dose. The regimen includes intravenous cyclophosphamide (CTX; 300 mg/m²) administered 48 hours prior to intradermal inoculation of irradiated SV-BR-1-GM cells (~20 million cells), followed by pegylated interferon alpha (IFNα; 0.1 mcg) at each inoculation site 2 days later. A Candida skin test is performed at cycle 1 to assess anergy. At each cycle, a delayed-type hypersensitivity (DTH) skin test is conducted using an intradermal test dose of SV-BR-1-GM prior to full dosing. Two SV-BR-1-GM cell formulations—with and without IFNγ pre-treatment—have been evaluated. In the randomized cohorts, two CPI administration sequences are compared: initiation at cycle 1 (immediate) versus initiation at cycle 2 (delayed).

RESULTS

Table 1: Patient Demographics

Characteristic	N (%)
Age, Median (Range)	61 (38-81) years
BMI, Median (Range)	28.1 (18.1-42.7)
Race/Ethnicity	
• White	42 (78%)
• Black	6 (11%)
• Hispanic	10 (19%)
• Asian	3 (6%)
• Other	3 (6%)
ECOG	
• ECOG 0	29 (54%)
• ECOG 1	25 (46%)
Tumor Grade	
• Grade 1	6 (11%)
• Grade 2	15 (28%)
• Grade 3	30 (56%)
• Unknown	3 (5%)
Prior systemic therapy, Median (Range)	6 (2-13)
Previous therapies	
• ADC	23 (44%)
• CPI	11 (20%)
• CDK4/6 inhibitors	34 (63%)
Number of HLA Match	
• 0	12 (22%)
• ≥ 1	40 (74 %)
• Unknown	2 (4%)

Table 2: Adverse Events Occurring in ≥ 10% of Patients

Adverse Event	Maximum Grade				Related
	Grade 1	Grade 2	Grade 3	Grade 4	N (%)
	N (percent)				
Fatigue	10 (18.5)	10 (18.5)	3 (5.6)	0	**12 (22)**
Injection Site Reaction	16 (29.6)	2 (3.7)	0	0	**17 (31.5)**
Nausea	12 (22)	5 (9.3)	0	0	**8 (14.8)**
Constipation	7 (13)	4 (7.4)	1 (1.9)	0	**3 (5.6)**
Diarrhea	7 (13)	3 (5.6)	0	0	**1 (1.9)**
Headache	8 (14.8)	2 (3.7)	0	0	**2 (3.7)**
Anemia	5 (9.3)	1 (1.9)	3 (5.6)	0	**8 (14.8)**
Rash/maculo-papular rash	6 (11.1)	1 (1.9)	1 (1.9)	0	**2 (3.7)**
Vomiting	4 (7.4)	3 (5.6)	1 (1.9)	0	**4 (7.4)**
*TSH increased/ hypothyroidism	3 (5.6)	5 (9.3)	0	0	**5 (9.3)**
Back Pain	1 (1.9)	5 (9.3)	0	0	**3 (5.6)**
Edema of the limbs/extremities or anasarca	4 (7.4)	3 (5.6)	0	0	**0**
Fever	3 (5.6)	3 (5.6)	0	0	**2 (3.7)**
Injections Site Erythema	5 (9.3)	1 (1.9)	0	0	**5 (9.3)**
Loss of appetite/ decreased appetite/ anorexia	6 (11.1)	0	0	0	**3 (5.6)**
Weakness	3 (5.6)	3 (5.6)	0	0	**2 (3.7)**
	4 (7.4)	2 (3.7)	1 (1.9)	0	**2 (3.7)**

Conclusion: Bria-IMT was well-tolerated with no discontinuations due to toxicity.

Figure 1: Clinical Benefit in Evaluable Patients

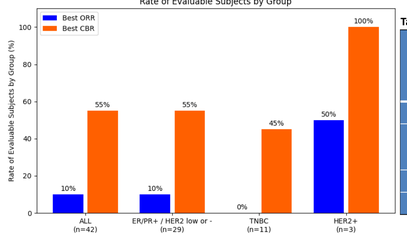

Table 3: Clinical Benefit in Evaluable Patients by MBC Subtype

Biomarkers	N (%)	Patients with Evaluable Outcome	Best ORR [CR, PR] in Evaluable Patients	Best CBR [CR, PR, SD] in Evaluable Patients
HER2+	3	2	50%	100%
HR + / HER2 -	33	29	10%	55%
TNBC	18	11	0%	45%
Overall	54	42	10%	55%

CONCLUSION

- Overall survival among patients treated with the phase 3 formulation remains encouraging and compares favorably to historical benchmarks in similar populations.
- The Bria-IMT regimen combined with an immune checkpoint inhibitor continues to demonstrate a favorable tolerability profile and evidence of clinical benefit in heavily pretreated patients with metastatic breast cancer.
- No statistically significant difference in overall survival was observed between ER/PR+/HER2– and TNBC subtypes
- The ongoing Phase 3 trial (NCT06072612) is enrolling patients in ER/PR+/HER2-, TNBC, as well as in HER+ MBC subgroups.
- These updated findings support continued refinement of the Bria-IMT regimen to optimize clinical outcomes in future trials.

RESULTS

Figure 2: Kaplan-Meier curves comparing overall survival (OS) by treatment sequencing of a checkpoint inhibitor (CPI) with immediate cycle 1 vs. delayed cycle 2 in the randomized phase 2 cohort

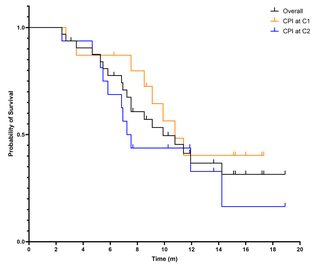

Table 4. Overall survival by CPI sequencing.

N = 32	Median (months)	Range
CPI at C1	10.8	2.73 – 17.33
CPI at C2	7.4	2.43 – 18.90
HR, 0.57; 95% CI, 0.23 to 1.44 (p = 0.20)		
Overall	9.9	2.43 – 18.90

There was no statistically significant difference in OS between the two arms in the Phase II cohort: Immediate C1 (CPI starting at cycle 1, 2 days prior to SV-BR-1-GM; 10.8 months) and Delayed C2 (CPI starting at cycle 2, 2 days after SV-BR-1-GM; 7.4 months). A similar trend clinically favored CPI at C1 was noted in the overall Phase I/II (N = 54) patient cohort. (**Figure 7**)

Conclusion: The immediate C1 approach was implemented in the Phase III trial.

Figure 3: Kaplan-Meier curve comparing OS by treatment formulation (with vs without IFNγ pretreatment) in the full phase 1/2 cohort

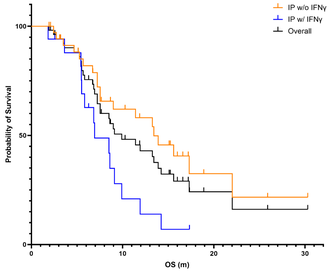

Table 5. Overall survival by IP formulation.

N = 54	Median (months)	Range
IP w/o IFNγ (Phase 3 formulation)	13.43	1.9 – 30.3
IP w/ IFNγ	6.93	1.8 – 17.3
HR, 0.34 ; 95% CI 0.15 to 0.77 (p = 0.01)		
Overall	9.9	2.43 – 18.90

There was a statistically significant difference in OS between the formulation of SV-BR-1-GM with/without pulsed IFNγ in cell culture between the two arms in the full phase I/II cohort (IP w/o IFNγ, 13.43 months vs IP w/ IFNγ, 6.93 months; p = 0.03).

Conclusion: The formulation without IFNγ pretreatment is being used in all future clinical trials.

Figure 4: Kaplan-Meier curve comparing OS by MBC Subtype in the Full Phase 1 / 2 Cohort in Patients Receiving IP w/o IFNγ

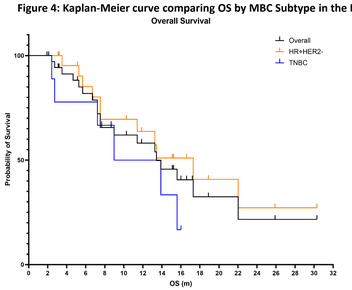

Table 6. Overall survival by MBC subtype.

N = 37	Median (months)	Range
ER/PR+/ HER2-	17.30	1.93 – 30.30
TNBC	11.44	2.1 – 16.00
HR, 0.49; 95% CI, 0.16 to 1.56 (p = 0.23)		
Overall	13.43	1.93 – 30.30

There was no statistically significant difference in OS between ER/PR+/HER2- and TNBC subtypes in patients receiving SV-BR-1-GM without IFNγ. Median OS was 17.3 months for ER/PR+/HER2- and 11.4 months for TNBC (HR 0.49; 95% CI, 0.16 to 1.56; p = 0.23).

Conclusion: As a result, both subtypes continue to be enrolled in the ongoing Phase III trial.

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Figure 5: Status of Individual Intracranial Oligometastases by Patient

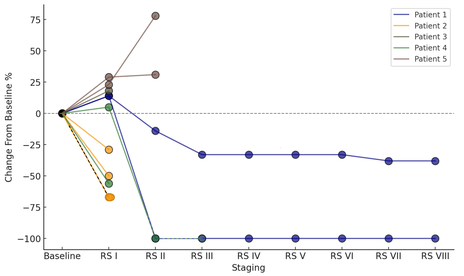

Figure 6: Waterfall Plot Showing Best % Change in Sum of Target Lesion Diameters from Baseline

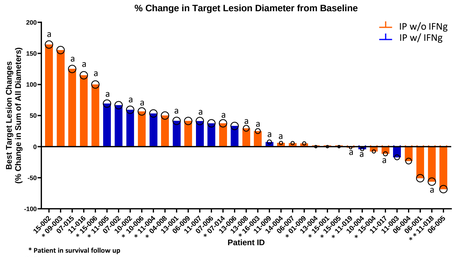

Figure 7 : Forest Plot of Hazard Ratios for Overall Survival from Secondary and Correlative Analyses in Full Phase 1 / 2 Cohort (N = 54)

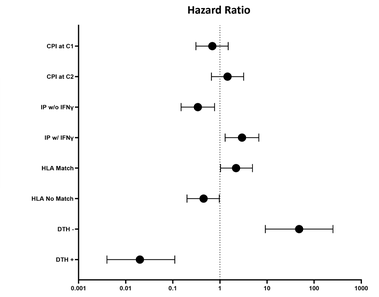

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Table 7. Clinical benefit in patients with intracranial lesions by MBC subtype.

MBC Subtype	N	Patients with Evaluable Outcome	Best ORR [CR, PR] in Evaluable Patients	Best CBR [CR, PR, SD] in Evaluable Patients
HER2+	1	1	100%	100%
HR + / HER2 -	1	1	100%	100%
TNBC	4	2	0%	50%
Overall	6	4	50%	75%

Table 8. Change in intracranial lesions in evaluable patients.

	Pretreatment	Post Treatment
Median sum of intracranial lesion diameters[a]	26 mm	15 mm
Median intracranial lesion diameter[a]	10.3 mm	5 mm
Median lesion diameter reduction[a]	–	50% reduction

a. in patients with evaluable outcomes

Table 9. Tumor burden changes in patients with at least 1 post baseline tumor assessment.

N = 35	Measurement	%
Best Response	Maximum decrease in lesion diameter	–70%
Tumor Burden Change	Percent of patients with decrease in sum of target lesion diameters vs baseline	26%
	Percent of patients with decrease or no increase in sum of target lesion diameters vs baseline(≤ 0% change)	34%
IP Formulation	Percent of patients with ≤ 0% change in sum of target lesion diameters who received the IP formulation w/o IFNg	83%
Prior ADC Exposure	Percent of patients with decrease in sum of target lesions diameters vs baseline with prior ADC exposure	44%

Among patients with at least one follow up tumor assessment (N = 35), 26% experienced a reduction in the sum of target lesion diameters from baseline, and 34% demonstrated either a decrease or no increase (≤ 0% change) at most recent tumor assessment vs baseline assessment.

Conclusion: The reduction in tumor burden reported in a sizeable number of patients suggests that treatment with the Bria-IMT regimen + CPI can overcome immune exhaustion in this heavily pretreated cohort.

Table 10. Survival outcomes by treatment timing, IFNγ exposure, HLA matching, and DTH response in evaluable patients.

Analysis	N (%)	OS months (range)	HR; 95% CI	p-value
CPI at C1	38 (70)	11.4 (1.83 – 30.30)	0.72; 0.33 to 1.57	0.34
CPI at C2	16 (30)	7.4 (2.43 – 18.90)	1.39; 0.64 to 3.03	
IP w/o IFNγ	37 (69)	13.4 (1.93 – 30.30)	0.34; 0.15 to 0.77	0.01
IP w/ IFNγ	17 (31)	6.9 (1.83 – 17.33)	2.94; 1.29 to 6.70	
HLA Match	39 (72)	8.6 (1.83 – 25.90)	2.30; 1.06 to 4.90	0.04
HLA No Match	13 (24)	Undefined	0.44; 0.20 to 0.94	
DTH -	9 (17)	4.7 (1.83 – 8.60)	48.01; 9.20 to 250.60	<0.0001
DTH +	45 (83)	13.3 (2.43 – 30.30)	0.02; 0.004 to 0.11	
Overall	54 (100)	9.9 (1.83 – 30.30)	-	-

Median overall survival (OS), hazard ratios (HR; 95% CI), and p-values for key subgroups. OS was longer in patients treated with CPI at C1, without IFNγ, with HLA mismatch, and with a positive DTH response. Significant differences were observed by IFNγ status (p = 0.01), HLA match (p = 0.04), and DTH response (p < 0.0001).

Conclusion: CPI sequencing, IP formulation, HLA matching status and DTH responses results in this analysis appear consistent with prior reports and with expectations for the phase 3 design.