Survival with Bria-IMT + CPI in Advanced Metastatic Breast Cancer at 12 and 24 Months

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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

Phase I/II evaluating the Bria-IMT regimen (SV-BR-1-GM with CPI (pembrolizumab or retifanlimab). In the phase II portion, pts were randomized 1:1 to CPI initiation at cycle 1 (C1) or delayed start at cycle 2 (C2). Two SV-BR-1-GM formulations were administered: IFNγ-stimulated (IFγ) or unstimulated (≠IFγ). Baseline circulating tumor cells (CTCs) and delayed-type hypersensitivity (DTH) responses to SV-BR-1-GM were assessed as biomarkers. Progression free survival (PFS) and overall survival (OS) were analyzed using Kaplan Meier (KM). Subgroup comparisons (CPI sequencing, IP formulation, DTH status, and HLA matching status) are exploratory.

Results

Table 1. Patient Demographics

Characteristic	Overall (N = 32)	Alive at 12 mo (n = 14)	Alive at 24 mo (n = 6)
	Phase 2 Cohort	← 12-Month Landmark →	← 24-Month Landmark →
Age; Median (range), years	60.5 (41–80)	59.5 (44–80)	58.5 (44–66)
ECOG Performance Status			
0	23 (72)	11 (79)	6 (100)
1	9 (28)	3 (21)	0 (0)
Race / Ethnicity			
White	26 (81)	11 (79)	6 (100)
Black or African American	5 (16)	2 (14)	0 (0)
Asian	1 (3)	1 (7)	0 (0)
Breast Cancer Subtype			
HR+/HER2–	20 (63)	9 (64)	4 (67)
HER2+	3 (9)	1 (7)	1 (17)
TNBC	9 (28)	4 (29)	1 (17)
Prior Lines of Therapy			
Median (range)	6 (2-13)	6 (2-10)	6 (2-8)
1–2	1 (3)	1 (7)	1 (17)
3–4	8 (25)	2 (14)	1 (17)
≥5	23 (72)	11 (79)	4 (67)
Prior Therapy Received, n (%)			
CPI	6 (19)	1 (7)	0 (0)
ADC	20 (63)	7 (50)	3 (50)
Tumor Grade			
Grade 1	2 (6)	2 (14)	1 (17)
Grade 2	8 (25)	3 (21)	3 (50)
Grade 3	13 (41)	5 (36)	2 (33)
Not Reported	9 (28)	4 (29)	0 (0)
Number of HLA Match			
0	7 (22)	6 (43)	5 (83)
≥ 1	23 (72)	7 (50)	1 (17)
Unknown	2 (6)	1 (7)	0 (0)

Table 2. Safety

Adverse Event	Maximum Grade				Total Related
	Grade 1	Grade 2	Grade 3	Grade 4	
	N (percent)				
Injection Site Rxn	16 (50)	1 (3.1)	0	0	17 (53.1)
Nausea	9 (28.1)	3 (9.4)	1 (3.1)	0	14 (43.8)
Fatigue	5 (15.6)	6 (18.8)	2 (6.3)	0	13 (40.6)
Anemia	3 (9.4)	1 (3.1)	2 (6.3)	0	6 (18.8)
Diarrhea	6 (18.8)	0	0	0	6 (18.8)
Fever	5 (15.6)	1 (3.1)	0	0	6 (18.8)
TSH increased	5 (15.6)	1 (3.1)	0	0	6 (18.8)
Vomiting	3 (9.4)	2 (6.3)	1 (3.1)	0	6 (18.8)
AST/ALT increased	3 (9.4)	2 (6.3)	1 (3.1)	0	5 (15.6)
Alkaline phosphatase increased	1 (3.1)	2 (6.3)	2 (6.3)	0	5 (15.6)
Constipation	4 (12.5)	0	1 (3.1)	0	5 (15.6)
Cough	3 (9.4)	2 (6.3)	0	0	5 (15.6)
GGT increased	2 (6.3)	1 (3.1)	2 (6.3)	0	5 (15.6)
Headache	4 (12.5)	1 (3.1)	0	0	5 (15.6)
Anorexia/appetite decreased	2 (6.3)	2 (6.3)	0	0	4 (12.5)
Lymphocyte count decrease	1 (3.1)	2 (6.3)	1 (3.1)	0	4 (12.5)
Rash	4 (12.5)	0	0		4 (12.5)
UTI	0	2 (6.3)	2 (6.3)	0	4 (12.5)
Weight loss	4 (12.5)	0	0	0	4 (12.5)

Table 3. Clinical Benefit in Long Term Survivors

Biomarkers	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 -	9	9	0%	56%
TNBC	4	3	0%	67%
Overall	14	13	8%	62%

Conclusions

- This randomized phase 2 trial confirms previously reported tolerability and potential meaningful clinical benefit in late-stage MBC.
- The updated overall survival on Bria-IMT, even after median 6 prior lines, is highly meaningful and supports the ongoing Phase 3 (NCT00000419).
- Bria-IMT shows potential across all breast cancer types including those without an existing IO indication.

Figure 1. Overall Survival of Phase 2 Cohort

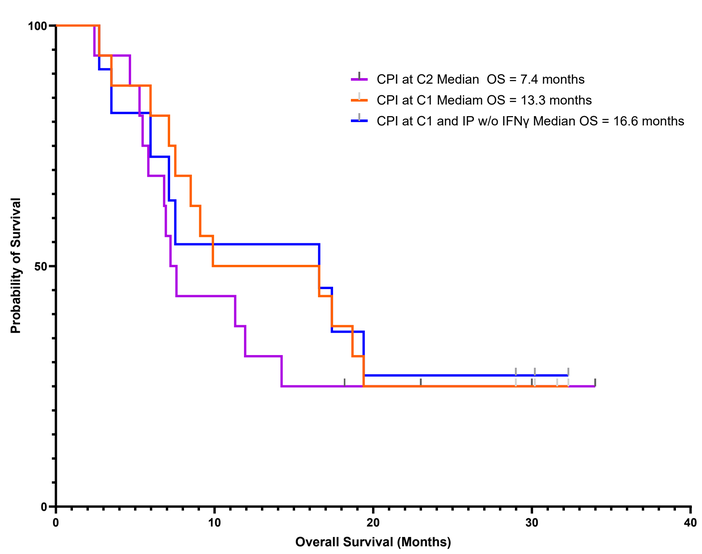

Figure 1. Kaplan-Meier analysis of overall survival (OS) in the Phase 2 cohort demonstrating a median OS of 13.3 months for the phase 3 sequence and 16.6 months for the phase 3 sequence and formulation, with estimated 12-month and 24-month OS rates of 55% and 27%, respectively.

The first author and presenting author declare no undisclosed conflicts of interest or financial relationships. For further correspondence please reach out to gdelpriore@msm.edu

Results

Figure 2. Swimmer Plot

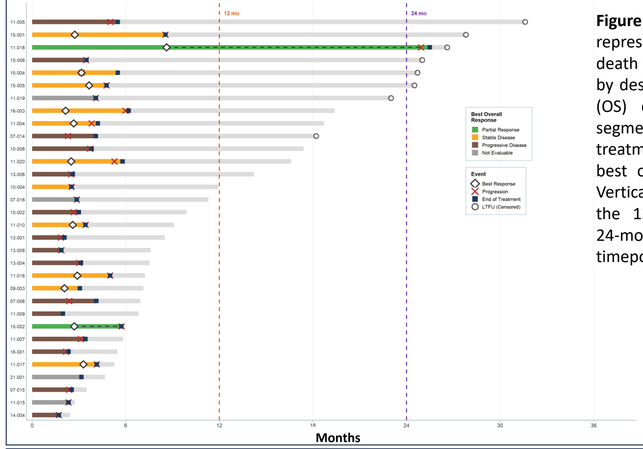

Figure 2. Horizontal bars represent time on trial to death or last follow-up, sorted by descending overall survival (OS) duration. The colored segment indicates the on-treatment period, classified by best overall response (BOR). Vertical dashed lines denote the 12-month (orange) and 24-month (purple) landmark timepoints. N = 32.

Figure 3. Best % Change in Sum of Lesion Diameters from Baseline

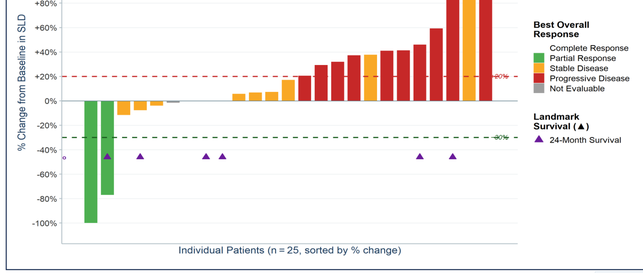

Figure 3. Waterfall plot showing best overall response as maximum percent change from baseline in target lesion sum of diameters (SLD) among evaluable pts (N=25). Long responders are designated as indicated in the legend.

Figure 4. Forest Plot of Exploratory Analyses

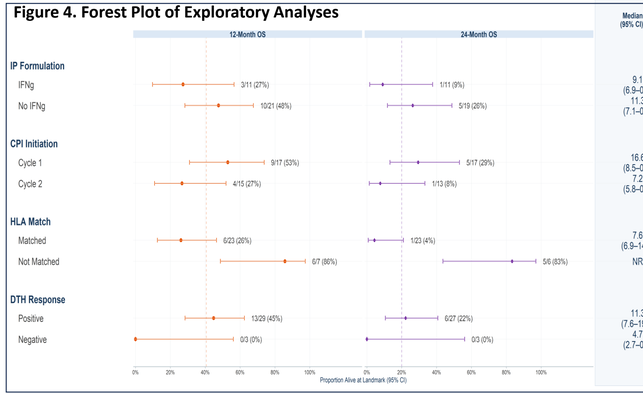

Figure 4. Circles represent OS proportions at landmark; error bars indicate 95% Wilson CIs. Dashed lines denote overall population landmark rates. Median OS (95% CI) shown at right. Analyses are exploratory and descriptive.