Bria-IMT + Checkpoint Inhibitior: Phase I/II Survival Results Compared to Benchmark Trials in Metastatic Breast Cancer

Saranya Chumsri, Chaitali Singh Nangia, Minal A. Barve, Kendrith M. Rowland, Ralph V. Boccia, John George Knecht, Blaise Bayer, Marcela Salgado, William Williams, Charles L. Wiseman, Giuseppe Del Priore, Carmen Calfa

Mayo Clinic Florida, Jacksonville, FL; Hoag, Newport Beach, CA; Sarah Cannon Research Institute at Mary Crowley, Dallas, TX; Carle Clinic, Champaign, IL; Center for Cancer and Blood Disorders, Bethesda, MD; Tranquil Clinical Research, Webster, TX; BriaCell Therapeutics Corp., Philadelphia, PA; Morehouse School of Medicine, Atlanta, GA; University of Miami, Plantation, FL

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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%)

Conclusion: Bria-IMT patient cohort was heavily pretreated.

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.

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.**
- **The ongoing Phase 3 trial (NCT06072612) is enrolling patients in ER/PR+/HER2-, TNBC, as well as in HER+ MBC subgroups.**
- **Patients with prior IO exposure have a comparable safety profile to IO-naïve patients with patients in the prior CPI only group experiencing no grade 3 or 4 AE.**

ASCO 2025 Bria-ABC Phase 3 Trial In Progress Poster

ASCO 2025 Bria-OTS Phase 1 Clinical Trial in Progress Poster

RESULTS

Figure 1: 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

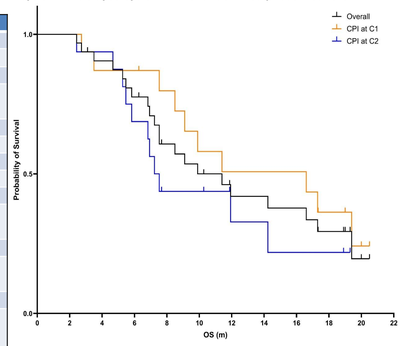


Figure 2: Kaplan-Meier curve comparing OS by treatment formulation (with vs without IFNγ pretreatment) in the full phase 1/2 cohort

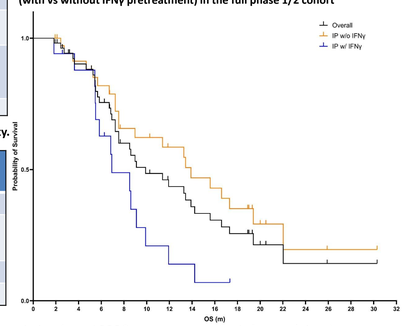


Table 4. Overall survival by CPI sequencing.

N = 32	Median (months)	Range
CPI at C1	16.6	2.73 – 20.50
CPI at C2	7.4	2.43 – 19.3
HR, 0.57; 95% CI, 0.23 to 1.40 (p = 0.22)		
Overall	11.4	2.43 – 20.50

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; 16.6 months) and Delayed C2 (CPI starting at cycle 2, 2 days after SV-BR-1-GM; 7.4 months). A similar trend clinically favoring CPI at C1 was noted in the overall Phase I/II (N = 54) patient cohort.

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

Table 5. Overall survival by IP formulation.

N = 54	Median (months)	Range
IP w/o IFNγ (Phase 3 formulation)	13.9	1.9 – 30.3
IP w/ IFNγ	6.93	1.8 – 17.3
HR, 0.33 ; 95% CI 0.15 to 0.75 (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, 13.9 months vs IP w/ IFNγ, 6.93 months; p = 0.01).

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

Figure 3: % Change in Sum of Lesion Diameters by IP Formulation

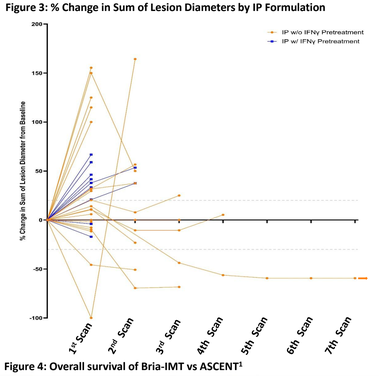


Table 6. Median Time to Best Response in Evaluable Patients

N = 23	Median Time to Best Response (months)	Duration of Response (PR) (months)	Duration of Response (SD) (months)
IP w/o IFNγ (Phase 3 formulation)	2.9 (0.3 – 8.8)	2.9 (1.1 – 11.9)	3.1 (8.6 – 18.7)
IP w/ IFNγ	2.6 (2.1 – 3.0)	N/A	1 (0.8 – 2.3)
Overall	2.7 (0.3 – 8.8)	2.9 (1.1 – 11.9)	2.4 (0.8 – 18.7)

Conclusion: Patients receiving SV-BR-1-GM cells w/o IFNγ pretreatment reported lower median % change in sum of lesion diameter at 1st post treatment assessment. Median time to best response was 2.7 months.

Figure 4: Overall survival of Bria-IMT vs ASCENT[1]

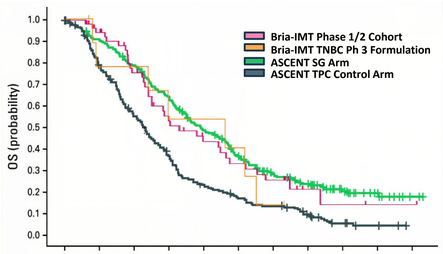


Figure 5: Overall survival of Bria-IMT vs TROPiCS-02[2]

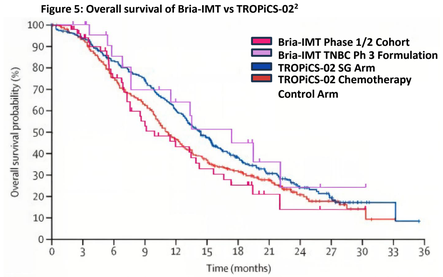


Table 7. Comparison of median OS in TNBC patients across Bria-IMT and ASCENT aMBC trials.

Trial (Cohort)	Age (Median, Range)	Prior Therapies (Median)	Prior ADC|CPI (%)	CNS Mets	OS (Median, mo)	CBR (%)
Bria-IMT (Overall Cohort)	61 (38-81)	6 (2-13)	43|20	6	9.9 (1.8-30.3)	55%
TNBC Bria-IMT (Ph 3 Formulation)	62 (44-80)	6 (2-13)	20|19	4	11.4 (2.1-19.0)	45%
ASCENT (SG)	54 (27-82)	4 (2-17)	27|None Listed	None Listed	11.8	40%
ASCENT (TPC)	53 (27-81)	4 (2-14)			6.9	8%

[1]Bardia, A., et al Journal of Clinical Oncology, 42(15), 1738–1744

Table 8. Comparison of median OS in TNBC patients across Bria-IMT and TROPiCS-02 aMBC trials.

Trial (Cohort)	Age (Median, Range)	Prior Therapies (Median)	Prior ADC|CPI (%)	CNS Mets	OS (Median, mo)	CBR (%)
Bria-IMT (Overall Cohort)	61 (38-81)	6 (2-13)	43|20	6	9.9 (1.8-30.3)	55%
HR+/HER2- Bria-IMT (Ph 3 Formulation)	62 (44-80)	6 (2-13)	17|2	1	17.3 (1.9-30.3)	60%
TROPiCS (SG)	57 (49-65)	3	None Listed	None Listed	14.4	34%
TROPiCS (Chemo)	55 (48-63)	3			11.2	22%

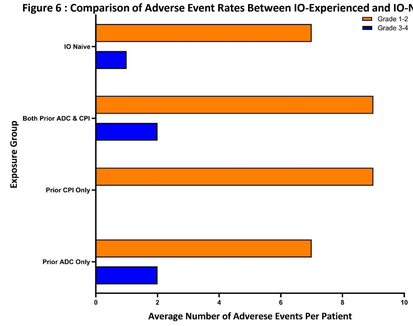
[2]Rugo, H. S., et al. The Lancet, 402(10411), 1423–1433.

Patients receiving the Bria-IMT Phase 3 investigational product (IP) formulation demonstrated superior overall survival (OS) compared to those treated with sacituzumab govitecan and chemotherapy in the TROPiCS-02 clinical trial, as well as the treatment of physician's choice (TPC) arm in the ASCENT study. In the TNBC subset, OS for patients treated with Bria-IMT approached that observed in the sacituzumab govitecan arm of the ASCENT trial and exceeded OS in the TPC arm.

Table 9. Adverse event occurrence and severity by prior exposure group

Exposure Group	AE Grade	Median AE Occurrences	AE Occurred n (%)	AE Did Not Occur n (%)
Prior ADC Failure	Grade 1–2	6.5	15 (94)	1 (6)
Prior CPI Failure		7	4 (100)	0 (0)
Prior ADC & CPI Failure		9	6 (86)	1 (14)
IO-Naïve		5	26 (96)	1 (4)
Prior ADC Failure	Grade 3–4	1	10 (63)	6 (37)
Prior CPI Failure		0	0 (0)	0 (0)
Prior ADC & CPI Failure		2	5 (71)	2 (29)
IO-Naïve		0	9 (33)	18 (67)

Figure 6 : Comparison of Adverse Event Rates Between IO-Experienced and IO-Naïve Patients



Horizontal Bar chart showing absolute incidence of AEs by IO exposure groups.

Contact: Giuseppe Del Priore Email: giuseppe@briacell.com