Update on phase III pivotal trial of Bria-IMT + CPI vs physician's choice in advanced metastatic breast cancer (BRIA-ABC).

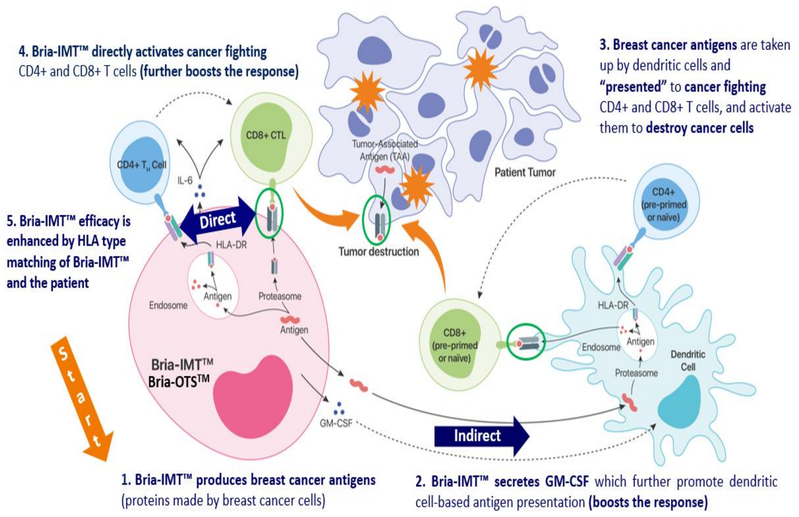
Saranya Chumsri, Joyce O'Shaughnessy, Azka Ali, Christopher Norman Vaughn, Kristine Rinn, Adam Brufsky, Lawrence M. Negret, Regina Michelle Stein, Blaise Bayer, Marcela Salgado, Giuseppe Del Priore, Sara A. Hurvitz

Mayo Clinic Florida, Jacksonville, FL; Texas Oncology-Baylor Charles A. Sammons Cancer Center, Dallas, TX; Cleveland Clinic Foundation - Taussig Cancer Institute, Cleveland, OH; Hematology and Oncology Associates of Fredericksburg, Fredericksburg, VA; Cancer Care Northwest, Spokane, WA; University of Pittsburgh School of Medicine, Pittsburgh, PA; University of Miami, Miller School of Medicine, Miami, FL; Northwestern, Chicago, IL; BriaCell Therapeutics Corp., Philadelphia, PA; Morehouse School of Medicine, Atlanta, GA; Fred Hutch at University of Washington Medical Center, Seattle, WA

ASCO 2025
Abstract ID
TPS1138

Background

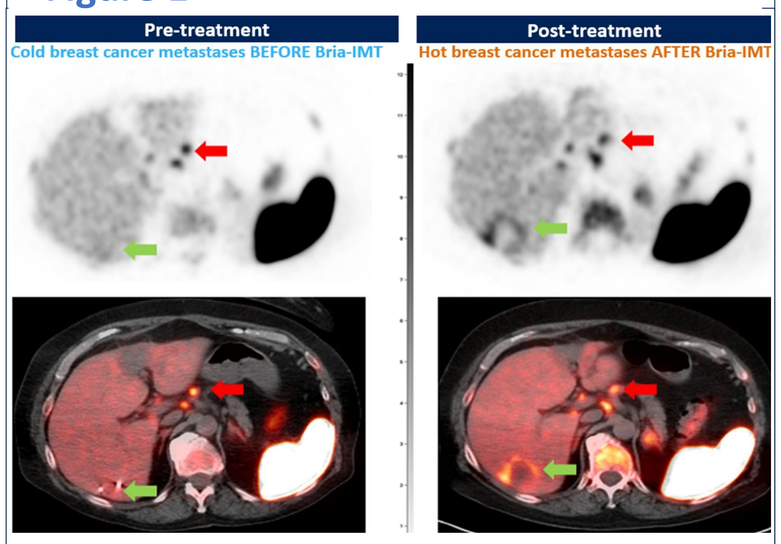
- **Bria-IMT™ Immunotherapy:** Combines the allogeneic whole-cell vaccine SV-BR-1-GM with low-dose cyclophosphamide, pegylated interferon alpha, and a checkpoint inhibitor, to enhance dendritic cell activation and presentation of tumor-associated antigens (HER2, PRAME) for anti-tumor immune responses.
- **Mechanism of Action:** SV-BR-1-GM breast cancer cells express class I and II HLA molecules, secrete GM-CSF, and act as antigen-presenting cells to activate immune responses.[1]



Phase 2 Clinical Outcomes

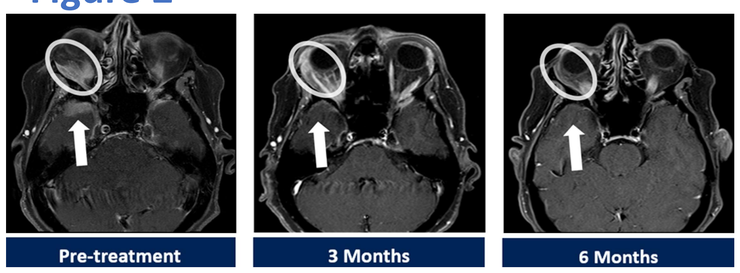
- The Bria-IMT regimen with an immune checkpoint inhibitor is well tolerated and is capable of producing clinical benefit in heavily pretreated patients with metastatic breast cancer.
- Patients reported a median of 6 (2-13) prior lines of therapy with 43% having previously received an antibody drug conjugate and 20% a checkpoint inhibitor therapy.[2]
- An overall survival of 11.4 (2.4 – 20.5) months was observed in the randomized phase 2 cohort (n = 32).[3]
- TNBC patients receiving the Phase 3 Formulation IP reported median overall survival of 11.4 (2.1 – 19.0) months and HR+/HER2- patients reported an OS of 17.3 (1.9 – 30.3) months.[3]
- Clinical benefits reported in 3 of 5 patients with intracranial metastasis with a 50% median reduction in lesion diameter observed post treatment.[2]
- 53% (9 out of 17 evaluable) of patients with prior ADC exposure showed disease control[4]
- Patients with prior IO exposure (either ADC, CPI, or both) demonstrated a comparable safety profile to IO-naïve patients throughout the trial.

[5]Figure 1



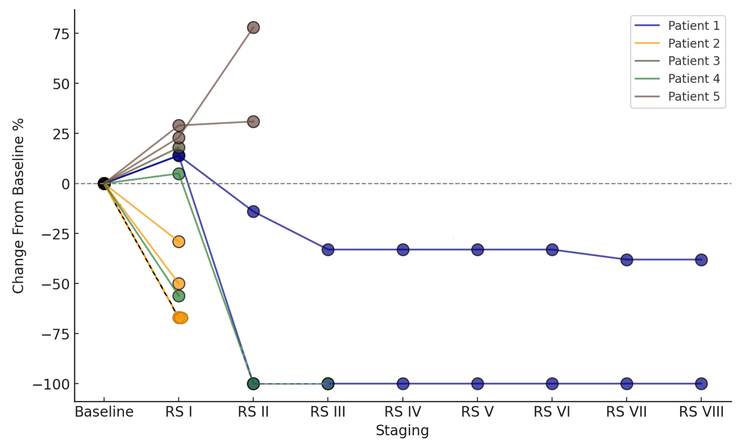
Left Image: Transaxial Zr-89 and fused PET/CT showing subtle increased 89Zr-CD8 uptake in the segment 7 lesion indicated by fiducial markers (green arrow). Venous T1+contrast MRI of the liver shows unchanged size of the segment 7 lesion compared to prior MRI (not shown). Incidentally noted small physiologic mesenteric and portahepatis lymph nodes (red arrow).**(B) Right Image:** Transaxial Zr-89 PET and fused PET/CT show new pronounced accumulation after vaccination with new area seen on MRI (green arrow).

[5]Figure 2



MRI Imaging showing regression of right orbital and temporal lobe lesion in patient 11-018. 3-month imaging showed uncertain changes in periorbital lesion but near CR in temporal lobe.

[2]Figure 3



% Change of individual intracranial oligometastases by patient at tumor assessment intervals (RS)

References

[1] Lopez-Lago M, et al., *Cancer Research* 83.7_Supplement (2023): 685-685.
[2] Chumsri S, et al., *Cancer Research* (2025)
[3] Chumsri S, et al., *J Clin Oncol* (2025 ASCO Abstract 1096)
[4] Nangia C, et al., *J Clin Oncol* 42, 2024 (suppl 16; abstr 1087)
[5] Parent E. et al., Cancer Research (2025)

Study Design

- Multicenter, randomized, open-label trial comparing the Bria-IMT regimen plus a checkpoint inhibitor (CPI) versus Treatment of Physicians' Choice (TPC) in metastatic breast cancer patients lacking approved meaningful therapeutic options.

Study Objectives

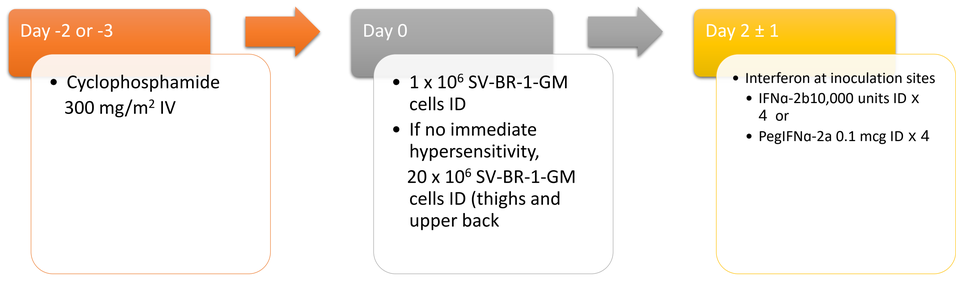
- **Primary Endpoint**: Overall survival, with an interim analysis planned at 144 events; target hazard ratio (HR) of 0.6.
- **Secondary Endpoints**: Progression-free survival (PFS), objective response rate (ORR), clinical benefit rate (CBR), CNS event-free survival, and time without symptoms or toxicity (TWiST).
- **Safety & Patient-Reported Outcomes**: Ongoing safety analyses; patient-reported outcomes assess subjective treatment impact.

Study Eligibility

- **Metastatic advanced breast cancer of all subtypes**
- **HER2 Positive:** ≥ 3 regimens (≥ 2 anti-HER2)
- **ER/PR+:** ≥ 2 hormone therapies
- **Triple Negative:** ≥ 2 chemotherapies, neoadjuvant or adjuvant
- **Genomic Mutations**: (eg. BRCA) must have received targeted Therapy
- **HER2-Low:** ≥ 1 HER2-targeted Therapy
- **HER2 Negative:** ≥ 2 chemotherapies and refractory to hormonal Therapy
- **CNS Metastasis:** clinically stable, no steroids ≥ 2wks, ≥ 3wks after surgery
- **CNS metastases allowed, ECOG ≤ 2, no limit on prior number of therapies**

Treatment Arms

- 1:1:1 ratio to 3 arms:
  - Bria-IMT + CPI
  - Treatment of Physicians' Choice
  - Bria-IMT alone (upon disease progression subjects may go on to combination with CPI but will not be included in primary analysis)
- After 150 patients (50 in each arm), Bria-IMT alone will stop enrolling. The remaining subjects will be randomized 1:1 to the other 2 arms (total of 177 in each of the main comparison arms)

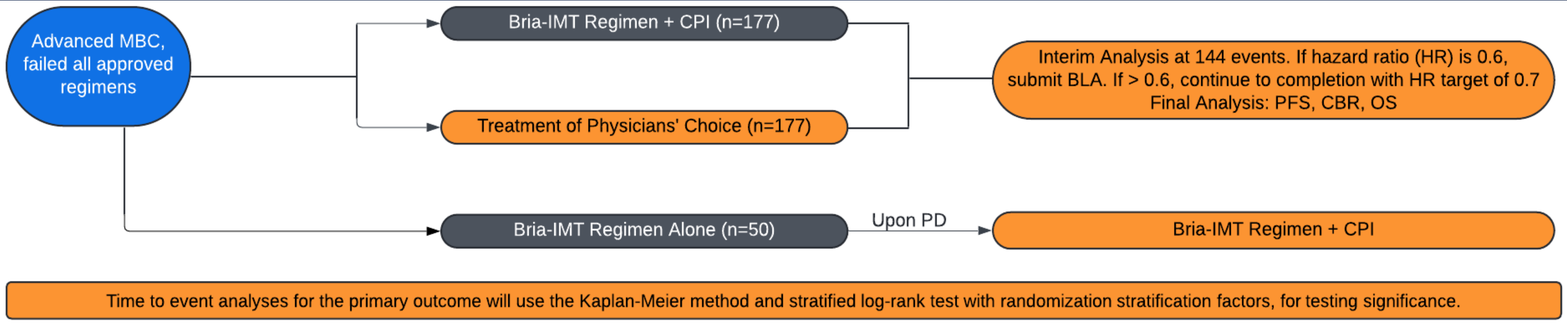


* CPI (retifanlimab 375 mg IV) can be any 1 of the 3 days consistently.

Current Trial Status

- **Planned Enrollment & Sites**: 100 sites across the U.S., Canada, and ex-North America targeting 404 patients; currently active at 68 locations with 248 sub-investigators.
- **Screening & Randomization**: As of early 2025, 122 patients screened, with 79 randomized.
- **Current Patient Demographics**: Median age of 57 (range 32–82) with 6 (range 2–13) prior lines of therapy.

Trial Design and Randomization



Bria-ROL Phase 1/2 Clinical Trial Update ASCO 2025

Bria-OTS Phase 1 Clinical Trial in Progress ASCO 2025

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