Trial in progress: A study of Bria-OTS cellular immunotherapy in metastatic recurrent breast cancer.

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BACKGROUND

Metastatic breast cancer is almost always fatal. BC-OTS-001 is a Phase 1/2a study of cellular immunotherapy in metastatic recurrent unresectable breast cancer patients. Thus far, patients have been enrolled in Phase 1, Part 1 of the study and have been treated with the BC1 cell line alone. BC1 is derived from breast cancer cell-line SV-BR-1 and SV-BR-1-GM.

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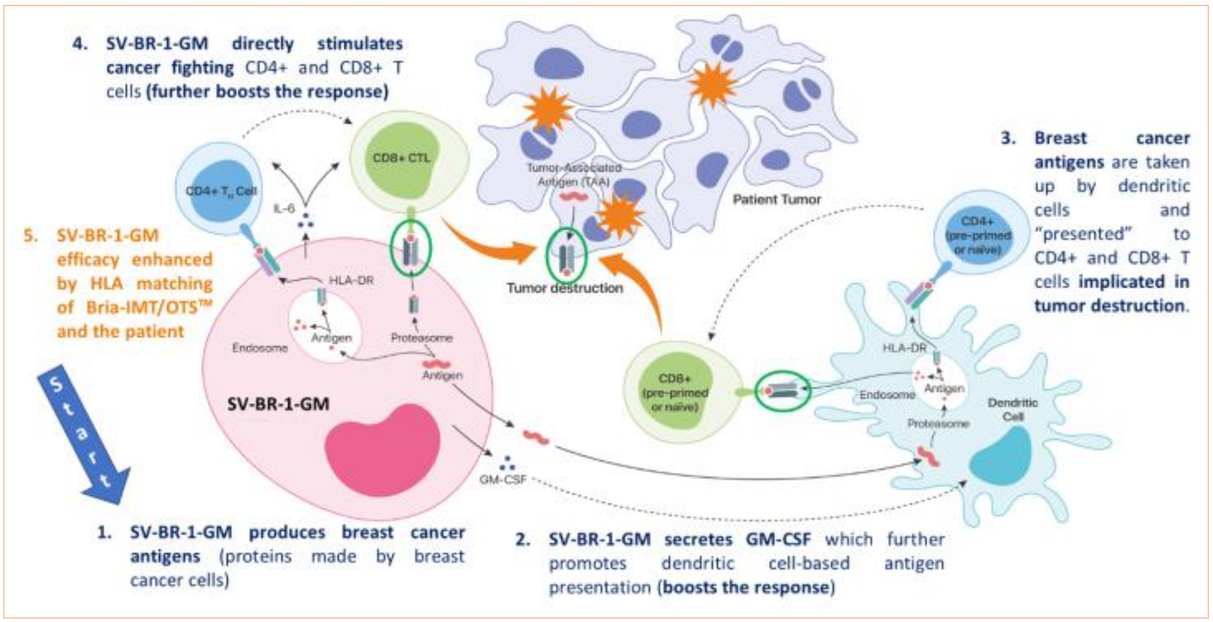

Figure 1. Hypothetical Mechanism of Action of SV-BR-1-GM and the BC1 Cell Line

Bria-IMT is an immunotherapy that comprises of the allogeneic whole-cell vaccine SV-BR-1-GM. 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).

Objectives:

Primary:

- To evaluate the safety of BC1 cell line immunotherapy in patients with advanced late-stage metastatic breast cancer

Secondary:

- To evaluate the tumor response to BC1 cellular immunotherapy

Exploratory:

- To evaluate progression-free (PFS) and overall survival (OS)
- To evaluate the immune responses elicited by BC1 cellular immunotherapy
- To evaluate patient and tumor characteristics that may be predictive of responses to HLA-matched cellular immunotherapy
- To evaluate time to subsequent therapy
- To evaluate PFS 2 on subsequent therapy.

METHODS

Study Population: Patients with metastatic recurrent breast cancer after progression on prior therapies.

This is an open-label study. Phase 1: BC1 cell line alone; Phase 2, Bria-OTS regimen with check point inhibitor (CPI). Phase 1: Patient 1: 20 million cells BC1 intradermally q2 wks x 8 wks (4 doses); Patient 2: 40 million cells of BC1; Patient 3: 60 million cells BC1. If no DLT with BC1 monotherapy, the combinational phase of the study will begin with BC1 and the Bria-OTS regimen q3 wks + CPI. During the Phase 1 combination and Phase 2 expansion phases, all patients will be treated with BC1 cells as part of the Bria-OTS regimen, which includes cyclophosphamide 300 mg/m 2-3 days prior to BC1 cell inoculation, and concurrent peg-interferon 0.6 mcg s.c. on the day of BC1 cell inoculation. Imaging studies: At screening, after monotherapy phase, before combination phase, and q9 weeks thereafter for 6 months, then q12 weeks. Patients who had PD but with clinical benefit may continue treatment. Subjects will continue to be followed for time on subsequent therapy (PFS2) and survival q3 mos. for 2 years. The phase 1 monotherapy part of the study has enrolled and treated 3 patients.

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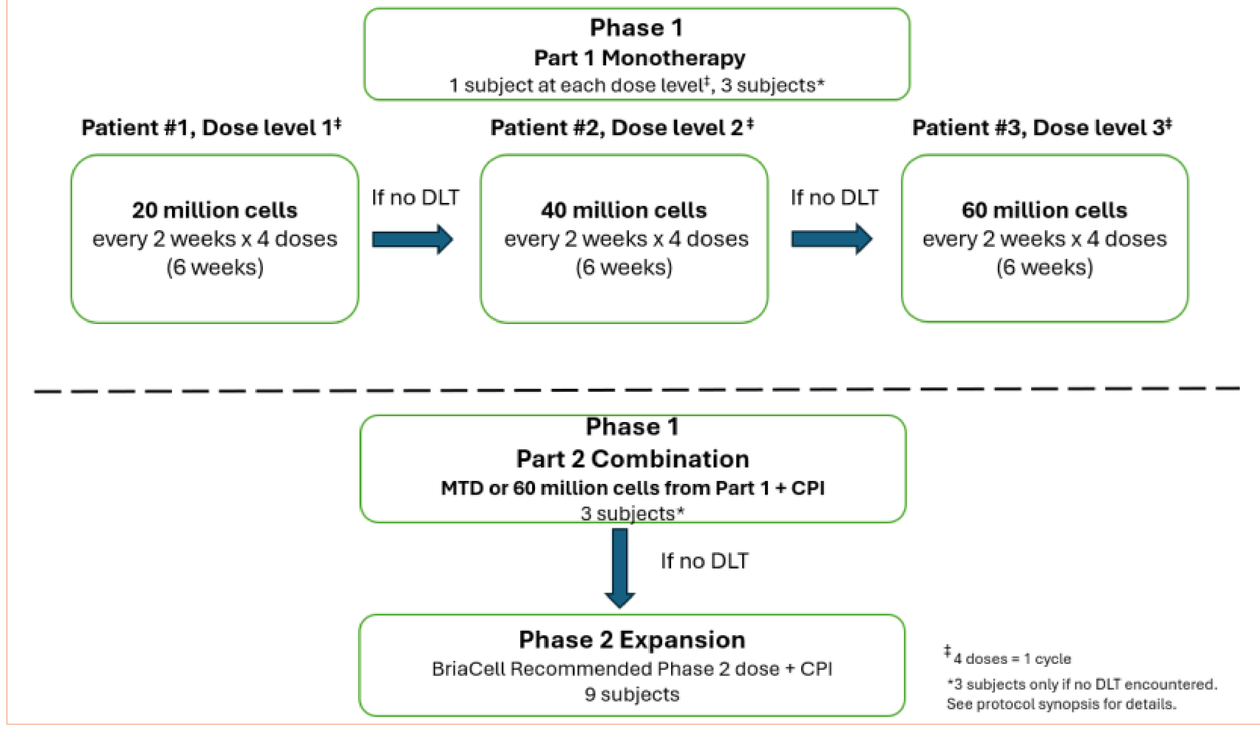

Figure 2. Study Design and Dosing Schema: Phase 1, Parts 1 and 2; and the Phase 2a and Phase 2

Enrollment Criteria:

Key Inclusion Criteria

- Histologically-confirmed metastatic breast cancer after failure of standard therapies
- ≥18 years old
- Expected survival of >4 months
- Adequate performance status (ECOG≤2
- Adequate hematologic and organ function
- Clinically stable with resolution of toxicities from previous treatment to baseline with the exception of alopecia

Key Exclusion Criteria

- Concurrent anti-cancer treatment or concurrent cancer
- Anti-cancer treatment within 3 weeks of first treatment
- History of hypersensitivity to study therapies
- New York Heart Association stage 3-4 cardiac disease
- Moderate-severe pleural or pericardial effusion
- Pregnant or nursing
- HIV+
- Known immunodeficiency or ongoing treatment with immunosuppressive therapy >10 mg/day prednisone equivalent
- Severe psychiatric or other clinically progressive major medical problems.

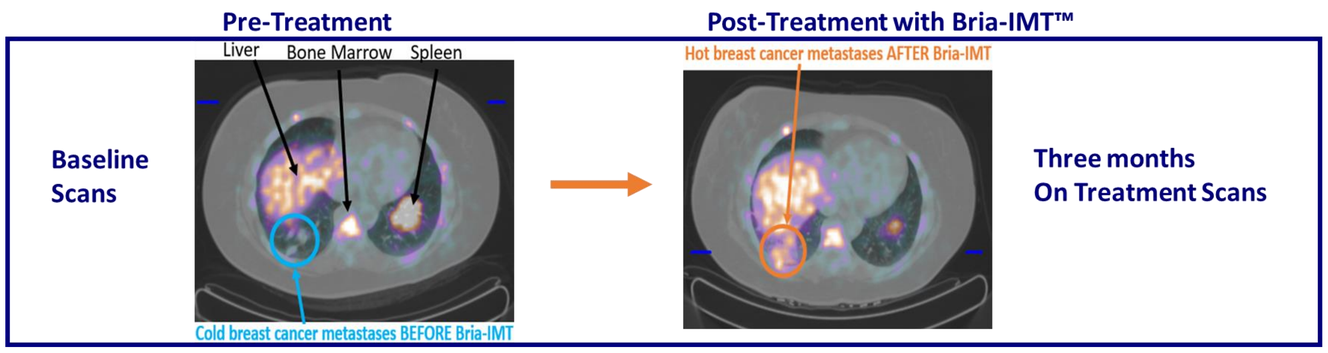

Figure 3. Immune response assessment 3 weeks post-treatment

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