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Safety and efficacy of a phase I/IIa trial (NCT03066947) of a modified whole tumor cell targeted immunotherapy in patients with advanced breast cancer.

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Background: SV-BR-1-GM is a GM-CSF transfected breast cancer cell line which expresses HLA class I & II antigens and has functional antigen-presenting cell activity. Prior studies suggest that partial matching of the HLA type of the patient with SV-BR-1-GM may be predictive of tumor regression. **Methods:** Subjects received low-dose cyclophosphamide 2-3d prior to ID injection of irradiated SV-BR-1-GM (20 million cells divided into 4 sites) and interferon-α into the inoculation sites ~2 & 4 days subsequently. Cycles were q2 weeks x 3 then q mo. **Results:** A total of 30 patients were screened and 23 inoculated (Table). The patients were heavily pretreated with a median of 4 prior chemo/biological therapy regimens. There were no serious or unexpected adverse events. Local injection-site irritation was the most common toxicity. Objective tumor regression was seen in 3 patients, all of whom matched SV-BR-1-GM at least at one HLA locus: one patient with regression or clearing of 20 lung metastases; one with reduction in cutaneous involvement of the breast from 80% to 30% and one with regression of a breast lesion. Another 3 patients had decreases in circulating cancer-associated macrophage-like cells (CAMLs), which has been shown to correlate with tumor stage. They also all matched at least at one HLA allele. Circulating tumor cells and circulating epithelial cells were present in low numbers and tended to parallel trends in CAMLs which were present in larger numbers. CAMLs in 21/23 patients stained positive for PD-L1. Patients with tumor regression had robust DTH responses to SV-BR-1-GM. **Conclusions:** SV-BR-1-GM in this regimen appears to be safe and well-tolerated and is associated with objective regression of metastatic breast cancer and/or with decreases in circulating cancer-associated cells in 6/23 (26%) or patients. HLA matching may be a predictor of response. Table of Patients

	HLA Allele Matches		
Characteristic	None (n = 6)	1+ (n = 17)	2+ (n = 5)
Age	55 ± 14	60 ± 8	66 ± 7
Median Prior Systemic Regimens	6 (range 2-13)	4 (range 1-7)	4 (range 3-7)
% ER/PR +	67%	46%	75%
% Her2/neu +	33%	46%	50%
% Triple Negative	33%	23%	0%
Tumor Regression	0	3 (18%)	2 (40%)
Decrease in CAMLs	0/4 (0%)	4/6 (67%)	2/2 (100%)

Title:
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Is this a late-breaking data submission?
No

Is this abstract a clinical trial?
Yes

Is this clinical trial registered?
Yes

Registry Name:
Clinicaltrials.gov

Registration Number:

NCT03066947

Research Funding Source:
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No

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No

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No

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No

Has this research been submitted for publication in a medical journal?
No

Type of Research:
Phase I/II
Research Category:
Clinical
Continued Trial Accrual:
No
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