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

William Williams, Jarrod P. Holmes, Saveri Bhattacharya, Carmen Califa, Shaker R. Dakhil, Jason Jerome Lukas, Elizabeth Tan-Chiu, Daniel Adams, George Peoples, Markus Lacher, Charles L. Wiseman; BrainCell Therapeutics Corporation, Berkeley, CA; Redwood Reg Med Group, Santa Rosa, CA; University of Pittsburgh Cancer Institute, Pittsburgh, PA; University of Miami/Sylvester Comprehensive Cancer Center, Miami, FL; Wichita NCCORP, Wichita, KS; Univ of California San Francisco, San Francisco, CA; Florida Cancer Specialists and Research Institute, Parkland, FL; Creativ MicroTech, Inc., Monmouth Junction, NJ; Cancer Insights, San Antonio, TX; BrainCell Therapeutics, Berkeley, CA; BrainCell Therapeutics Corp, Berkeley, CA

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 (10 million cells divided into 4 sites) and interferon-α into the injection sites 2 & 4 days subsequently. Cycles were 2 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 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

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

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Submitter's E-mail Address: williams@braincell.com

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First Author

Presenting Author

Corresponding Author
William Williams, MD
BriaCell Therapeutics Corporation
820 Heinz Ave
Berkeley, CA 94710
Phone Number: 1-888-685-6340
Email: williams@briacell.com

Second Author
Jarrod P. Holmes, MD
Redwood Reg Medc l Grp
3643 Hadley Hill Dr
Santa Rosa, CA 95404
Phone Number: 707-542-7324
Fax Number: 707-542-9196
Email: jarrod.holmes@stjoe.org

Third Author
Saven Bhatnacharya, DO
University of Pittsburgh Cancer Institute
5150 Centre Avenue
Room 463
Pittsburgh, PA 15232
Alternate Phone: 607-992-3835
Email: saven.bhatnacharya@jefferson.edu

Fourth Author
Carmen Caff, M.D.
University of Miami/Sylvester at Plantation
Plantation, FL 33324
Email: ccaffa@med.miami.edu

Fifth Author
Shaker R. Dakhil, MD, FACP
Wichita NCORP
818 N Emporia St Ste 403
Wichita, KS 67214
Phone Number: 316 262 4467
Fax Number: 316-262-0706
Email: shaker.dakhi@cancercenterokansas.com

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Sixth Author

Jason Jerome Lukas, MD, PhD
Univ of California San Francisco
505 Parnassus
Moffit Hosp M 1286 Mailbox 1270
San Francisco, CA 94143-1270
Email: jjlukas@gmail.com

Click to view Conflict of Interest Disclosure

Seventh Author

Elizabeth Tan-Chiu, MD
Florida Cancer Specialists and Research Institute
12172 NW 72nd St
Parkland, FL 33076
Email: drzz@ascancercare.com

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Eighth Author

Daniel Adams
Creatv MicroTech, Inc.
1 Deer Park Drive, Suite L-4
Munmouth Junction, NJ 08882
Phone Number: 301-861-4924
Email: dan@creativmicrotech.com

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Ninth Author

George Peoples
Cancer Insights
c/o Geekdom 110 E. Houston St.
San Antonio, TX 78205
Email: gpeoples@cancerinsight.com

Click to view Conflict of Interest Disclosure

Tenth Author

Markus Lacher
BiaCell Therapeutics
Berkeley, CA 94710
Email: mlacher@biacell.com

Click to view Conflict of Interest Disclosure

Eleventh Author

Charles L. Wiseman, MD, FACP
BiaCell Therapeutics Corp
820 Heinz Ave
Berkeley, CA 94710
Phone Number: 323-377-4741
Email: ctwmd@aol.com

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