TPS1136 Poster Session

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

Neal Shiv Chawla, Jason Ballon, Victoria Chua, Samantha Jeffrey, Anmol Dia Agarwal, Tamar Aghajanian, Kelly Elizabeth McCann, Blaise Bayer, Giuseppe DiPriore, Erlinda Maria Gordon, Sant P. Chawla; Sarcoma Oncology Center, Santa Monica, CA; Sarcoma Oncology Research Center, Santa Monica, CA; BriaCell Therapeutics Corp., Philadelphia, PA; Division of Hematology/Oncology, David Geffen School of Medicine at the University of California, Los Angeles and Beverly Hills Cancer Care, Los Angeles, CA; BriaCell Therapeutics, Philadephia, PA; Sarcoma Oncology Research Center LLC, Santa Monica, CA

Background: Metastatic breast cancer is almost always fatal. 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; and To evaluate PFS 2 on subsequent therapy. **Methods:** Study Population: Patients with metastatic recurrent breast cancer after progression on prior therapies. 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. Study Design: 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 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. Clinical trial information: NCT06471673. Research Sponsor: BriaCell Therapeutics Corp.