



BriaCell Announces Positive Clinical and Quality of Life Data in Advanced Metastatic Breast Cancer at 2022 San Antonio Breast Cancer Symposium®

- *Positive clinical data reported includes tumor shrinkage, disease control, progression free survival, and potential long term survival benefit in advanced metastatic breast cancer patients treated with the Bria-IMT™ combination regimen.*
- *“Better quality of life” and “less pain” reported by many gravely ill advanced metastatic breast cancer patients treated with the Bria-IMT™ combination regimen.*
- *Notably, many patients remained in our study longer than other prior therapies, suggesting excellent tolerability and clinical effectiveness of the Bria-IMT™ combination regimen.*
- *More positive data is expected as patients remain on the study.*
- *Treatment remained well-tolerated with no dose-limiting toxicities.*

PHILADELPHIA and VANCOUVER, British Columbia, Dec. 08, 2022 -- **BriaCell Therapeutics Corp. (Nasdaq: BCTX, BCTXW) (TSX: BCT) (“BriaCell” or the “Company”)**, a clinical-stage biotechnology company specializing in targeted immunotherapies for cancer, presented positive safety/tolerability and efficacy data from its lead product candidate, Bria-IMT™, summarized in three poster sessions during the 2022 San Antonio Breast Cancer Symposium® (SABCS).

Mayo Clinic Professor and Principal Clinical Investigator, Saranya Chumsri, M.D., stated in an audio summary of the poster: “First, this is a heavily pretreated group of end-stage metastatic breast cancer (“MBC”) patients. For many of these patients, other therapies don’t exist or cannot be tolerated. Bria-IMT™ does not have any theoretical cross-resistance or overlapping toxicity with other MBC treatments, which is why it is so encouraging to see responses across all MBC subtypes and a very manageable adverse event experience.”

“We are impressed with the positive clinical and quality of life data in this very difficult-to-treat patient population who have failed multiple prior treatments. We’re delighted that many patients stayed on our study longer than their last therapy, suggesting the Bria-IMT™ combination regimen is both well tolerated and clinically effective,” stated Dr. William V. Williams, BriaCell’s President and CEO. “These results have positive implications, both for our ongoing, randomized phase II study and for planned meetings with the FDA on the design of our pivotal study. Advanced MBC remains one of the most difficult cancers to treat. There remains an urgent, unmet medical need to find well-tolerated and effective treatments for these gravely ill cancer patients who have only months to live and cannot tolerate the harsh side effects of other cancer treatments.”

The posters are summarized below and linked here: <https://briacell.com/scientific-publications/>.

Poster 1: Combination Study Efficacy

Title: *Allogeneic, Antigen-Presenting, GM-CSF-Secreting, SV-BR-1-GM Whole Cell Therapeutic Vaccine in Advanced Metastatic Breast Cancer*

Poster ID: P3-07-12

Summary: 22 advanced metastatic breast cancer patients were treated with the Bria-IMT™ regimen with PD-1 inhibitors: 11 patients with pembrolizumab and 12 patients with retifanlimab, with one patient transitioning from one combination to another. Patients had previously been heavily pre-treated with a median of 6.5 prior therapies.

Efficacy Data in all 22 patients:

- As [previously disclosed](#), clinical benefits were observed across multiple subtypes of advanced metastatic breast cancer patients, especially in patients with hormone receptor positive (“HR+”) cancer, a very large segment of the patient population.
- Significant tumor reductions were reported in patients treated in combination with either pembrolizumab (Merck) (3 out of 5 evaluable patients) or retifanlimab (Incyte) (3 out of 5 evaluable patients), suggesting additive or synergistic effects of the Bria-IMT™ combination regimen with PD-1 inhibitors. Most patients experienced progression free survival (“PFS”) that was similar or better than their last therapy, suggesting the clinical effectiveness of the Bria-IMT™ combination regimen. More positive data is expected as patients remain on the study.
- **New subset of top-responding patients:** A clinical benefit rate (“CBR”) of 63% (5 out of 8 evaluable patients), PFS of 5.8 ± 2.9 months, and objective response rate (“ORR”) of 25% were observed in a subset of patients with grade I/II HR+ cancers, suggesting a potentially better responding subgroup of patients. It is noteworthy to mention that this represents a large segment of the patient population.
- As [previously reported](#), 70% of evaluable patients treated in the combination regimen with retifanlimab showed either disease control or PFS benefits compared with their most recent prior therapy regimen. A disease control rate (“DCR”) of 57% (4 out of 7 evaluable patients) represents the percentage of patients who have achieved certain clinical end

points (i.e. complete response, partial response or stable disease). DCR is a cross study metric commonly used in cancer clinical trials to evaluate the clinical effectiveness of a treatment. Importantly, DCRs were higher in patients who matched Bria-IMT™ at one or more HLA type, supporting our strategy of developing off-the-shelf personalized treatments for cancer patients.

Quality of Life Data: Patients who experienced disease control reported “better quality of life” scores and “less pain” with the BriaCell combination regimen. “Better quality of life”, and “less pain” are life changing factors for patients with advanced metastatic breast cancer who have already failed several prior therapies and face a very short survival outlook.

To summarize, our positive clinical and quality of life data to date suggest an additive or synergistic effect of Bria-IMT™ with PD-1 inhibitors in advanced metastatic breast cancer patients and supports our strategy of using the Bria-IMT™ combination regimen with PD-1 inhibitors. We look forward to sharing additional data in the coming months, as patients continue to remain in the study and are recruited into the randomized phase II part of the study.

Poster 2: CTCs/CAMLs Biomarker Tools

Title: Decreases in Circulating Tumor Associated Cells Predict PFS and OS in a Pooled Analysis of Phase I Clinical Trials Using SV-BR-1-GM Therapy with or without Immune Check Point Inhibitors in Metastatic Breast Cancer Patients
Poster ID: P1-05-28

Found in the blood of 90% of the advanced metastatic breast cancer patients, Cancer Associated Macrophage Like cells (“CAMLs”) (Adams DL, et al. JCO abstr 3056, 2022 40:suppl 16), are suggested as an additional marker, along with Circulating Tumor Cells (“CTCs”), for predicting, evaluating, and monitoring patients’ responsiveness (i.e., clinical benefit, including survival benefit) to the Bria-IMT™ regimen.

Our findings support that utilizing the CTCs/CAMLs system provides BriaCell with a powerful biomarker tool to potentially select, evaluate, and monitor patients’ clinical responses to the Bria-IMT™ regimen, and could improve the probability of success in clinical studies. Most importantly, PFS and overall survival (OS) data from our findings suggest long term clinical benefit in patients treated with the Bria-IMT™ regimen in a subset of patients.

Poster 3: Enhancing Personalized Immunotherapy (Bria-OTS2.0)

Title: Turning Tumor Cells into Antigen-Presenting Cells for Cancer Immunotherapy
Poster ID: P3-06-08

BriaCell expects the next generation (enhanced version) of our off-the-shelf personalized immunotherapies (Bria-OTS2.0) to be more effective in activating patients’ immune cells, leading to faster and more effective tumor destruction in patients.

Development of a novel personalized (HLA matched with patients) immunotherapy (Bria-OTS2.0) that is off-the-shelf (i.e. premade), may represent a significant milestone in the field of personalized cancer immunotherapy. We expect superior patient efficacy using Bria-OTS2.0 because (1) it is personalized to each patient by design (HLA matching), (2) it produces multiple immune boosting factors to further activate immune cells in patients, and 3) it is manufactured in advance, and therefore available to patients upon completion of a simple, rapid, and inexpensive HLA typing saliva test.

BriaCell will seek to further evaluate Bria-OTS2.0’s activity in advanced metastatic breast cancer patients.

About BriaCell Therapeutics Corp.

BriaCell is an immuno-oncology-focused biotechnology company developing targeted and effective approaches for the management of cancer. More information is available at <https://briacell.com/>.

Safe Harbor

This press release contains “forward-looking statements” that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “target,” “aim,” “should,” “will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Examples of forward-looking statements in this news release include statements that the Company makes regarding the expectation of additional clinical data from the ongoing study; the potential of using the CTCs/CAMLs system as a biomarker tool to improve the probability of success in clinical studies; the long term clinical benefits of the Bria-IMT™ regimen on patients; the potential opportunity for treatment in terminal patients; the effect(s) of Bria-IMT™ on patients, including the ability of Bria-IMT™ to control disease, shrink tumors, and produce potential survival benefit; the clinical efficacy of the Bria-IMT™ combination treatment; the effectiveness of BriaCell’s treatment without harmful side effects; the potential success of the Bria-IMT™ program and the ability of the Company to further advance its clinical study. Forward-looking statements are based on BriaCell’s current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully under the heading “Risks and Uncertainties” in the Company’s most recent Management’s Discussion and Analysis, under the heading “Risk Factors” in the Company’s most recent Annual Information Form, and under “Risks and Uncertainties” in the Company’s other filings with the Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission, all of which are available under the Company’s profiles on SEDAR at www.sedar.com and on EDGAR at www.sec.gov. Forward-looking statements contained in this announcement are made as of this date, and BriaCell Therapeutics Corp. undertakes no duty to update such information except as required under applicable law.

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Contact Information

Company Contact:

William V. Williams, MD
President & CEO
1-888-485-6340
info@briacell.com

Media Relations:

Jules Abraham
Director of Public Relations
CORE IR
917-885-7378
julesa@coreir.com

Investor Relations Contact:

CORE IR
investors@briacell.com