

BriaCell Reports Positive Overall Survival (OS) in Metastatic Breast Cancer

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- Median overall survival of 15.6 months in Phase 2 Bria-IMT™ study patients treated in combination with immune checkpoint inhibitor
- OS of 15.6 months compares favorably with 6.7-9.3 months reported for similar patients in the literature
- Ongoing Phase 3 study investigating Bria-IMT™ in similar metastatic breast cancer population
- No drug related discontinuations to date

PHILADELPHIA and VANCOUVER, British Columbia, Sept. 11, 2024 (GLOBE NEWSWIRE) -- BriaCell Therapeutics Corp. (Nasdaq: BCTX, BCTXW) (TSX: BCT) ("BriaCell" or the "Company"), a clinical-stage biotechnology company that develops novel immunotherapies to transform cancer care, is pleased to announce positive overall survival data of its Phase 2 clinical study of Bria-IMT™ in combination with an immune check point inhibitor (CPI) in late stage metastatic breast cancer.

Median overall survival of 15.6 months is reported in BriaCell's most recent patients (treated since 2022) vs. 6.7-9.3 months for similar patients reported in the literature (see table below). These patients are being treated with the same Bria-IMT™ formulation currently being used in BriaCell's ongoing Phase 3 pivotal study in metastatic breast cancer (listed on [ClinicalTrials.gov](https://clinicaltrials.gov) as **NCT06072612**) and represent patients enrolled post-COVID when full study activities resumed.

This represents a substantial improvement over BriaCell's **13.4 months** median overall survival previously reported in December 2023.

"Overall survival in patients with heavily pre-treated metastatic breast cancer is very poor," stated Sara A. Hurvitz,

MD, Professor of Medicine, Fred Hutch Cancer Center and University of Washington and BriaCell medical advisory board member. “The BriaCell early data is quite encouraging from both efficacy and tolerability standpoints.”

“We wanted to look at the Phase 2 data of those patients who most closely resemble the patients being treated in our ongoing phase 3 study and compare them to similar patients in the literature,” stated Dr. William V. Williams, BriaCell’s President and CEO. “The nearly two-fold overall survival benefit we are seeing with the Bria-IMT™ regimen, together with the similar previously reported approximate doubling of progression free survival, compared with literature controls, strongly support our belief that Bria-IMT™ could have a meaningful impact in the lives of heavily pre-treated metastatic breast cancer patients. We look forward to further clinical development of Bria-IMT™ with the goal of establishing it as a new standard of care for patients with metastatic breast cancer.”

“The Bria-IMT™ regimen is the only investigational drug we have seen to show these impressive survival numbers in heavily pre-treated metastatic breast cancer patients who have failed numerous prior treatments including immune check point inhibitors and antibody drug conjugates,” stated Giuseppe Del Priore, MD, MPH, BriaCell’s Chief Medical Officer. “These survival and clinical benefit data support BriaCell’s hypothesis of additive and/or synergistic effects of immune check point inhibitors with Bria-IMT™ and drive the ongoing pivotal study of our combination regimen in the treatment of metastatic breast cancer.”

The Phase 2 study enrolled 54 heavily pre-treated metastatic breast cancer patients (average number of prior treatments = 6) who were treated with the Bria-IMT™ regimen and an immune checkpoint inhibitor. Of these 54 patients, 37 were treated with the Phase 3 formulation and 25 of these were treated post-COVID when full study activities resumed. This data represents an additional six months of follow-up of the survival data presented at the San Antonio Breast Cancer Symposium in December 2023.

Table 1. Comparative Median Overall Survival (OS) and Progression-Free Survival (PFS) in Similar Patients (Interim Analysis Using Kaplan-Meier Estimate)

Study	Prior Lines of Therapy (median, range)	Number of Patients	OS (months)	PFS (months)
BriaCell’s Phase 2 study patients who received pivotal Phase 3 study formulation (since 2022)	5.5 (2-13)	25	15.6	4.1
BriaCell’s Phase 2 study patients who received pivotal Phase 3 study formulation (total)	6 (2-13)	37	13.4	3.9
Bardia, A. et. al. 1 (TNBC)	4 (2-14)	262	6.9	1.7
Tripathy D. et. al. 2 (Brain metastases)	≥4 in 91%	178	7.5-7.8	1.9-2.8
O’Shaughnessy J. et. al. 3 non-TNBC at initial diagnosis	5 (2-14)	76	6.7	2.3
O’Shaughnessy J. et. al. 3 TNBC at initial diagnosis	4 (2-10)	157	6.9	1.6
Cortes et. al. 4	4 (0-13)	594	9.1-9.3	1.9-2.5

References

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3. O'Shaughnessy J et al. Analysis of patients without and with an initial triple-negative breast cancer diagnosis in the phase 3 randomized ASCENT study of sacituzumab govitecan in metastatic triple-negative breast cancer. *Breast Cancer Res Treat*. 2022 Sep;195(2):127-139. doi: 10.1007/s10549-022-06602-7. Epub 2022 May 11. PMID: 35545724; PMCID: PMC9374646.
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About BriaCell Therapeutics Corp.

BriaCell is a clinical-stage biotechnology company that develops novel immunotherapies to transform cancer care. More information is available at <https://briacell.com/>.

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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.sedarplus.ca 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

CORE IR

julesa@coreir.com

Investor Relations Contact:

CORE IR

investors@briacell.com

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