

# BriaCell Doses First Patient in Phase I/IIa Study Evaluating Bria-IMT<sup>™</sup> in Combination with INCMGA00012 and Epacadostat in Patients with Advanced Breast Cancer

- Patient dosing has begun in the Phase I/IIa study evaluating the anti-tumor effects of BriaCell's lead candidate, Bria-IMT<sup>™</sup> in combination with Incyte's INCMGA00012 and epacadostat in patients with advanced breast cancer.
- Cancer blocks the immune system preventing it from fighting and destroying cancer cells. Bria-IMT<sup>™</sup> activates the immune system to fight and eliminate the cancer cells.

**BERKELEY, Calif., and VANCOUVER, British Columbia, October 7, 2019 -- BriaCell Therapeutics Corp. ("BriaCell" or the "Company") (TSX-V:BCT) (OTCQB:BCTXF)**, a clinical-stage biotechnology company specializing in targeted immunotherapy for advanced breast cancer, today announced that it has initiated dosing in a Phase I/IIa clinical study of its lead product candidate, Bria-IMT<sup>™</sup>, in combination with Incyte's INCMGA00012 and epacadostat in patients with advanced breast cancer whose disease has progressed following standard of care therapies. No effective treatment options for this patient population currently exists making advanced breast cancer an unmet medical need.

The study design includes an initial group of patients to be treated with the Bria-IMT<sup>™</sup> regimen in combination with INCMGA00012 to establish safety. A subsequent group of patients will be treated with the triple combination of the Bria-IMT<sup>™</sup> with INCMGA00012 and epacadostat. The starting dose of epacadostat has been established to be safe when given in combination with INCMGA00012 in patients with cancer. The goal is to remove cancer-induced suppression of the immune system (i.e., taking the foot off the brakes that the cancer puts on the immune system) thereby awakening the immune response. This should permit the potent immune responses induced by the Bria-IMT<sup>™</sup> regimen (i.e., putting the foot on the gas pedal) to attack the cancer.

"The initiation of Bria-IMT<sup>™</sup> clinical study is a major milestone for BriaCell, marking the launch of BriaCell's first clinical collaboration with Incyte. This Phase I/IIa clinical trial of Bria-IMT<sup>™</sup> builds upon the early clinical findings of our novel immunotherapy, as well as biomarker analysis from patients who benefitted the most in our monotherapy trial with Bria-IMT<sup>™</sup> versus those who did not," said Dr. Bill Williams, President & CEO of BriaCell. "Both INCMGA00012 and epacadostat have been shown to reverse cancer-induced suppression of immune cells, making them a rational performance booster for Bria-IMT<sup>™</sup> in the clinical study. We are pleased with the initiation of the clinical study and expect to report preliminary safety data in 4Q 2019."

## About the Study

Phase I/IIa clinical trial is an open-label, multi-center study to evaluate the safety and efficacy of Bria-IMT<sup>™</sup> in combination with INCMGA00012, and epacadostat in patients with advanced breast cancer. In the initial stage,

BriaCell expects to enroll up to 24 patients with advanced breast cancer. The primary endpoint is safety and overall response rate (ORR) and secondary endpoints include duration of response, progression free survival (PFS) and overall survival (OS). Additional analysis will include evaluation of potential predictive biomarkers including HLA. BriaCell expects to report preliminary efficacy and biomarker findings on up to 30 patients.

For further information on the clinical trial, please visit https://clinicaltrials.gov (Identifier: NCT03328026).

## About BriaCell

BriaCell is an immuno-oncology focused biotechnology company developing targeted and safe approaches for the management of cancer.

BriaCell is conducting a Phase I/IIa clinical trial of Bria-IMT<sup>™</sup>, BriaCell's lead candidate, in a Combination Study with immune checkpoint inhibitors such as the Incyte drugs INCMGA00012 (an anti-PD-1 antibody similar to pembrolizumab [KEYTRUDA<sup>®</sup>; manufactured by Merck & Co., Inc. (NYSE: MRK)]) and epacadostat, an orally bioavailable small-molecule inhibitor of indoleamine 2,3-dioxygenase 1 (IDO1). The combination study is listed in ClinicalTrials.gov as <u>NCT03328026</u>.

BriaCell currently has a non-exclusive clinical trial collaboration with Incyte Corporation to evaluate the effects of combinations of novel clinical candidates. Under the agreement, Incyte and BriaCell will be evaluating novel combinations of compounds from Incyte's development portfolio with BriaCell's drug candidates in advanced breast cancer patients.

BriaCell is also developing Bria-OTS<sup>™</sup>, an off-the-shelf personalized immunotherapy, for advanced breast cancer. Bria-OTS<sup>™</sup> immunotherapy treatments are personalized to match the patient without the need for personalized manufacturing. Bria-OTS<sup>™</sup>, which is expected to cover over 99 percent of the patient population, is designed to produce a potent and selective immune response against the cancer of each patient while eliminating the time, expense and complex manufacturing logistics associated with other personalized immunotherapies.

For additional information on BriaCell, please visit: <u>https://briacell.com/</u>.

### **Cautionary Note Regarding Forward-Looking Information**

Except for the statements of historical fact, this news release contains "forward-looking information" within the meaning of the applicable Canadian securities legislation which involves known and unknown risks relevant to the Company in particular and to the biotechnology and pharmaceutical industries in general, uncertainties and other factors that may cause actual events to differ materially from current expectation. These risks are more fully described in the Company's public filings available at www.sedar.com.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. The Company disclaims any intention or obligation, except to the extent required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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