



## BriaCell Therapeutics Corp.

**BriaCell**  
THERAPEUTICS CORP.

OTCQB: **BCTXF**  
TSX-V: **BCT**

*January 2017*

# Forward-Looking Statements

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Except for historical information, this presentation contains forward-looking statements, which reflect BriaCell's current expectations regarding future events. These forward-looking statements involve known and unknown risks and uncertainties that could cause BriaCell's actual results to differ materially from those statements. Those risks and uncertainties include, but are not limited to, our ability to access capital, the successful and timely completion of clinical trials, the receipt of all regulatory approvals and other risks detailed from time to time in our ongoing quarterly and annual filings. The forward-looking statements in this presentation are also based on a number of assumptions which may prove to be incorrect.

Forward-looking statements contained in this presentation represent views only as of the date of this presentation and are presented for the purpose of assisting potential investors in understanding BriaCell's business, and may not be appropriate for other purposes. BriaCell does not undertake to update forward-looking statements, whether written or oral, that may be made from time to time by or on its behalf, except as required under applicable securities legislation.

Investors are cautioned not to rely on these forward-looking statements and are encouraged to read BriaCell's continuous disclosure documents, including its financial statements which are available on SEDAR at [www.sedar.com](http://www.sedar.com).

# Investment Highlights

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- ✓ **Leading Technology:** Novel cancer immunotherapy
- ✓ **Right Timing:** Initiating a Ph I/IIa clinical trial to validate the impressive safety and efficacy data of the two preliminary Ph I clinical trials
- ✓ **Unique Approach:** Companion diagnostic co-development
- ✓ **Significant Market Potential:** A multi-billion dollar target market.
- ✓ **Solid Management:** Experts in immunotherapy, drug discovery, drug development, diagnostics, & corporate governance
- ✓ **Poised to Unlock Value:** Significantly undervalued. Several short- and long-term milestones. Potential partnerships.

# Management and Board

## Management

### **William V. Williams, MD, President & CEO**

- VP, Exploratory Development, Incyte Corporation
- VP, Experimental Medicine, GlaxoSmithKline
- Head, Rheumatology Research, University of Pennsylvania
- Facilitated entry of over 20 compounds into the clinic including ruxolitinib (Jakafi), baricitinib, & epacadostat. NDAs including Jakafi, Boniva, Bexxar
- Author of over 120 peer-reviewed publications & over 20 patents

### **Gadi Levin, CA, MBA, CFO**

- CFO of Labstyle Innovations Ltd
- VP of Finance for two Israeli investment houses in the fields of private equity, hedge funds and real estate
- Financial Consultant, various firms
- Accountant, Arthur Andersen

### **Markus Lacher, PhD, Senior Director, R&D**

- Founder, T cell Therapeutics, Inc., an immune-oncology company
- Sr. Clinical Scientist, Cesca Therapeutics, Inc., a clinical-stage autologous cell therapy company where he played a lead role in the bone marrow transplantation program
- Former scientist at Scientist at BioTime, Inc. and OncoCyte Corporation.
- Editorial advisory board; Recent Patents on Anti-Cancer Drug Discovery.

### **Farrah Dean, MSc, MBA, Manager, Corp. Development**

- Investor relations, CytRx Corporation, & CCG Investor Relations
- Senior Associate Equity Analyst, Oppenheimer & Co., Rodman & Renshaw, & ThinkEquity LLC

## Board

### **Saeid Babaei, PhD, MBA, Chairman**

- Entrepreneur. 20 yrs of biotech leadership roles
- CEO, AbCelex: Develop. 1<sup>st</sup> in class Ab-based product for Animal Health and Human Diagnostics, funded by a top-tier agri-tech VC
- VP, Bus. Develop @ Lorus Therapeutics: out-licensing a Ph III immuno-oncology program
- Dir. of Corp. Development, Northern Therapeutics: Led strategic partnership to United Therapeutics (NASDAQ: UTHR)

### **Rahoul Sharan, CA, Director**

- Chairman, Potash Ridge. 30 yrs of finance & accounting experience
- Director of the Board, Ansell Capital Corp, Parallel Resources, & Galaxy Capital Corporation
- Partner, S&P Group - Led financings in excess of \$100M
- Public Accountant, Coopers & Lybrand

### **Martin Schmieg, CPA, Director**

- 35 yrs of biotech, med-tech, and pharma experience
- CFO: Sirna Therapeutics, Inc., & Isolagen, Inc.
- CEO, Freedom-2, Inc. (now PharmaCyte, Inc.)
- Advisor, Caladrius Biosciences, Inc., Beckman Coulter Genomics, Calimmune, Inc., Cryoport, Inc., Vetbiologics, a division of U.S. Stem Cell, Inc., Sapientia Pharmaceuticals, Inc., & Rokk3r Labs, LLC

### **Charles Wiseman, MD, Co-Founder & Director**

- Oncologist - 45 years experience, pioneered chemotherapies
- Director, Immunotherapy Lab, St. Vincent Medical Center
- Chief, Breast Cancer Basic Research Lab, Univ. of Texas MD Anderson Hospital & Tumour Institute; Assist. Prof., Dept of Molecular Carcinogenesis & Virology, MD Anderson; Acting Chief, Div. of Oncology, White Memorial Medical Center, Los Angeles

## **Clinical-Stage, Public, Immunotherapy Company:**

- BriaVax™: whole-cell cancer vaccine. Phase I/IIa
- BriaDx™ : companion Dx for BriaVax™

## **Team:**

- Experts in immunotherapy, oncology product development, management of clinical trials, companion diagnostic product development , and corporate finance

## **R&D:**

- Research Lab in Berkeley, CA
- Manufacturing at UC Davis GMP facility (Sacramento, CA)
- Leveraging programs by outsourcing of special procedures/projects

## **Plans:**

- Near-term strategic partnerships and collaborations
- Combination therapies (e.g., BriaVax™ + Immune Checkpoint Inhibitors)

# Valuation

Significantly lower enterprise value vs peers

Company	Therapeutic Area	Trial Stage (Breast Cancer)	Development stage	EV (In Mil \$US)	BriaCell Discount
TapImmune Inc. (OTCQB: TPIV)	Immuno-oncology (breast cancer)	Ph I/II	Ph I/II	25.4	47%
Del Mar Pharmaceuticals Inc. (DMPI)	Immuno-oncology		Ph II	30.7	56%
Regen BioPharma Inc. (RGBP)	Immuno-oncology (breast cancer)	Ph I	Ph I/II	11.9	-13%
VBI Vaccines Inc (VBIV)	Vaccines & immuno-oncology		Ph I	118.2	89%
Immunovaccine Inc (IMV.TO)	Vaccine (Cancer/Infectious Diseases)		Ph II	54.7	75%
Cascadian Therapeutics, Inc. (CASC)	Immuno-oncology (breast cancer)	Ph II	Ph II	43.4	69%
Immune Design Corp. (IMDZ)	Vaccines (breast cancer)	Ph I	Ph II	29.8	55%
Loxo Oncology, Inc. (LOXO)	Immuno-oncology (breast cancer)	Ph II	Ph II	553.1	98%
Celldex Therapeutics, Inc. (CLDX)	Immuno-oncology (breast cancer)	Ph II	Ph II	177.5	92%
Zopharm Oncology, Inc. (ZIOP)	Immuno-oncology (breast cancer)	Ph II	Ph II	660.9	98%
Xencor, Inc. (XNCR)	Vaccines & immuno-oncology		Ph II	951.7	99%
Inovio (INO)	Vaccines (breast cancer)	Ph I	Ph II	423.2	97%
<b>Average</b>				<b>256.7</b>	<b>95%</b>
<b>BriaCell</b> <b>(TSX: BCT.V; OTCQB: BCTXF)</b>	<b>Immuno-oncology (Breast Cancer)</b>		<b>Ph I/IIa</b>	<b>13.5</b>	

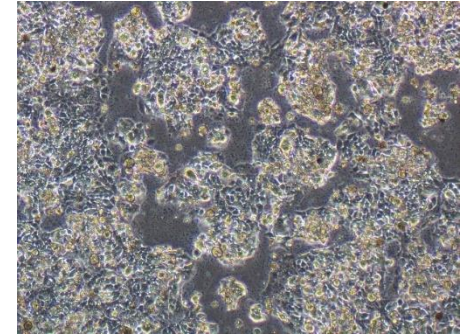
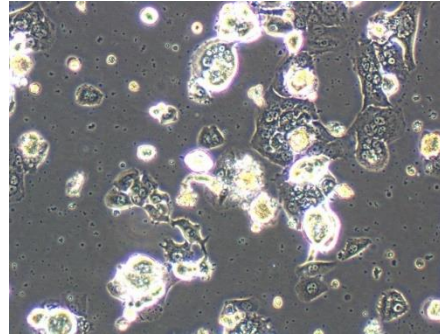
*Data as of Jan 6, 2017*

# Current Position

<b>Ticker:</b>	<b>TSX: BCT.V</b>
<b>Other Listing:</b>	OTCQB:BCTXF
<b>Shares Outstanding (in millions)</b>	99.99
<b>Market Cap (in Million CAD\$):</b>	20.00
<b>Cash (in Million CAD\$) as of Oct 31, 2016</b>	2.21
<b>Number of stock options issued (in millions)</b>	5.65
<b>Warrants (in millions)</b>	~20 (exercise price between \$.25 and \$.35)

Data as of Jan 6, 2017

## BriaVax™ (SV-BR-1-GM)



- Breast cancer cell line
- Allogeneic whole-cell vaccine secreting GM-CSF (“GVAX”).
- Scalable production - grows as cancer cell line in RPMI 1640 + 10% FBS + GlutaMAX™.
- Irradiation prior to injection to prevent replication.
- Used in combination with cyclophosphamide, and post-treatment interferon- $\alpha$ .
- **Expected Result:** Boosting the patient’s overall immune response to the tumor cells.

## Target Population

- 2<sup>nd</sup> line use for late stage **breast cancer**.
- Potential use for early stage cancers sharing antigen(s) of vaccine cells.
- **Potential** use for **non-breast cancers** sharing antigen(s) of vaccine cells.
- Maintenance therapy for duration of disease



# Clinical Data to-date

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## First Phase I:

- Used unmodified cell line + GM-CSF + cyclophosphamide
- N = 14 late stage, treatment-refractory breast cancer patients
- No significant adverse events, well tolerated
- Median Overall Survival = **12.1 months**

## Second Phase I:

- Used GM-CSF-engineered cell line + cyclophosphamide + interferon- $\alpha$
- N = 4 late stage, treatment-refractory (3 breast cancer, and 1 ovarian cancer) patients
- No significant adverse events, well tolerated
- Median Overall Survival = **35 months**
- One robust responder with **>90% regression during treatment**, subsequent relapse (upon halting treatment) **responded to re-treatment**

## Second Phase I (using BriaVax™)

1 out of 4 Subjects responded with substantial tumor regression

### Initial BriaVax™ Series:



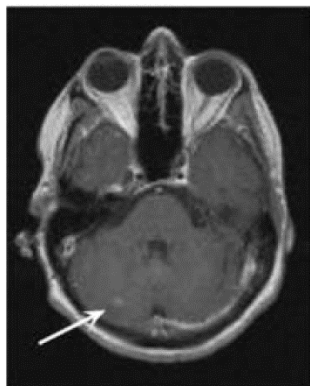
Source: Wiseman and Kharazi, Breast J. 2006 Sep-Oct;12(5):475-80

# Clinical Data to-date

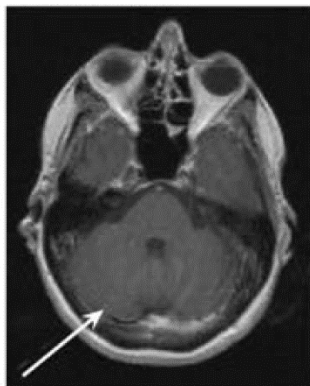
## BriaVax™ series after relapse:

Lesion 1

baseline

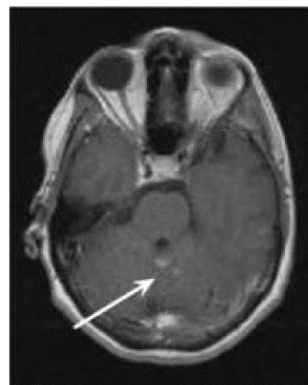


3 re-inoculations

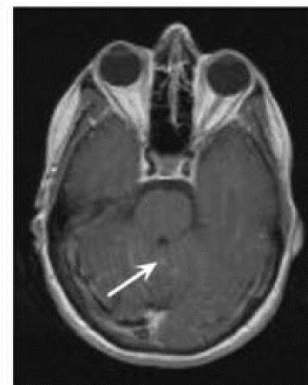


Lesion 2

baseline

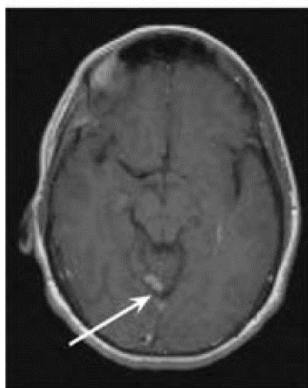


3 re-inoculations

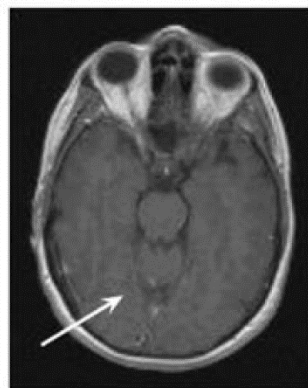


Lesion 3

baseline



3 re-inoculations



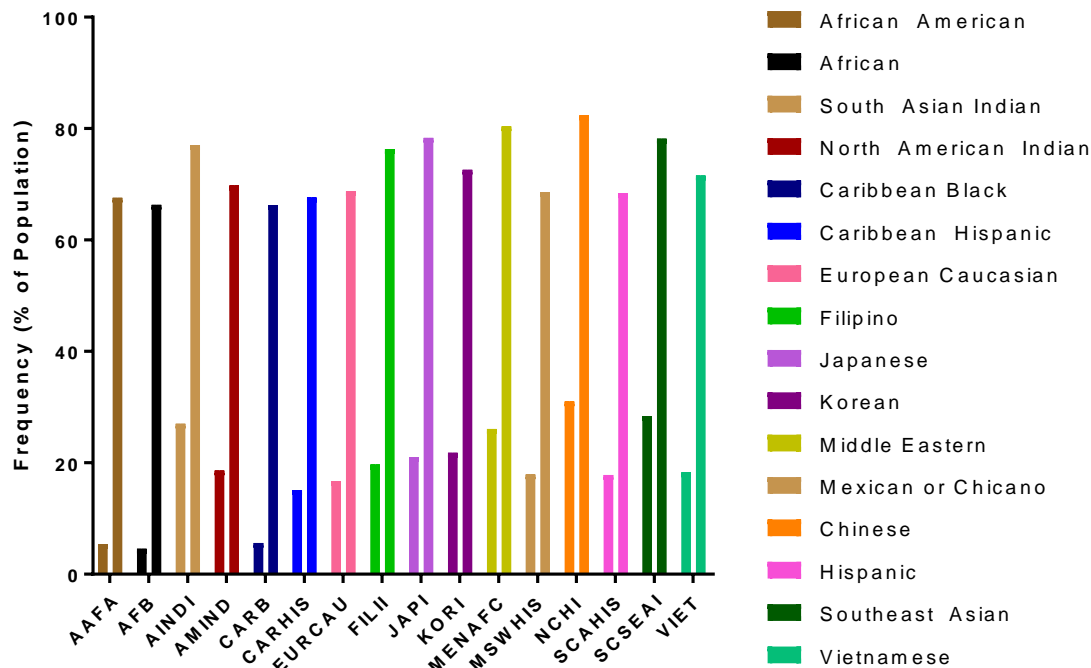
# HLA Types of BriaVax™ and Phase I Clinical Trial Subjects

Subject ID	Tumor Type	Survival (months)	Tumor regression	HLA-A		HLA-B		HLA-DRB3	
A001	Breast	40.7	No	02:01	24:02	13:02	41:01	03:01	-
A002	Breast	33.7	Yes	02:01	11:01	18:03	44:02	02:02	-
A003	Ovarian	35.6	No	02:01	03:01	07:02	13:02	Negative	-
B001	Breast	7.0	No	11:01	-	35:01	40:01	Negative	-
BriaVax	Breast	N/A	N/A	11:01	24:02	35:08	55:01	01:01	02:02

BriaVax™ and Subject A002 with tumor regressions even at metastatic sites (reported in Wiseman and Kharazi, 2006) share both MHC class I (HLA-A) and class II (HLA-DRB3) alleles.

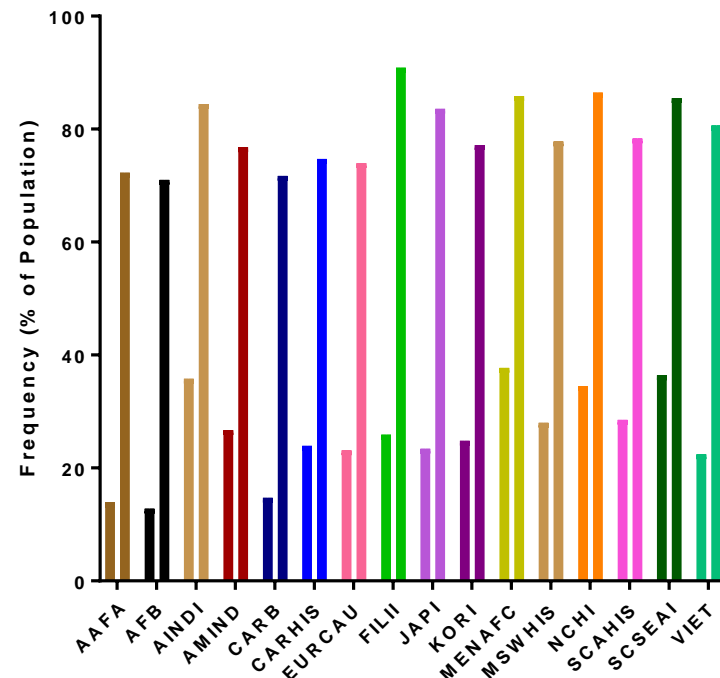
# Allele Frequencies for Various Ethnic Groups

HLA Matching Frequencies for BriaVax  
Specific Allele



(HLA I & HLA II) vs (HLA I or HLA II)

HLA Matching Frequencies for BriaVax  
Allele Group



(HLA I & HLA II) vs (HLA I or HLA II)

- ~ 20% of individuals will match with BriaVax™ at two HLA alleles
- ~60% of individuals will match with BriaVax™ at one HLA allele

# Hypothetical Mechanism of Action

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## **BriaVax™ (SV-BR-1-GM) is a breast cancer cell line with features of immune cells**

- Expresses immune-stimulatory factors including HLA class I and II components
- Overexpresses multiple tumor-associated antigens (measured at RNA level) including HER2 and PRAME (cancer/testis antigen)

## **Best clinical response: HLA class I and II matches between patient and BriaVax™**

- HLA analysis of BriaVax™ and peripheral blood lymphocytes from the 4 patients showed that the special responder had HLA class I (HLA-A\*11:01) and class II (HLA-DRB3\*02:02) alleles also found in BriaVax™. This double-match may explain BriaVax™ 's potent anti-tumor effect in that subject.

# Initial Patient Population for BriaVax™

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- Proposed indication for the treatment of patients with metastatic breast cancer (MBC) who have failed at least one line of therapy
- Initial approach to approval and marketing will be second line therapy in MBC
- High unmet need with potential for accelerated approval
- May be necessary to match patients at 1 or 2 HLA alleles
- Conservative assumption is use will be limited to patients who match at 2 HLA alleles
- Considerable upside (~3x higher patient population) if response rate in single HLA matched patients is similar

# Breast Cancer Epidemiology

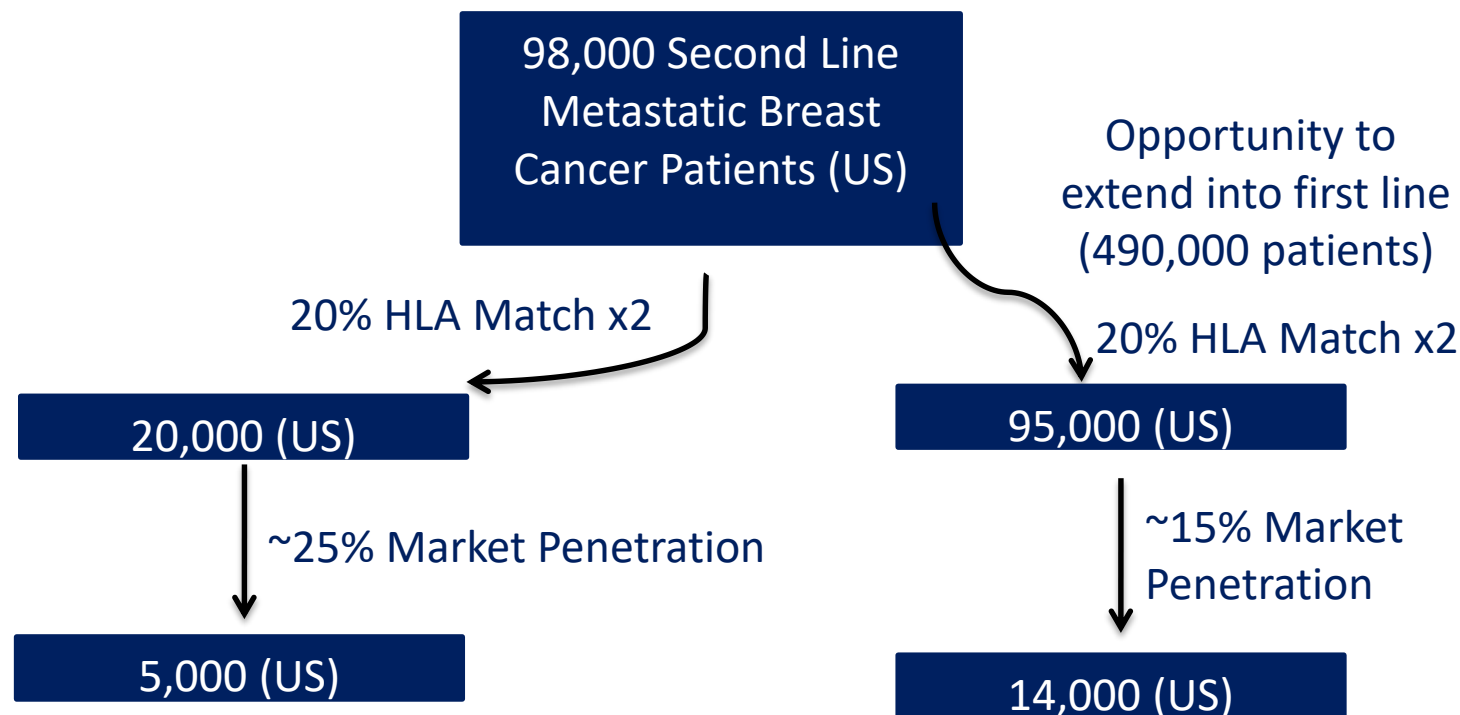
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- Approximately 80% of breast cancer cases present with invasive disease
- 2.8 million (total cases) x 80% = ~2,200,000 cases of invasive breast cancer in the USA
- 2.2 million (invasive) x 22% (metastatic) = ~490,000 patients with metastatic breast cancer
- 490,000 x 20% (progress to second line) = ~98,000 patients available

*Reference: Howlader, et al, J Natl Cancer Inst. 2014 Apr 28;106(5)*



# Market Opportunity in Metastatic Breast Cancer



# Revenue Opportunity

Opportunity	Calculation				Revenue
<b>2<sup>nd</sup> Line:</b> BriaVax™ in combination with immunotherapy	5,000 pts (US)	x	6months treatment	x \$8000 /m = \$200 - \$330 MM	>\$200M
<b>1<sup>st</sup> Line:</b> BriaVax™ in combination with immunotherapy	19,000 pts (US)	x	6months treatment	x \$8000 /m = \$900 - \$1,100	>\$900M

## Indication:

- Indication 1: Treatment of patients with metastatic breast cancer matched at 2 HLA alleles after one prior therapy as monotherapy or in combination with immunotherapy → INITIAL SECOND LINE INDICATION
- Indication 2: Treatment of patients with metastatic breast cancer matched at 2 HLA alleles alone or in combination with immunotherapy → MOVE INTO FIRST LINE

## Opportunity:

- Opportunity for combination with immunotherapy resides in favorable mechanism of action
- Larger opportunity exists with combination with immunotherapy in 1st line
- If single HLA allele matched patients also respond, considerable upside opportunity exists → Expands opportunity ~3x
- Expansion into ex-USA markets would expand the market opportunity ~2x

## Value Proposition:

- Opportunity 1: Improved efficacy vs. current second line therapy with limited additional safety concern
- Opportunity 2: Need significant improvement in efficacy vs. current first line therapy, but very limited additional toxicity

## **Rationale:**

- Favorable initial clinical data and mechanism of action that should be synergistic with current immunotherapies
- Clear unmet need in second line (high relapse rate) and opportunity to move into first line

## **Potential Issues:**

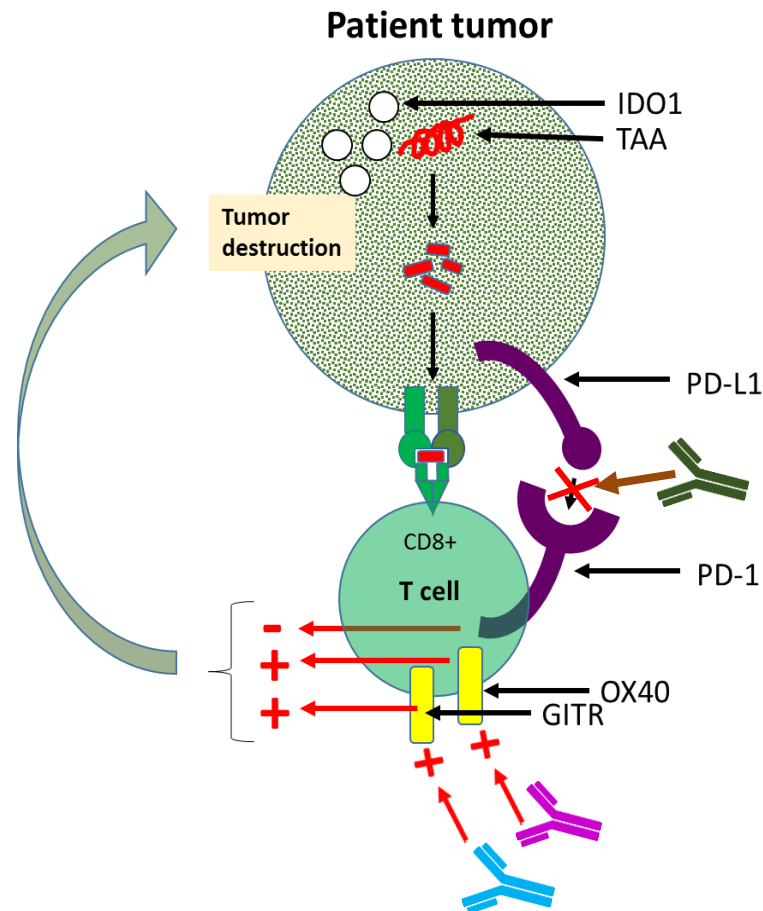
- Current manufacturing scheme difficult to scale-up (requires cells get from production facility to patient the same day)
- Plans in place to simplify and use frozen cells for future clinical studies
- High number of therapies with other MOAs in development for this indication
- Could limit uptake as other therapies are being rolled out, even if they could be used in combination

## **PRAME (cancer antigen) is expressed by BriaVax™ and in several human cancers**

- 88% of primary melanomas and 95% of metastases express PRAME
  - (Ikeda et al., 1997).
- Also expressed in other human malignancies, including:
  - Acute and chronic leukemias,
  - Medulloblastoma
  - Non-small cell lung carcinoma,
  - Head and neck cancer
  - Renal carcinoma
  - Multiple myeloma
  - Sarcomas
    - (Boon et al., 2003; Ikeda et al., 1997; Oberthuer et al., 2004; van Baren et al., 1998; van't Veer et al., 2002).
- High PRAME expression is an independent prognostic marker of poor clinical outcome in breast cancer and neuroblastoma
  - (Oberthuer et al., 2004; van't Veer et al., 2002).
- High PRAME expression inversely correlates with recurrence-free survival (no metastases) and overall survival in breast cancer
  - (van't Veer et al., 2002).
  - From Epping et al, Cell, Vol. 122, 835–847, 2005

# Combination BriaVax™ with other Immunotherapies

- BriaVax™ should synergize well with other immunotherapies
- This includes check point inhibitors such as antibodies to PD-1, CTLA4 and IDO inhibitors which eliminate immunosuppression
- Immunostimulatory antibodies to molecules such as GITR and OX40 should enhance responses to BriaVax™



Source : BriaCell Therapeutics Corp.

**The initial Phase I/IIa study is designed to recruit 24 subjects using monotherapy with BriaVax™**

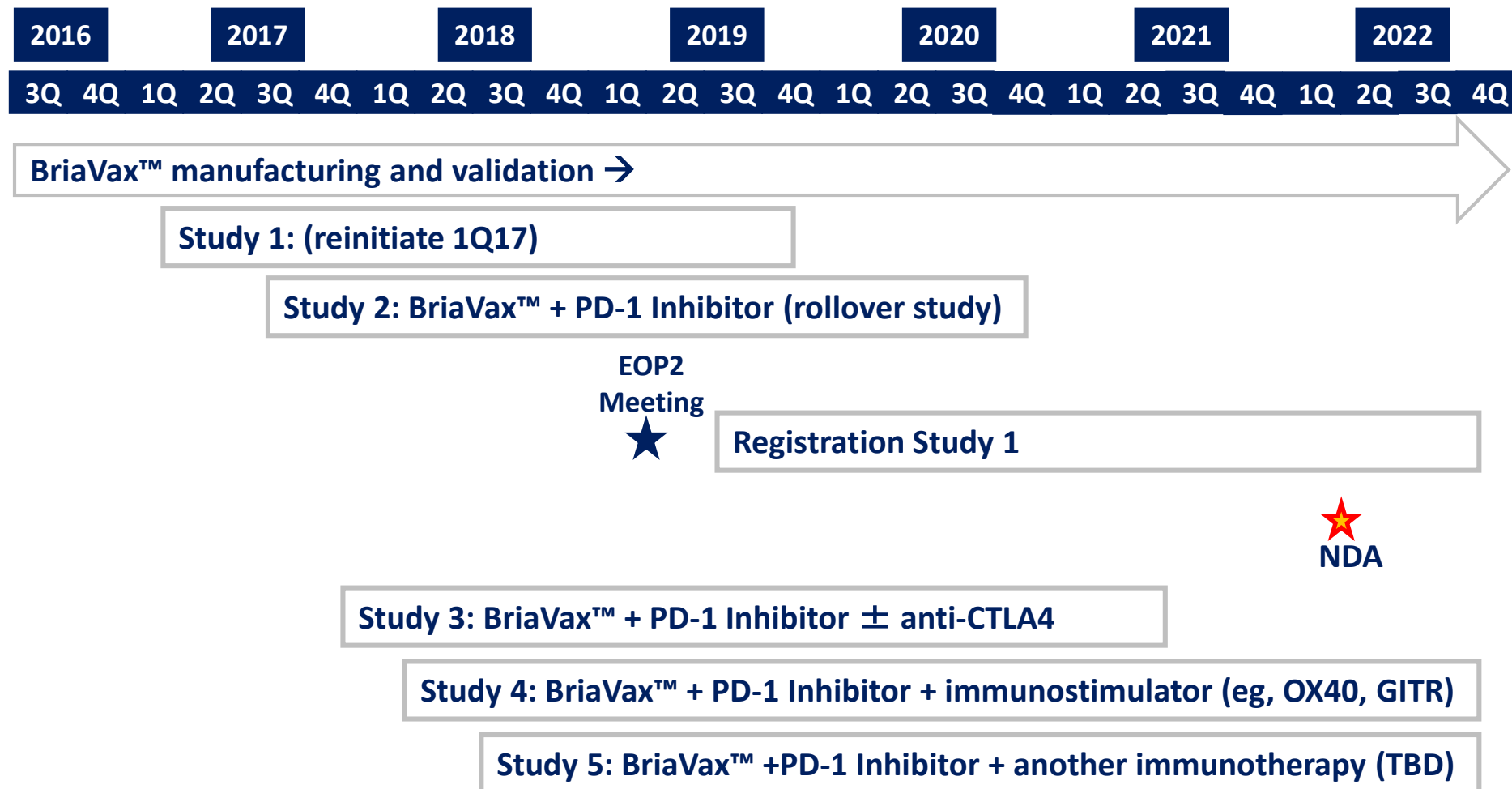
- Will add a roll-over protocol to permit treatment with a PD-1 inhibitor if no response after 3 months

**Combination Therapy studies would all have similar designs:**

- Initial cohort of 12 patients to look for responses in  $\geq 3/12$
- If positive expand to ~60 subjects and determine response rate

**If positive response is confirmed, move on to a registration study (~300 patients)**

# BriaVax™ Clinical Development Plan – Breast Cancer Indication





# Summary

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- Proprietary vaccine for 2<sup>nd</sup> line use for advanced breast cancer with potential for 1<sup>st</sup> line use.
- Initiating Phase I/IIa to further validate the impressive preliminary Phase I data:
  - Rapid response rate with little side effects
  - Second response following relapse
- Planning to co-develop companion diagnostics.
- The management consists of leading experts in drug discovery, drug development, immunotherapy, diagnostics, & corporate governance
- Potential for combination studies.



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**info@BriaCell.com | 1-888-485-6340 | BriaCell.com**