BriaCell

The Future of Cancer Immunotherapy

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

Breast Cancer Immunotherapy: Novel Combinations of Bria-IMT™ with Checkpoint Inhibitors

William V. Williams, M.D.
President and CEO, BriaCell Therapeutics Corp.

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Immunotherapy for Breast Cancer

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The Problems

- **Checkpoint Inhibitors:**
  - Anti-PD-1 Abs, anti-PD-L1 Abs, anti-CTLA-4 and others reduce the tumor's ability to suppress immune system.
  - They only work in 20%-30% of patients and can cause autoimmune disease.
  - Response appears to correlate with tumor mutational burden.
  - In breast cancer, only triple negative disease tends to have a high mutational burden

- **Therapeutic Cancer Vaccines:**
  - Have not been successful in solid tumors or blood cancers except those specific to the patient.

- **Personalized Immunotherapies:**
  - Provenge® is effective for prostate cancer and uses a prostate antigen coupled to GM-CSF to pulse dendritic cells.
  - This indicates that immune responses to a tissue-specific antigen can be an effective immunotherapy.
  - This further suggests that a Class II HLA restricted CD4+ Helper T cell response may be key in effectiveness of the immunotherapy.

Therapeutic Cancer Vaccines

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Varieties of Targeted Immunotherapies/Therapeutic Cancer Vaccines

- **Peptide and protein tumor antigens:**
  - **Advantages:** Easy to manufacture and administer; can elicit helper T cell (T_H) responses; may elicit antibody (Ab) and cytotoxic T cell (CTL) responses.
  - **Disadvantages:** Limited antigenic repertoire elicited; difficult to break tolerance against some antigens; have had multiple clinical failures.

- **Peptide Neoantigens:**
  - **Advantages:** Induce an immune response specific to the patient's cancer; can induce T_H and CTL responses, may induce Ab responses.
  - **Disadvantages:** Need to determine neoantigen sequences in each specific patient and may need to manufacture peptides specific to each patient. Also identifying an active neoantigen responsible for tumor growth is like finding a needle in haystack.

- **Whole-Cell Approaches:**
  - **Advantages:** May display a wide variety of tumor-associated antigens; can induce T_H, CTL and Ab responses.
  - **Disadvantages:** HLA-restriction of immune responses may hinder cross-reactivity of elicited T cell response to the tumor; also multiple clinical failures.

Development of SV-BR-1

- **SV-BR-1 – First developed by Dr. Charles Wiseman at Saint Vincent Medical Center (Los Angeles)**
- **Derived from a chest wall metastasis from a patient with metastatic breast cancer (MBC)**
- **Grows as an adherent cell in simple tissue culture media – Her2 strong+, ER/PR-**
- **Initially used to immunize 14 patients with advanced breast cancer in a regimen including:**
  - Pre-dose low-dose cyclophosphamide (300 mg/m^2) 2-3 days prior to inoculation
  - Intradermal inoculation of ~20 million irradiated SV-BR-1 cells (split into 4 sites)
  - Follow-up local injections of GM-CSF on the day of SV-BR-1 inoculation and then daily x 8 days
  - Cycles every 2 weeks x 3 and then monthly
- **Generally safe and well tolerated, median Overall Survival = 12.1 months**

Development of SV-BR-1-GM (Bria-IMT™)

- **SV-BR-1 transfected (engineered) with the CSF2 gene (encoding GM-CSF) to produce SV-BR-1-GM (Bria-IMT™)**
- **Used to immunize 4 patients with advanced cancer in a regimen including:**
  - Pre-dose low-dose cyclophosphamide (300 mg/m^2) 2-3 days prior to inoculation
  - Intradermal inoculation of ~20 million irradiated Bria-IMT™ cells (split into 4 sites)
  - Follow-up injections of interferon-α2b (Intron A) 10,000 IU per inoculation site ~2&4 days later
  - Cycles every 2 weeks x 3 and then monthly
- **Well tolerated, no life-threatening drug related adverse events**
- **Median Overall Survival = 35 months**
- **One robust responder with >90% regression during treatment, subsequent relapse (upon halting treatment) responded to re-treatment**
- **The patient matched Bria-IMT™ at the HLA-DRB3 locus**

Bria-IMT™ Expresses Multiple Breast/Cancer related Antigens

ABCA12	AP000322.53	AZIN1	CCL28	CSN3	ELF5	FOXI1	HIST1H4H	KIT	KRTAP21-1	MIA	NQO1	PGAP3	SCGB1D2	SLCO1B7	SYNE4	XDH
ABCC11	APCDD1L	BTN1A1	CENPN	CST9	ELOVL3	GJC3	IGFBP5	KRT15	LALBA	MIEN1	OBP2B	PIGK	SCGB2A2	SPAG1	TBX15	XPOT
ACSM1	APOD	C10orf90	CEP55	CYP4Z1	EN1	GLRA3	IL17B	KRT17	LGALS7	MMP27	OIP5	PIP	SCGB3A1	SPINK14	TFAP2A	ZNF80
AKR1B15	ARHGAP40	C1orf64	CHIT1	DCAF10	ERBB2	GLYATL1P3	IL22RA2	KRT19	LGALS7B	MRGPRX2	OXGR1	PLAC1	SDR16C5	SPINK8	TNPO1	
AKR1C2	ARHGEF38	C2orf82	CLDN8	DCD	ESR1 ??	GLYATL2	INTS7	KRT25	LMX1B	MS4A18	OXTR	PNLIPRP3	SERHL2	ST8SIA6	TRPS1	
ALDH3B2	ARPC5L	C5orf46	CLEC3A	DGAT2L6	FABP7	GPR88	IRX1	KRT27	MAB21L1	MTHFD2	PAK1	PRAME	SFRP1	STAC2	TTC6	
ALG8	ATP13A5	C6orf223	CMA1	DHRS2	FABP9	GSTM5	IRX2	KRT28	MAP1LC3C	MUCL1	PAX3	PRSS51	SHB	STARD3	UBR5	
ALOX15B	ATP6V1B1	CABYR	COL8A1	DUSP4	FAM180B	GSTT2B	IRX3	KRT71	MATN4	MYB	PBK	PTHLH	SHISA2	STC2	UGT2B11	
ALX4	AWAT2	CARD18	CSN1S1	EFHD1	FAM196B	HIST1H2AE	IRX5	KRT79	MGAT4A	MYEOV	PDCD6	RFC5	SLC28A3	SULT1C3	UGT2B28	
ANKRD30A	AZGP1	CBX2	CSN2	EIF3H	FAM25C	HIST1H2BG	KIF2C	KRT81	MGP	NPY2R	PDRG1	RSF1	SLC35A2	SYCP2	VTCN1	

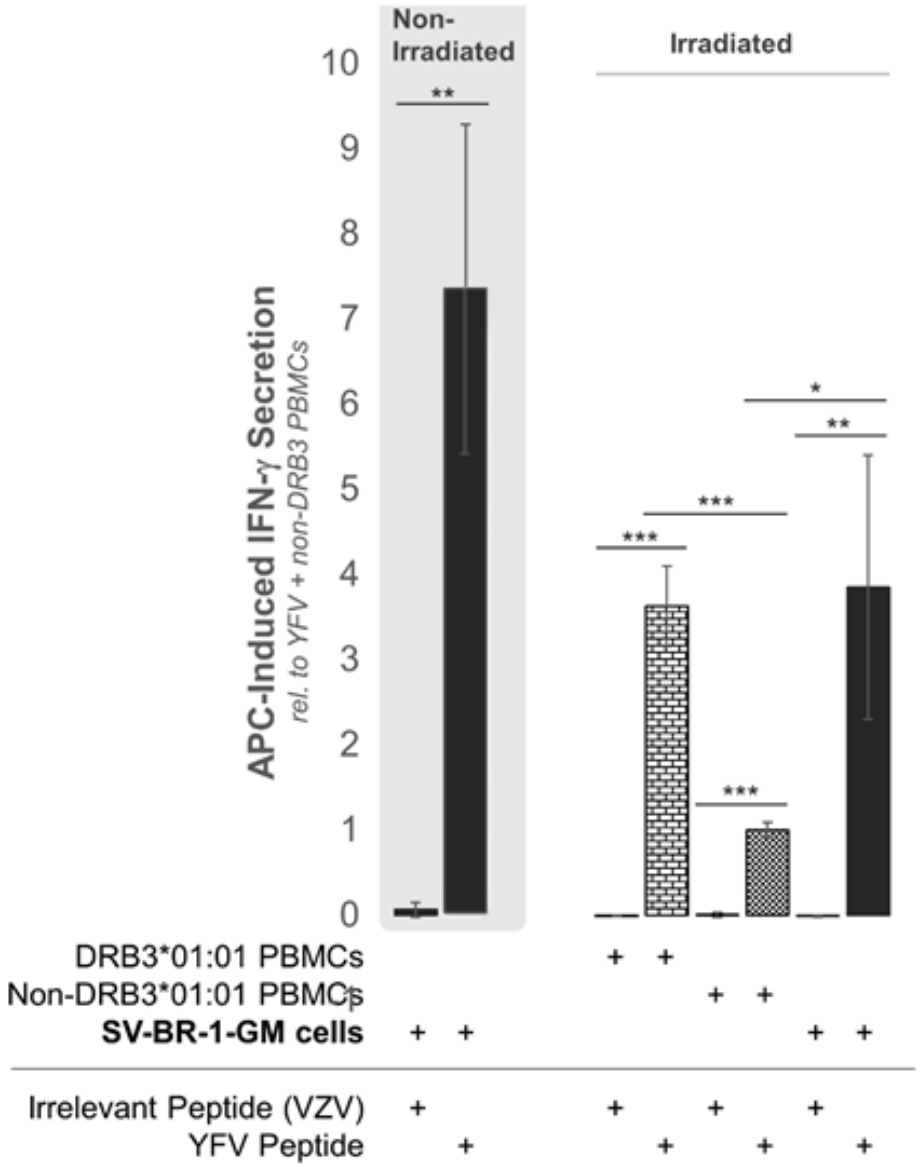
ERBB2, MIEN1, PGAP3, STARD3: on "HER2 amplicon

- **Bria-IMT™ expresses dozens of breast cancer and breast tissue antigens (by RNA-seq)**
- **The spectrum of antigens enhances the chance for a broad immune response against multiple breast cancer-related antigens**
- **There is evidence for immune responses against some of these antigens in patients treated with the Bria-IMT™ regimen**

Bria-IMT™ Mechanism of Action

Bria-IMT™ Acts as an Antigen-Presenting Cell

- Bria-IMT™ cells were cultured and serum-starved for 24 h then co-incubated with yellow fever virus (YFV) Envelope (Env) 43–59 peptides known to bind to HLA-DR complexes with an HLA-DRB3*01:01-based β chain and a YFV-DRB3*01:01-specific CD4+ T cell clone.
- After 72 h of coculturing with a YFV peptide – DRB3*01:01 restricted T cell, activation was assessed by determining the levels of secreted interferon (IFN)-γ. Values shown are arithmetic means from technical triplicates ± SDs, normalized to the mean IFN-γ level obtained from the YFV peptide-treated non-DRB3 PBMC reference wells.
- Background IFN-γ levels obtained from T cells treated with peptides in the absence of APCs (Bria-IMT™ or PBMCs) were subtracted.
- **Note that Bria-IMT™ is as potent as DRB3*01:01 peripheral blood mononuclear cells**

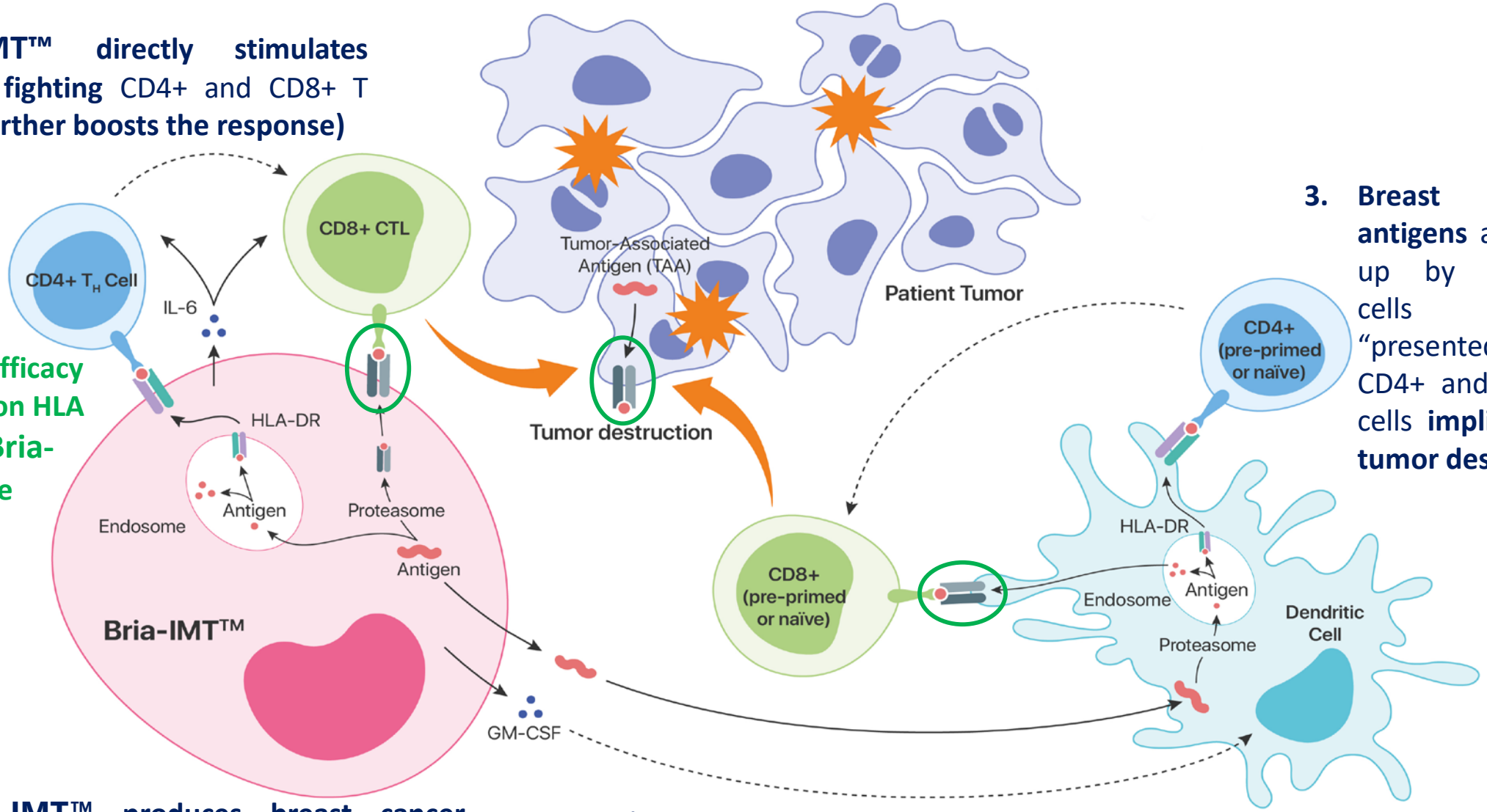


Bria-IMT™

Potential Mechanisms of Specific Immune Activation in Advanced Breast Cancer

4. **Bria-IMT™ directly stimulates cancer fighting** CD4+ and CD8+ T cells **(further boosts the response)**

5. **Bria-IMT™ efficacy may depend on HLA matching of Bria-IMT™ and the patient**

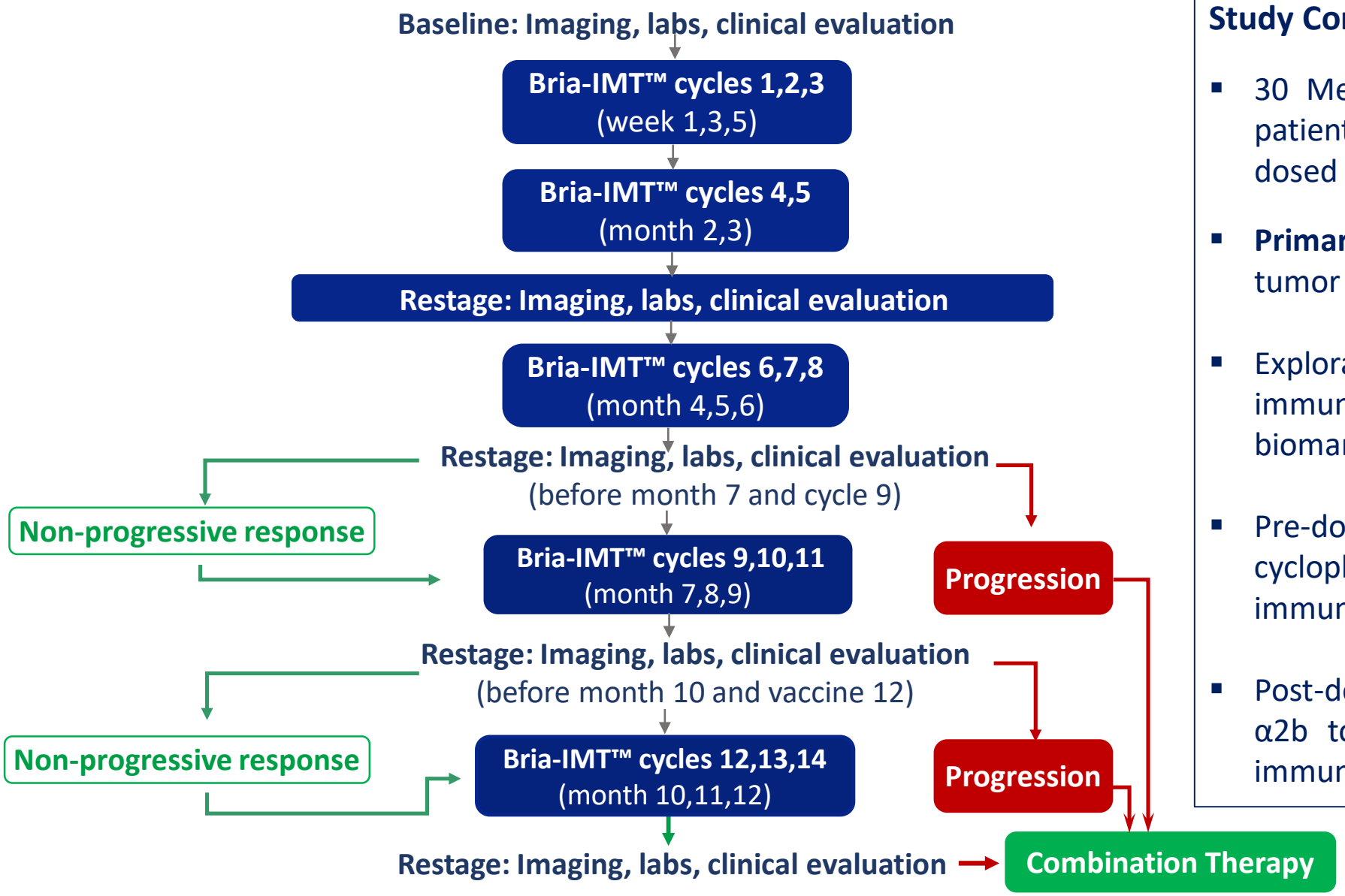


1. **Bria-IMT™ produces breast cancer antigens** (proteins made by breast cancer cells)

2. **Bria-IMT™ secretes GM-CSF** which further promotes dendritic cell-based antigen presentation (**boosts the response**)

3. **Breast cancer antigens** are taken up by dendritic cells and "presented" to CD4+ and CD8+ T cells **implicated in tumor destruction**.

Bria-IMT™ Phase IIa Monotherapy Trial Design



Study Completed:

- 30 Metastatic Breast Cancer patients screened and 23 dosed
- **Primary objectives**: Safety & tumor response
- Exploratory objectives include immune response to tumor, biomarkers, Quality of Life
- Pre-dose low dose cyclophosphamide to reduce immune suppression
- Post-dose intradermal IFN-α2b to boost cell mediated immunity

Bria-IMT™

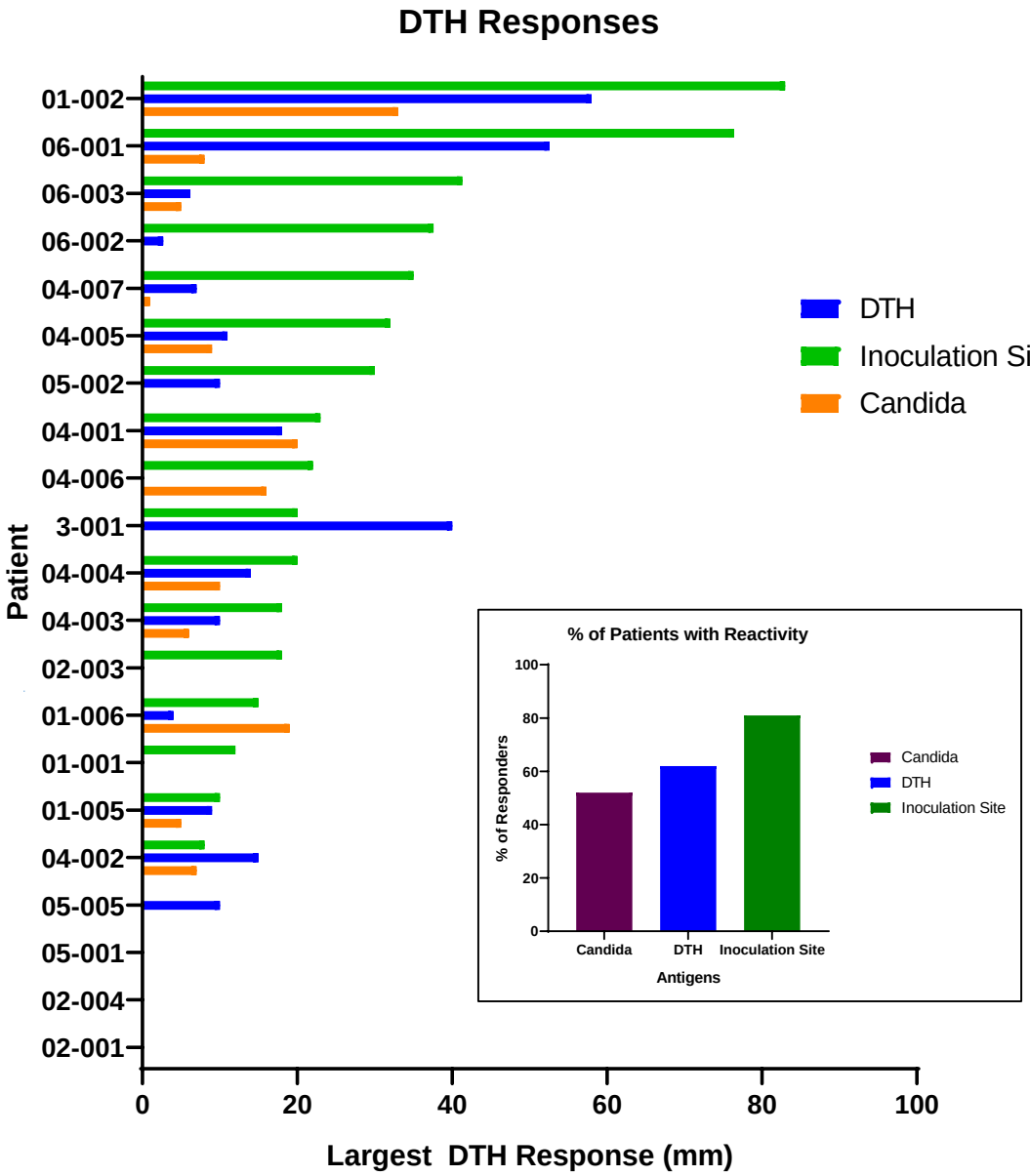
Study WRI-GEV-007 – Monotherapy Patient Characteristics

Patient Characteristics (23 total)	No HLA Allele Matches (n=6)	1+ HLA Allele Matches (n=17)	2+ HLA Allele Matches (n=4)
Age	55 ± 14	60 ± 8	68 ± 7
Median Prior Systemic Regimens	5.5 (range 2-13)	4 (range 0-10)	3.5 (range 3-7)
% ER/PR +	67%	33%	33%
% Her2/neu +	47%	41%	24%
% Triple Negative	75%	50%	0%

The patients are heavily pre-treated and generally similar regardless of HLA matching with Bria-IMT™

Bria-IMT™

Delayed Type Hypersensitivity to Bria-IMT™

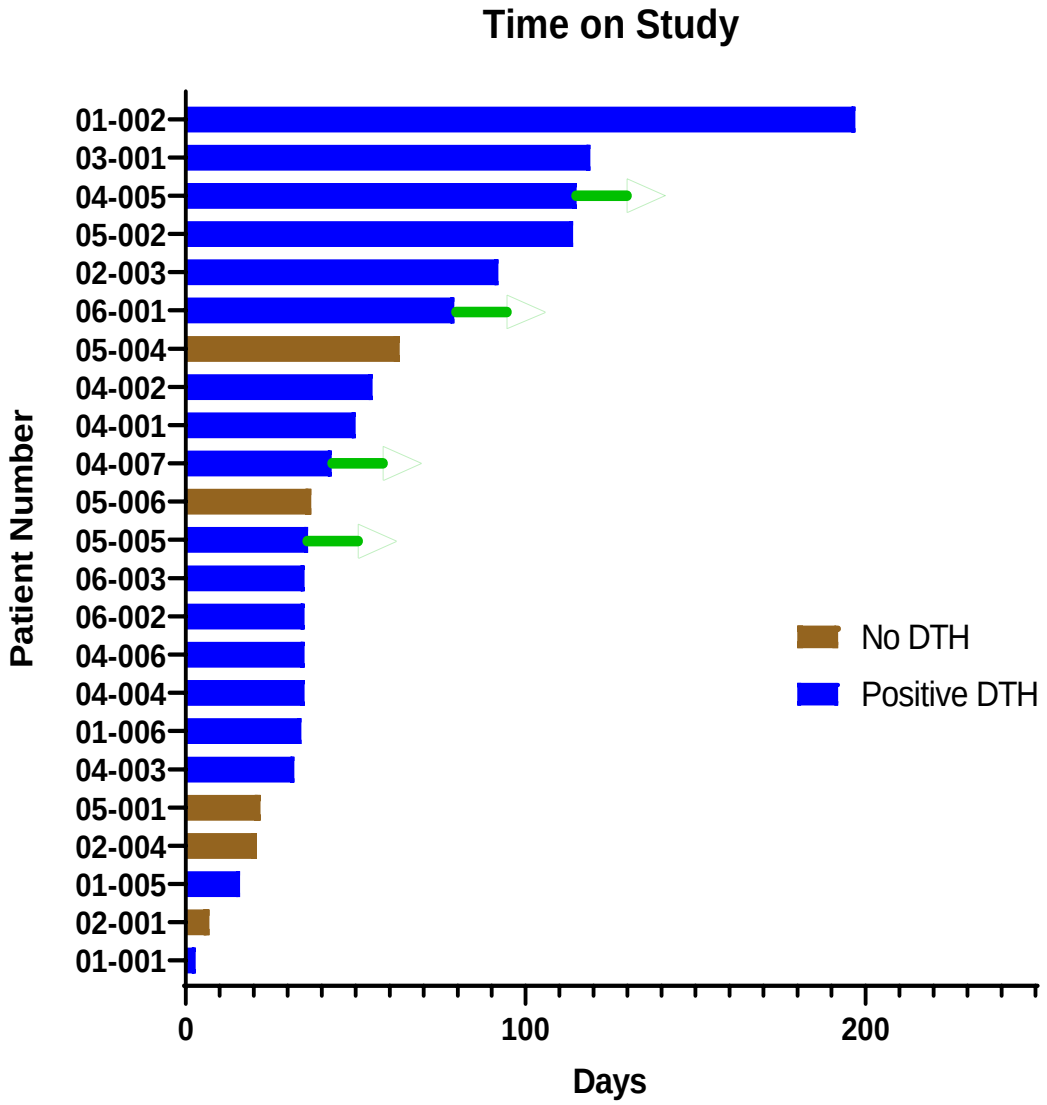


Rationale: Delayed-type hypersensitivity (DTH) is a good marker of cellular (T cell) immune responses. Briefly, for each cycle, Bria-IMT™ was injected intra-dermally with 5 x 10^6 irradiated cells in each of 4 sites in the upper back and thighs. 2 ±1 days later, these sites were assessed for erythema and induration. The largest response (size) for each patient is shown. The insert notes the % of patients able to mount a DTH response (erythema or induration ≥5 mm to the antigen)

Conclusion: A substantial proportion of patients with follow-up information develop DTH to Bria-IMT™, in spite of anergy to test antigens (Candida) in some patients. The most robust response was seen in a patient with regression of multiple pulmonary metastases (01-002).

Bria-IMT™

Study WRI-GEV-007 – Monotherapy Time on Study



Brown bars indicate patients unable to mount a DTH response

Blue bars indicate patients able to mount a DTH response

Arrows → indicate the patients rolled over to combination therapy

Conclusion: In spite of being very heavily pre-treated (median of 4 prior chemotherapy or biological therapy regimens), patients were able to remain on the Bria-IMT™ regimen for protracted periods of time. Lack of a DTH response tended to correlate with shorter time on study.

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Study WRI-GEV-007 – Monotherapy Safety Data

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Adverse Events seen in 2 or More Patients

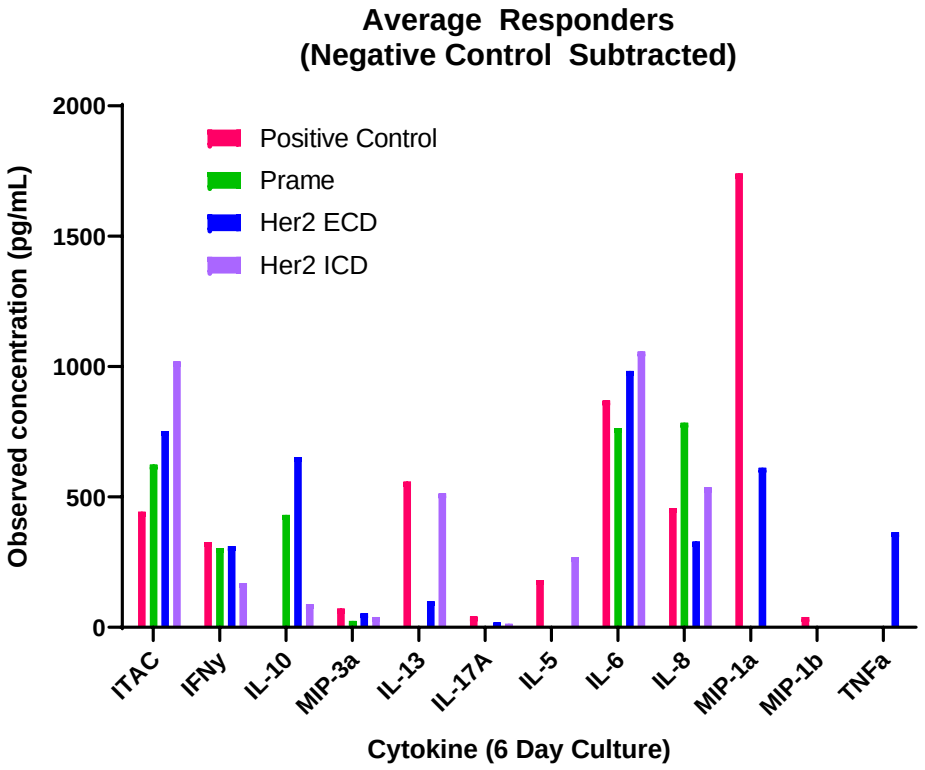
ADVERSE EVENT TERM	Occurrences	Patients
Erythema	42	11
Induration	32	7
Pruritis	13	7
Abdominal pain	9	6
Fatigue	8	6
Nausea	8	6
Pain, musculoskeletal	9	6
constipation	5	5
Diarrhea	5	4
Flu like symptoms	5	4
peripheral neuropathy	3	3
Urinary Tract Infection	3	3
Abdominal distension	2	2
Anorexia	2	2
Bruising, Facial	2	2
Chills	2	2
Decreased appetite	2	2
Dehydration	2	2
Dizziness	2	2
Dyspepsia	2	2
Erythema multi form	2	2
GGTP Increased	3	2
Hypertension	2	2
Increased Alkaline Phosphatase	3	2
Increased ALT	2	2
Increased AST	4	2
Increased GGT	2	2
Injection site reaction	3	2
Myalgia	2	2
Numbness in hands	2	2
Pleural effusion	2	2
Rash	3	2
High uric acid	2	2
Urticaria	3	2
Vomiting	2	2

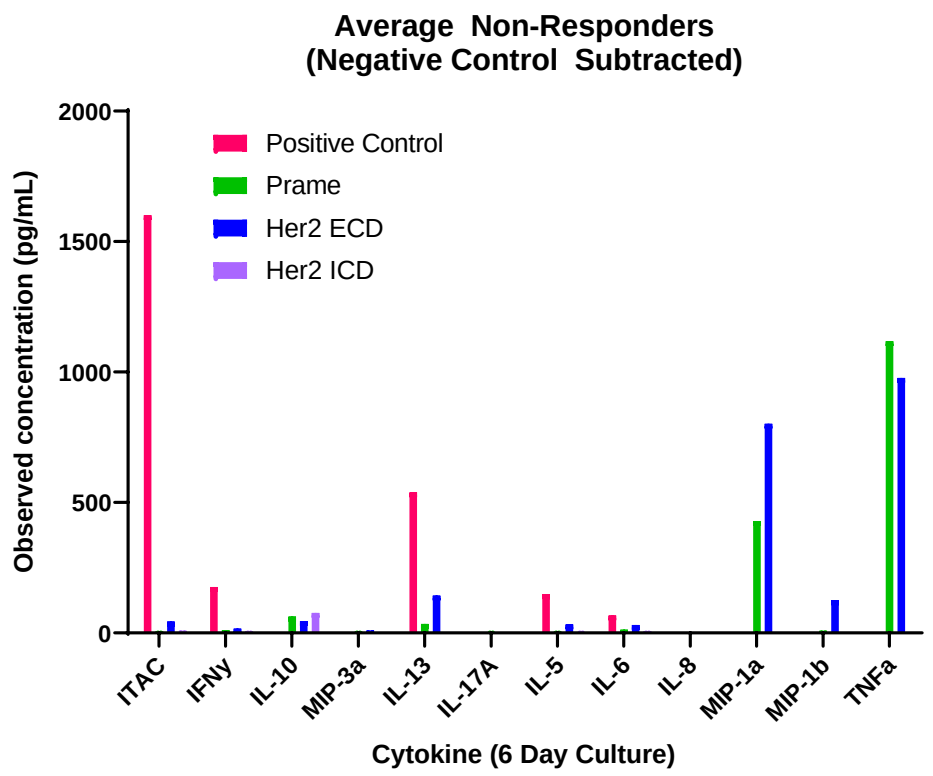
Serious Adverse Events

Serious Adverse Event	Severity	Relationship to Bria-IMT™
Fever	Grade 1	Unrelated
Influenza A	Grade 2	Unlikely Related
Palpitations	Grade 2	Unlikely Related
GERD	Grade 2	Possibly Related
Bone pain	Grade 3	Unrelated
Urinary Tract Infection	Grade 3	Unlikely Related
Hyponatremia	Grade 3	Unrelated
Hypercalcemia	Grade 4	Unlikely Related
Worsening of Hypercalcemia	Grade 4	Unlikely Related
Sepsis	Grade 4	Unlikely Related
Pleural Effusion	Grade 4	Unrelated
Respiratory Failure Death	Grade 4	Unrelated
Restrictive Cardiomyopathy	Grade 5	Unlikely Related

Conclusion: Bria-IMT™ was generally safe and well tolerated

Bria-IMT™ Treatment Enhances Immune Responsiveness



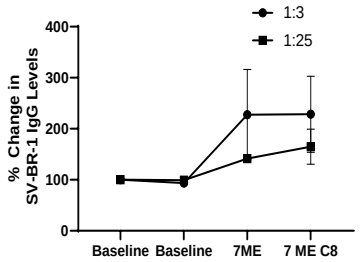


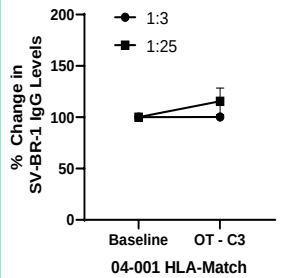
T cell responses to PRAME (a cancer testis antigen) and HER2/neu peptides (ECD = extracellular domain; ICD = intracellular domain) in patients with and without tumor regression

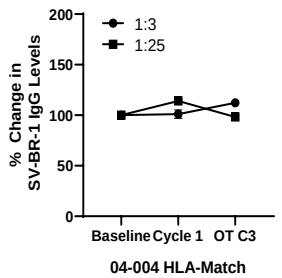
Working Model - Tumor regression requires HLA matching to Bria-IMT™ and the ability to mount a cellular immune response (DTH and *ex vivo* T cell activation)

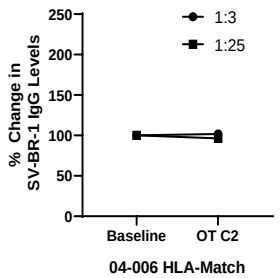
Conclusion: Responders with tumor regression have a higher propensity to develop T cell responses to the cancer-related antigens PRAME and HER2/neu.

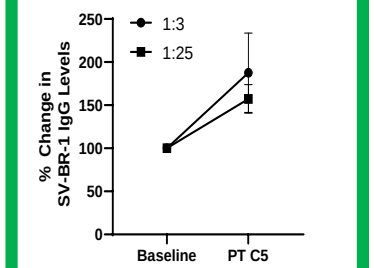
Anti-SV-BR-1 Antibodies in Patients

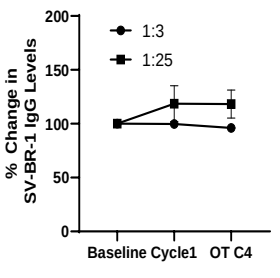


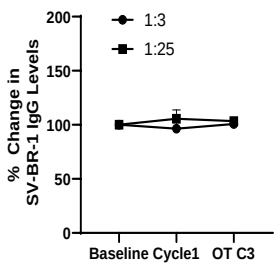


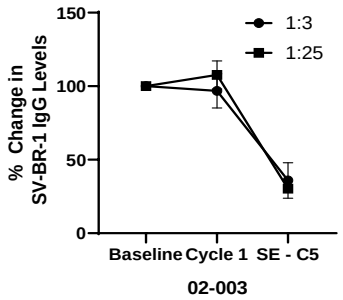


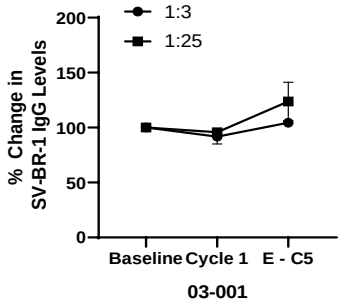


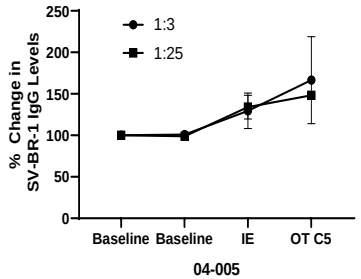


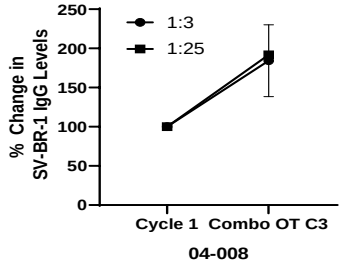


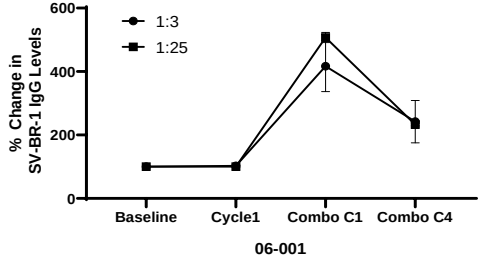












Anti-SV-BR-1 antibody titers in patient sera. SV-BR-1 cells were incubated with 1:3 or 1:25 diluted patient sera then stained with fluorescently labeled anti-human IgG and analyzed by flow cytometry. Anti-SV-BR-1 antibodies in all patient's sera samples segregated either as HLA matched (≥ 1 allele) or non-HLA matched. Baseline: before treatment with first dose of Bria-IMT™.

Conclusions: IgG responses to SV-BR-1 are elicited by Bria-IMT™ treatment.
The best responses are seen in those with tumor shrinkage.

Bria-IMT™- Activity Dependent on Ability to Develop DTH

Bria-IMT™ appears to be most effective in patients who match with Bria-IMT™ at HLA loci and who are able to mount a DTH response further supporting our "HLA Matching Hypothesis"

HLA Matching and Biological Activity

Patients	HLA Match	Tumor Shrinkage	Tumor Shrinkage in Immune Responders*
N=5	≥ 2	40%	50%
N=17	≥ 1	18%	30%
N=6	0	0%	0%

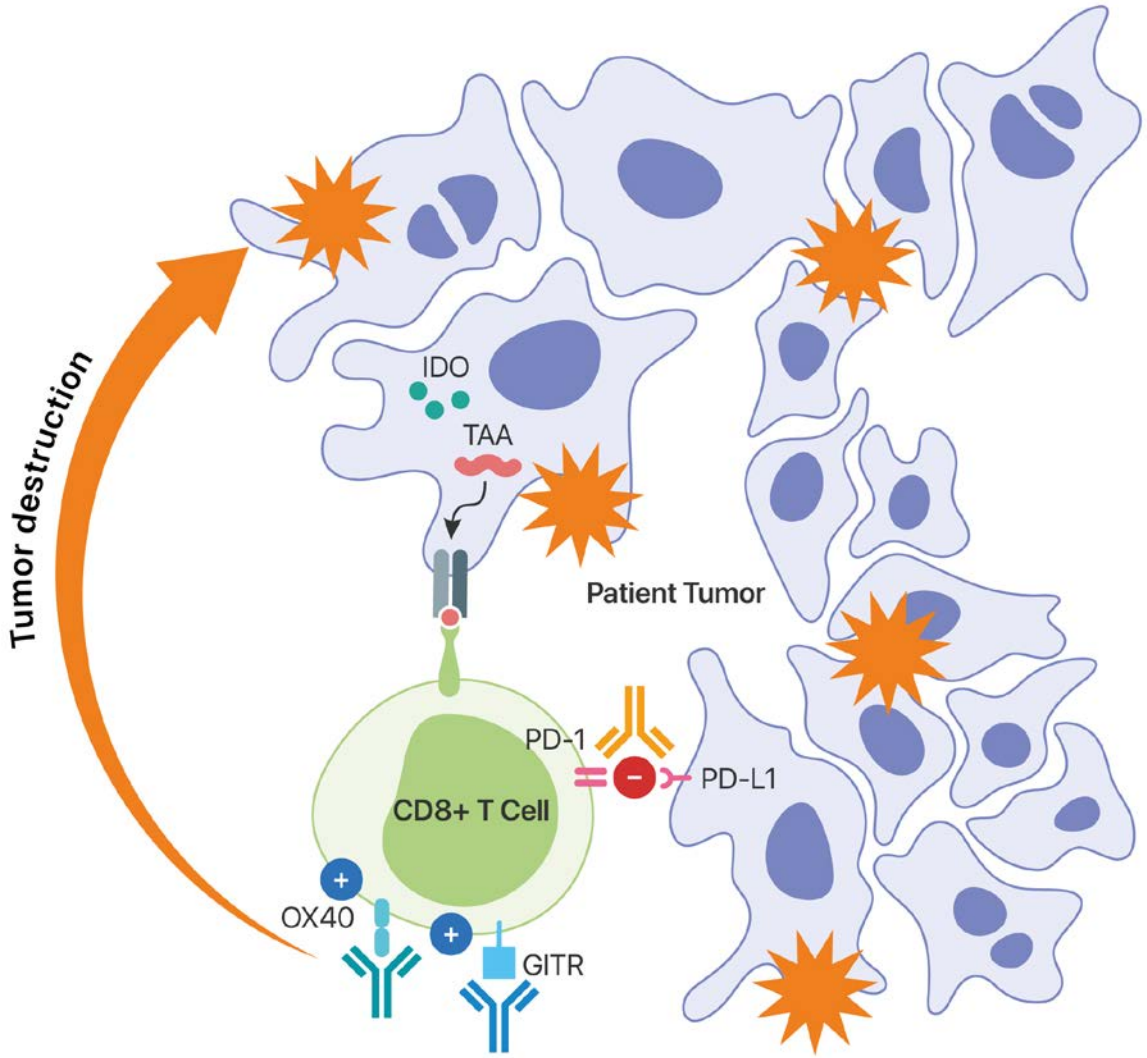
*Immune response measured by delayed-type hypersensitivity.

- PD-L1 expression on circulating cancer cells & cancer-associated cells in >90% of patients → Strong rationale for combination with checkpoint inhibitors

Bria-IMT™ Combination Therapy

Bria-IMT™ & Bria-OTS™
Immunotherapy Combination Considerations

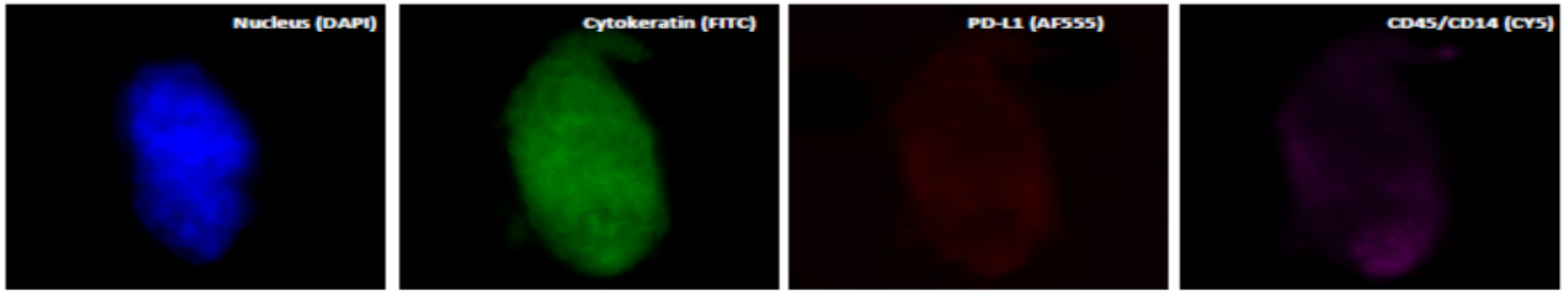
- Bria-IMT™ and Bria-OTS™ should **synergize with existing approved immunotherapies** as well as those still under development
- This includes immune checkpoint inhibitors such as antibodies to PD-1, CTLA-4, GITR and CD73 and IDO inhibitors which **eliminate tumor immunosuppression**
- Checkpoint Inhibitors were the subject of the 2018 Nobel Prize in Physiology or Medicine
- In addition, **immunostimulatory antibodies** to molecules such as OX40 should **enhance responses** to Bria-IMT™ and Bria-OTS™

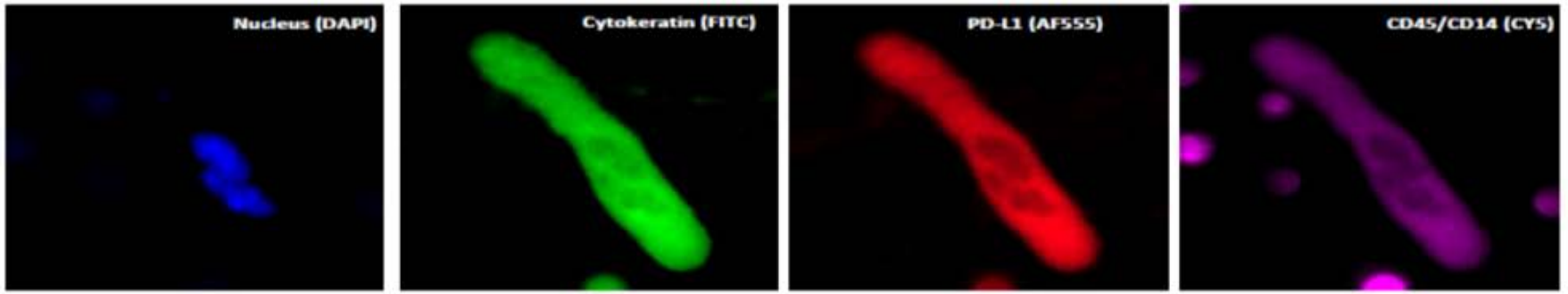


Circulating Tumor Cells & CAMLs: PD-L1 expression

- To date, 90% of patients analyzed have had PD-L1 expression on their CAMLs and CTCs
- In Patient 01-002 (monotherapy study) CTCs and CAMLs were analyzed for PD-L1 Expression.
- Mean levels during treatment increased from 97 ±7 to 437 ±72 (SEM).

Pre-Treatment PD-L1 Expression Level 105





Post-Treatment PD-L1 Expression Level 815

Conclusion: Increases in PD-L1 expression in CAMLs are seen during therapy indicating potential synergy with PD-1/PD-L1 inhibition.

Anti-PD-1 and Anti-PD-L1 Ineffective as Monotherapy in Breast Cancer

- Brahmer 2012: treated 4 patients with breast cancer (sub-type not specified) – 0 response rate

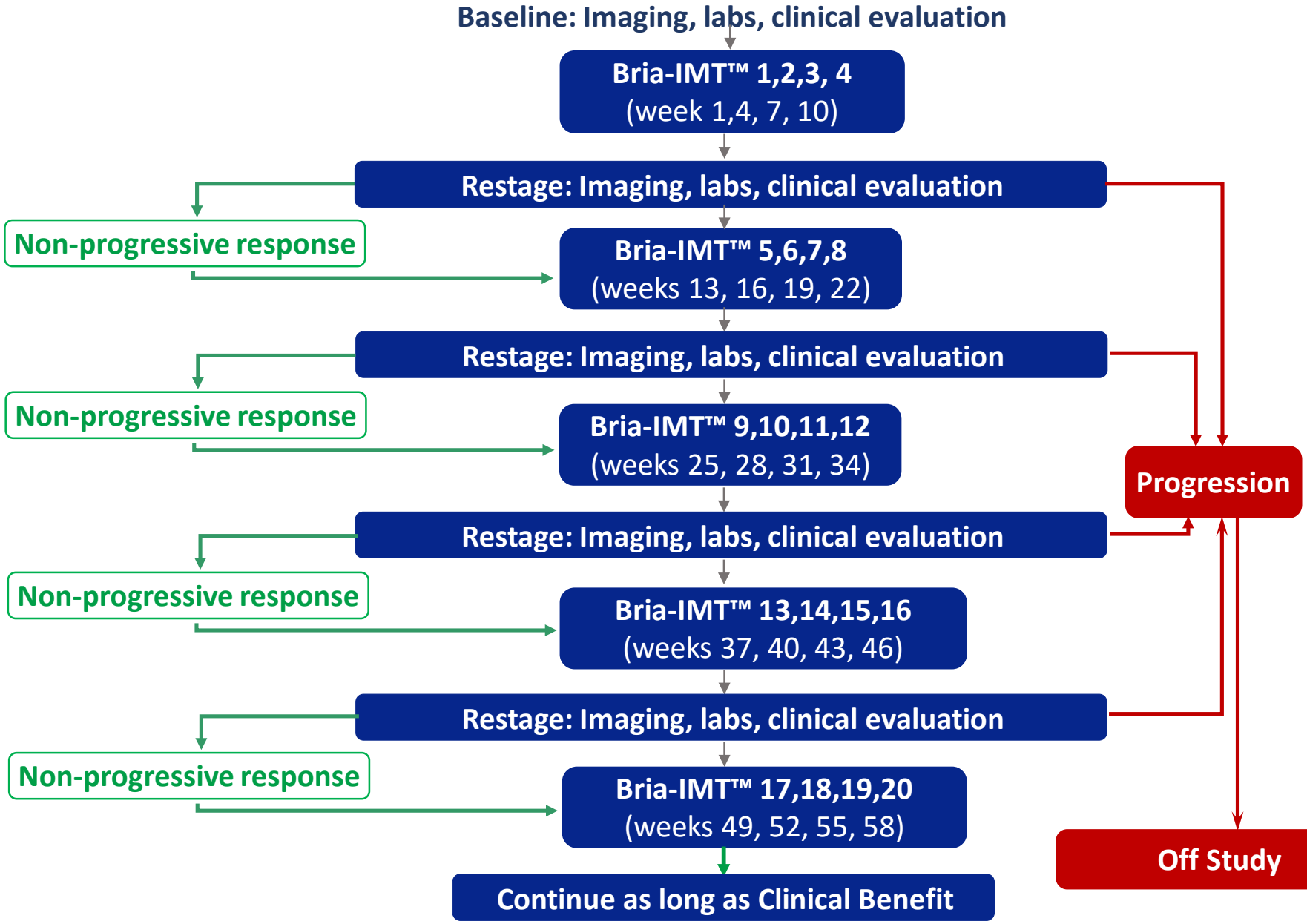
- Nanda 2016: treated 32 patients with triple negative breast cancer (TNBC) with KEYTRUDA®, data on 27, all PD-L1+
  - 18.50% response rate
  - Median time to response 17.9 weeks (range, 7.3 to 32.4 weeks)

- Dirix 2017: treated 168 patients with avelumab (anti-PD-L1)
  - **Response rate of 3%**
  - 5.2% response rate in Triple Negative Breast Cancer (3 of 58 patients)
  - **Response Rate of 1.84%** in other types of breast cancer (2 of 110 patients)

- Patients 06-001 and 06-005 were not TNBC (both were HR+, HER2-), so the chances this was due to KEYTRUDA® is almost nil

PD-1 and PD-L1 Inhibitors are Ineffective as Monotherapy in Advanced Breast Cancer → Responses seen to Bria-IMT™ Combined With KEYTRUDA® unlikely due to KEYTRUDA® alone, May Indicate Additive of Synergistic Effects of the Combination

Bria-IMT™ Phase I/IIa Combination Therapy Trial



Combination Details:

- Treatment in combination with Keytruda® (Merck & Co., Inc.) q3wks x up to 24 cycles, then Bria-IMT alone q3wks
- Pre-dose low dose cyclophosphamide to reduce immune suppression
- Post-dose intradermal IFN-α2b to boost cell mediated immunity
- Imaging every 8 -12 weeks
- **First 11 patients have enrolled, and safety and tolerability is excellent**
- **Initial efficacy data suggests additive or synergistic activity**

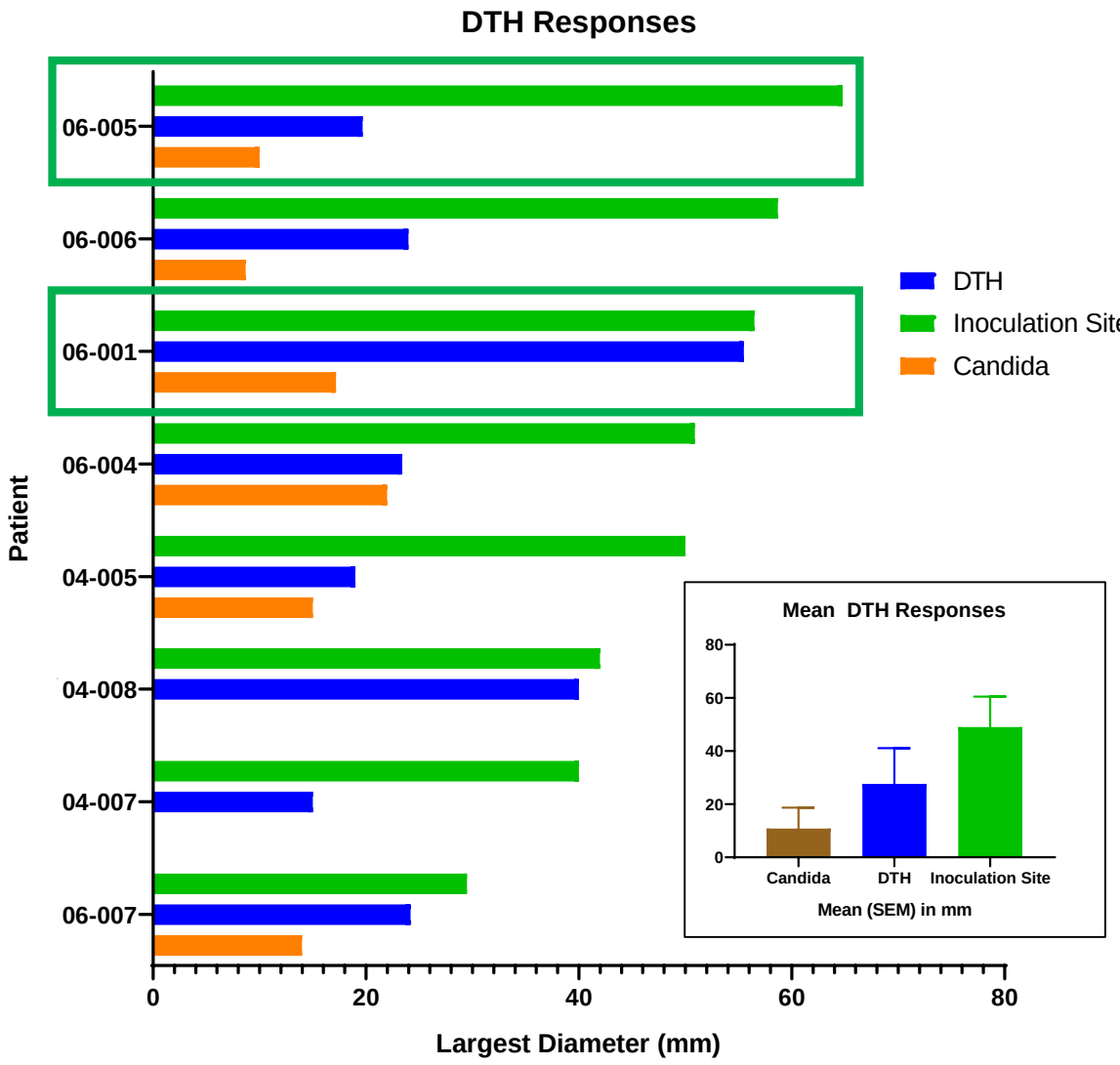
Bria-IMT™

Study BRI-ROL-001 – Combination Therapy Patient Characteristics

Patient Characteristics (11 total)	No HLA Allele Matches (n=4)	1+ HLA Allele Matches (n=7)	2+ HLA Allele Matches (n=5)	All Patients (n=11)
Age	61 ± 11	62 ± 9	62 ± 12	62 ± 9
Median Prior Systemic Regimens	6 (range 2-10)	4 (range 1-14)	4 (range 1-14)	4 (range 1-14)
% ER+ or PR +	75%	67%	50%	70%
% Her2/neu +	50%	50%	50%	50%
% Triple Negative	0%	0%	0%	0%

The patients are heavily pre-treated and generally similar regardless of HLA matching with Bria-IMT™

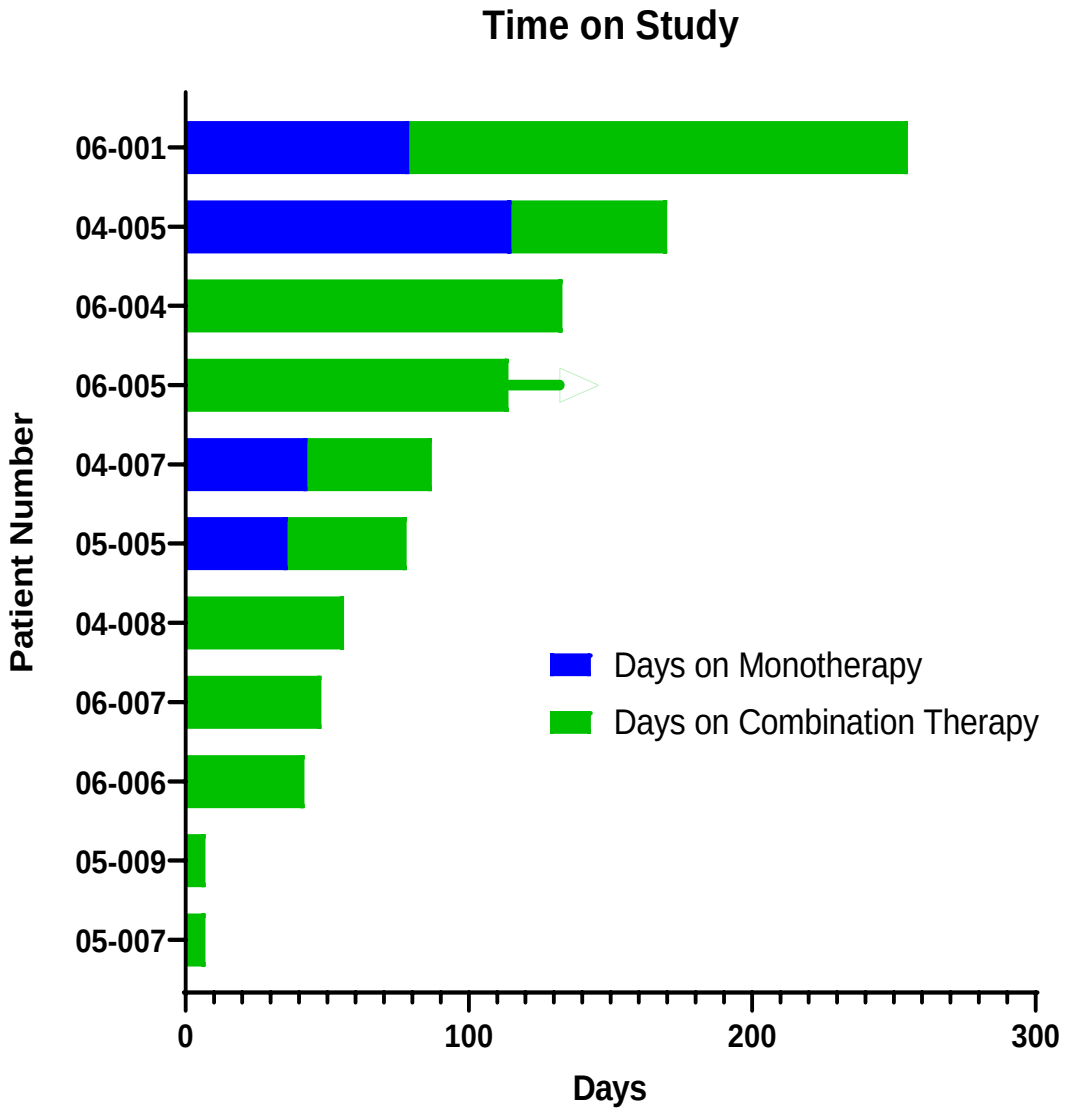
Delayed Type Hypersensitivity to Bria-IMT™



Rationale: Delayed-type hypersensitivity (DTH) is a good marker of cellular (T cell) immune responses. Candida (positive control) or $1x10^6$ irradiated Bria-IMT™ cells were injected intra-dermally in the forearm (DTH) and $5x10^6$ in 4 sites in the upper back and thighs (Inoculation Site). 2±1 days later, these sites were assessed for erythema and induration. The largest response (diameter of erythema or induration) for each patient is shown. The insert notes the mean DTH responses seen.

Conclusion: All the patients with follow-up information developed DTH to Bria-IMT™, despite anergy to test antigens (Candida) in some patients, indicating potent immunogenicity of Bria-IMT™. The most robust responses were seen in patients with objective tumor regression.

Bria-IMT™ Phase IIa Combination Therapy Time on Study



Blue indicates roll-over subjects time on Study 1
Green indicates time on combination therapy
Arrows → indicate ongoing in the study

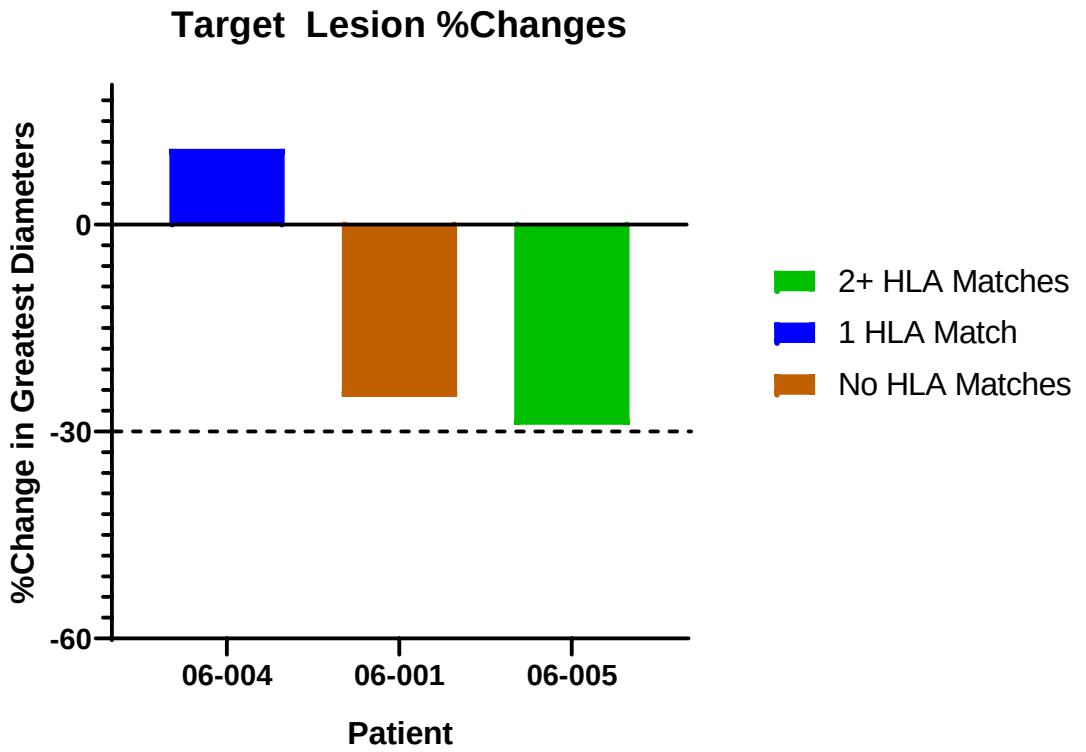
Results: To date treatment has been generally safe and well tolerated with no serious adverse events (AEs) or withdrawals from AEs.

Conclusion: The combination of the Bria-IMT™ regimen with pembrolizumab has been safe.

Tumor Responses and Serum Markers

Tumor Markers in Patients with Follow-up Information

	06-001	06-004	06-005
Baseline CEA	167.8	0.2	139.2
Initial Eval CEA	48.15 **(-68%)**	1.55	15.21 **(-89%)**
Baseline 15-3	196.5	93.4	1886
Initial Eval 15-3	114.9 **(-42%)**	114.4	533.7 **(-72%)**



- Patient 06-001: ER+/HER2-, Hepatic Metastases, Robust DTH, no HLA Matches with Bria-IMT™
- Patient 06-005: ER+/HER2-, Adrenal and Dural Metastases, Robust DTH, two HLA matches with Bria-IMT™

The Bria-IMT™ Regimen Combined With KEYTRUDA®: Patients with Robust DTH (06-001 and 06-005) had a Marked Reduction in Tumor Markers and Tumor Size, Suggesting that a Robust Immune Response Correlates with Tumor Regression even Without HLA Matching

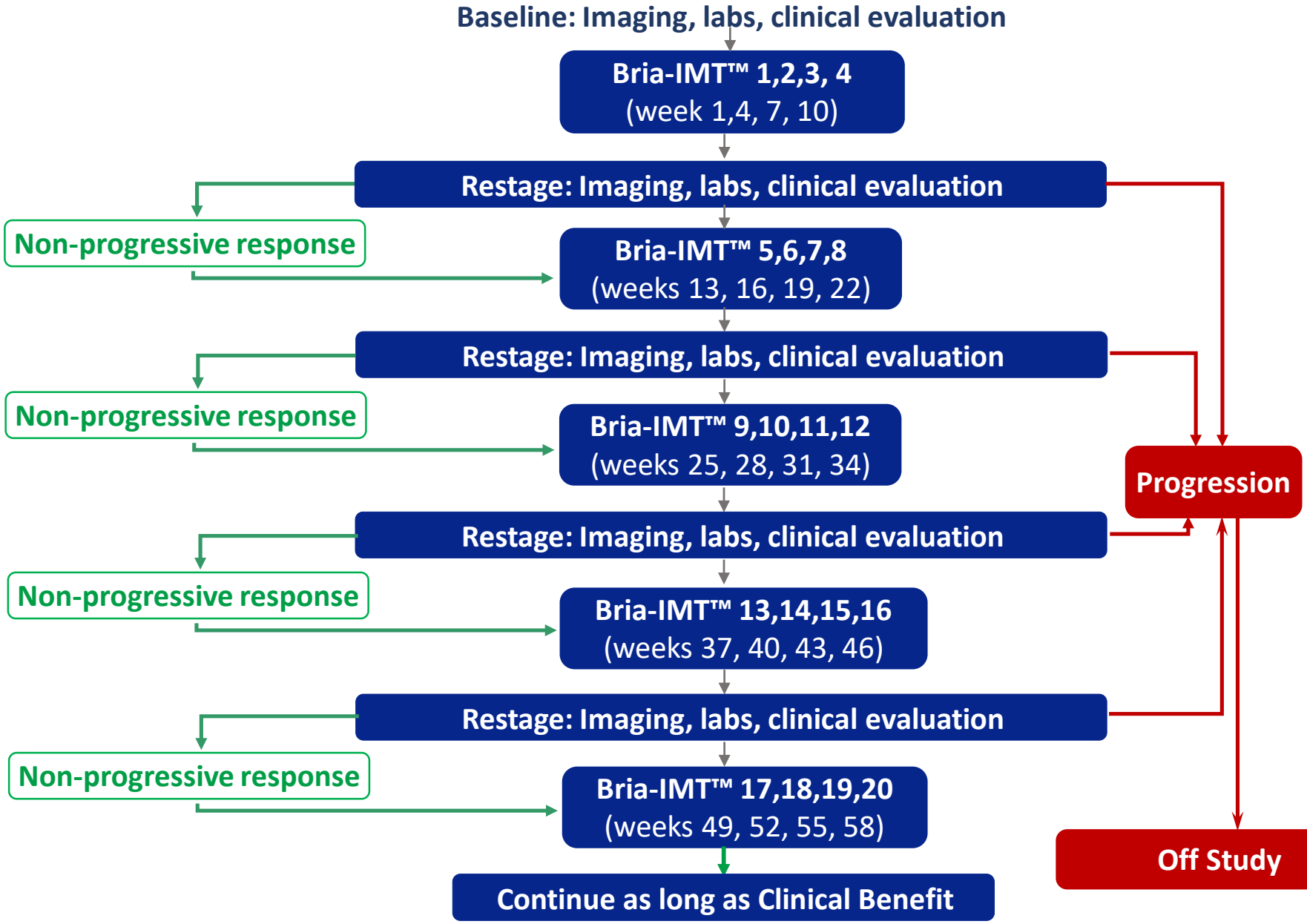
Characteristics of Responders

- **Patient 06-001**
  - 73-year-old woman
  - Ductal adenocarcinoma diagnosed April 2010
  - Stage IV Tumor grade II – Moderate
  - ER+, PR-, HER2-
  - 7 prior chemotherapy regimens with 9 agents + Avastin
  - Did not match at any HLA loci
  - Entered the monotherapy study with 4 liver metastases
  - One of the best immune responders (DTH & Ab)
  - Stable disease on monotherapy (slight increase in tumor sizes)
  - Reduction in all 4 liver metastases on combination therapy

- **Patient 06-005**
  - 70-year-old woman
  - Ductal adenocarcinoma diagnosed Dec 2009
  - Stage IV Tumor grade II – Moderate
  - ER+, PR-, HER2 1+
  - 12 prior regimens with 16 agents (13 chemo 3 hormonal)
  - Matched at 2 HLA loci – HLA-C and HLA-DRB3
  - Entered the monotherapy study with adrenal, bone and dural metastases
  - One of the best immune responders (DTH & Ab)
  - Reduction in adrenal (target) and dural metastases

The Bria-IMT™ regimen in combination with checkpoint inhibition can be effective even in patients who have failed multiple prior lines of therapy

Bria-IMT™ Phase I/IIa Combination with Incyte Drugs



Currently Recruiting:

- Treatment in combination of the Bria-IMT™ regimen with INCMGA00012 (anti-PD-1) and epacadostat (indoleamine dioxygenase inhibitor); cycles q3wks up to 24 cycles, then Bria-IMT™ alone q3wks
- Imaging every 8 -12 weeks
- **Initial cohort of 6 patients for the combination with INCMGA00012 alone**
- **Subsequent combination with epacadostat in successive cohorts of 6 patients**
- **Expansion at a dose of epacadostat that normalizes serum kynurenine**

BriaCell

Off-The-Shelf Personalized Immunotherapy Approach

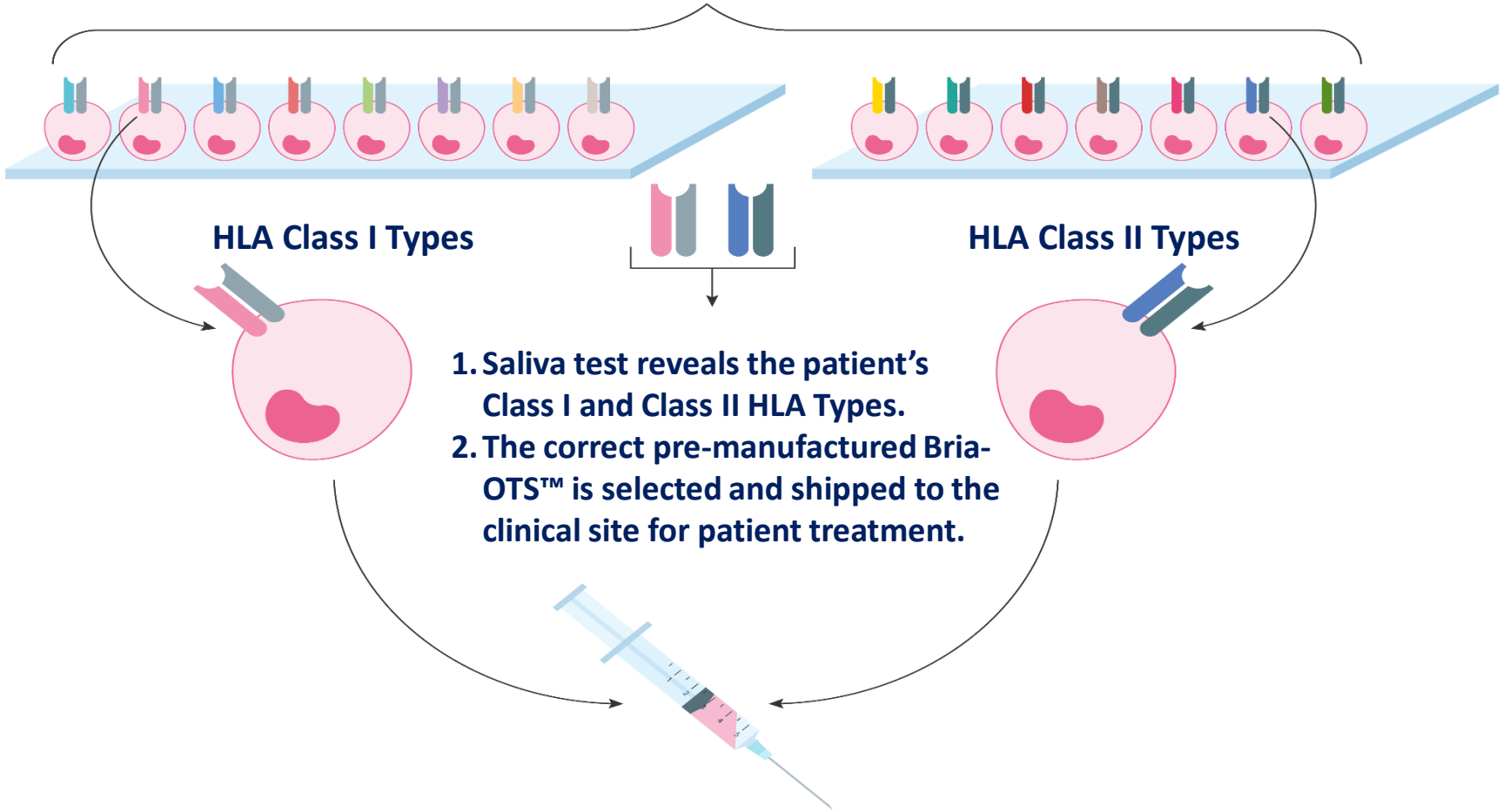
Personalized *Off-the-Shelf Immunotherapy*

- **The SV-BR-1 cell line is being modified to express both GM-CSF and interferon-α PLUS patient-specific matching HLA alleles**
- **Using 8 HLA-A alleles and 7 HLA-DRB3/4/5 alleles in a lentiviral expression system**
- **Cell lines will be pre-manufactured which express HLA alleles covering/matching with >99% of the overall advanced breast cancer population (double matches in ~90% of the population)**

Off-The-Shelf Personalized Immunotherapy Approach

15 Unique HLA Alleles for Tailored Immunotherapies

A simple test determines the correct "off-the-shelf" immunotherapy to select



Summary

Bria-IMT™: Breast cancer cell lines with dendritic cell characteristics

- Bria-IMT™ expresses multiple breast cancer associated antigens, and expresses multiple immune stimulating factors, including Class II HLA molecules
- **Bria-IMT™ has been shown to be able to directly activate CD4+ T cells**
- Bria-IMT™ has been in 2 phase I/IIa clinical trials in patients with late stage breast cancer
- Bria-IMT™ induces both delayed-type hypersensitivity and antibody responses
- **Several patients have responded with marked tumor shrinkage or other evidence of anti-tumor activity**
- For monotherapy patients, all patients with tumor shrinkage matched Bria-IMT™ at least at one HLA locus
- The ability to develop DTH also appears to correlate with clinical responses
- Circulating tumor cells or cancer-associated cells express PD-L1 in >90% of patients analyzed to date
- **Combination study with KEYTRUDA® shows evidence of additive or synergistic activity especially in patients with robust DTH responses**
- Under development – Bria-OTS™: a series of cell lines derived from the SV-BR-1 parent cell line that will express multiple HLA types to match >99% of the breast cancer population

Acknowledgements

Cancer Insight, LLC is BriaCell's Collaborator and CRO

George E. Peoples, CEO

Providence Regional Medical Center Everett

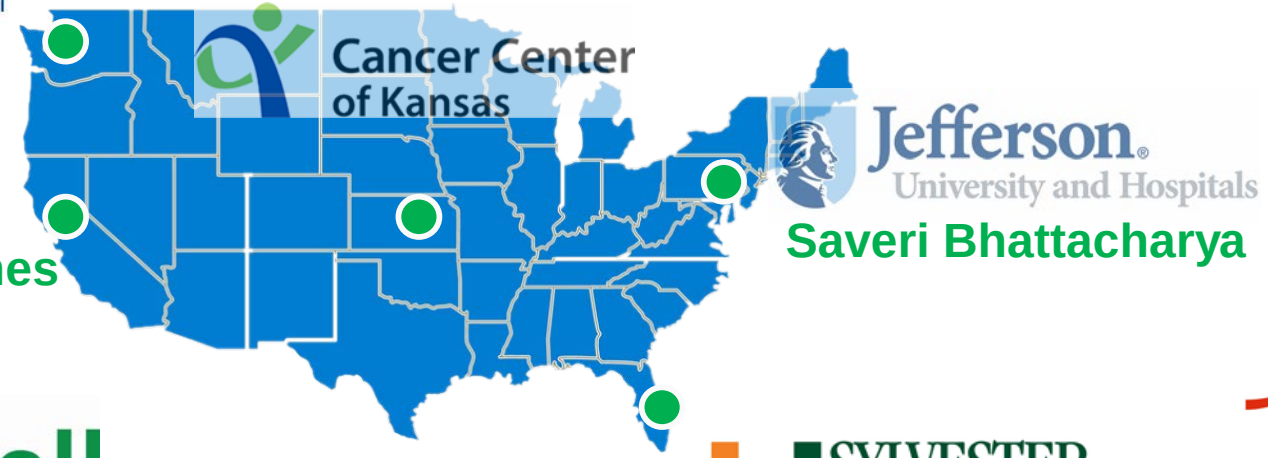
Ajay Kundra

St. Joseph Health

Jarrod P. Holmes

Shaker R. Dakhil

Cancer Center of Kansas



Jefferson University and Hospitals

Saveri Bhattacharya

UCDAVIS INSTITUTE FOR REGENERATIVE CURES

Keck Medical Center of USC

Keck Medicine of USC

BriaCell

William V. Williams

Markus Lacher

Vivek Sunkari

Charles L. Wiseman

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

Thank You!