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The Future of Cancer Immunotherapy

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Can Cancer Immunotherapy be both Personalized and Off-the-Shelf?

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Cancer Immunotherapy

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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-specific 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.

- **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's 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 parenteral injections of GM-CSF locally 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

- SV-BR-1 transfected with the CSF2 gene (encoding GM-CSF) to produce SV-BR-1-GM
- 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 SV-BR-1 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
- One patient with transient urticaria reported as grade 3, responded to antihistamines
- Median Overall Survival = 35 months
- One robust responder with >90% regression during treatment, subsequent relapse (upon halting treatment) responded to re-treatment
- She matched SV-BR-1-GM at the HLA-DRB3 locus

SV-BR-1-GM 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	

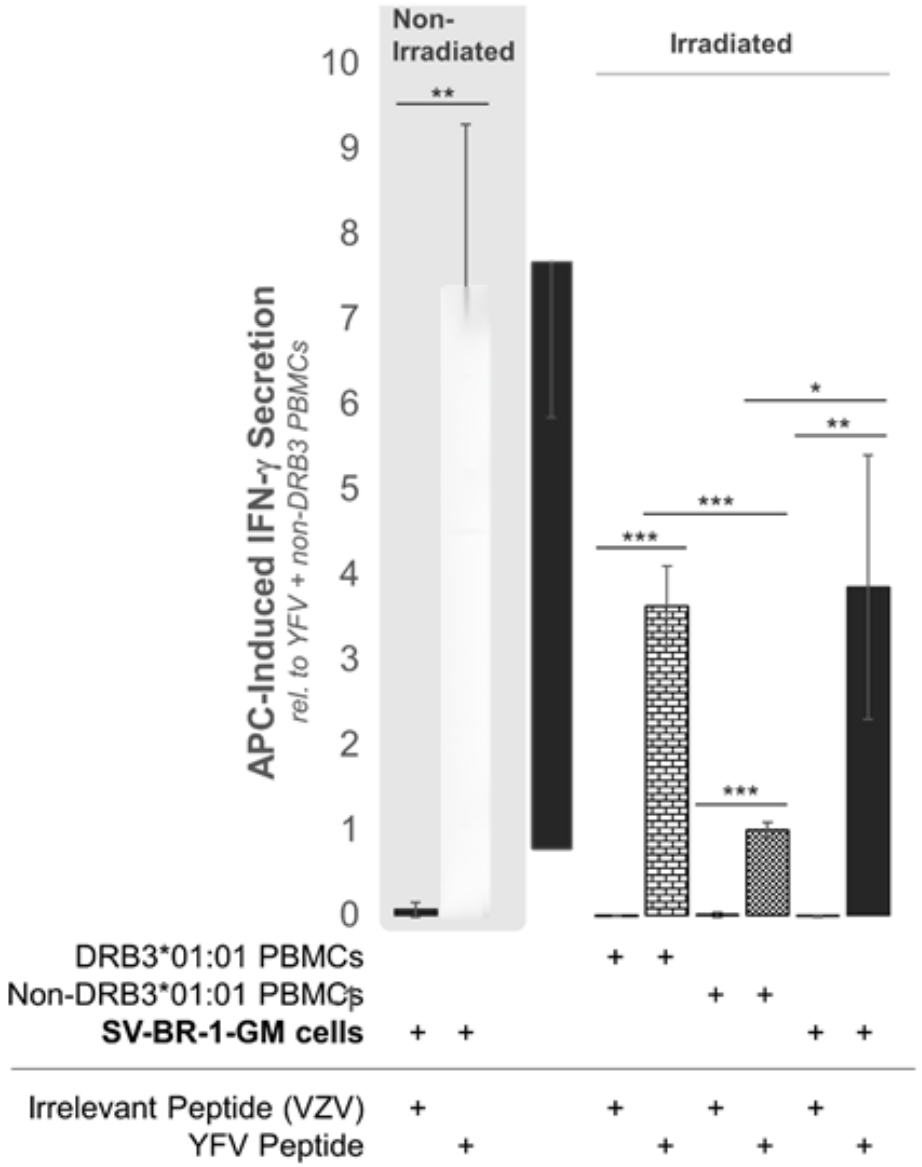
ERBB2, MIEN1, PGAP3, STARD3: on "HER2 amplicon

- SV-BR-1-GM expresses dozens of breast tissue and breast cancer antigens (by RNA-seq)
- This enhances the chance for a broad immune response against multiple breast tissue and breast cancer-related antigens
- There is evidence for immune responses against some of these antigens in patients treated with the SV-BR-1-GM regimen

SV-BR-1-GM Mechanism of Action

SV-BR-1-GM Acts as an Antigen-Presenting Cell

- SV-BR-1-GM cells were cultured and serum-starved for 24 h then coincubated 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, 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 (SV-BR-1-GM or PBMCs) were subtracted.
- Note that SV-BR-1-GM is as potent as DRB3*01:01 peripheral blood mononuclear cells



SV-BR-1-GM

Potential Mechanisms of Specific Immune Activation in Advanced Breast Cancer

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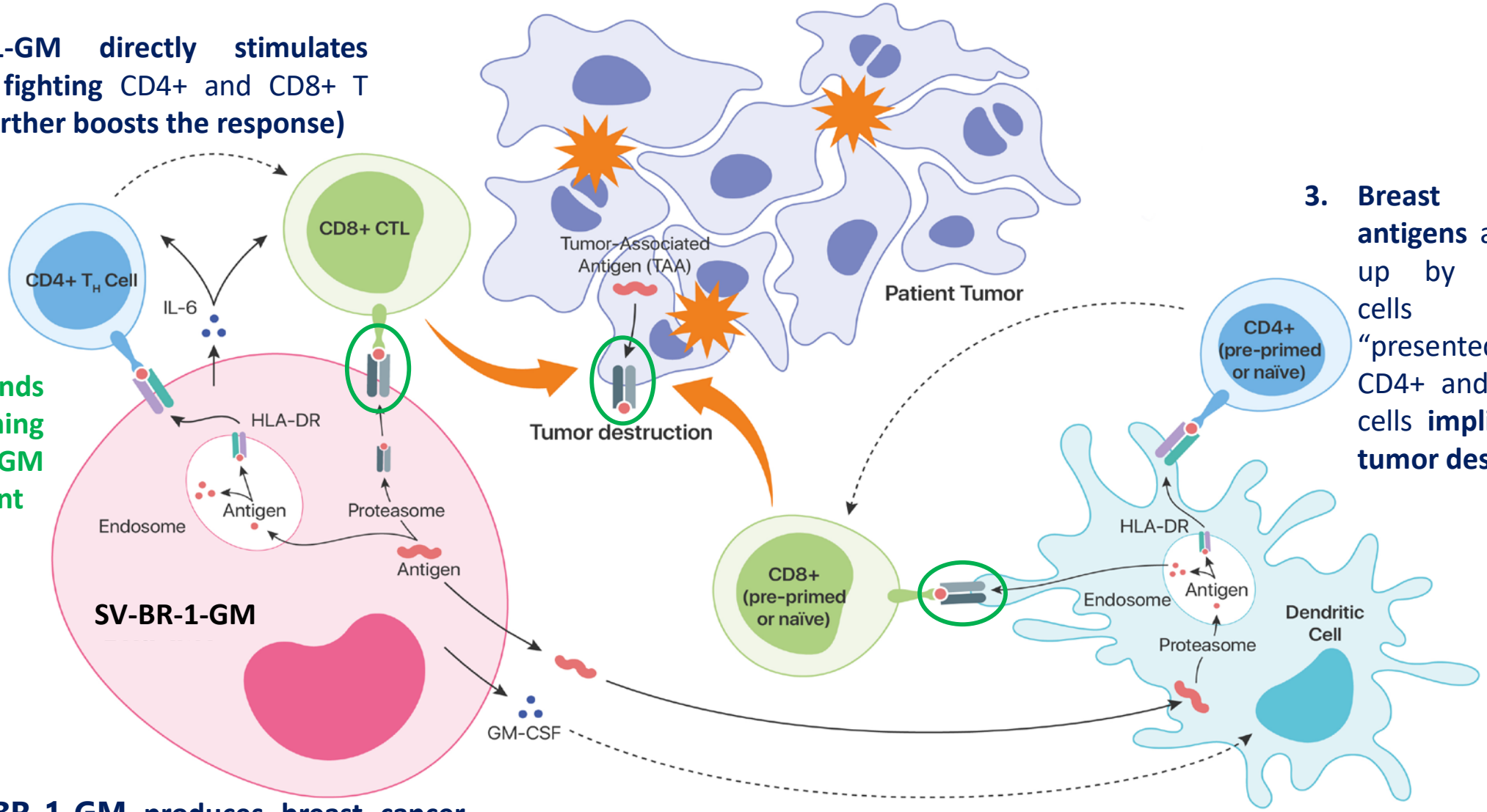
4. **SV-BR-1-GM directly stimulates cancer fighting** CD4+ and CD8+ T cells **(further boosts the response)**

5. **SV-BR-1-GM efficacy depends on HLA matching of SV-BR-1-GM and the patient**

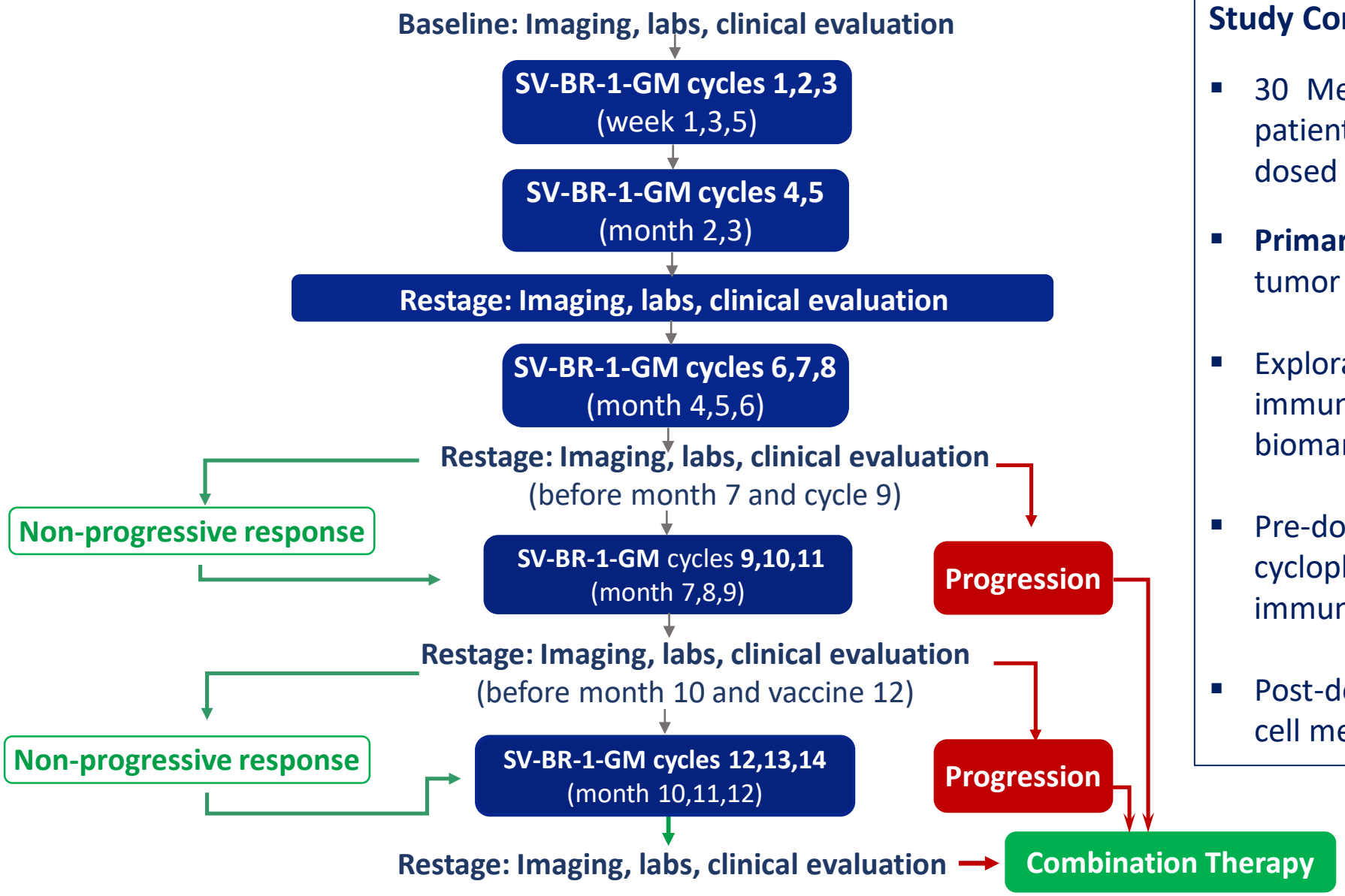


3. **Breast cancer antigens** are taken up by dendritic cells and "presented" to CD4+ and CD8+ T cells **implicated in tumor destruction**.

1. **SV-BR-1-GM produces breast cancer antigens** (proteins made by breast cancer cells)

2. **SV-BR-1-GM secretes GM-CSF** which further promotes dendritic cell-based antigen presentation (**boosts the response**)

SV-BR-1-GM 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 IFN-α2b to boost cell mediated immunity

SV-BR-1-GM

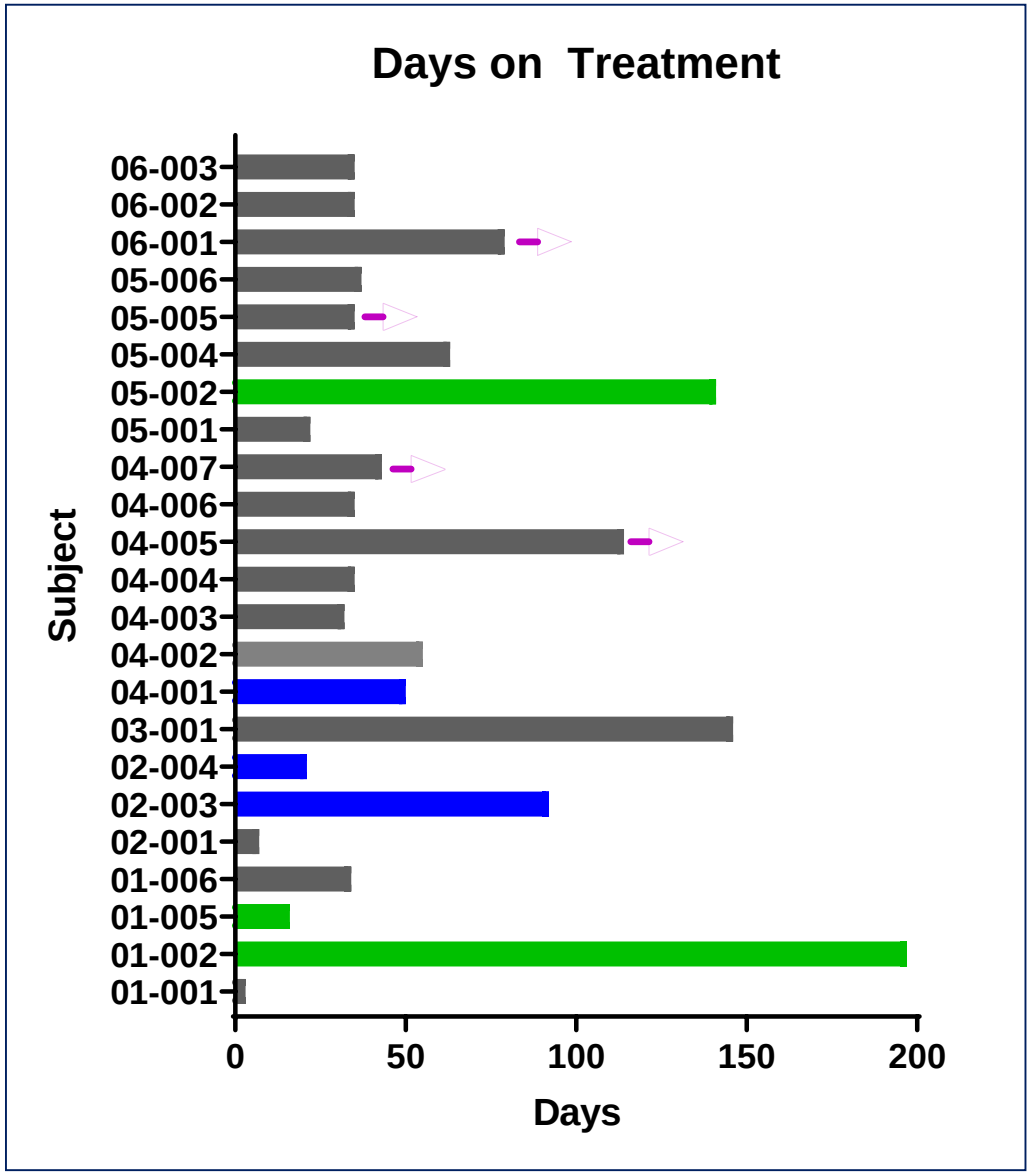
Study WRI-GEV-007 – Monotherapy Patient Characteristics

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 SV-BR-1-GM

SV-BR-1-GM

Study WRI-GEV-007 – Monotherapy Time on Study



Green bars indicate patients with objective evidence of tumor regression

Blue bars indicate patients with decreased circulating Cancer-Associated Macrophage-like Cells (CAMLs) compared to baseline

Arrows → indicate the patients rolled over to combination therapy

Conclusion: In spite of being very heavily pre-treated (median of 4 prior chemotherapy /biological therapy regimens), patients were able to remain on the SV-BR-1-GM regimen for protracted periods of time.

SV-BR-1-GM
Study WRI-GEV-007 – Monotherapy Safety Data

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Adverse Events seen in 2 or More Patients

AE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Erythema	34				
Fatigue	4	1			
Flu Like Symptoms	2	1			
Injection Site Reaction	3				
Constipation	3				
Diarrhea	3	1			
Increased Peritoneal Fluid		2			
Nausea	3				
Sensory Neuropathy	2				
Induration	23				
Pruritus	10	2			
Rash	2				
Urticaria	3				

Serious Adverse Events

Body System	AE Term	Severity
Respiratory	Respiratory Failure	Grade 4
Cardiac	Restrictive Cardiomyopathy	Grade 5
Nervous System	Dizziness	Grade 2
Respiratory	Pleural Effusion	Grade 4
Metabolism and nutrition disorders	Dehydration	Grade 3

- **None of the Serious Adverse Events were considered Related to SV-BR-1-GM**

Conclusion: SV-BR-1-GM was generally safe and well tolerated

SV-BR-1-GM - Efficacy as Predicted

- **SV-BR-1-GM appears to be most effective in patients who match with SV-BR-1-GM at HLA loci (types) further supporting our "HLA Matching Hypothesis"**

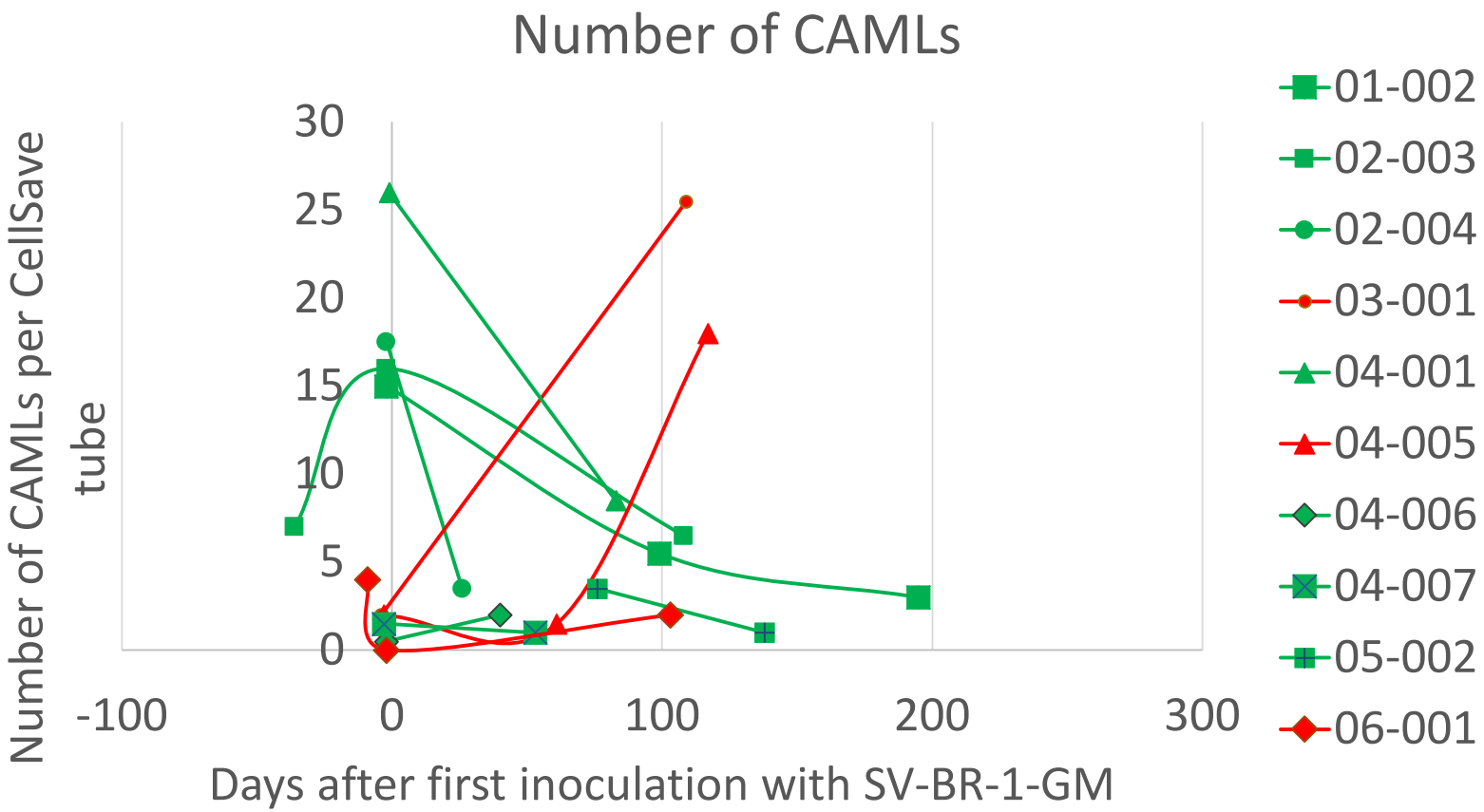
HLA Matching and Biological Activity

Patients (n)	HLA Match	Tumor Shrinkage	Biological Response*
4	≥2	50%	75%
17	≥1	18%	35%
6	0	0%	0%

*Biological response includes tumor shrinkage or lower circulating cancer associated cells

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

Circulating Cancer-Associated Macrophage-Like Cells

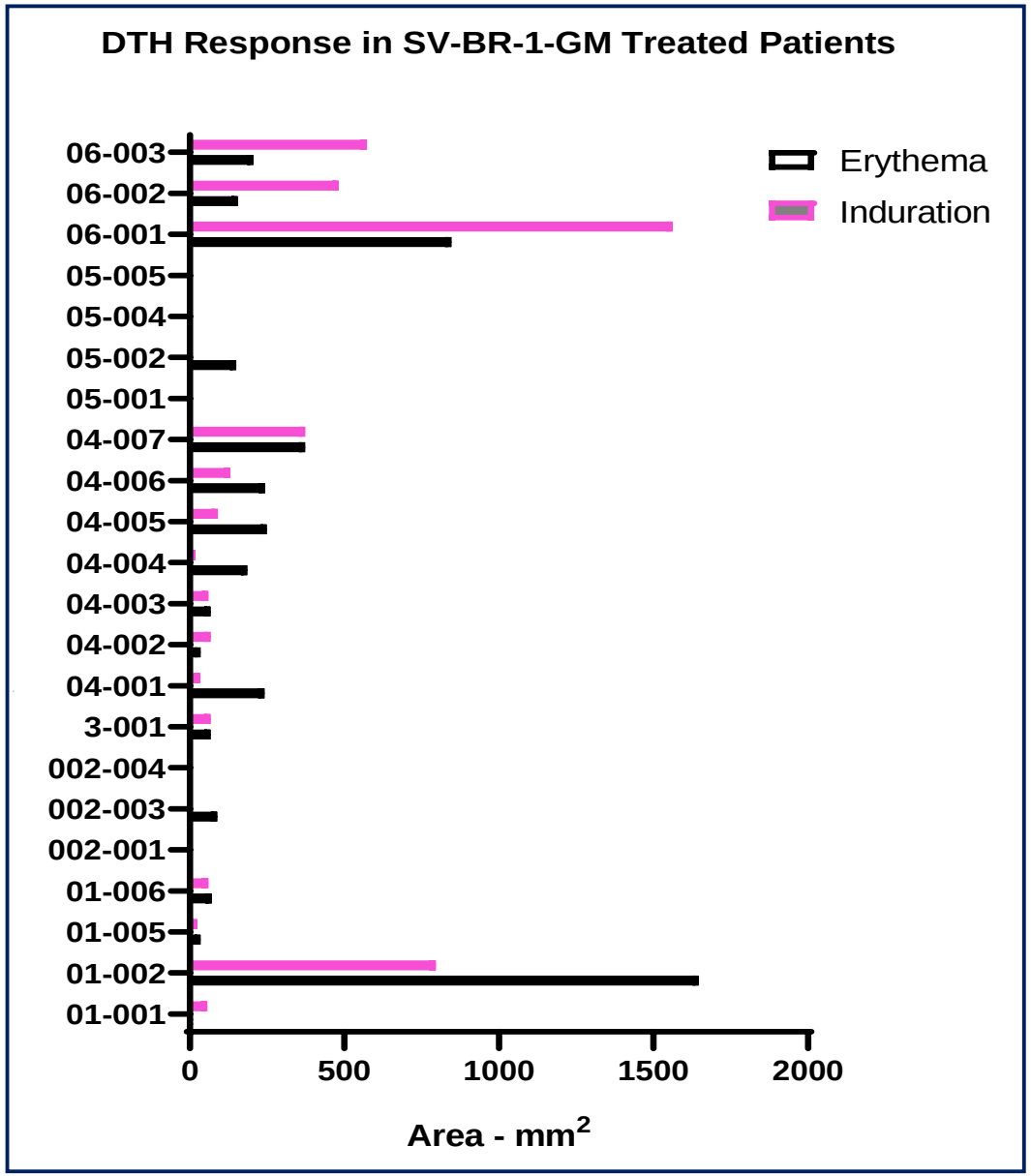


CAMLs are giant macrophage-like cells associated with patient tumors and found in the circulation of cancer patients from a variety of cancer types. The presence of tumor markers in CAMLs suggests that CAMLs phagocytose tumor material. Reduction in CAML frequency and max. CAML size following treatment may indicate a favorable prognosis.

Reduction of CAML numbers in subjects with at least 1 HLA allele match to SV-BR-1-GM (green) compared to mismatching subjects (red). Subjects **01-002** and **05-002** experienced tumor regressions.

Conclusion: Reductions in CAMLs (a marker of tumor bulk) appear to decrease in responders and especially are seen in in HLA matched patients treated with SV-BR-1-GM.

SV-BR-1-GM - Delayed Type Hypersensitivity to SV-BR-1-GM



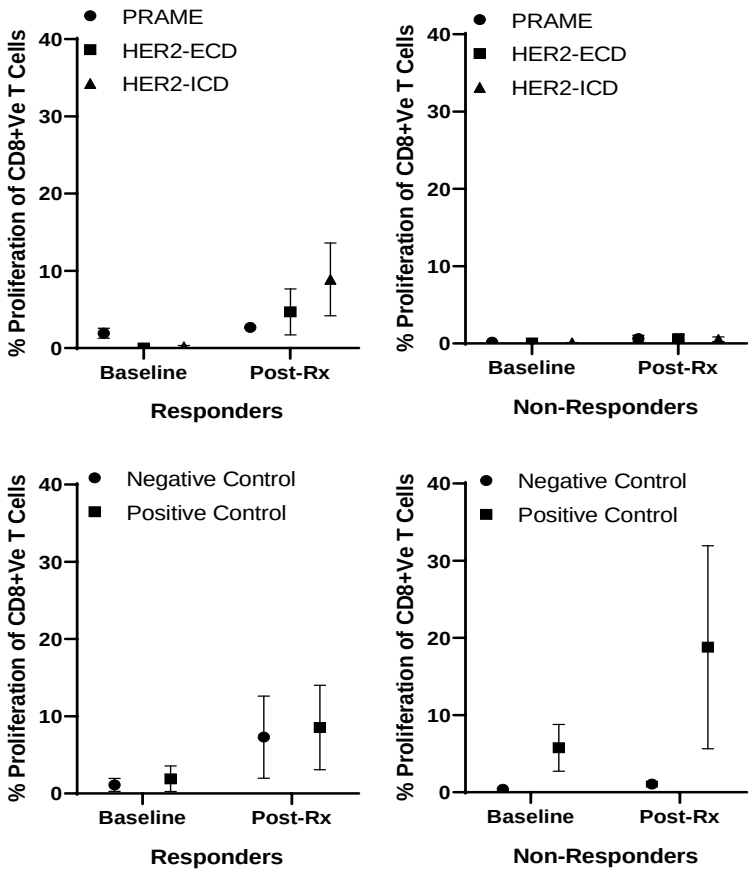
Rationale: Delayed-type hypersensitivity (DTH) is a good marker of cellular (T cell) immune responses. Briefly, for each cycle, SV-BR-1-GM was injected intra-dermally with 5 x 10^6 irradiated cells in 4 sites in the upper back and thighs.

2 ±1 days later, these sites were assessed for erythema and induration. The largest average response (size) for each patient (induration and corresponding erythema), with largest induration used to determine which of the 4 inoculation sites was chosen for analysis.

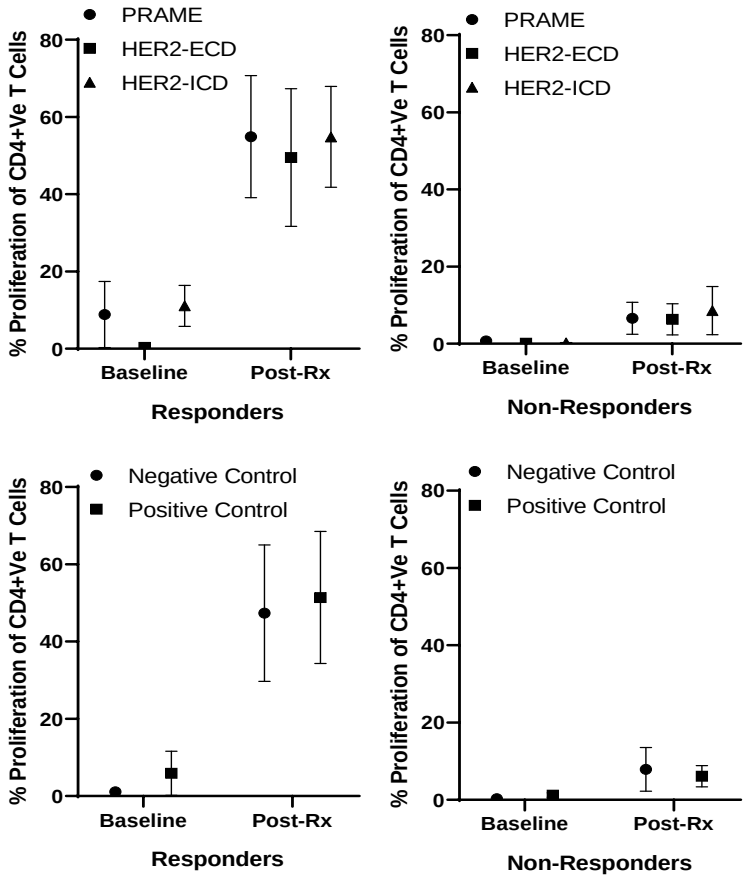
Conclusion: A substantial proportion of patients with follow-up information develop DTH to SV-BR-1/SV-BR-1-GM, in spite of anergy to test antigens (Candida) in some patients. The most robust response was seen in a patient with regression of multiple pulmonary metastases (01-002).

SV-BR-1-GM Treatment Enhances Immune Responsiveness

CD8+



CD4+



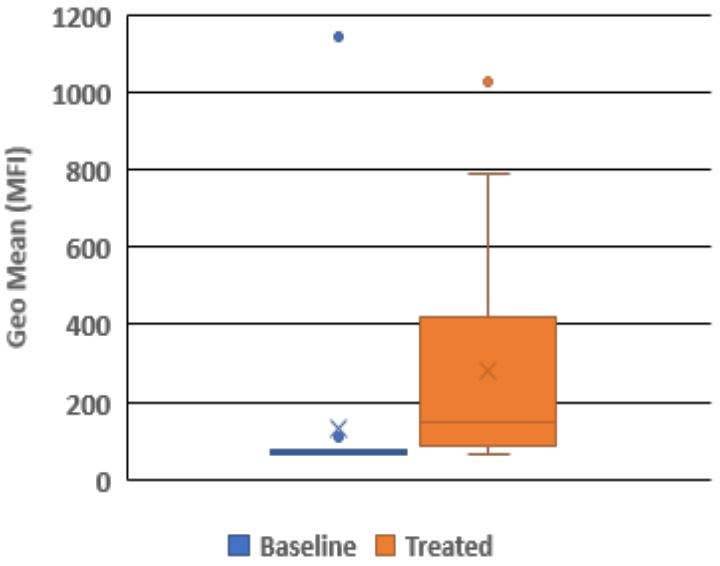
T cell responses to PRAME (a cancer testis antigen) and HER2/neu peptides (ECD = extracellular domain; ICD = intracellular domain) in patients with and without tumor regression

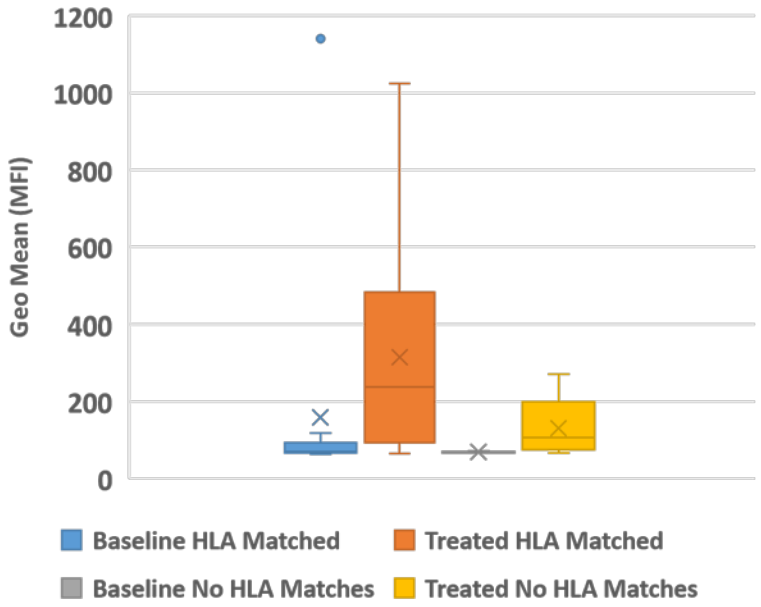
Working Model - Tumor regression requires: HLA matching to SV-BR-1-GM and the ability to mount a cellular immune response (DTH and *ex vivo* T cell proliferation)

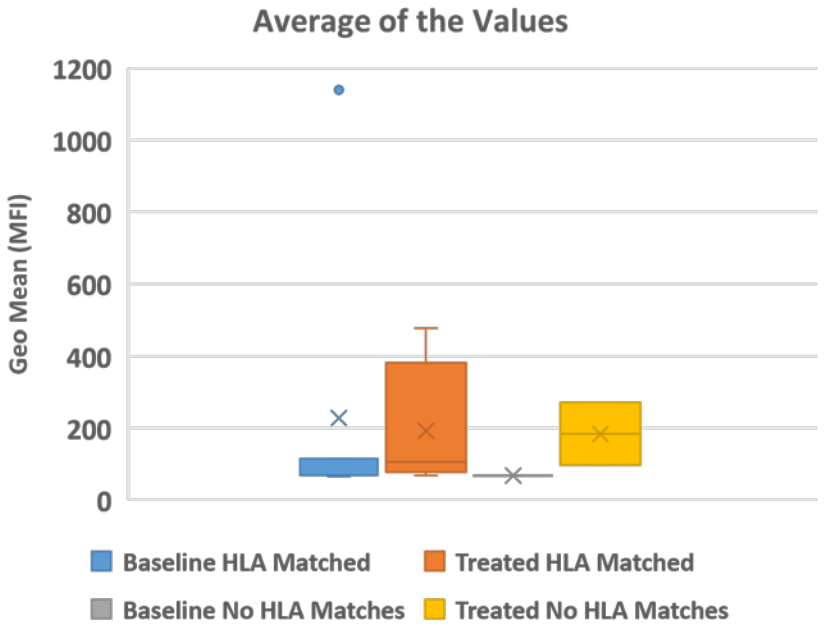
Conclusion: Responders with tumor regression have a higher propensity to develop T cell responses to the cancer-related antigens PRAME and HER2/neu.

BCT.V; BCTXF

Anti-SV-BR-1 Antibodies in Patients







Anti-SV-BR-1 antibody titers in patient sera. SV-BR-1 cells were incubated with 1:10 diluted patient sera then stained with fluorescently labeled anti-human IgG and analyzed by flow cytometry. **A.** Anti-SV-BR-1 antibodies in all patient's sera samples. **B.** Data as in A. but samples segregated either as HLA matched (≥ 1 allele) or non-HLA matched. Baseline: before treatment with first dose of SV-BR-1-GM.

Conclusions: IgG responses to SV-BR-1 are elicited by SV-BR-1-GM treatment. Robust antibody responses to SV-BR-1 are seen in patients treated with SV-BR-1-GM.

SV-BR-1-GM - Efficacy Dependent on Ability to Develop DTH

- **SV-BR-1-GM appears to be most effective in patients who match with SV-BR-1-GM at HLA loci and are able to develop a DTH response to SV-BR-1-GM**

HLA Matching and DTH Responses

Patients (n)	No HLA Match (n=6)	1+ HLA Match (n=15)	2+ HLA Matches (n=4)	All Patients (n=23)
No DTH (n=8)	0%	0%	0%	0%
+ DTH (n=17)	0%	33%	67%	23%

- Note that patients who were anergic to candida antigen at baseline were able to mount a DTH response to SV-BR-1-GM and did have evidence of clinical responses in some cases

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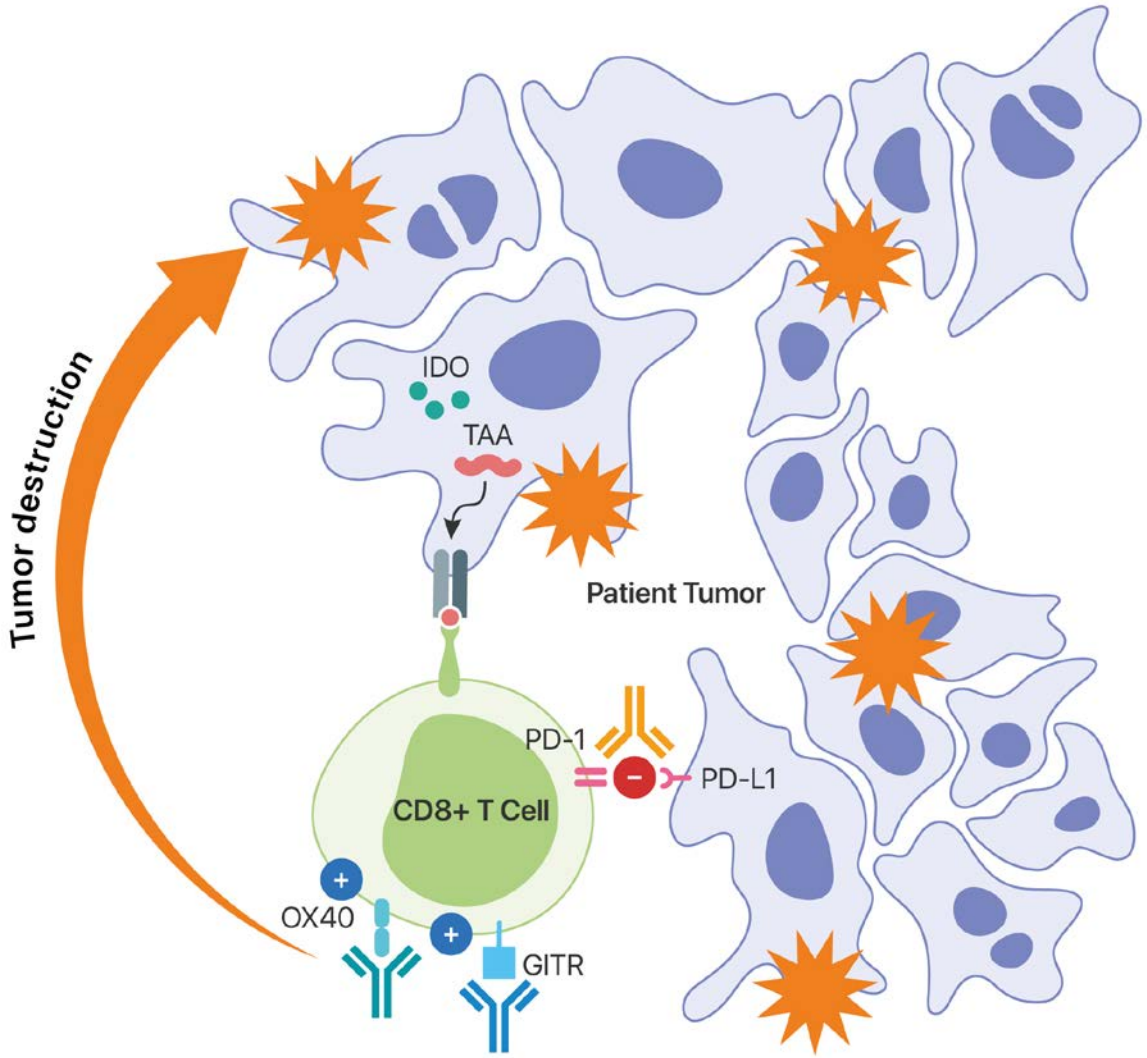
SV-BR-1-GM Combination Therapy

SV-BR-1-GM & Bria-OTS™
Immunotherapy Combination Considerations

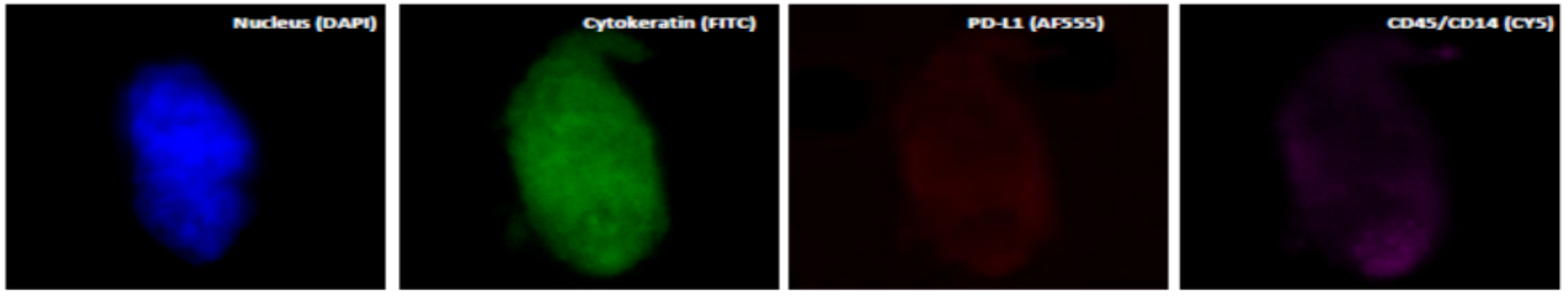
- SV-BR-1-GM and Bria-OTS™ should **synergize with existing approved immunotherapies** as well as those still under development
- This includes immune checkpoint inhibitors such as antibodies to PD-1, CTLA-4, GITR and CD73 and IDO inhibitors which **eliminate tumor immunosuppression**
- **Checkpoint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

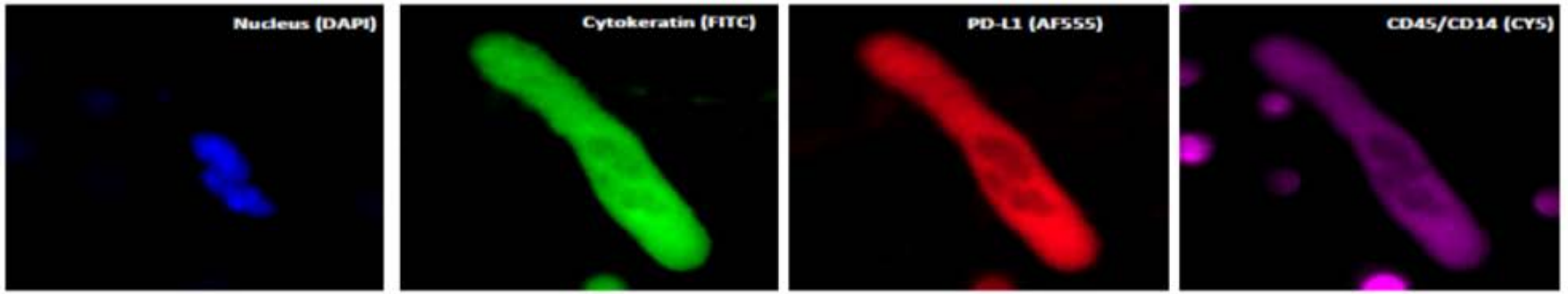


CTC & CAML PD-L1 expression

- 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 increased from 97 ±7 to 437 ±72 (SEM). Representative Photos are Shown Below

Pre-Treatment PD-L1 Expression Level 105

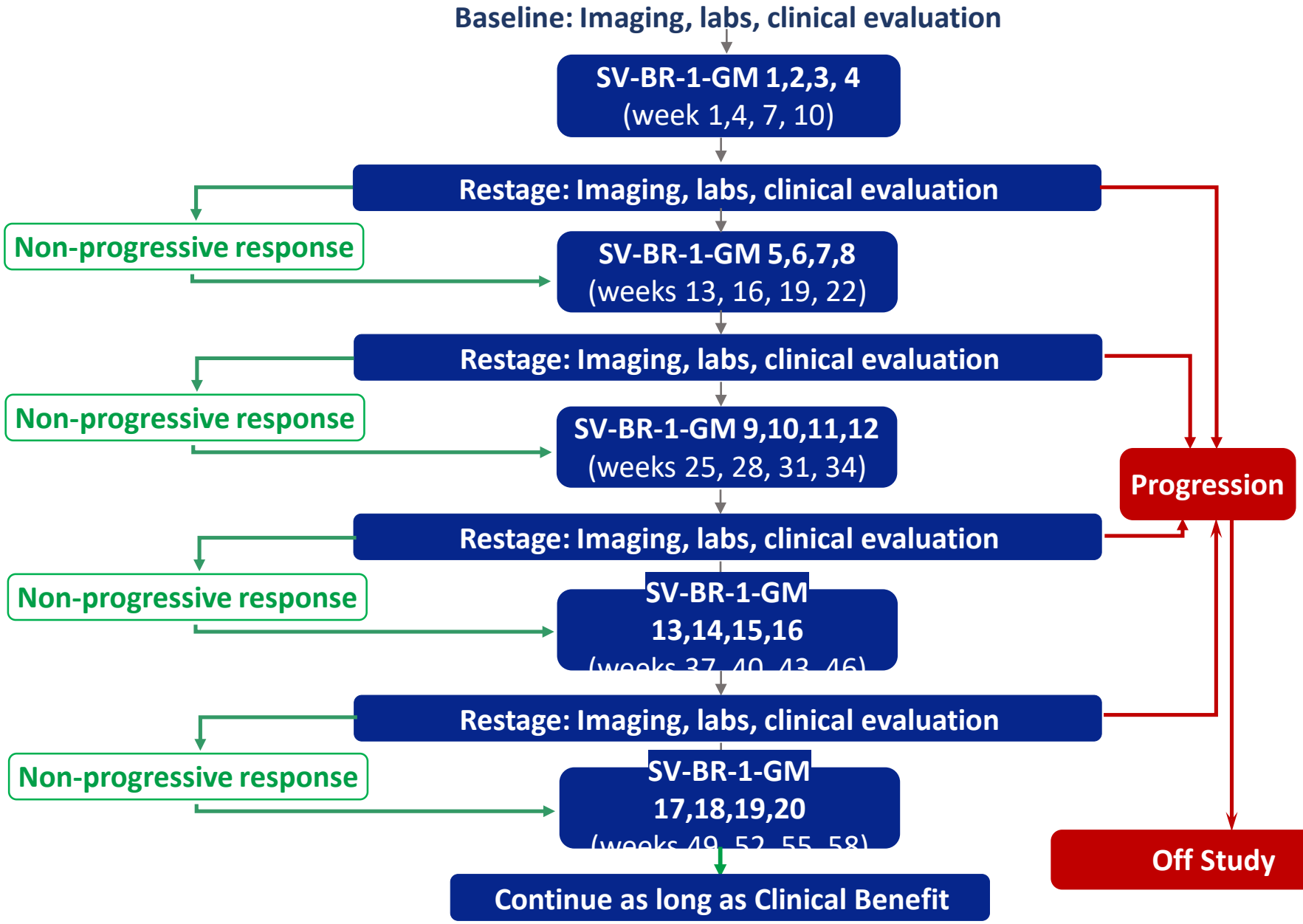




Post-Treatment PD-L1 Expression Level 815

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

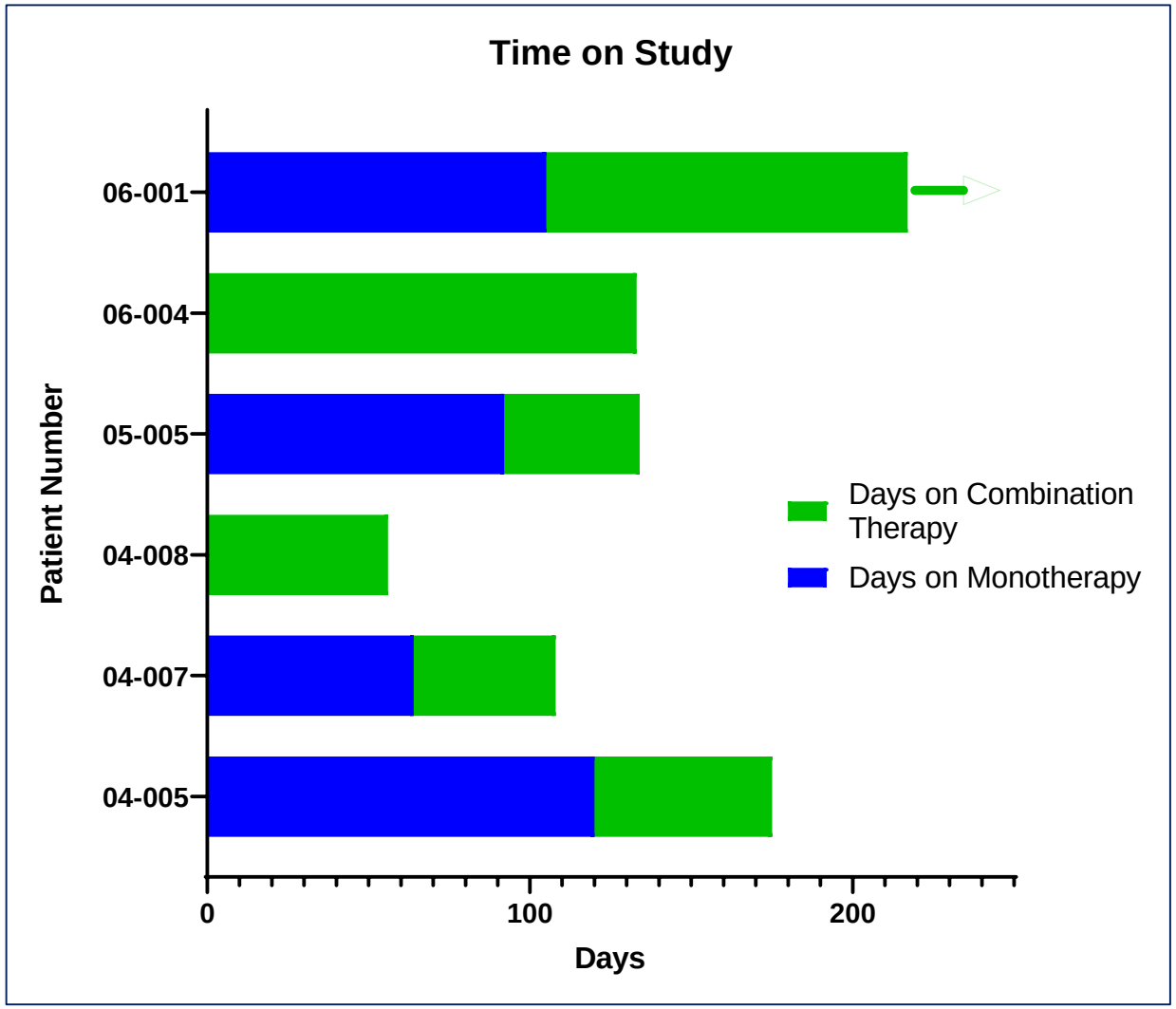
SV-BR-1-GM Phase I/IIa Combination Therapy Trial



Currently Recruiting:

- Treatment in combination with Keytruda® (Merck & Co., Inc.) for PD-L1(+) or PD-L2(+) tumors q3wks x up to 24 cycles, then SV-BR-1-GM alone q3wks
- Imaging every 6 -12 weeks
- **First 6 patients have enrolled and safety and tolerability is excellent**
- **Initial efficacy data shows evidence of additive of synergistic activity**

SV-BR-1-GM 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 subjects 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 SV-BR-1-GM regimen with pembrolizumab has been safe. The study is ongoing.

Patient Characteristics and Best Response for the SV-BR-1-GM Regimen

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Subject	Age Ethnicity	HLA Allele Matches	Tumor Characteristics			Prior Therapies	Cycles on Monotherapy Study – Best Response on Monotherapy	Cycles on Combo Study – Best Response on Combo
			Her2	ER	PR			
04-005	62 yo WF	0	2+	+	+	4 chemo 2 hormonal	5 - PD	3 – PD
04-007	66 yo WF	1	0	+	+	3 chemo 1 hormonal	3 - PD	2 – Hospice
04-008	63 yo WF	0	0	+	+	2 chemo 1 hormonal	0	3 – PD
05-005	64 yo WF	3	2+	0	0	4 chemo	3 - PD	2 – Hospice
06-004	59 yo WF	1	2+	+	+	3 chemo 3 targeted 3 biol. 5 hormonal	0	7 – SD
06-001	73 yo WF	0	0	+	0	8 chemo, 1 biological	4 - SD	6 – SD

A 17% decrease in target lesion diameters was noted for patient 06-001.

Bi-dimensional measurements of all lesions in patient 06-001 showed a 43% decrease.

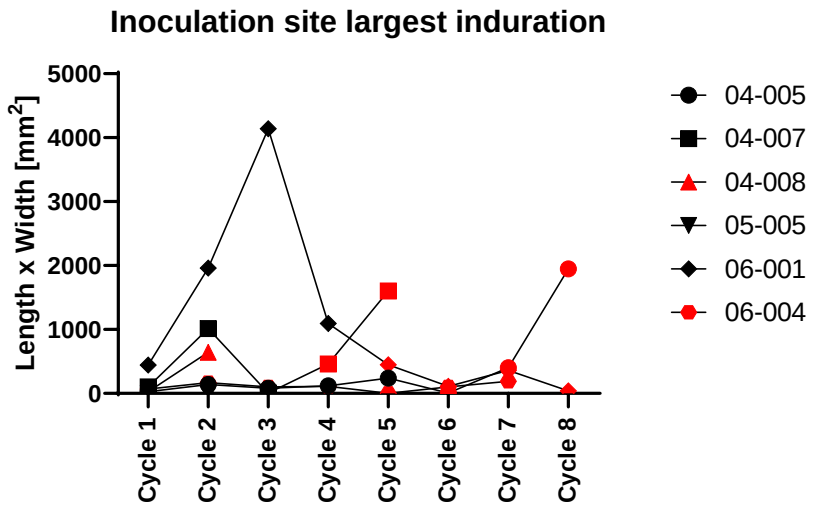
Serum Biomarkers – decrease in responding subject (06-001)

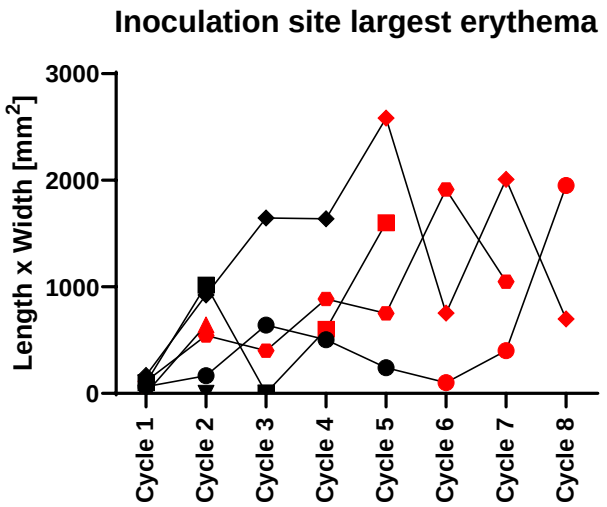
	04-005	04-007	04-008	05-005	06-004	06-001
Baseline CEA	11.6	17.7	2.6	1.3	0.2	167.8
Baseline 15-3	47	748	22	16.2	93.4	164.4
Initial Eval CEA	*	*	*	*	1.55	48.15
Initial Eval 15-3	*	*	*	*	114.4	114.9

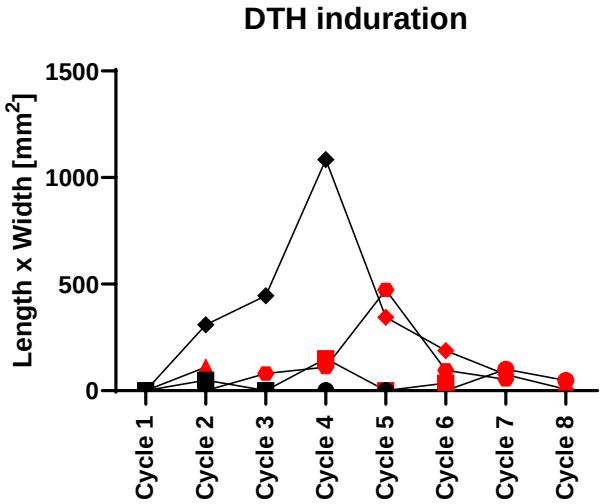
* not available

SV-BR-1-GM Combined With KEYTRUDA®: Patient 06-001 (best responder) has continued Improvement in Cancer Markers

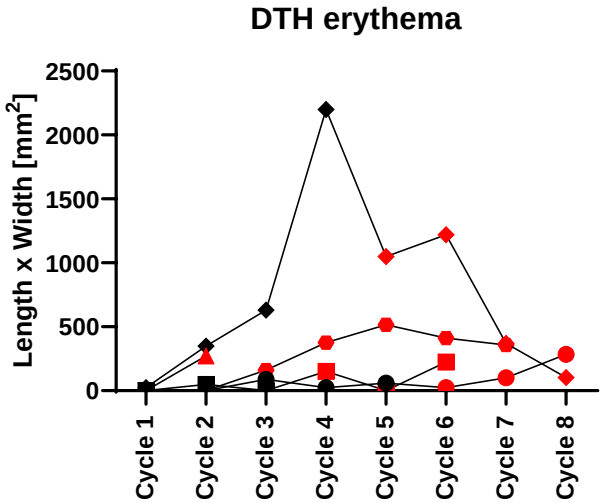
Delayed-Type Hypersensitivity Responses for SV-BR-1-GM







Black dots are from the monotherapy study, red dots from the combination therapy study



Robust DTH Responses Correlate with Clinical Response to SV-BR-1-GM With pembrolizumab

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 (Bavencio)
  - **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)

- Patient 06-001 was not TNBC, so the chances this was due to KEYTRUDA® is almost nil

PD-1 and PD-L1 Inhibitors are Ineffective as Monotherapy in Breast Cancer →
Responses seen to SV-BR-1-GM Combined With KEYTRUDA® unlikely due to KEYTRUDA alone

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Off-The-Shelf Personalized Immunotherapy Approach

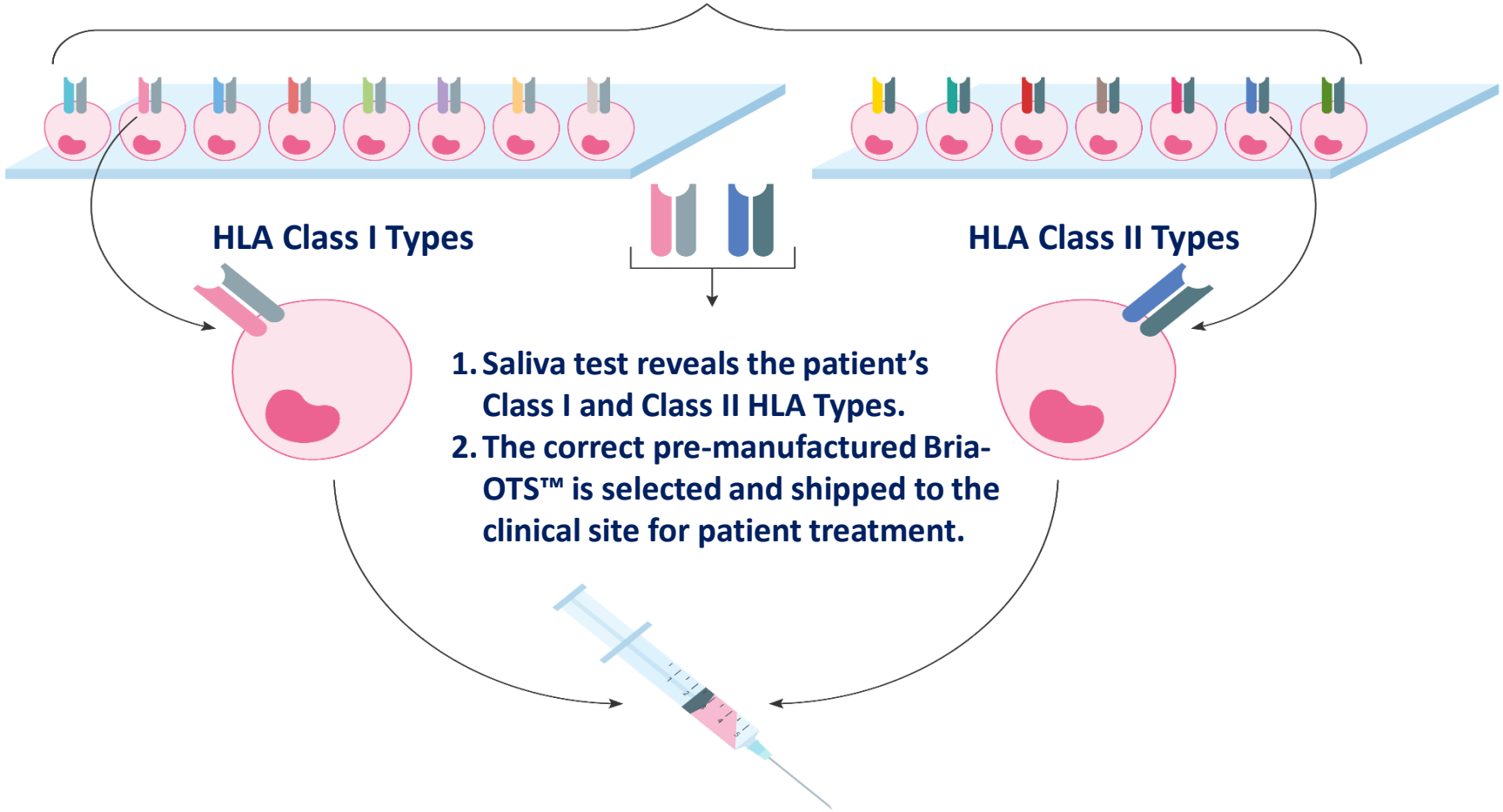
Personalized *Off-the-Shelf Immunotherapy*

- 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-BDRB3/4/5 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



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Timelines, Milestones and Catalysts

Summary

SV-BR-1-GM: Breast cancer cell lines with dendritic cell characteristics

- SV-BR-1-GM expresses multiple breast cancer associated antigens, but also expresses multiple immune stimulating factors, including Class II HLA molecules
- **SV-BR-1-GM has been shown to be able to directly activate CD4+ T cells**
- SV-BR-1-GM has been in 2 phase I/IIa clinical trials in patients with late stage breast cancer
- SV-BR-1-GM 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 with tumor shrinkage matched SV-BR-1-GM 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**
- Under development – a series of cell lines derived from the SV-BR-1-GM parent cell line that will express multiple HLA types to match >99% of the breast cancer population

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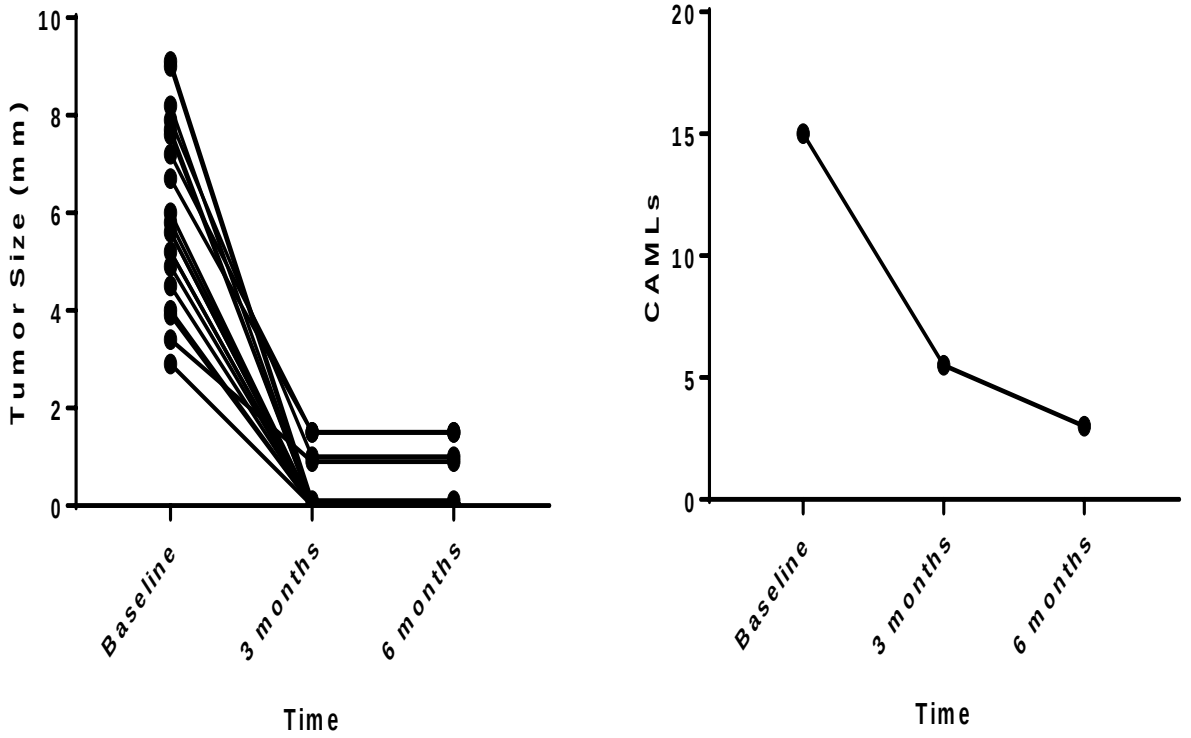
Additional Clinical Data

SV-BR-1-GM Responders: *Patient 01-002*

- Patient 01-002 is a 73-year-old woman with breast cancer diagnosed in 1995. She developed liver metastases in 2010, and lung metastases in 2017.
- Previously treatment included 7 rounds of chemotherapy with 8 different chemotherapy agents.
- She received 5 cycles of SV-BR-1-GM over 3 months, then monthly cycles (6 months total).
- Evaluated after 3 months and 6 months showed a clear response in the multiple bilateral pulmonary nodules".
- Cancer-associated macrophage-like cells (CAMLs) also decreased
- The response was maintained after 6 months of SV-BR-1-GM treatment.
- The liver tumors were stable to slightly increased at 3 months, and then progressed after 6 months.
- She matched SV-BR-1-GM at 2 HLA types
- This supports our hypothesis of heightened anti-tumor activity in patients with a matched HLA types.

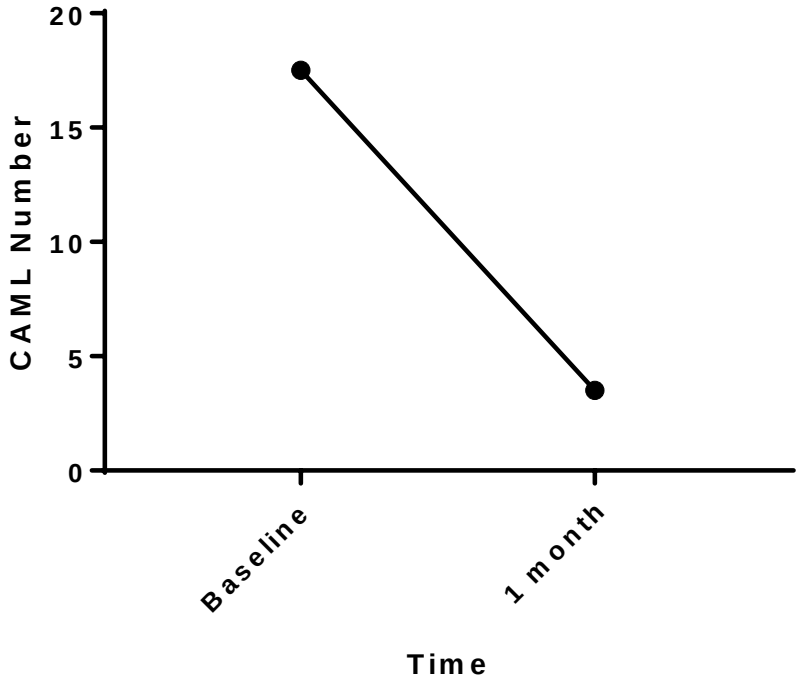
Lung Metastases Size and Cancer Associated Cells Decrease with Treatment



SV-BR-1-GM Responders: *Patient 02-004*

- Patient 02-004 is a 74-year-old woman with breast cancer diagnosed in 2014. Her breast cancer spread to the skin and was of the inflammatory type.
- Previously treatment included 3 rounds of chemotherapy with 10 different chemotherapy or biological agents.
- She received 2 cycles of SV-BR-1-GM and developed worsening breast inflammation.
- She discontinued the study due to the worsening inflammation and was lost to follow-up
- She was noted to have a marked reduction in circulating cancer-associated cells.
- She matched SV-BR-1-GM at 2 HLA types

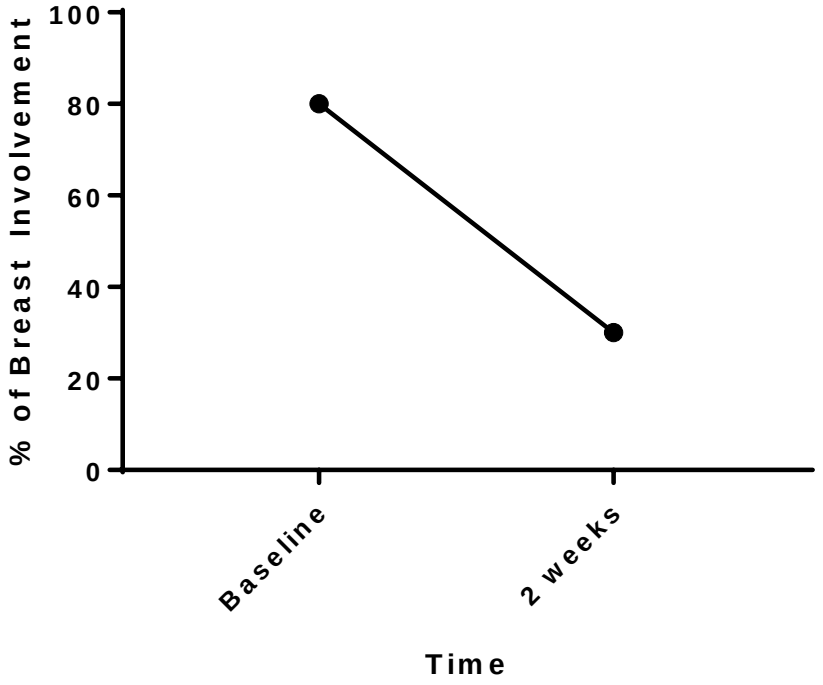
Circulating Cancer Associated Cells Decrease with Treatment



SV-BR-1-GM Responders: *Patient 01-005*

- Patient 01-005 was a 54-year-old woman with breast cancer diagnosed in 2014. Her breast cancer spread to the skin and involved ~80% of the breast.
- Previously treatment included 3 rounds of chemotherapy with 5 different chemotherapy or biological agents.
- She received 2 cycles of SV-BR-1-GM and had a marked improvement in the breast with reduction to ~30% involvement after the first treatment.
- She developed restrictive cardiomyopathy and died (judged unrelated)
- She matched SV-BR-1-GM at the HLA-A type

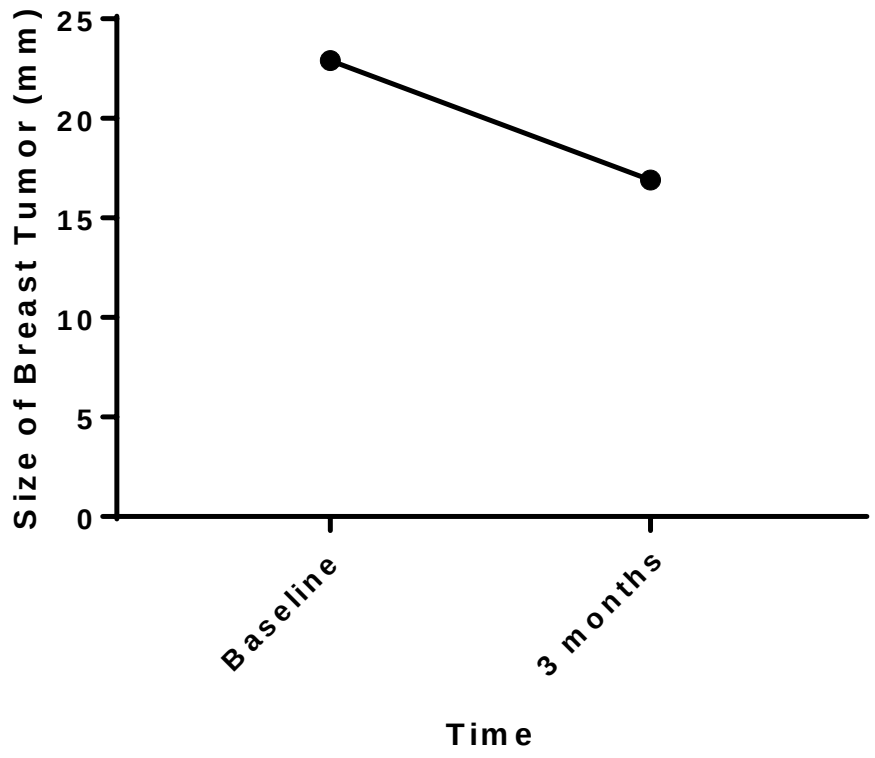
Cutaneous Breast Involvement Decrease with Treatment



SV-BR-1-GM Responders: *Patient 05-002*

- Patient 05-002 is a 59-year-old woman with breast cancer diagnosed in 2011. Her breast cancer spread to the bone and the liver.
- Previously treatment included 3 rounds of chemotherapy with 5 different chemotherapy agents, radiation and hormone therapy.
- She received 5 cycles of SV-BR-1-GM over 3 months and had a marked improvement in the breast tumor with 26% reduction in the size of the tumor.
- Her bone tumor was stable but the liver increased.
- She matched SV-BR-1-GM at the HLA-DRβ3 type and was a partial match at the HLA-B type.

Breast Tumor Size
Decrease with Treatment



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Thank You!