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# **BriaCell**

**INVESTOR PRESENTATION**

**Fall 2025**

*Developing Novel Therapeutics to Destroy Cancer*

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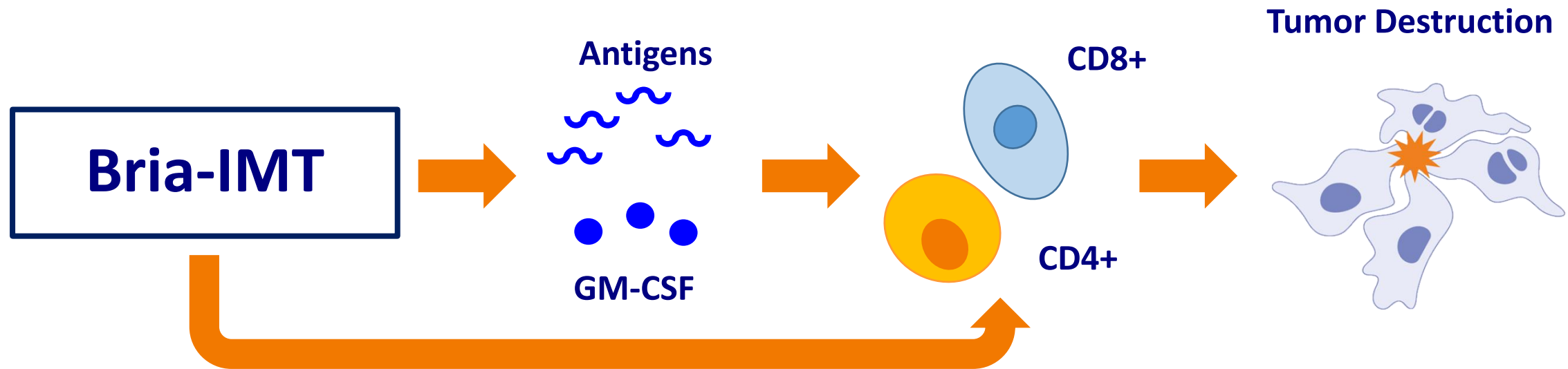
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- **Clinical stage immuno-oncology company developing an entirely new class of targeted immunotherapies to transform cancer care**
- **Lead drug candidate Bria-IMT™**
  - **Pivotal Phase 3 study underway in metastatic breast cancer (over 40K US deaths/year)**
  - Phase 2 study demonstrated 2-fold increase in survival vs comparable patients in the literature
    - Unprecedented clinical benefit in checkpoint inhibitor (CPI) and antibody-drug conjugate (ADC) resistant patients
    - Remarkable clinical efficacy in patients with central nervous system (CNS) metastases
  - Awarded Fast Track designation by FDA
  - Single agent and combination check point inhibitor (+ CPI) activity
- **Bria-OTS™ & Bria-OTS+™: Next generation, cell-based cancer immunotherapy platform**
  - Ongoing Phase 1/2a study in breast cancer
    - Bucket trial with other cancer indications to be added
    - Next generation prostate cancer candidate scheduled to enter clinic 2025
  - National Cancer Institute SBIR awards
  - **Bria-OTS+ more potent version of Bria-OTS**

- Bria-IMT - a cell based, patented, targeted immunotherapy
- Derived from a well characterized breast cancer cell line
- Expresses tumor antigens and GM-CSF to activate cancer fighting CD4+ and CD8+ T cells
- Stimulates the immune system to enhance targeted killing of cancer cells
- Off-the-shelf approach easy to distribute and administer
  - Cells are grown (cGMP), harvested, irradiated and cryopreserved for shipment to clinical sites where they are thawed and injected intradermally (upper back and thighs)



Evaluable Patients	HLA Match	Disease Control (CR, PR, and SD)	Disease Control in Immune Responders (DTH)
N=5	$\geq 2$	80% (4/5)	100% (4/4)
N=15	$\geq 1$	47% (7/15)	58% (7/13)
N=18	Any	50% (9/18)	60% (9/15)

- 27 total heavily pre-treated (median 5 prior regimens) metastatic breast cancer patients treated with Bria-IMT monotherapy regimen, 18 evaluable
- Presence of HLA-type matching correlates with response to Bria-IMT
- Immune response measured by delayed-type hypersensitivity (DTH) to Bria-IMT correlates with disease control
- Tolerability excellent with no dose-limiting toxicities
- Clinical benefit demonstrated: 1 PR and 8 SD in 15 evaluable immune responders

The Bria-IMT regimen includes Bria-IMT with low dose cyclophosphamide and micro-dose interferon alpha CR = Complete Response, PR = Partial Response and SD = Stable Disease DTH = Delayed-type Hypersensitivity  
Wiseman CL, Kharazi A. Objective clinical regression of metastatic breast cancer in disparate sites after use of whole-cell vaccine genetically modified to release sargramostim. Breast J. 2006;12(5):475–480.  
Wiseman CL, et al. Regression of breast cancer metastases following treatment with irradiated SV-BR-1-gm, a GM-CSF overexpressing breast cancer cell line. Recent Pat Anticancer Drug Discov. 2022;18(2):224–240.  
Wiseman CL, et al. Results of a phase I/IIa trial of SV-BR-1-GM inoculation with low-dose cyclophosphamide and interferon alpha (Bria-IMT) in metastatic breast cancer. Hum Vaccin Immunother. 2024 Dec 31;20(1):2379864.

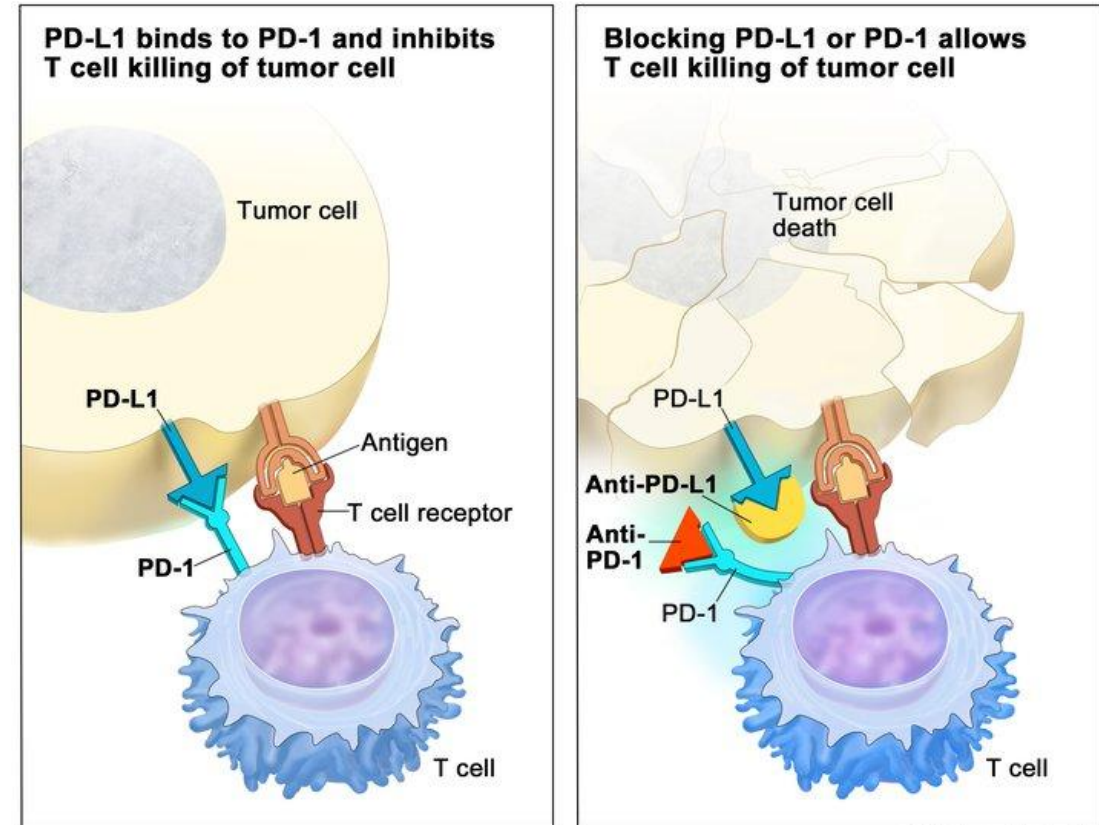


## How Do CPIs Work?

- PD-L1 expression protects cancer cells from tumor antigen driven T-cell attack
- PD-1 and PD-L1 inhibitors, also known as CPIs, neutralize this immune suppression

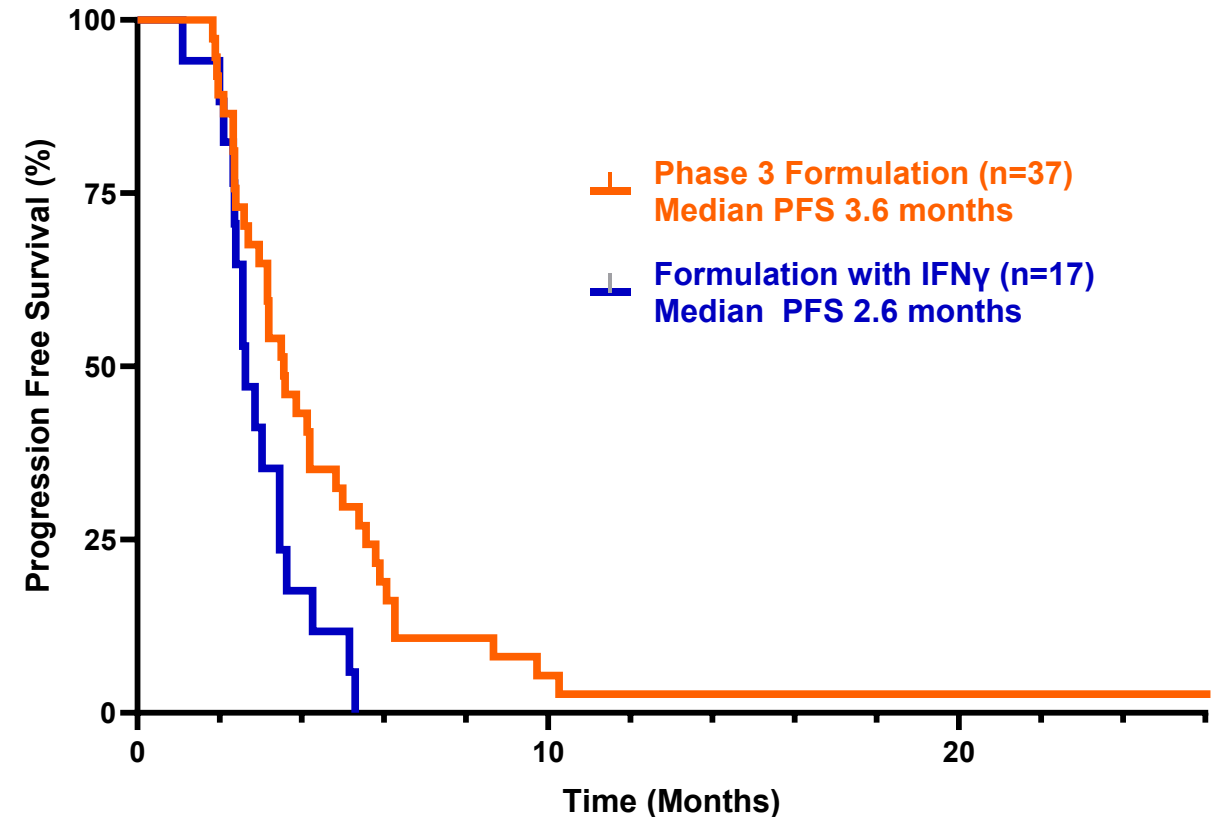
## Why combine Bria-IMT with CPIs?

- >90% of patients express PD-L1 in our studies
- Potential synergy between Bria-IMT activated immune system and CPI's unblocking of immune system
- BriaCell's hypothesis: Combining CPIs with Bria-IMT providing powerful synergistic anti-tumor activity



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- Total of 54 patients enrolled
  - 11 treated in combination with pembrolizumab
  - 44 treated in combination with retifanlimab
    - one cross-over
- Median 6 prior regimens
- Evaluated 2 formulations:
  - Bria-IMT treated with IFN $\gamma$ , n = 17
  - Bria-IMT not treated with IFN $\gamma$ , n = 37
- Progression-free survival (PFS) 3.6 months vs 2.6 months favored no IFN $\gamma$  (p<0.05)
- PFS of similar patients in the literature is 1.6-2.5 months<sup>1</sup>
- Bria-IMT without IFN $\gamma$  selected as formulation for Phase 3



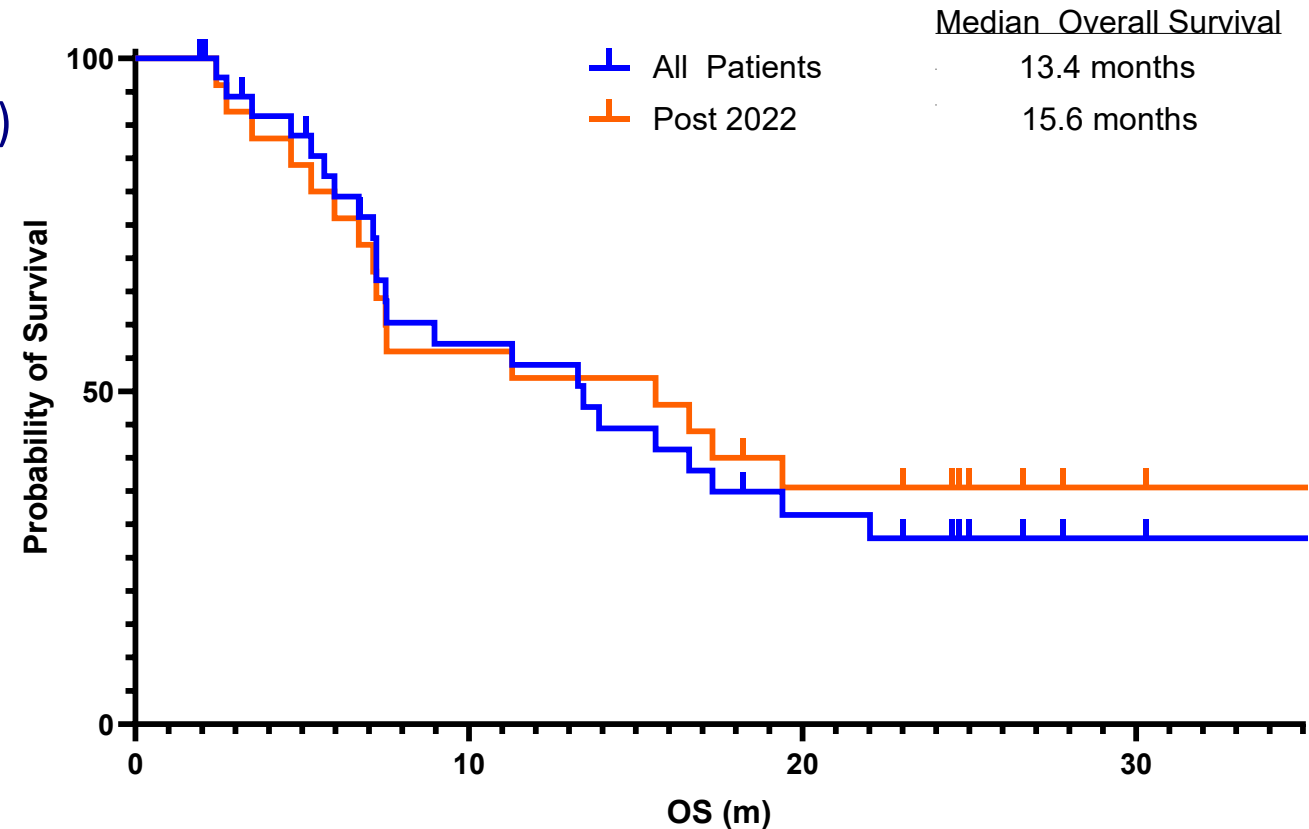
Data presented at ASCO 2024 see Calfa et al. Journal of Clinical Oncology 42, 6\_suppl  
[https://doi.org/10.1200/JCO.2024.42.16\\_suppl.1022](https://doi.org/10.1200/JCO.2024.42.16_suppl.1022)

<sup>1</sup> Cortes J, et al. Annals of Oncology 2018; Kazmi S, et al. Breast Cancer Res Treat. 2020 Aug 17; O'Shaughnessy J et al. Breast Cancer Res Treat. 2022; Tripathy D, et al. JAMA Oncol. 2022; Bardia A, et al. J Clin Oncol. 2024 May 20;42(15):1738-1744



- 37 patients treated with Phase 3 formulation
  - 12 patients pre 2022
  - 25 patients post 2022
- Median 6 lines of prior therapies (range 2-13)
- Overall survival (OS) 13.4 months (pre and post 2022)
- Overall survival (OS) 15.6 months post 2022
- OS compares favorably to 5.9-9.8 months<sup>1</sup> reported in comparable metastatic breast cancer patients
- No dose limiting toxicities to date

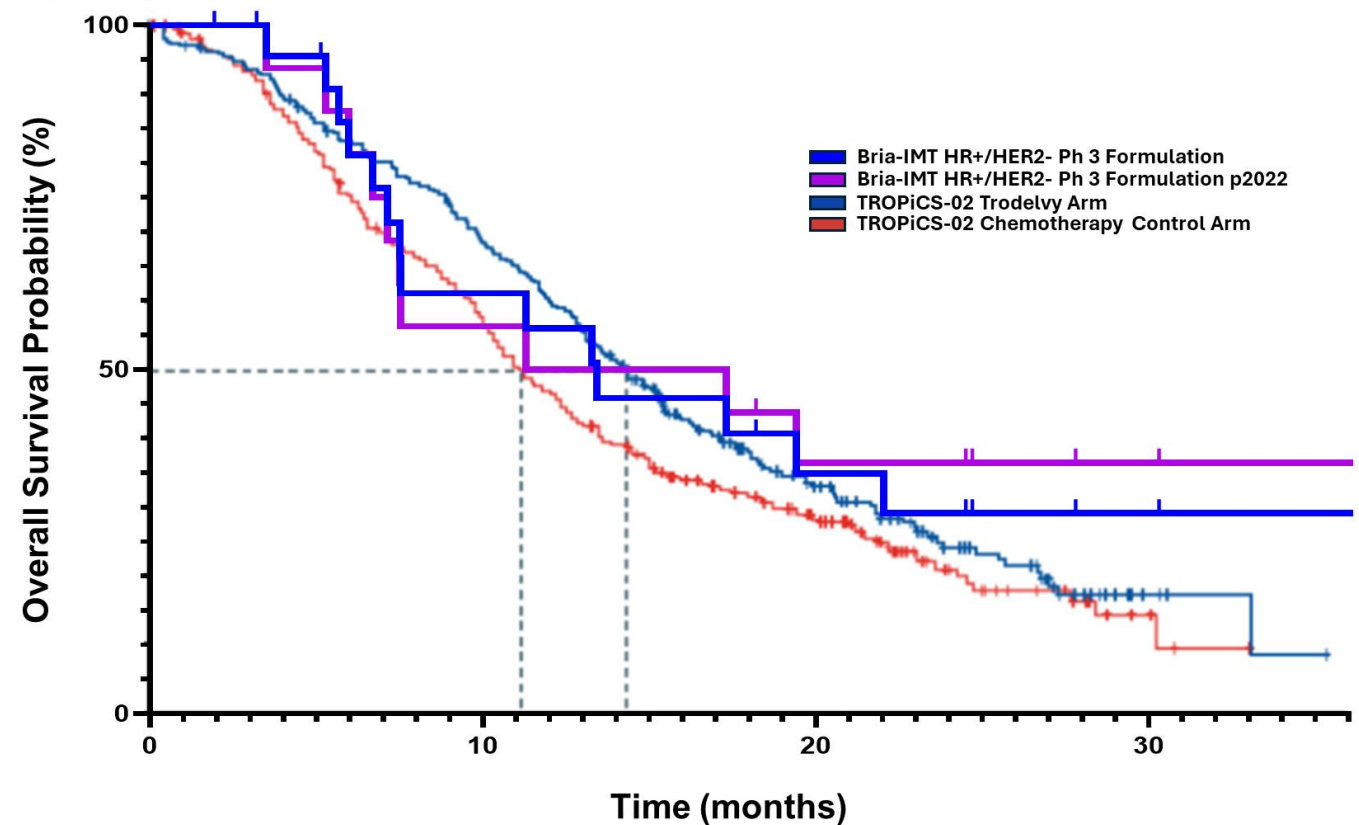
Survival of Phase 3 Formulation Cohort by Time Period



<sup>1</sup>Cortes J, et al. Annals of Oncology 2018; Kazmi S, et al. Breast Cancer Res Treat. 2020 Aug 17; O'Shaughnessy J et al. Breast Cancer Res Treat. 2022; Tripathy D, et al. JAMA Oncol. 2022; Bardia A, et al. J Clin Oncol. 2024 May 20;42(15):1738-1744

- 37 patients treated with Phase 3 formulation
  - Median 6 prior lines of therapy
  - 24 patients hormone receptor (HR)+
  - Overall survival (OS) 13.4 months for HR+ Patients
  - OS 14.3 months for HR+ Patients treated since 2022
- **Compares well to Trodelvy pivotal registration study in HR+ Patients**
  - Median 4 prior lines of systemic therapy
  - OS 14.4 months for Trodelvy
  - OS 11.2 months for single agent chemotherapy

Overall survival of Bria-IMT vs TROPiCS-02<sup>2</sup>



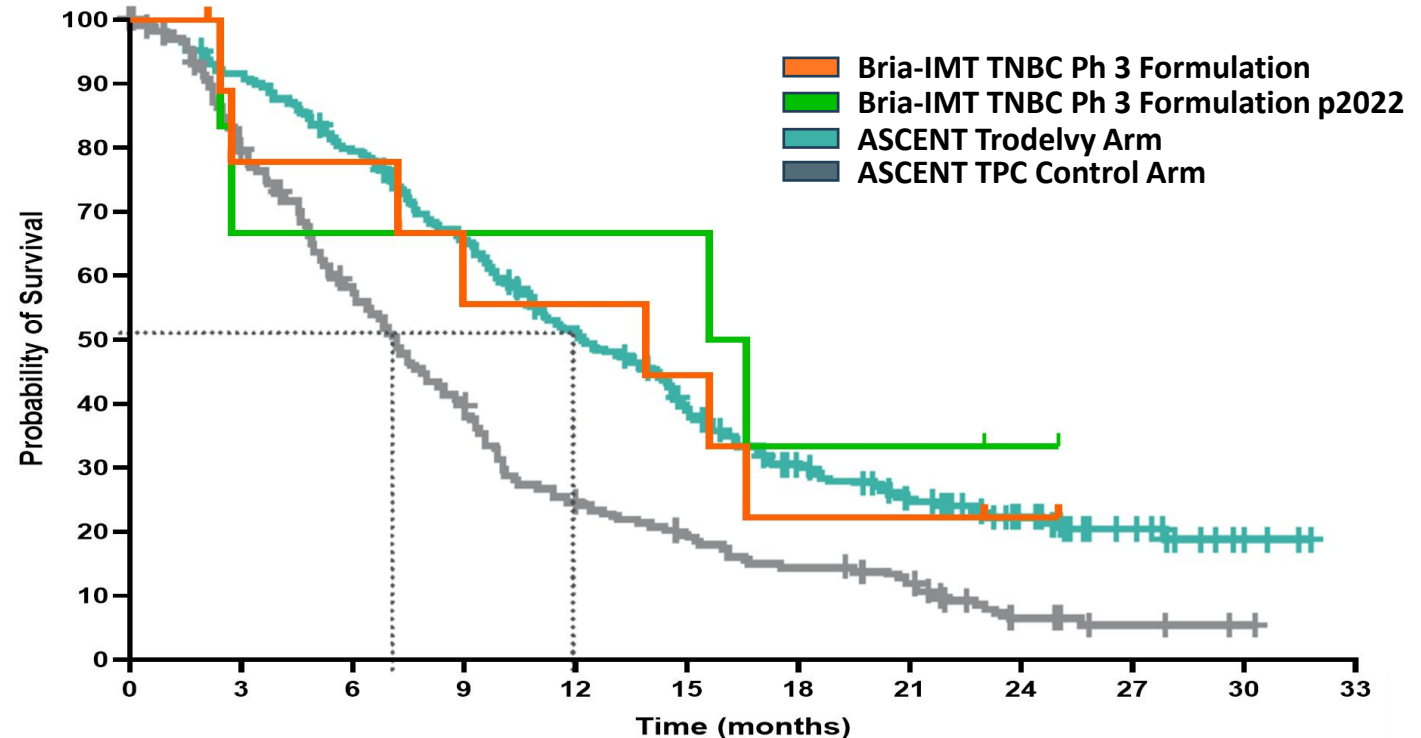
<sup>2</sup>Rugo, H. S., et al. The Lancet, 402(10411), 1423–1433.

ClinicalTrials.gov ID [NCT03328026](https://clinicaltrials.gov/ct2/show/study/NCT03328026)

# Bria-IMT + CPI Phase 2 Overall Survival vs Trodelvy

- 37 patients treated with Phase 3 formulation
  - Median 6 prior regimens
  - 10 patients with triple-negative breast cancer (TNBC)
  - Overall survival (OS) 13.9 months for TNBC
  - OS median 16.1 months for TNBC patients treated since 2022
- **Compares favorably to Trodelvy pivotal registration study in TNBC**
  - Median 4 prior regimens
  - OS 11.8 months for Trodelvy
  - OS 6.9 months for single agent chemotherapy

Overall survival of Bria-IMT vs ASCENT<sup>1</sup>



<sup>1</sup>Bardia, A., et al Journal of Clinical Oncology, 42(15), 1738–1744

ClinicalTrials.gov ID [NCT03328026](https://clinicaltrials.gov/ct2/show/study/NCT03328026)

# Comparison to Other Similar Patients

- ~4 months median progression-free survival (PFS) twice that seen in comparable patients treated with best available therapy, including antibody-drug conjugate (ADC) resistant patients<sup>1,2,3</sup>
- Clinical benefit seen in **53%** of evaluable patients in **all subtypes** of breast cancer who had failed an ADC
  - Compared with **7-10%** in comparable patients treated with best available therapy (the comparator for Phase 3)

Study	Progression-Free Survival (months)	Objective Response Rate (%)	Clinical Benefit Rate (%)
BriaCell's ADC Resistant Phase 2 patients who received pivotal Phase 3 study formulation (Bria-IMT regimen)	<b>4.1</b>	<b>12**</b>	<b>53**</b>
Bardia, A. et. al. <sup>1</sup>	1.7	4	8
Tripathy D. et. al. <sup>2</sup>	1.9	3	10
O'Shaughnessy J. et. al. non-TNBC <sup>3</sup>	2.3	4	7
O'Shaughnessy J. et. al. TNBC <sup>3</sup>	1.6	5	10

\*Data is for evaluable patients, n=42 with 12 not evaluable.

\*\* Data is for evaluable patients, n = 17 with 6 not evaluable.

References: Data is shown for the intent to treat population for the control group treated with treatment of physician's choice, which is the comparator in the BriaCell phase 3 study

1. Bardia A, et al. Final Results From the Randomized [Phase III](#) ASCENT Clinical Trial in Metastatic Triple-Negative Breast Cancer and Association of Outcomes by Human Epidermal Growth Factor Receptor 2 and Trophoblast Cell Surface Antigen 2 Expression. J Clin Oncol. 2024 May 20;42(15):1738-1744.

2. Tripathy D, Tolaney SM, Tagliaferri M. Etrirnotecan Pegol Treatment for Patients With Metastatic Breast Cancer and Brain Metastases-Reply. JAMA Oncol. 2022 Nov 1;8(11):1700-1701. jamaoncol.2022.4346. PMID: 36136348. This paper describes patients with brain metastases.

3. O'Shaughnessy J, et al. Analysis of patients without and with an initial triple-negative breast cancer diagnosis in the 3 randomized ASCENT study of sacituzumab govitecan in metastatic triple-negative breast cancer. Breast Cancer Res Treat. 2022 Sep;195(2):127-139.

# Robust Market Potential

Drug	Trial	Prior Lines	ORR (%)	PFS (months)	WW 2024 Sales* (Bil \$)
Bria-IMT™	Ph 2	5.5	10	4.1	
KISQALI® (ribociclib)	Ph 1/2a (MBC previously Rx trastuzumab, pertuzumab, and trastuzumab emtansine) <sup>1</sup>	5	0	1.3	\$ 3.0
KEYTRUDA® ** (pembrolizumab)	Ph 2 (MBC HER2 negative) <sup>2</sup>	1	0	1.9	\$ 29.5
LYNPARZA® (Olaparib) + cediranib	Ph 1 (MBC triple negative) <sup>3</sup>	3	0	3.7	\$ 3.7
IBRANCE® (palbociclib)	Ph 2a (MBC retinoblastoma+) <sup>4</sup>	2	0	3.7	\$ 4.4
	Ph 2 (MBC HR+/HER2-) <sup>5</sup>	2		6	
PERJETA® (pertuzumab)	Ph 1 (MBC) <sup>6</sup>	2	0		\$ 4.0
PERJETA® (pertuzumab) + docetaxel	Ph 1b (MBC) <sup>7</sup>	2	0		
PERJETA® (pertuzumab) + Herceptin	Ph 2 (MBC HER2+ progressed on trastuzumab) <sup>8</sup>	1-3	0	5	
TRODELVY® (sacituzumab govitecan-hziy)	Ph 1/2 MBC (TNBC; HR+ HER2-) <sup>9</sup>	3	0	5.5	\$ 1.3
Verzenio® (abemaciclib)	Ph 1/2 (HR+/HER2- MBC progressed on endocrine Rx and prior chemo) <sup>10</sup>	4	0	6	\$ 5.3
Verzenio® (abemaciclib)	Ph 1/2 (MBC HR+ Intracranial mets) <sup>11</sup>	1-12	5.2/0	4.4/2.7	
KADCYLA® (ado-trastuzumab emtansine)	Ph 1 (MBC HER2+ failed trastuzumab) <sup>12</sup>	4	21	~5.8	\$ 2.2
	Ph 1 (MBC HER2+ failed HER2 directed Rx) <sup>13</sup>	5	26	4.6	
HERCEPTIN HYLECTA® (trastuzumab & hyaluronidase-oysk)	Ph 3 (HER2+ MBC) <sup>14</sup>		26	4.6	\$ 1.5
ENHERTU® (HER2low) (fam-trastuzumab deruxtecan-nxki)	Ph 2 <sup>15</sup>	1	52		\$ 3.8
ENHERTU® (HER2high) (fam-trastuzumab deruxtecan-nxki)	Ph 2 <sup>15</sup>	5	60		

\$2-5 billion Bria-IMT opportunity<sup>#</sup>

\*Worldwide sales figure is based on SEC filings

\*\*Approved for multiple cancer indications

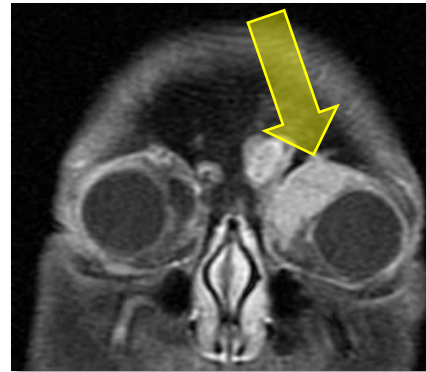
<sup>#</sup>Independent market analysis

## References:

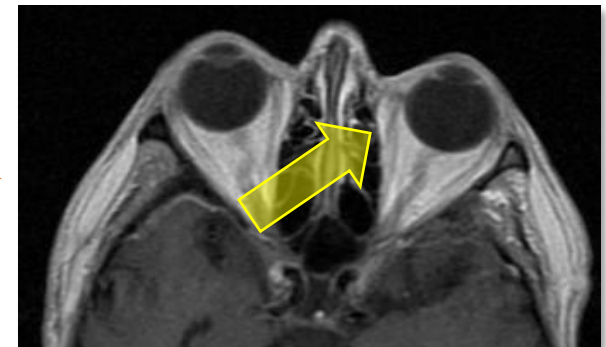
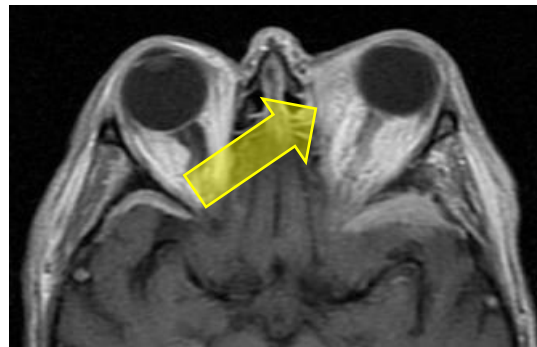
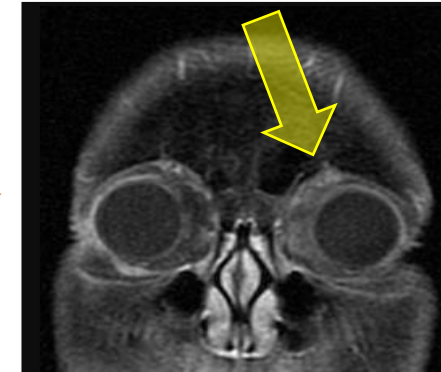
- <https://pubmed.ncbi.nlm.nih.gov/31235441/>
- [https://ascopubs.org/doi/10.1200/JCO.2023.41.16\\_suppl.1095](https://ascopubs.org/doi/10.1200/JCO.2023.41.16_suppl.1095)
- <https://pubmed.ncbi.nlm.nih.gov/23810467/>
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- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5581697/>
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- <https://pubmed.ncbi.nlm.nih.gov/36780610/>
- <https://medicalinformation.astrazeneca-us.com/home/prescribing-information/enhertu.html>

- Patient failed 13 prior regimens
- Baseline breast cancer metastases
  - Behind the left eye (orbit)
  - Outside lining of the brain (dura mater)
  - Adrenal gland
- 6 months of treatment
  - Orbital tumor completely resolved
  - The patient judged an overall partial responder

**Baseline Scans**



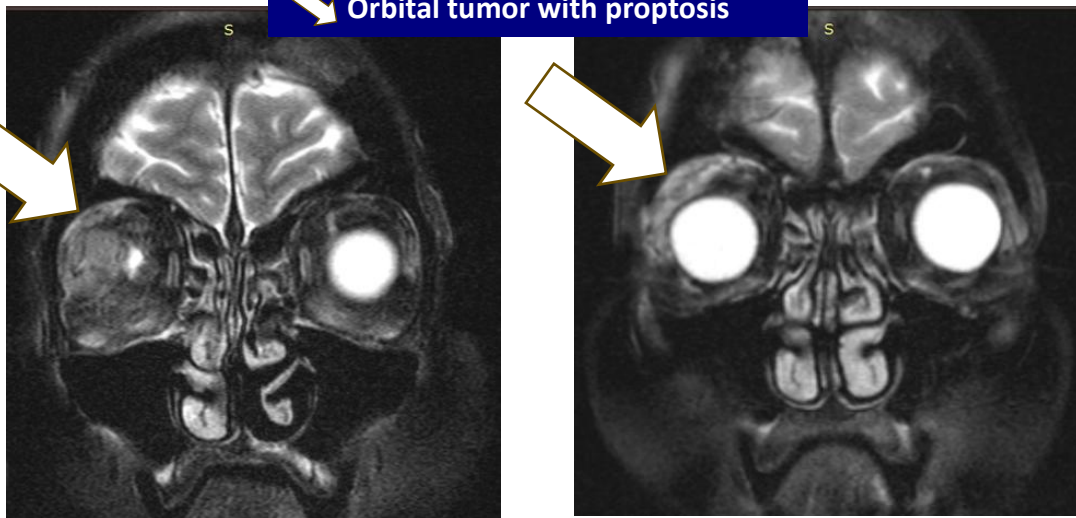
**On Treatment Scans**





# Bria-IMT + CPI Remarkable CNS Responder Case #2

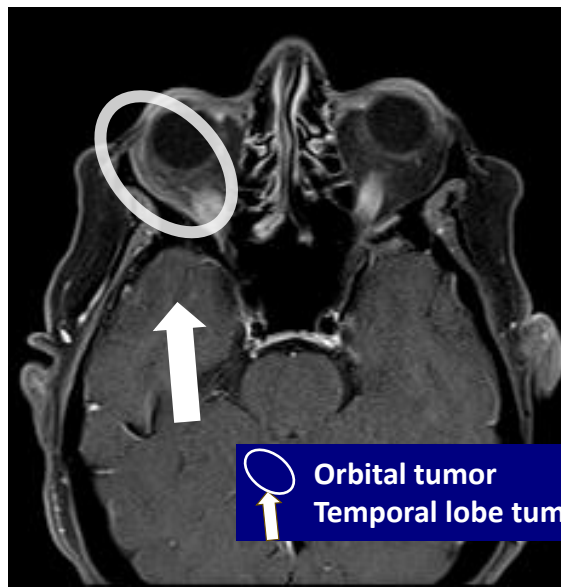
Orbital tumor with proptosis



- Patient failed 8 prior regimens including ADC Enhertu®
- Baseline tumor status
  - Extensive proptosis (eye bulging) & brain (temporal lobe) metastasis
- Marked tumor reduction at 11 months
  - Near complete proptosis resolution at 3 months with orbit (eye socket) tumor: 42 mm → 28 mm
  - Brain temporal lobe tumor: 22 mm → 0
  - Overall, 56% reduction (PR)
  - Improvement in eye pain and reduction in tumor markers
- On study for >21 months

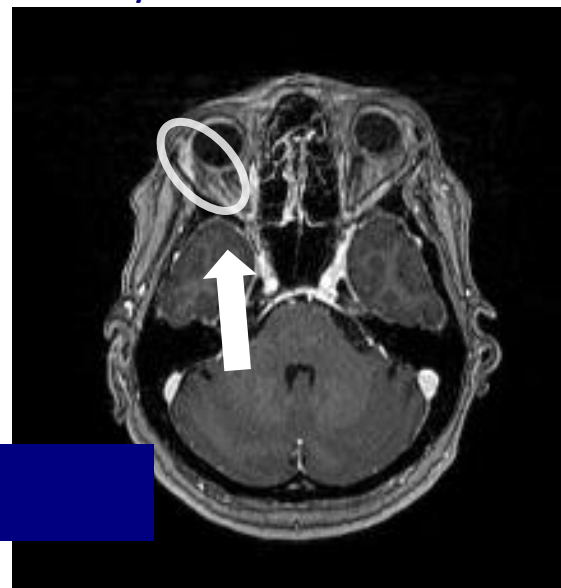


Pre-treatment

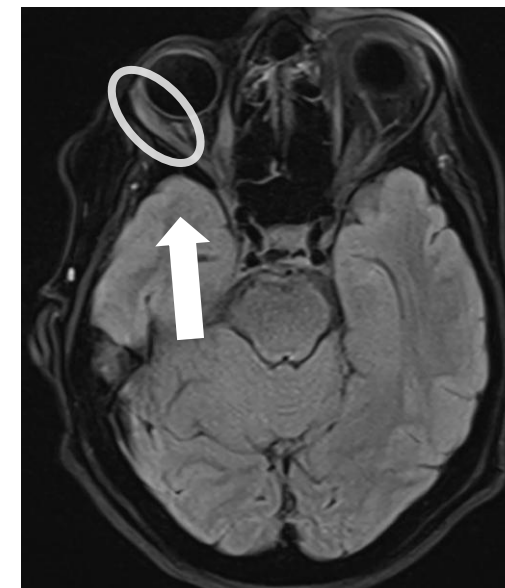


6 Months

Orbital tumor  
Temporal lobe tumor



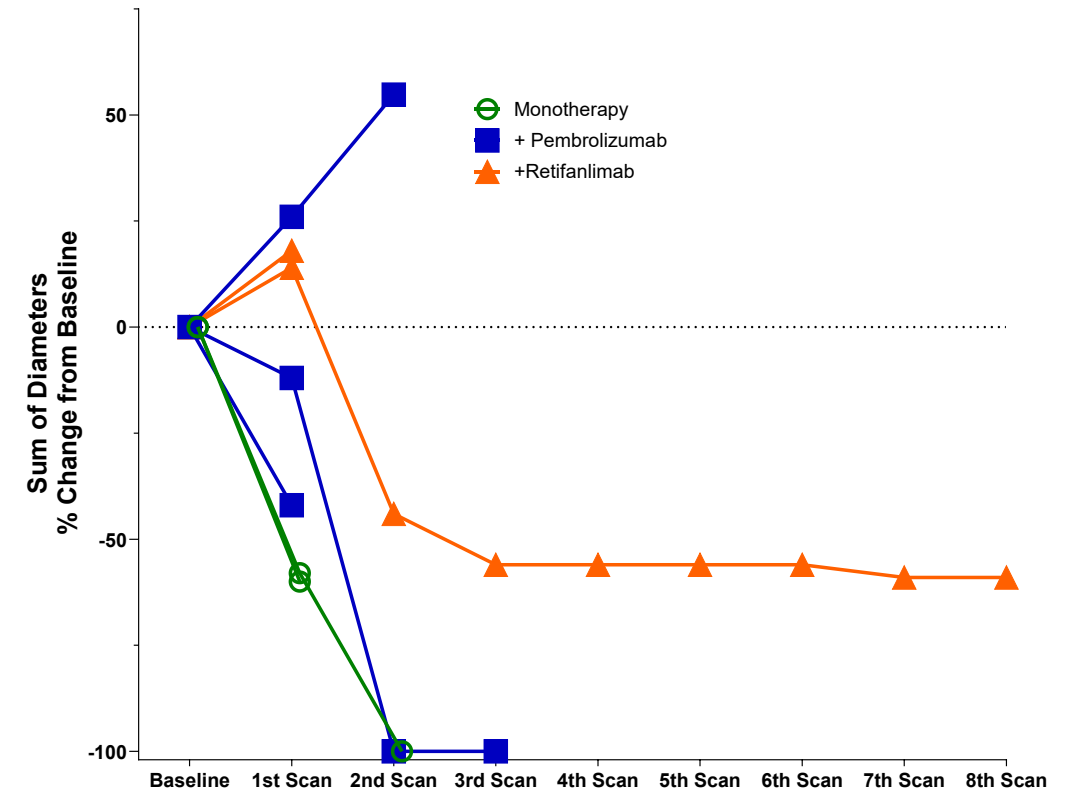
12 Months



20 Months

- **71% (5/7) intracranial objective response rate (iORR)**
  - Positive results in both Bria-IMT monotherapy and CPI combination
- **iORR in comparable patients typically <20%<sup>1,2</sup>**
- Response across all subtypes of breast cancer
- Heavily pre-treated population includes 1 ADC resistant patient
- Planned CNS disease subgroup analysis in pivotal phase 3
- **Data highlight strong Bria-IMT potential in CNS metastases**

**Intracranial Tumor Responses\***



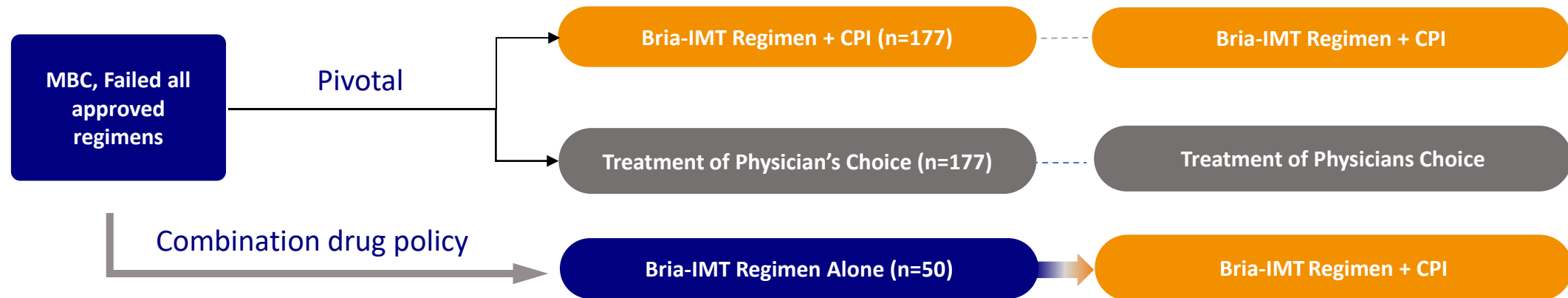
<sup>1</sup> Niwinska A, Pogoda K, Jagiello-Grusfeld A, Duchnowska R. Intracranial Response Rate in Patients with Breast Cancer Brain Metastases after Systemic Therapy. *Cancers (Basel)*. 2022 Feb 15;14(4):965. doi: 10.3390/cancers14040965. PMID: 35205723; PMCID: PMC8869862.

<sup>2</sup> Tripathy D, Tolane SM, Seidman AD, Anders CK, Ibrahim N, Rugo HS, Twelves C, Diéras V, Müller V, Du Y, Currie SL, Hoch U, Tagliaferri M, Hannah AL, Cortés J; ATTAIN Investigators. Treatment With Etrinecan Pegol for Patients With Metastatic Breast Cancer and Brain Metastases: Final Results From the Phase III ATTAIN Randomized Clinical Trial. *JAMA Oncol*. 2022 Jul 1;8(7):1047-1052. doi: 10.1001/jamaoncol.2022.0514. PMID: 35552364; PMCID: PMC9100460.

\*Data in evaluable patients

# Bria-IMT + CPI Pivotal Phase 3 Study

- Ongoing pivotal Phase 3 study in Advanced Breast Cancer (Bria-ABC)
- **Primary endpoint of overall survival**
  - Interim efficacy at 144 events
  - 97.5% powered to detect a 40% reduction in mortality
- **Positive interim results could support FULL approval of Bria-IMT + CPI**



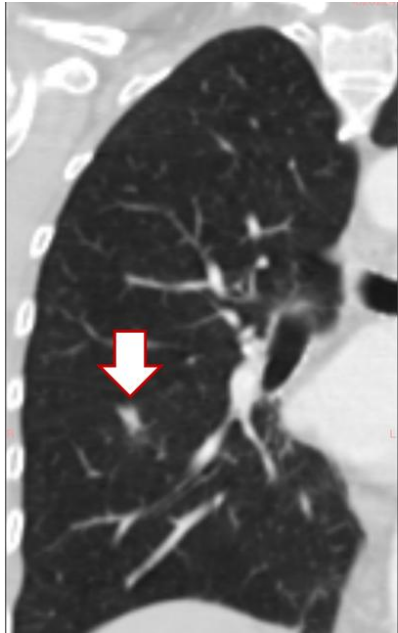
Analyze at 144 events. If hazard ratio (HR) is  $\leq 0.6$ , submit BLA. If  $> 0.6$ , continue to completion with HR target of 0.7

- BriaCell immunotherapy is most effective in human leukocyte antigen (HLA) type matched patients
- HLA typing identifies patient specific T cell presenting antigens necessary for immune response
- Bria-OTS expresses 15 HLA types in 4 cell lines, providing matched treatment to >99% of patients
- Simple saliva test delivers personalized Bria-OTS immunotherapy
- **Breast cancer Phase 1/2a study enrolling**
  - Bucket trial with other cancer indications to be added (prostate, melanoma and lung)
- Enhanced Bria-OTS+ to enter clinic 2025
  - Positive pre-IND meeting for Bria-OTS+ completed

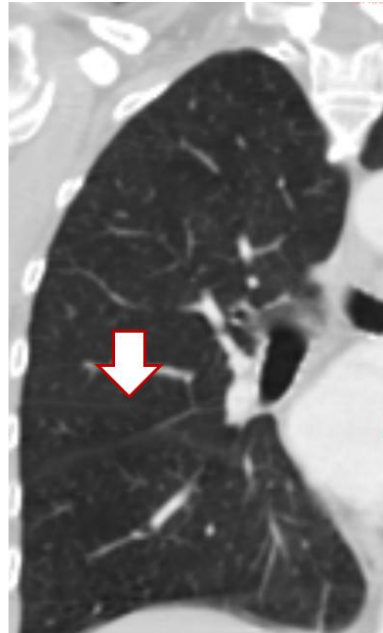




# Bria-OTS Metastatic Breast Cancer Phase 1/2a



Pre-Treatment



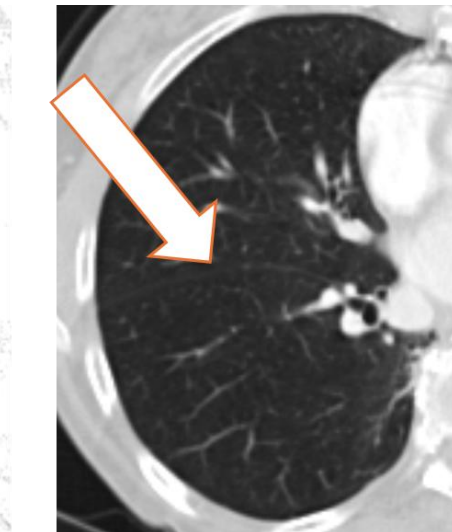
2 months



4 months



6 months



- Initial monotherapy dose escalation then dose expansion in combination with CPI
  - Up to 18 patients including 9 patient dose expansion
- Results of first patient treated:
  - Complete resolution of lung lesion at two months sustained for 6 months
  - Stable disease elsewhere
  - Multiple prior therapy failures

# From Bria-IMT to Bria-OTS to Bria-OTS+: Engineering Stronger, Broader Immune Activation



## Bria-IMT™ (1st Generation)

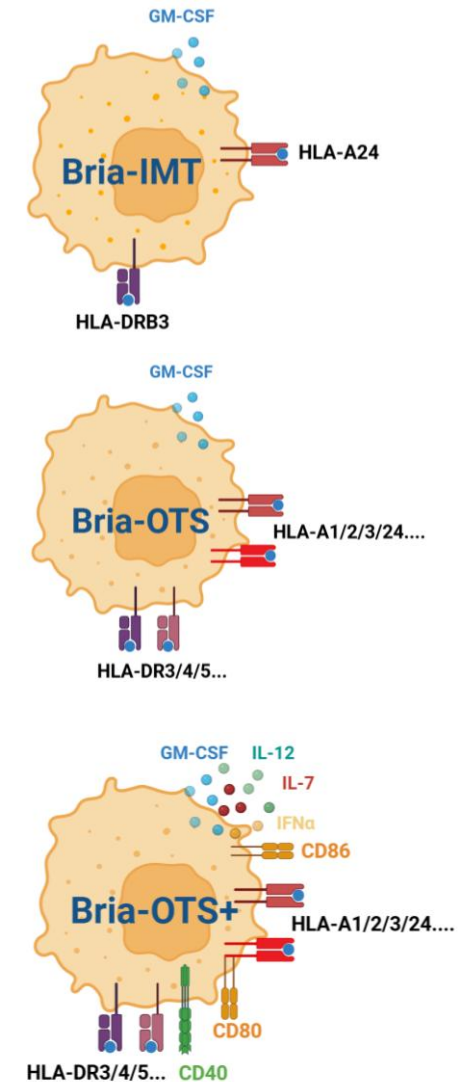
- ❑ Breast cancer cell line engineered to express GM-CSF
- ❑ Demonstrated clinical activity and survival benefit in Phase 1/2a
- ❑ Validates whole-cell immunotherapy and provides the foundation for OTS

## Bria-OTS™ (2nd Generation: HLA-Matched Platform)

- ❑ Evolution of Bria-IMT™ engineered to express 15 HLA alleles
- ❑ Four semi-allogeneic, off-the-shelf cell lines providing >99% population coverage
- ❑ Enables scalable, rapid, and personalized matching without autologous manufacturing

## Bria-OTS+™ (3rd Generation: Engineered for Potency)

- ❑ Adds co-stimulatory molecules (CD80, CD86, CD40)
- ❑ Adds immune-modulatory cytokines (GM-CSF, IL-12, IL-7, IFN- $\alpha$ )
- ❑ Broad activation of CD4<sup>+</sup>, CD8<sup>+</sup>, NK, NKT, and dendritic cells
- ❑ OTS+ variants now in development for multiple indications (prostate, lung, melanoma)
- ❑ Supported by a National Cancer Institute Small Business Innovative Research award
- ❑ *Bria-BRES+ and Bria-PROS+ scheduled to enter the clinic 1Q2026*





# Development Timeline and Catalysts

## Bria-IMT + CPI

Phase 2 safety & efficacy data with presentations at scientific conferences, DSMB updates on pivotal Phase 3 study

**Phase 3 interim analysis**

**Potential BLA submission**

**Potential marketing approval**



## Bria-OTS/OTS+

Phase 1/2a dose escalation in breast cancer  
Initiation of Bria-BRES+  
Ongoing data readouts from breast cancer study

Continuous basket study readouts with additional indications (lung, melanoma and others)

Bria-PROS+ IND Submission and Initiation of Clinical Study in prostate cancer

**Identify lead indications and initiate Bria-OTS+ pivotal registration study**



**William V. Williams, MD, FACP**  
**President & CEO, Director**

- Incyte, GlaxoSmithKline
- University of Pennsylvania



**Giuseppe Del Priore, MD, MPH**  
**Chief Medical Officer**

- Cancer Treatment Centers of America
- NYU School of Medicine, New York Presbyterian



**Gadi Levin, CA, MBA**  
**CFO & Corporate Secretary**

- Arthur Andersen
- University of Cape Town, Bar Ilan University



**Miguel A. Lopez-Lago, PhD**  
**Chief Scientific Officer**

- Memorial Sloan-Kettering Cancer Center
- Stony Brook University, New York



**Clinical Strategy Team involved in 20 previous drug or device approvals**



**Jamieson Bondarenko, CFA, CMT**  
**Chairman of the Board**

- Eight Capital, Dundee Securities, Wellington West Capital Markets and HSBC Securities



**William V. Williams, MD, FACP**  
**President & CEO, Director**

- Incyte, GlaxoSmithKline



**Vaughn Embro-Pantalony, MBA, FCPA, FCMA, CDir, ACC**  
**Director**

- Teva Novopharm Limited, Bayer Healthcare, Zeneca Pharma Inc.



**Jane Gross, PhD**  
**Director**

- aTyr Pharma Inc., ZymoGenetics Inc. (acq. by Bristol Myers Squibb)



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

- Clear Intradermal Technologies, Inc., Sirna Therapeutics, Inc., Advanced Bionics Corporation



**Rebecca A. Taub, MD**  
**Director**

- Madrigal Pharmaceuticals, Hoffmann-La Roche Company, Bristol-Myers Squibb;

# Capitalization Table & Balance Sheet Summary\*



Capitalization Table	
Shares Outstanding:	1,883,906
RSUs	205,936
Options (\$242.43 WAEP):	50,951
Warrants (\$58.86 WAEP):	1,681,986

Balance Sheet Summary	As of 7/31/2025
Cash and cash equivalents**	\$17,866,281
Total assets	\$21,649,706
Total liabilities	\$4,315,660
Total shareholders' equity	\$17,334,046

\* Dollar figures in USD

\*\* Includes ~\$7.4mm of short-term investments

- **Bria-IMT™ + CPI:** Pivotal phase 3 study underway in metastatic breast cancer.
  - Up to 2-fold increase in survival compared to comparable patients in the literature.
  - Phase 3 interim analysis expected 1H 2026.
- **Bria-OTS/OTS+™:** Ongoing phase 1/2a study for Bria-BRES™. Bucket trial with other cancer indications to be added.
  - Bria-PROS+ IND submission and initiation of clinical study in prostate cancer expected in 1H 2026.
- **Proven Management Team:** Clinical strategy team involved in 20 previous drug or device approvals.



*Developing Novel Therapeutics to Destroy Cancer*

***Thank-you!***