Evaluation of anti-PD-1 Cemiplimab plus anti-LAG-3 REGN3767 in Combination with Paclitaxel in Early-Stage, High-Risk HER2-negative Breast Cancer: Results from the Neoadjuvant I-SPY 2 TRIAL

Claudine Isaacs, Rita Nanda, Christina Yau, Jo Chien, Megna Trivedi, Erica Stringer-Reasor, Christos Vaklavas, Judy Boughey, Amy Sanford, Anne Wallace, Amy Clark, Alexandra Thomas, Kathy Albain, Laura Kennedy, Tara Sanft, Kevin Kalinsky, Heather Han, Williams N, Mili Arora, Anthony Elias, Carla Falkson, Smita Asare, Ruixiao Lu, Maria Pitsiouni, Amy Wilson, Jane Perlmutter, Hope S Rugo, Richard Schwab, Frasier Symmans, Nola Hylton, Laura Van 't Veer, Douglas Yee, Angela DeMichele, Don Berry, Laura Esserman

on behalf of the I-SPY 2 TRIAL Consortium

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Disclosures

Consultancies: Genentech, PUMA, Seattle Genetics, AstraZeneca, Novartis, Pfizer, ESAI, Sanofi; ION; Gilead
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Medical Director: SideOut Foundation (non-profit)
Research Support (to institution): Tesaro/GSK; Seattle Genetics; Pfizer; AZ; BMS; Genentech; Novartis

¹Nanda et al, JAMA Oncology 2020; ²Schmid et al, NEJM 2020; ³Hamid et al. ESMO 2022; Tawbi et al. NEJM 2022

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REGN3767: LAG-3 Antagonist

• REGN3767 (Fianlimab) is a fully humanized, high-affinity mAb that binds to and antagonizes lymphocyte activation gene 3 (LAG-3)\(^1\)

• LAG-3
  • Cell surface molecule expressed on immune cells including T cells
  • Binds to MHC class II leading to inhibition of T-cell proliferation and activation\(^1\)
  • REGN3767 blocks LAG-3/MHC class II-driven T cell inhibition\(^1\)
  • Often co-expressed with PD-1

• Cemipimab is anti-PD-1\(^2\) approved for treatment of NSCLC and cutaneous and squamous cell CA

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Rationale for REGN3767 + Cemiplimab Combination

• The addition of pembrolizumab, an anti-PD-1, to standard neoadjuvant chemotherapy improves outcomes
  • Phase 2 I-SPY2 trial: near tripling of estimated pathologic complete response (pCR) rate in TN and high-risk HR+ signatures¹
  • Phase 3 Keynote 522: improved pCR and EFS in TNBC²

• Preclinical data suggest a synergistic interaction between anti-LAG3 and anti-PD-1 therapy

• In previously untreated melanoma:
  • Phase 1 expansion cohort (n=80) of cemiplimab + REGN3767 in anti-PD-1/PDL-1- naïve advanced melanoma³: ORR 64%
  • RELATIVITY-047 phase 2/3 RCT⁴: median PFS 10.1 months with nivolumab + relatlimab (anti-LAG-3) vs 4.6 months with nivolumab + placebo (p = 0.006)

¹Nanda et al, JAMA Oncology 2020; ²Schmid et al, NEJM 2020; ³Hamid et al. ESMO 2022; Tawbi et al. NEJM 2022

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**Eligibility**

- Tumor > 2.5 cm
- Her2-negative
- If HR+, MammaPrint high

**Adaptive Randomization**

**Control arm**

- Paclitaxel 80 mg/m2 weekly x 12

**Paclitaxel + REGN3767 + Cemiplimab**

**Other Investigational Arms including Paclitaxel + Cemiplimab**

- MRI, Blood
- Core Biopsy

**12 weeks**

**Doxorubicin**

- (60 mg/m2)
- Cyclophosphamide

- (600 mg/m2)
- q2-3wk x 4

**8-12 weeks**

**MRI, Blood**

**Primary endpoint**

pCR (ypT0/is and ypN0)

---

- REGN3767 + Cemiplimab was studied in **3 HER2-negative** biomarker signatures: all HER2-; TNBC; HR+/HER2
- Agent Graduation:
  - >85% predicted probability of success in a 300-patient phase 3 neoadjuvant trial
  - Graduation is assessed for each pre-specified biomarker signature
I-SPY 2 TRIAL Design

Eligibility
- Tumor > 2.5 cm
- Her2-negative
- If HR+, MammaPrint high

Adaptive Randomization

Control arm
- Paclitaxel 80 mg/m² weekly x 12

Other Investigational Arms including Paclitaxel + Cemiplimab

Other Investigational Arms
- MRI, Blood
- Core Biopsy

12 weeks

MRI, Blood

Paclitaxel + REGN3767 + Cemiplimab

Doxorubicin (60 mg/m²) q2-3wk x 4
- Cyclophosphamide (600 mg/m²) q2-3wk x 4

8-12 weeks

MRI, Blood

Tissue

Primary endpoint
pCR (ypT0/is and ypN0)

12 weeks

- MRI, Blood
- Core Biopsy

8-12 weeks

- MRI, Blood
- Tissue

Agent | Dose | Route | Treatment Week
--- | --- | --- | ---
REGN3767 | 1600 mg q3wks | IV | wk 1,4,7,10
Cemiplimab | 350 mg q3wks | IV | wk 1,4,7,10
Paclitaxel | 80 mg/m² q1wk | IV | wk 1–12

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### Demographics (all HER2-negative)

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>REGN 3767 + Cemiplimab (n=76)</th>
<th>Control (n=350)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>47 (26-78)</td>
<td>48 (19-80)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>57 (75%)</td>
<td>273 (78%)</td>
</tr>
<tr>
<td>African American</td>
<td>11 (14%)</td>
<td>46 (13%)</td>
</tr>
<tr>
<td>Asian</td>
<td>5 (7%)</td>
<td>30 (9%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (4%)</td>
<td>1 (0%)</td>
</tr>
<tr>
<td>HR status, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>40 (53%)</td>
<td>195 (56%)</td>
</tr>
<tr>
<td>Negative</td>
<td>36 (47%)</td>
<td>155 (44%)</td>
</tr>
<tr>
<td>Tumor size by MRI, cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>3.45 (1.6 - 10.9)</td>
<td>3.8 (1.2 - 15.0)</td>
</tr>
<tr>
<td>Clinical nodal status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Node positive</td>
<td>31(41%)</td>
<td>151(43%)</td>
</tr>
</tbody>
</table>

**Randomization period**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Randomization period</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGN3767 + Cemiplimab</td>
<td>Feb. 13, 2020 – Dec. 9, 2021</td>
</tr>
<tr>
<td>Paclitaxel (control)</td>
<td>Apr. 12, 2010 – Dec. 9, 2021</td>
</tr>
</tbody>
</table>

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Efficacy Analysis

**HER2-**
- Paclitaxel: 21% (95% PI: 17% - 25%)
- Paclitaxel + REGN3767 + Cemi: 44% (95% PI: 34% - 54%)

**HR-HER2-**
- Paclitaxel: 29% (95% PI: 22% - 36%)
- Paclitaxel + REGN3767 + Cemi: 53% (38% - 67%)

**HR+HER2-**
- Paclitaxel: 14% (95% PI: 9% - 19%)
- Paclitaxel + REGN3767 + Cemi: 36% (95% PI: 23% - 49%)

**Table: Predictive Probability of Success in Phase 3**

<table>
<thead>
<tr>
<th>Signature</th>
<th>Estimated pCR Rate (95% Probability Interval)</th>
<th>Probability Pac + REGN3767 + Cemi Superior to Control</th>
<th>Predictive Probability of Success in Phase 3 (relative to Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HER2-</td>
<td>Pac + REGN3767 + Cemi (n=76): 44% (34% - 54%)</td>
<td>&gt;0.999</td>
<td>0.955</td>
</tr>
<tr>
<td></td>
<td>Control (n=350): 21% (17% - 25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR-HER2-</td>
<td>Pac + REGN3767 + Cemi Superior to Control: 53% (38% - 67%)</td>
<td>0.999</td>
<td>0.915</td>
</tr>
<tr>
<td></td>
<td>Pac + REGN3767 + Cemi (n=76): 29% (22% - 36%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR+HER2-</td>
<td>Pac + REGN3767 + Cemi Superior to Control: 36% (23% - 49%)</td>
<td>&gt;0.999</td>
<td>0.940</td>
</tr>
<tr>
<td></td>
<td>Pac + REGN3767 + Cemi (n=76): 14% (9% - 19%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pac + REGN3767 + Cemiplimab graduated in all 3 eligible biomarker signatures by demonstrating increased pCR.

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Cemiplimab + REGN 3767 downshifted residual cancer burden class (RCB)¹ across all subtypes

**HER2-**
RCB 0/1: 37% vs 64%

**HR-HER2-**
RCB 0/1: 48% vs 70%

**HR+HER2-**
RCB 0/1: 29% vs 60%

Excludes patients who were considered non-pCR per protocol (eg received non-protocol therapy or withdrew consent)


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Cemiplimab + REGN 3767 downshifted residual cancer burden class (RCB) across all subtypes

**HER2-**
- RCB 0/1: 37% vs 64%

**HR-HER2-**
- RCB 0/1: 48% vs 70%

**HR+HER2-**
- RCB 0/1: 29% vs 60%

Excludes patients who were considered non-pCR per protocol (eg received non-protocol therapy or withdrew consent)

### Treatment-Emergent Adverse Events (non-immune) (≥ 10% difference)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>REGN3767 + Cemi (n=76)</th>
<th>Control (n=350)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Grade≥3</td>
<td>All Grade</td>
</tr>
<tr>
<td><strong>Blood and lymphatic system disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>1 (1%)</td>
<td>24 (32%)</td>
</tr>
<tr>
<td><strong>General Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>3 (4%)</td>
<td>64 (84%)</td>
</tr>
<tr>
<td>Headache</td>
<td>2 (3%)</td>
<td>35 (46%)</td>
</tr>
<tr>
<td>Fever</td>
<td>0</td>
<td>20 (26%)</td>
</tr>
<tr>
<td>Pain</td>
<td>0</td>
<td>22 (29%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>21 (28%)</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1 (1%)</td>
<td>37 (49%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>0</td>
<td>37 (49%)</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>0</td>
<td>13 (17%)</td>
</tr>
<tr>
<td>Decreased appetite/dysgeusia</td>
<td>0</td>
<td>26 (34%)</td>
</tr>
<tr>
<td><strong>Laboratory/Investigations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>1 (1%)</td>
<td>16 (21%)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>0</td>
<td>27 (36%)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>na</td>
<td>52 (68%)</td>
</tr>
<tr>
<td>Hot flashes</td>
<td>0</td>
<td>31 (41%)</td>
</tr>
</tbody>
</table>

Based on available data as of October 15th, 2022
Immune-Related Adverse Events (irAEs)

40 (53%) patients in REGN3767 + Cemi arm experienced irAE

<table>
<thead>
<tr>
<th>irAE</th>
<th>Grade 1/2</th>
<th>Grade 3</th>
<th>All Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothyroidism</td>
<td>24 (32%)</td>
<td>0 (0%)</td>
<td>24 (32%)</td>
</tr>
<tr>
<td>Adrenal insufficiency/Hypophysitis</td>
<td>10 (12%)</td>
<td>6 (5%)</td>
<td>16 (21%)</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus</td>
<td>0</td>
<td>3 (4%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Autoimmune hepatitis</td>
<td>0</td>
<td>2 (3%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Pneumonitis</td>
<td>2 (3%)</td>
<td>0 (0%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Renal failure acute</td>
<td>1 (1%)*</td>
<td>1 (1%)</td>
<td>2 (3%)</td>
</tr>
</tbody>
</table>

1 case of arthritis (G3)
1 case of immune-related Rash maculo-papular (G3)
1 case of thyroiditis (G2)
No Grade 4+ irAEs

Based on available data as of October 15th, 2022

San Antonio Breast Cancer Symposium®, December 6 -10, 2022
Immune-Related Adverse Events (irAEs)

40 (53%) patients in REGN3767 + Cemi arm experienced irAE

- 63% of irAEs occurred after > 12 weeks of treatment start
- Timing of irAE onset similar to prior I-SPY2 experience with other immune-targeting agents

### irAE by Grade

<table>
<thead>
<tr>
<th>irAE</th>
<th>Grade 1/2</th>
<th>Grade 3</th>
<th>All Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypothyroidism</td>
<td>24 (32%)</td>
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<td>0 (0%)</td>
<td>3 (4%)</td>
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<tr>
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<td>0 (0%)</td>
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<td>1 (1%)*</td>
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</tr>
</tbody>
</table>

1 case of arthritis (G3)
1 case of immune-related rash maculo-papular (G3)
1 case of thyroiditis (G2)
No Grade 4+ irAEs

### Timing of irAE onset by Time from Treatment Start

<table>
<thead>
<tr>
<th>Time from Treatment Start</th>
<th>Cemi/LAG3 +P W 1-6</th>
<th>Cemi/LAG3 +P W 7-12</th>
<th>AC Cycle 1-2</th>
<th>AC Cycle 3-4</th>
<th>Post-op 0-3 m</th>
<th>Post-op 3-6 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 case of arthritis (G3)</td>
<td>1</td>
<td>11</td>
<td>9</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1 case of immune-related rash maculo-papular (G3)</td>
<td>4</td>
<td>2</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1 case of thyroiditis (G2)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Grade 4+ irAEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Based on available data as of October 15th, 2022
**ImPrint: 53-gene Signature of Neoadjuvant Immunotherapy Response**

- Developed to predict response to neoadjuvant immunotherapy in pts with HR-HER2- and HR+HER2- BC
- Derived from patients treated on the I-SPY 2 pembrolizumab arm and independently validated in durvalumab/olaparib arm
- In partnership with Agendia developed a diagnostic, ImPrint
- IDE filed and approved on March 2022
- Further refined by introducing subtype-specific templates to improve performance in triple negative patients

---

\[1\] Wolff et al. *Cancer Cell* 2022; \[2\] *Journal of Clinical Oncology* 40, no. 16_suppl (June 01, 2022) 514-514
Observed (not modeled) pCR rates are shown. 345 control and 76 cemi+REGN3767 of primary efficacy analysis population have ImPrint data.
How do these results compare with cemiplimab + paclitaxel arm?

**HER2-**

- Paclitaxel: 21%
  (95% PI: 17-25%)
- Cemiplimab: 31%
  (95% PI: 22%-41%)

**HER2-**

- Paclitaxel: 21%
  (95% PI: 17% - 25%)
- REGN3767 + Cemi: 44%
  (95% PI: 34% - 54%)

---

**Immune+ Subtype**

- Paclitaxel (81):
  - RCB-0: 32 (40%)
  - RCB-I: 14 (17%)
  - RCB-II: 23 (28%)
  - RCB-III: 12 (15%)
- Cemiplimab (19):
  - RCB-0: 14 (73.7%)
  - RCB-I: 2 (10.5%)
  - RCB-II: 2 (10.5%)
- REGN3767 + Cemi (27):
  - RCB-0: 24 (89%)
  - RCB-I: 1 (4%)

- Overall RCB-0: 57%
- Overall RCB-I: 14 (73.7%)
- Overall RCB-II: 2 (10.5%)
- Overall RCB-III: 12 (15%)
- Overall survival: 84%
- Overall overall survival: 93%
Conclusions

• Cemiplimab + REGN 3767 highly effective combination in both TNBC and HR+/HER2 negative breast cancer

• ImPrint signature identified greatest benefit from checkpoint inhibitor based therapy
  • In Immune+ signature, Cemiplimab + Paclitaxel (84%) performed very similarly to Cemiplimab + REGN3767 + paclitaxel (91%)

• Addition of REGN3767 associated with increased incidence of AI as well as 3 cases (5%) of Type 1 diabetes
  • This rate has not been observed in other patient populations
  • Small studies have suggested lower irAEs with lower doses of immunotherapy

• Given activity, evaluating safety profile of lower dose REGN3767 given in combination with cemiplimab + paclitaxel
Acknowledgements

WORKING GROUP CHAIRS

<table>
<thead>
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<tr>
<td>Biomarkers</td>
<td>L. van’t Veer</td>
<td>Ct DNA: A. DeMichele</td>
<td></td>
<td>Return of Results: A. DeMichele</td>
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<tr>
<td>Ct DNA</td>
<td>A. DeMichele</td>
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<td>QED</td>
<td>A. DeMichele</td>
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<tr>
<td>IP Project Oversight: A. Barker</td>
<td></td>
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<tr>
<td>Surgery: J. Boughey, R. Mukhtar</td>
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<td>Safety: H. Rugo, R. Nanda</td>
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<tr>
<td>Clinical Operations: M. Pitsiouni</td>
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<td>Pathology: F. Symmans</td>
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<tr>
<td>IRB Working Group: T. Helsten</td>
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</tbody>
</table>

SITE PRINCIPAL INVESTIGATORS: 28 sites

City of Hope: Jennifer Tseng
Cleveland Clinic: Erin Roesch
Columbia: Meghan Trivedi
Denver: Anthony Elias
Emory: Kevin Kalinsky
Georgetown: Claudine Isaacs
HOAG: Chaitali Nangia
Huntman: Christos Vakilas
Loyola: Kathy Albain
Mayo: Judy Boughey
Mount: Heather Han
OSU: Nicole Williams
OHSU: Zahi Mitr
Rutgers: Coral Omene
Sanford: Amy Sanford
Sparrow: Brittani Thomas
UB: Erica Stringer-Reasor
UC Davis: Mili Arora
UC Chicago: Rita Nanda
UCSD: Anne Wallace
UCSF: A. Jo Chien
UMN: Doug Yee
UPenn: Carla Falckson
USC: Amy Clark
UC: Evanthia Roussos Torres
Vanderbilt: Laura Kennedy
Wake Forest: Alexandra Thomas
Yale: Tara Sanft

PROJECT OVERSIGHT

Anna Barker/USC; Patrizia Cavazzoni/FDA CDER; Reena Phillip/FDA; Janet Woodcock/FDA; Eric Rubin/Merck, FNIH Biomarker Consortium; Lisa LaVange/UNC; Ken Ehlerl/UGH

QUANTUM LEAP HEALTHCARE COLLABORATIVE/ UCSF:

CEO: J. Palazzolo
Director of Clinical Operations: M. Pitsiouni
Oncology Clinical Operations:

Safety:
M. Saleem (QLHC), A. Kelley, S. Bezwada, B. Smolich, M. Bozorginia (CCSA)

Site Regulatory: E. Guerrero, S. Rice

Drug Management: F. Chu, A. Spivak, A. Sangwan, J. Ritchie

Manuscripts/Strategy: L. Sit, J. Matthews

Collaborations
P. Henderson, S. Jafari, H. Fraser

Biomarkers/Specimens:

Imaging Lab:

Data Analysis, Data Management & IT:

DSMB & INDEPENDENT AGENT SELECTION COMMITTEE (IASC) Members

PRIOR COLLABORATORS and STAFF


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# Participating Organizations

## FUNDING PARTNERS
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- University of California San Francisco (UCSF)
- The Biomarkers Consortium
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- California Breast Cancer Research Program
- Breast Cancer Research – Atwater Trust
- Stand Up to Cancer
- National Institutes of Health (NIH/NCI)

## INVESTIGATIONAL AGENT PROVIDERS
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## DATA SUPPORT
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- The Translational Genomics Research Institute (TGen™)

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