Role of ADCs in Ovarian Cancer

David O’Malley, M.D.
Professor
Director, Division of Gynecologic Oncology
The Ohio State University and the James Cancer Center
Clinical Trial Advisor (Ovarian Cancer) GOG-Partners
VERBAL DISCLOSURE – 3 years

- Dr. O'Malley reports personal fees (consulting and/or advisory boards) and funding for clinical research from AstraZeneca, personal fees (consulting and/or advisory boards) and funding for clinical research from Tesaro/GSK, personal fees (consulting and/or advisory boards) and funding for clinical research from Immunogen, personal fees (consulting and/or advisory boards) from Ambry, personal fees (consulting and/or advisory boards) and funding for clinical research from Janssen/J&J, personal fees (consulting and/or advisory boards) and funding for clinical research from Regeneron, personal fees (consulting and/or advisory boards) and funding for clinical research from Amgen, personal fees (consulting and/or advisory boards) and funding for clinical research from NovoNordisk, personal fees (consulting and/or advisory boards) and funding for clinical research from Bristol-Myers Squibb, personal fees (consulting and/or advisory boards) and funding for clinical research from Genentech/Roche, personal fees (consulting and/or advisory boards) and funding for clinical research from VentiRx, personal fees (consulting and/or advisory boards) and funding for clinical research from Array Biopharma, personal fees (consulting and/or advisory boards) and funding for clinical research from EMD Serono, personal fees (consulting and/or advisory boards) and funding for clinical research from结束

- I serve as Clinical Trial Advisor (Ovarian Cancer) for GOG Partners and am on the GOG Foundation BOD
Agenda

• Background
• Targets
  • NaPi2b
    • Lifastuzumab (LIFA)
    • Upifitamab rilsodotin (UpRi):
  • Folate receptor alpha
    • STRO-002
    • MORAb-202
    • Mirvetuximab soravtansine (Mirv)
FDA-Approved Drugs for Ovarian Cancer

12+ Approvals since Nov 2014

More approvals in the last 6 years than the prior 60 years combined
## Target Antigens

<table>
<thead>
<tr>
<th>Target antigen</th>
<th>Function</th>
<th>Expression</th>
<th>ADC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folate receptor alpha</td>
<td>Transmembrane protein involved in transport of folate into cells necessary for metabolism, DNA synthesis, repair, and proliferation</td>
<td>Ovarian: 80-96%&lt;br&gt;Endometrial: 41%</td>
<td>Mirvetuximab soravtansine&lt;br&gt;STRO-002&lt;br&gt;MORAb-202</td>
</tr>
<tr>
<td>NaPi2b</td>
<td>Sodium-dependent phosphate transport protein expressed in epithelial cells.</td>
<td>Ovarian: 80-100%</td>
<td>Lifastuzumab vedotin&lt;br&gt;XMT-1536</td>
</tr>
<tr>
<td>Tissue Factor</td>
<td>Thromboplastin or factor III, involved in extrinsic coagulation pathway leading to generation of thrombin/clot formation.</td>
<td>Ovarian: 96%&lt;br&gt;Endometrial: 15%&lt;br&gt;Cervical: 34%</td>
<td>Tisotumab vedotin</td>
</tr>
<tr>
<td>Mesothelin</td>
<td>Hypothesized to be involved in cell adhesion. Expressed on mesothelial cells.</td>
<td>Ovarian: 60-88%</td>
<td>Anetumab ravtansine&lt;br&gt;DMOT4039A&lt;br&gt;BMS-986148</td>
</tr>
<tr>
<td>MUC16</td>
<td>Transmembrane protein with role in adhesion/peritoneal metastases. CA-125 represents the extracellular, cleaved portion.</td>
<td>Ovarian: 80%</td>
<td>DMUC4064A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADC</th>
<th>Target Antigen/Antibody</th>
<th>Cytotoxic Payload and mechanism of action</th>
<th>Linker</th>
<th>DAR</th>
<th>Phase of development</th>
</tr>
</thead>
</table>
| Mirvetuximab soravtansine (ImmunoGen, Inc) | Folate receptor α  
Humanized IgG1 (M9346A)                              | Soravtansine (Maytansinoid DM4)  
Microtubule inhibitor                                   | Sulfo-PDB                                           | 3-4 | Phase III            |
| STRO-002 (Sutro Biopharma, Inc.)         | Folate receptor α  
Human anti-FRα IgG1 antibody (SP8166)             | Proprietary 3-aminophenyl hemiasterlin agent: SC209  
Proprietary tubulin-targeting payload | Proprietary cleavable linker: SC239                  | 4   | Phase I dose escalation/expansion ongoing |
| MORAb-202 (Eisai Inc.) (NCT03386942)     | Folate receptor α  
Humanized anti-human FRα farletuzumab              | Eribulin mesylate  
Microtubule inhibitor                                  | Cathepsin B-cleavable linker             | 4   | Phase I ongoing      |
| XMT-1536 (Mersana Therapeutics) (NCT03319628) | NaPi2b  
Humanized monoclonal antibody (SLC34A2)                        | Proprietary auristatin derivative (auristatin F-HPA)  
Microtubule inhibitor                                  | Proprietary hydrophilic polymer scaffold         | 10-12 | Phase I dose escalation/expansion ongoing |
| Lifastuzumab vedotin (LIFA/DNIB0600A) (Genentech, Inc.) | NaPi2b  
Humanized monoclonal antibody (SLC34A2) | MMAE  
Microtubule inhibitor                                    | Cleavable maleimidocaproyl-valyl-citrullinyl-p-aminobenzyloxycarbonyl (mc-val-cit-PABC) | 3-4 | Randomized phase II completed; further development discontinued |
<table>
<thead>
<tr>
<th>ADC</th>
<th>Target Antigen/ Antibody</th>
<th>Cytotoxic Payload and mechanism of action</th>
<th>Linker</th>
<th>DAR</th>
<th>Phase of development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tisotumab vedotin (HuMax-TF-ADC; TF011-MMAE) (Seattle Genetics, Inc.)</td>
<td>Tissue factor&lt;br&gt; Fully human monoclonal antibody</td>
<td>MMAE&lt;br&gt; Microtubule inhibitor</td>
<td>Protease cleavable valine-citrulline linker</td>
<td></td>
<td>Phase II ongoing; Phase III in cervical cancer ongoing</td>
</tr>
<tr>
<td>Anetumab ravtansine (BAY 94-9343) (Bayer)</td>
<td>Mesothelin&lt;br&gt; Fully human IgG1 (MF-T)</td>
<td>Ravtansine/DM4&lt;br&gt; Microtubule inhibitor</td>
<td>Sulfo-PDB</td>
<td>3.2</td>
<td>Phase II ongoing</td>
</tr>
<tr>
<td>DMOT4039A (RG7600) (Genentech, Inc.)</td>
<td>Mesothelin&lt;br&gt; Humanized IgG1 antibody (h7D9.v3)</td>
<td>MMAE&lt;br&gt; Microtubule inhibitor</td>
<td>Protease cleavable valine-citrulline linker</td>
<td>3.5</td>
<td>Phase II</td>
</tr>
<tr>
<td>BMS-986148 (Bristol-Myers Squibb)</td>
<td>Mesothelin&lt;br&gt; Fully human IgG1 monoclonal antibody</td>
<td>Duocarmycin-related DNA alkylation</td>
<td>Protease cleavable valine-citrulline linker</td>
<td>1.4</td>
<td>Phase I/IIa ongoing</td>
</tr>
<tr>
<td>Sofituzumab vedotin (DMUC5754A) (Genentech, Inc.)</td>
<td>MUC16&lt;br&gt; Humanized IgG1 monoclonal antibody</td>
<td>MMAE&lt;br&gt; Microtubule inhibitor</td>
<td>Protease cleavable valine-citrulline linker (maleimidocaproyl-valine-citrulline-p-aminobenzyloxycarbonyl)</td>
<td>3.5</td>
<td>Phase I completed; further development discontinued</td>
</tr>
<tr>
<td>Anti-MUC16 TDC (DMUC4064A) (Genentech, Inc.)</td>
<td>MUC16&lt;br&gt; Humanized anti-MUC16 IgG1</td>
<td>MMAE&lt;br&gt; Microtubule inhibitor</td>
<td>Cysteine-engineered THIOMAB™</td>
<td>2</td>
<td>Phase I completed</td>
</tr>
</tbody>
</table>

NaPi2b
RPh2 Lifastuzumab vs. PLD

HR for stratified PFS was 0.78
(95% CI 0.46-1.31; p=0.34)

Banerjee et al. Annals of Oncology 2018
RPh2 Lifastuzumab vs. PLD Efficacy and Safety

<table>
<thead>
<tr>
<th></th>
<th>Lifastuzumab</th>
<th>PLD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ORR</strong></td>
<td>34% (95% CI 22-49%)</td>
<td>15% (95% CI 7-28%)</td>
</tr>
<tr>
<td>Grade 3 AEs</td>
<td>46%</td>
<td>51%</td>
</tr>
<tr>
<td>SAEs</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>AEs leading to discontinuation</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Grade ≥ 2 neuropathy</td>
<td>11%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Banerjee et al. Annals of Oncology 2018
- NaPi2b membranous staining level was scored according to the following algorithm, where at least 50% of tumor cells had to be stained in order to qualify as positive in each category

$$\text{NaPi2b H score: } [1 \times (\% \text{ cells } 1+) + 2 \times (\% \text{ cells } 2+) + 3 \times (\% \text{ cells } 3+)]$$

- NaPi2b transcript levels in the tumor tissues were also determined by qRT-PCR using a validated NaPi2b/TMEM (house-keeping gene) duplex assay (Cobas z480 Real-time PCR Platform), (Roche Molecular Systems, Pleasanton, CA)
Phase Ib Lifastuzumab plus carboplatin in platinum sensitive recurrent ovarian cancer

<table>
<thead>
<tr>
<th>Best Response</th>
<th>All Patients N=41 N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>24 (59)</td>
</tr>
<tr>
<td>PR</td>
<td>6 (15)</td>
</tr>
<tr>
<td>SD</td>
<td>13 (32)</td>
</tr>
<tr>
<td>PD</td>
<td>2 (5)</td>
</tr>
<tr>
<td>UE</td>
<td>2 (5)</td>
</tr>
</tbody>
</table>

ORR 74%

LIFA: Lifastuzumab Vedotin (DNIB0000A), an antibody drug conjugate of anti-NapI2b monoclonal antibody (MNIB2126A) and an anti-mitotic agent (MMAE)
Carbo: carboplatin at dose AUC 6 mg/min/min
Bev: bevacizumab at 15 mg/kg

Moore et al. Gynecol Oncol 2020
**XMT-1536 (upifitamab rilsodotin; UpRi): NaPi2b Dolaflexin ADC**

**Dolaflexin**
Improved therapeutic index vs other platforms

- Polymer scaffold
- High Drug to Antibody Ratio (DAR) ~10-12
- Excellent drug like properties

**DolaLock Payload**
Efficacy without severe neutropenia, neuropathy, or ocular toxicity

- Novel auristatin
- Controlled bystander effect
- Selectively toxic to rapidly dividing cells
- Not a PgP substrate
- Induces immunogenic cell death
Design for the Ovarian Cancer Cohort of the XMT-1536 (UpRi) Phase 1 Expansion Study

Patient population: High grade serous ovarian cancer (including fallopian tube and primary peritoneal cancer) progressing after standard treatments

- Measurable disease per RECIST v1.1
- ECOG Performance Status 0 or 1

Dosing: IV every 4 weeks until disease progression or unacceptable toxicity
- 36 mg/m² cohort initiated in August 2019 and enrollment closed
- 43 mg/m² cohort initiated in December 2019 and ongoing; current dose evaluated in EXP

Primary Objectives:
- Evaluate safety and tolerability of MTD
- Assess preliminary efficacy (ORR, DCR)

Secondary Objectives:
- Association of tumor NaPi2b expression and objective tumor response using an immunohistochemistry (IHC) assay with a broad dynamic range to distinguish tumors with higher and lower NaPi2b expression (as previously reported\textsuperscript{1,2,3})
- Further assessment of preliminary anti-neoplastic activity (DOR)

Assessments:
- Tumor imaging (MRI or CT): baseline and every 2\textsuperscript{nd} cycle; response assessed per RECIST v1.1

Ovarian Cancer Cohort

- 1-3 prior lines in platinum resistant
- 4 prior lines regardless of platinum status
- High grade serous histology
- Archived tumor and fresh biopsy (if medically feasible) for NaPi2b
- Exclusion: primary platinum-resistant defined as lack of response or disease progression within 3 mos after completing front-line platinum containing

Patient population:

- High grade serous ovarian cancer (including fallopian tube and primary peritoneal cancer) progressing after standard treatments

Abbreviations: mos = months; EXP = expansion; RECIST = Response Evaluation Criteria in Solid Tumors; ECOG = Eastern Cooperative Oncology Group; MTD = maximum tolerated dose; ORR = objective response rate; DCR = disease control rate; DOR = duration of response

\textsuperscript{1}Tolcher TW et al. J Clin Oncol 37, 2019 (suppl; abstr 3010)
\textsuperscript{2}Richardson DL et al. Presented at SGO Annual Meeting 2020; LBA8
\textsuperscript{3}Hamilton E et al. Presented during the 2020 European Society of Medical Oncology (ESMO) Virtual Congress
## Efficacy

### Best Response in Evaluable Patients with Ovarian Cancer (n = 47)

<table>
<thead>
<tr>
<th></th>
<th>All (n = 47)</th>
<th>Higher NaPi2b(^{\circ}) (n = 31)</th>
<th>Lower NaPi2b(^{\circ\circ}) (n = 13)</th>
<th>NaPi2b Not Yet Determined (n = 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR; n(%)</td>
<td>2 (4)</td>
<td>2 (6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PR; n(%)</td>
<td>11 (23)</td>
<td>8 (26)</td>
<td>2 (15)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>SD; n(%)</td>
<td>19 (40)</td>
<td>13 (42)</td>
<td>5 (38)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>PD; n(%)</td>
<td>15 (32)</td>
<td>8 (26)</td>
<td>6 (46)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>ORR; n (%)</td>
<td>13 (28)</td>
<td>10 (32)</td>
<td>2 (15)</td>
<td>1 (33)</td>
</tr>
<tr>
<td>DCR; n (%)</td>
<td>32 (68)</td>
<td>23 (74)</td>
<td>7 (54)</td>
<td>2 (67)</td>
</tr>
</tbody>
</table>

All Responses are Confirmed

*25 patients were not evaluable for RECIST response: 10 patients discontinued prior to first scans: 1 clinical progression; 1 related SAE (G5 pneumonitis); 3 unrelated SAEs; 5 withdrew consent; 15 patients did not yet have RECIST assessment as of the data cut

\(^{\circ}\) Higher NaPi2b Expression: defined in dose escalation as at / above lowest H-score at which response observed (≥110)

\(^{\circ\circ}\) Lower NaPi2b Expression: defined in dose escalation as below the lowest H-score at which response observed (<110)

Richardson DL et al. Presented at SGO Annual Meeting 2020;
**Efficacy**

Maximum % Change from Baseline in Target Lesions in Patients with Ovarian Cancer (n = 45*)

- 30/45 (67%) had reductions in target tumor lesions
- 2 patients not included in waterfall plot as tumor measurement data missing in the database as of data cut; both patients had BOR of PD due to new lesions
- Unconfirmed response, BOR per RECIST v1.1 is SD
- CR of target lesions and non-CR/non-PD of non-target lesions, BOR per RECIST v1.1 is PR
- H = Higher NaPi2b Expression; L = Lower NaPi2b Expression; ND = NaPi2b Expression not yet determined or tissue not available

*2Richardson DL et al. Presented at SGO Annual Meeting 2020;
Clear Trend to Longer Time on Study with Higher NaPi2b Expression

Time on XMT-1536 Study in Patients with Ovarian Cancer (n = 72)

NaPi2b Expression

Higher

Lower

ND

Time on Study (Weeks)

36 mg/m2
43 mg/m2
Dose Reduction

Abbreviations: CR = complete response; PR = partial response; H = Higher NaPi2b Expression; L = Lower NaPi2b Expression; ND = NaPi2b Expression not yet determined or tissue not available

Richardson DL et al. Presented at SGO Annual Meeting 2020;
### Best Response in Evaluable Patients with Ovarian Cancer (n = 75)

<table>
<thead>
<tr>
<th></th>
<th>NaPi2b High (TPS≥75)</th>
<th>NaPi2b Low (TPS&lt;75)</th>
<th>Not Yet Determined NaPi2b</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>38</td>
<td>23</td>
<td>14</td>
<td>75</td>
</tr>
<tr>
<td><strong>CR</strong></td>
<td>2 (5)</td>
<td>0</td>
<td>0</td>
<td>2 (3)</td>
</tr>
<tr>
<td><strong>PR</strong></td>
<td>11 (29)</td>
<td>2 (9)</td>
<td>2 (14)</td>
<td>15 (20)</td>
</tr>
<tr>
<td><strong>uPR</strong></td>
<td>1 (3)</td>
<td>0</td>
<td>2 (14)</td>
<td>3 (4)</td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td>19 (50)</td>
<td>8 (35)</td>
<td>7 (50)</td>
<td>34 (45)</td>
</tr>
<tr>
<td><strong>PD</strong></td>
<td>5 (13)</td>
<td>13 (57)</td>
<td>3 (21)</td>
<td>21 (28)</td>
</tr>
<tr>
<td><strong>Confirmed ORR</strong></td>
<td>13 (34)</td>
<td>2 (9)</td>
<td>2 (14)</td>
<td>17 (23)</td>
</tr>
<tr>
<td><strong>DCR</strong></td>
<td>33 (87)</td>
<td>10 (43)</td>
<td>11 (79)</td>
<td>54 (72)</td>
</tr>
</tbody>
</table>

Data Cut: June 10, 2021

https://ir.mersana.com/static-files/f50f16b7-c8bf-4268-903c-8f9860ccc3f5
GOG 3048 UPLIFT: Single-Arm US Registration Strategy in Platinum Resistant Ovarian Cancer

### UPLIFT Design

<table>
<thead>
<tr>
<th>Platinum-Resistant High-Grade Serous Ovarian Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>• N=~100 Higher NaPi2b, up to ~180 Overall</td>
</tr>
<tr>
<td>• 1-4 prior lines</td>
</tr>
<tr>
<td>• Prior bevacizumab not required for patients with 3 – 4 prior lines</td>
</tr>
<tr>
<td>• No exclusion for baseline peripheral neuropathy</td>
</tr>
<tr>
<td>• Enrolling regardless of NaPi2b expression</td>
</tr>
</tbody>
</table>

- Primary Endpoint: Confirmed ORR in higher NaPi2b
- Key Secondary Endpoint: Confirmed ORR in overall population
- Other Secondary Endpoints: Duration of Response; Safety

Dose: 43 mg/m² IV q28d  
Global: US, Europe, Australia, Canada

PI: Deb Richardson, presented at ASCO
GOG 3048 UPLIFT: Single-Arm US Registration Strategy in Platinum Resistant Ovarian Cancer

**UPLIFT Design**

Platinum-Resistant High-Grade Serous Ovarian Cancer

- N=\textasciitilde100 Higher NaPi2b, up to \textasciitilde180 Overall
- 1-4 prior lines
- Prior bevacizumab not required for patients with 3 – 4 prior lines
- No exclusion for baseline peripheral neuropathy
- Enrolling regardless of NaPi2b expression

**Primary Endpoint:** Confirmed ORR in higher NaPi2b

**Key Secondary Endpoint:** Confirmed ORR in overall population

**Other Secondary Endpoints:** Duration of Response; Safety

**Dose:** 43 mg/m² IV q28d

Global: US, Europe, Australia, Canada

**New UPLIFT Dose:** 36 mg/m² up to a maximum of 80 mg

https://ir.mersana.com/static-files/f50f16b7-c8bf-4268-903c-8f9860ccc3f5

PI: Deb Richardson, presented at ASCO
UP-NEXT GOG-3049

Key Enrollment Criteria:
- Platinum-sensitive recurrence, following platinum induction
- NaPi2b High biomarker selection by TPS>75
- 1 – 3 prior platinum-based regimes
- Prior PARPi therapy allowed, but only required for BRCAmut
- SD in addition to CR/PR as best response following platinum induction

Primary Endpoint:
- PFS

Final Design Pending CHMP Scientific Advice Plans to Initiate in 2022

PI: Deb Richardson, M.D.  
https://ir.mersana.com/static-files/f50f16b7-c8bf-4268-903c-8f9860ccc3f5
Folate Receptor Alpha
**Part 1: Dose-escalation cohort in ovarian cancer**

- All comers ovarian cancer
  - N = 39

- 34 patients treated at clinically active dose (≥ 2.9 mg/kg Q3W)

- Of which, 31 patients were evaluable for RECIST

- Recommended doses for expansion cohorts
  - STRO-002 2.9 mg/kg
    - STRO-002 4.3 mg/kg
    - STRO-002 5.2 mg/kg
    - STRO-002 5.6 mg/kg
    - STRO-002 6.0 mg/kg

**Part 2: Dose-expansion cohorts (ovarian and endometrial cancers)**

- All comers ovarian cancer
  - Tissue required prior to enrollment
    - First-line platinum-refractory patients excluded
  - 1 to 3 prior regimens for platinum-resistant patients
  - 2 to 3 prior regimens for platinum-sensitive patients
  - Baseline peripheral neuropathy grade ≥ 2 excluded

- FRe-selected endometrial cancer
  - Relapsed/refractory disease
  - No standard-of-care treatment

- *CR* in patient treated at 2.0 mg/kg with resolution of peritoneal disease. CR, complete response; PD, progressive disease; PRu, unconfirmed partial response; Q3W, every 3 weeks; SD, stable disease.

**Key endpoints:** Safety (DLTs and TEAEs), ORR, PK profile, DOR, PFS1, OS1, Biomarkers

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**R. Wendel Naumann et al ASCO 2021**

**FOLR1 PS2+ score:**

<table>
<thead>
<tr>
<th>Expression</th>
<th>Weak/absent</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>PRu</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>SD</td>
<td>5</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>PD</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Figure 3. Treatment duration* and response in RECIST-evaluable patients treated with STRO-002 ≥ 2.9 mg/kg Q3W (N = 31)

Objective response was observed in 15 patients

<table>
<thead>
<tr>
<th>Dose level (mg/kg)</th>
<th>PR</th>
<th>CR</th>
<th>PRu</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.9</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3.5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4.3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5.2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5.6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6.0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6.4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Duration calculated as date of PD or time from first dose to last dose given (including 4 patients deriving clinical benefit post progression per investigator assessment). CR, complete response; PD, progressive disease; PRu, unconfirmed partial response; Q3W, every 3 weeks; SD, stable disease.

Figure 2. Maximum change in tumor target lesions in RECIST-evaluable patients treated with STRO-002 ≥ 2.9 mg/kg Q3W (N = 31)

Objective response was observed in 15 patients

<table>
<thead>
<tr>
<th>Treatment ongoing</th>
<th>Starting dose (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR</td>
<td>2.9</td>
</tr>
<tr>
<td>CR</td>
<td>0</td>
</tr>
<tr>
<td>PRu</td>
<td>0</td>
</tr>
</tbody>
</table>

*Maximum percentage change from baseline in sum of longest diameter in evaluable patients treated with STRO-002 at ≥ 2.9 mg/kg Q3W (N = 31); **CR in patient treated at 2.9 mg/kg with resolution of peritoneal disease; PR, progressive disease; PRu, unconfirmed partial response; Q3W, every 3 weeks; SD, stable disease.

R. Wendel Naumann et al ASCO 2021
### ORR by TPS Expression Levels (Total Samples N=33)

<table>
<thead>
<tr>
<th>TPS</th>
<th>Overall</th>
<th>TPS ≤ 25%</th>
<th>TPS &gt; 25%</th>
<th>TPS &gt; 50%</th>
<th>TPS &gt; 75%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR</td>
<td>33.3%</td>
<td>12.5%</td>
<td>40.0%</td>
<td>42.1%</td>
<td>43.8%</td>
</tr>
<tr>
<td>Number of patient samples</td>
<td>N=33</td>
<td>N=8</td>
<td>N=25</td>
<td>N=19</td>
<td>N=16</td>
</tr>
<tr>
<td>PR(1)</td>
<td>11</td>
<td>1</td>
<td>10</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Potential Market Size (%)</td>
<td>100%</td>
<td>~30%</td>
<td>~70%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients at the **5.2 mg/kg starting dose** and TPS > 25% demonstrated **53.8% ORR** (n=13)
<table>
<thead>
<tr>
<th>TPS</th>
<th>Overall</th>
<th>TPS ≤ 25%</th>
<th>TPS &gt; 25%</th>
<th>TPS &gt; 50%</th>
<th>TPS &gt; 75%</th>
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<td>43.8%</td>
</tr>
<tr>
<td>Number of patient</td>
<td>N=33</td>
<td>N=8</td>
<td>N=25</td>
<td>N=19</td>
<td>N=16</td>
</tr>
</tbody>
</table>

August 18, 2021
Sutro Biopharma Announces STRO-002 FDA Fast Track Designation for Patients with Advanced Ovarian Cancer

Patients at the **5.2 mg/kg starting dose** and **TPS > 25%** demonstrated **53.8% ORR (n=13)**
MORAb-202

- MORAb-202 is an antibody–drug conjugate consisting of farletuzumab joined to eribulin by a cathepsin-B cleavable linker
- Farletuzumab is thought to induce immune-dependent cell death, although the exact underlying mechanism is unknown
- Farletuzumab negative phase III*

Mirvetuximab soravtansine (Mirv) – FIH/Expansion

Table 3. Summary of Efficacy Measures Grouped by FRα Expression

<table>
<thead>
<tr>
<th>FRα Expression</th>
<th>No. of Patients</th>
<th>CR</th>
<th>PR</th>
<th>SD</th>
<th>PD</th>
<th>ND</th>
<th>ORR (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>9</td>
<td>0</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>22.2</td>
<td>2.8 to 60.0</td>
</tr>
<tr>
<td>Medium</td>
<td>14</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>2</td>
<td>0</td>
<td>28.6</td>
<td>8.4 to 58.1</td>
</tr>
<tr>
<td>High</td>
<td>23</td>
<td>1</td>
<td>5</td>
<td>14</td>
<td>2</td>
<td>1</td>
<td>26.1</td>
<td>10.2 to 48.4</td>
</tr>
<tr>
<td>Total</td>
<td>46</td>
<td>1</td>
<td>11</td>
<td>28</td>
<td>4</td>
<td>2</td>
<td>26.1</td>
<td>14.3 to 41.1</td>
</tr>
</tbody>
</table>

Abbreviations: CR, complete response; FRα, folate receptor alpha; ND, not determined; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.


FORWARD-2
ASCO 2017

Study Schema

<table>
<thead>
<tr>
<th>Escalation</th>
<th>Expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirvetuximab soravtansine + Bevacizumab</td>
<td>Bevacizumab (BEV-naive EOC)</td>
</tr>
<tr>
<td>Mirvetuximab soravtansine + Carboplatin</td>
<td>Bevacizumab (BEV-pretreated EOC)</td>
</tr>
<tr>
<td>Mirvetuximab soravtansine + PLD</td>
<td></td>
</tr>
<tr>
<td>Mirvetuximab soravtansine + Pembrolizumab</td>
<td>Pembrolizumab</td>
</tr>
</tbody>
</table>

Patients with FRα-positive epithelial ovarian cancer (EOC), primary peritoneal, or fallopian tube cancer

Confirmed ORR and Progression-Free Survival

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Bevacizumab</th>
<th>Carboplatin</th>
<th>PLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR (confirmed)</td>
<td>29%</td>
<td>65%</td>
<td>13%</td>
</tr>
<tr>
<td>95% CI</td>
<td>(8, 58)</td>
<td>(38, 86)</td>
<td>(2, 38)</td>
</tr>
<tr>
<td>PFS (months)</td>
<td>9.5</td>
<td>12.1</td>
<td>7.0</td>
</tr>
<tr>
<td>Median (months)</td>
<td>(3.5, 15.2)</td>
<td>(9.0, 15.0)</td>
<td>(1.7, -)</td>
</tr>
</tbody>
</table>

Percent Tumor Change in Target Lesions by FRα Expression

Safety findings from FORWARD II: a phase 1b study evaluating the folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC) mirvetuximab soravtansine (IMGN853) in combination with bevacizumab, carboplatin, pegylated liposomal doxorubicin (PLD), or pembrolizumab in patients with ovarian cancer

David M. O’Malley1, Kathleen N. Moore2, Igraçe Viegas2, Luana J. Maroto1, Javier Gil-Orozco1, Adrianna González-Martín1, Karin Majek1, Michael J. Birrer4, Linus A. Malbon5

1The Ohio State University. 2Clinical Trials. 3University of Massachusetts Medical School. 4Memorial Sloan Kettering Cancer Center. 5Icahn School of Medicine at Mount Sinai. 6Fox Chase Cancer Center. 7Philips. 8Mount Sinai Health System. Toronto, Canada. 9National Institute of Public Health and the Environment. 10AstraZeneca. 11University Hospital of the University of Freiburg. 12AstraZeneca. 13University of Southern California. 14AstraZeneca.
**Mirv + Bev**

ASCO 2019

---

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Total (n = 66)</th>
<th>Low (n = 13)</th>
<th>Medium (n = 24)</th>
<th>High (n = 28)</th>
<th>AURELIA-type** (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR (confirmed) 95% CI</td>
<td>39% (28, 52)</td>
<td>31% (9, 61)</td>
<td>46% (26, 67)</td>
<td>39% (22, 59)</td>
<td>56% (30, 80)</td>
</tr>
<tr>
<td>PFS (months)</td>
<td>Median 95% CI</td>
<td>6.9 (4.9, 8.6)</td>
<td>6.0 (2.1, 8.8)</td>
<td>6.9 (4.4, 9.9)</td>
<td>7.1 (4.4, 14.5)</td>
</tr>
<tr>
<td>DOR (months)</td>
<td>Median 95% CI</td>
<td>8.6 (4.9, 14.9)</td>
<td>ND (3.7, -)</td>
<td>7.4 (2.6, -)</td>
<td>12.0 (4.9, -)</td>
</tr>
</tbody>
</table>

**ORR**
- **Low FRα:** 31%
- **Medium FRα:** 46%
- **High FRα:** 39%
- **AURELIA-type:** 56%

**PFS (months)**
- **Low FRα:** 6.9 months
- **Medium FRα:** 6.0 months
- **High FRα:** 6.9 months
- **AURELIA-type:** 9.9 months

**DOR (months)**
- **Low FRα:** 8.6 months
- **Medium FRα:** ND
- **High FRα:** 7.4 months
- **AURELIA-type:** 12.0 months

---

Mirv + Carbo + Bev
ESMO 2020

### Dosing Schema and Summary of Drug Exposure

**A**
- Carboplatin (AUC 5) Q3W - may be discontinued after 6 cycles at discretion of investigator
- Mirvetuximab (6 mg/kg IV) Q3W to progression
- Bevacizumab (15 mg/kg) Q2W to progression

**B**

<table>
<thead>
<tr>
<th>No. of Cycles Received</th>
<th>Carboplatin</th>
<th>Mirvetuximab</th>
<th>Bevacizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>6</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>(range)</td>
<td>(3-11)</td>
<td>(4-30)</td>
<td>(1-36)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (n = 41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of prior systemic therapies, n (%)</td>
<td>1 (31 (76)) 2 (10 (24))</td>
</tr>
<tr>
<td>Platinum-free treatment interval, n (%)</td>
<td>≤ 12 months (24 (59)) &gt; 12 months (17 (41))</td>
</tr>
<tr>
<td>FRα expression* n (%)</td>
<td>High (20 (49)) Medium (21 (51))</td>
</tr>
</tbody>
</table>

### Confirmed ORR and Time-to-Event Endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Total (n=41)</th>
<th>Medium (n=21)</th>
<th>High (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR (confirmed; 95% CI)</td>
<td>83% (68, 93)</td>
<td>86% (64, 97)</td>
<td>80% (56, 94)</td>
</tr>
<tr>
<td>DOR mo. (median; 95% CI)</td>
<td>10.9 (7.7, 13.6)</td>
<td>13.3 (6.7, 15.2)</td>
<td>9.9 (7.5, 12.3)</td>
</tr>
<tr>
<td>PFS mo. (median; 95% CI)</td>
<td>12.8 (9.1, 14.6)</td>
<td>12.9 (8.1, 16.2)</td>
<td>12.4 (9.0, 14.6)</td>
</tr>
</tbody>
</table>

DOR, duration of response; ND, not determined
* Pts (n=30) with 1 prior had an ORR of 90%, DOR of 9.7 mo. (7.6, 12.3) and PFS of 11.9 (9.0, 14.8)

### Maximum Tumor Change (%) in Target Lesions from Baseline

CRs with ≥ 90% decrease; Lymph node target lesions that met CR definition per PERCIST 1.1 (i.e., all pathological lymph nodes had reduction in short axis to <10 mm)

- Confirmed tumor responses were observed in 34 patients, consisting of 10 complete responses (CR) and 24 partial responses (PR); two additional patients had unconfirmed PRs as best response

---

**Mirvetuximab soravatansine**, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with carboplatin and bevacizumab: final results from a Phase 1b study in patients (pts) with ovarian cancer

David M. O'Malley¹, Debra L. Richardson², Ignace Verpenn³, Lucy Gilbert², Lamie P. Martin⁴, Gina M. Manita-Smaldone⁵, Cesar M. Castro⁶, Diane Provencher⁷, Ursula A. Maldonado⁷, Patrick Zweidler-McKay⁸, Kathleen M. Moore⁸

---

¹Despite target lesion PR, overall response of patient at cycle 4 was PD due to appearance of new lesions

- Confirmed tumor responses were observed in 34 patients, consisting of 10 complete responses (CR) and 24 partial responses (PR); two additional patients had unconfirmed PRs as best response
**Mirv + Bev – Platinum Agnostic**

**ASCO 2021**

- **50% ORR (30/60)** for overall cohort
- **64% ORR (21/33)** in high FRα tumors
  - 59% ORR (10/17) in PROC subset
  - 69% ORR (11/16) in PSOC subset
- **9.7 mo mDOR** for overall cohort
- **11.8 mo mDOR** in high FRα tumors
  - 9.4 mo mDOR in PROC subset
  - 12.7 mo mDOR in PSOC subset

O’Malley DM, et al ASCO 2021
Moore, K, ESMO 2019

**STUDY DESIGN**

- **FORWARD I**
  - Platinum-resistant ovarian cancer
  - FRα-positive tumor expression
    - Medium (50-74% cells positive)
    - High (≥75% cells positive)
  - ECOG performance status 0 or 1
  - 1-3 prior therapies

**Statistical Assumptions**
- Hochberg procedure
- α=0.05 (two-sided), power = 90%
  - HR=0.58; control arm mPFS 3.5 mos

**Mirvetuximab Soravtansine**
- (n=248)
  - 6 mg/kg (adjusted ideal body weight) once every 3 weeks

**2:1 Randomization**
- **Stratification Factors:**
  - FRα expression (medium or high)
  - Prior therapies (1 and 2, or 3)
  - Choice of chemotherapy

**Primary Endpoint**
- Progression-free survival (PFS; by BIRC*) for ITT and high FRα populations
- *BIRC = Blinded Independent Review Committee; analyzed by Hochberg procedure

**Secondary Endpoints**
- Overall response rate (ORR)
- Overall survival (OS)
- Patient reported outcomes (PRO)

**Investigator’s Choice Chemotherapy**
- Paclitaxel, PLD†, or Topotecan
  - (n=118)
  - **Paclitaxel:** 80 mg/m² weekly
  - **PLD:** 40 mg/m² once every 4 weeks
  - **Topotecan:** 4 mg/m² on Days 1, 8, and 15 every 4 weeks; or 1.25 mg/m² on Days 1-5 every 3 weeks

†Pegylated liposomal doxorubicin
ClinicalTrials.gov Identifier: NCT02631876
**Efficacy Results at a Glance**

**Intent to treat (ITT) population**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Treatment effect size</th>
<th>p-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS by BIRC</td>
<td>HR: 0.981 mPFS: 4.1 vs 4.4</td>
<td>0.897</td>
</tr>
<tr>
<td>ORR by BIRC</td>
<td>22% vs 12%</td>
<td>0.015</td>
</tr>
<tr>
<td>DOR (mos)</td>
<td>HR: 0.982 5.7 vs 7.3</td>
<td>0.974</td>
</tr>
<tr>
<td>OS</td>
<td>HR: 0.815 mOS: 16.4 vs 14.0</td>
<td>0.248</td>
</tr>
<tr>
<td>PFS by INV</td>
<td>HR: 0.809 mPFS: 4.3 vs 4.2</td>
<td>0.116</td>
</tr>
<tr>
<td>ORR by INV</td>
<td>29% vs 16%</td>
<td>0.008</td>
</tr>
<tr>
<td>CA125 ORR</td>
<td>51% vs 27%</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

*Nominal P-value

**FRa high subgroup**

<table>
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<tbody>
<tr>
<td>PFS by BIRC</td>
<td>HR: 0.693 mPFS: 4.8 vs 3.3</td>
<td>0.049</td>
</tr>
<tr>
<td>ORR by BIRC</td>
<td>24% vs 10%</td>
<td>0.014</td>
</tr>
<tr>
<td>DOR (mos)</td>
<td>HR: 0.598 5.7 vs 4.2</td>
<td>0.374</td>
</tr>
<tr>
<td>OS</td>
<td>HR: 0.618 mOS: NR vs 11.8</td>
<td>0.033</td>
</tr>
<tr>
<td>PFS by INV</td>
<td>HR: 0.667 mPFS: 5.0 vs 4.2</td>
<td>0.018</td>
</tr>
<tr>
<td>ORR by INV</td>
<td>29% vs 13%</td>
<td>0.007</td>
</tr>
</tbody>
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**Efficacy Results ORR and DOR**

**Intent to treat (ITT) population**

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**FRa high subgroup**

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<td>0.374</td>
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<tr>
<td>ORR by INV</td>
<td>29% vs 13%</td>
<td>0.007</td>
</tr>
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</table>

*BIRC = Blinded Independent Review Committee  NS based on Hochberg Procedure

**Moore, K, ESMO 2019**

*NS per Hochberg procedure

**Moore KM et al; Annals of Oncology; 32 (6) 2021**

- **FORWARD-1**
  - Negative for primary objectives
  - ITT
  - HIGH FORa
  - FORa predictive marker for Mirv
  - FORa prognostic markers

![Graph showing efficacy results](image-url)
FORWARD I 10X SCORING COMPARED WITH EXPLORATORY PS2+ SCORING

Rescoring of the FORWARD I samples using PS2+ indicates:
- 34% of patients enrolled in FORWARD I had low FRα levels that should have precluded enrollment; and
- the protocol-defined FRα high subset contained patients with a mixture of FRα expression levels.

PS2+ RE-SCORING: PFS TRENDS ACROSS SUBGROUPS

PFS Hazard Ratio Plot

PFS (by BIRC) - FRα High (n=116)

HR: 0.549 P=0.015
mPFS: 5.6 vs 3.2 months

PFS by BIRC (mo.)
HR: 1.456 (0.878, 2.420)
mPFS: 3.8 vs 5.5
HR: 1.015 (0.611, 1.687)
mPFS: 4.3 vs 5.6
HR: 0.549 (0.336, 0.897)
mPFS: 5.6 vs 3.2

ORR by BIRC 95% CIs
16% vs 16%
(8%, 26%) vs (8%, 31%)
28% vs 18%
(16%, 40%) vs (7%, 35%)
29% vs 6%
(20%, 40%) vs (1%, 20%)

OS (August 2019) (mo.)
HR: 0.923 (0.548, 1.554)
mOS: 14.0 vs 13.4
HR: 0.936 (0.542, 1.616)
mOS: 15.9 vs 20.7
HR: 0.678 (0.410, 1.119)
mOS: 16.4 vs 11.4

PFS by INV (mo.)
HR: 1.149 (0.732, 1.803)
mPFS: 4.0 vs 4.5
HR: 0.810 (0.523, 1.254)
mPFS: 5.1 vs 2.8
HR: 0.619 (0.394, 0.975)
mPFS: 5.6 vs 3.7

ORR by INV 95% CIs
18% vs 21%
(11%, 25%) vs (10%, 37%)
36% vs 24%
(25%, 49%) vs (11%, 41%)
38% vs 9%
(27%, 49%) vs (2%, 24%)

Moore, K, ESMO 2019
SORAYA

SINGLE-ARM PIVOTAL TRIAL OF MIRVETUXIMAB IN FRα-HIGH PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER

**INCLUSION CRITERIA**

- Platinum-resistant disease (PFI < 6 months)
- FRα-high only
- Prior bevacizumab required
- Prior PARPi allowed
- 1 to 3 prior lines allowed
- Patients with BRCA mutations allowed

**PRIOR TREATMENT**

- 51% received 3 prior lines of therapy
- 100% received prior bevacizumab
- 48% received prior PARPi

**SAFETY AND TOLERABILITY**

- Favorable tolerability data with >700 patients treated to date
- In SORAYA, the most common AEs were low-grade gastrointestinal and ocular events, including blurred vision, keratopathy, and nausea; 7% of patients discontinued due to treatment-related AEs, including one patient due to ocular AE

**MET PRIMARY ENDPOINT**

<table>
<thead>
<tr>
<th>ORR</th>
<th>AURELIA by Inv</th>
<th>SORAYA by Inv</th>
<th>SORAYA by BICR</th>
</tr>
</thead>
<tbody>
<tr>
<td>12%</td>
<td>32.4%</td>
<td>31.6%</td>
<td></td>
</tr>
</tbody>
</table>

Responses were irrespective of number of prior lines or prior PARPi use.

**KEY SECONDARY ENDPOINT**

5.9 months mDOR

By Investigator at Data Cutoff (95% CI: 5.6, 7.7)

Nearly half of responders still receiving mirvetuximab at data cutoff; with longer follow-up, mDOR could range from 5.7 to above 7 months


2Disclaimer: These comparisons are not based on head-to-head clinical studies. The results from these two studies are not directly comparable.

GOG 3045 MIRASOL

PHASE 3 RANDOMIZED TRIAL FOR MIRVETUXIMAB IN FRA-HIGH PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER

TARGET TIMELINES
- ENROLLING GLOBALLY
- TOP-LINE DATA Q3 2022
- EXPECTED APPROVAL 2023

1: RANDOMIZATION

INVESTIGATOR'S CHOICE CHEMOTHERAPY
- Platinum, PLD, or Topotecan

PRIMARY ENDPOINT
- PFS by Investigator
- BCR for Sensitivity Analysis

SECONDARY ENDPOINTS
- ORR by Investigator, OS, and PRO

ENROLLMENT AND KEY ELIGIBILITY
- 430 patients/330 events for PFS by Investigator
- Platinum-resistant disease (primary PFI > 3 months)
- 1 to 3 prior lines of therapy
- Prior bevacizumab+ and prior PARPI allowed
- Patients with BRCA mutations allowed

GLORIOSA

RANDOMIZED PHASE 3 TRIAL FOR MIRVETUXIMAB + BEVACIZUMAB MAINTENANCE IN FRA-HIGH PLATINUM-SENSITIVE OVARIAN CANCER

INITIATING IN Q2 2022

420 STUDY

SINGLE-ARM PHASE 2 TRIAL OF MIRVETUXIMAB + CARBOPLATIN FOLLOWED BY MIRVETUXIMAB CONTINUATION IN FRα-LOW, MEDIUM, AND HIGH PATIENTS WITH PLATINUM-SENSITIVE OVARIAN CANCER

INITIATING IN Q2 2022

PICCOLO

SINGLE-ARM TRIAL FOR MIRVETUXIMAB IN FRA-HIGH PATIENTS WITH PLATINUM-SENSITIVE OVARIAN CANCER

NOW ENROLLING

PRIMARY ENDPOINT
- ORR by Investigator

SECONDARY ENDPOINT
- DOR by Investigator

ENROLLMENT AND KEY ELIGIBILITY
- ~75 patients
- Platinum-sensitive ovarian cancer
- 2 or more prior systemic treatments
- At least 2 prior platinum-containing regimens
- Prior PARPI required if BRCA+
- Appropriate for single-agent therapy

PRIMARY ENDPOINT
- PFS

SECONDARY ENDPOINTS
- OS, DOR

ENROLLMENT AND KEY ELIGIBILITY
- 438 patients
- Platinum-sensitive ovarian cancer
- 1 prior platinum treatment
- Prior PARPI required if BRCA+
- CR, PR, or SD after treatment with platinum-based doublet + bevacizumab required

https://www.immunogen.com/what-we-do/our-pipeline/
Conclusions

• ADCs are going to likely impact our treatment paradigm in ovarian cancer
  • Likely approval in PROC
  • Earlier Lines of Therapy?

• Diagnostic Testing
  • NaPi2b
  • FORa
  • Others

• Impact of approval on other agents and development?
Questions?