Updated Results From the Phase 1b Expansion Study of Upifitamab Rilsodotin (UpRi; XMT-1536), a NaPi2b-directed Dolaflexin Antibody Drug Conjugate (ADC) in Ovarian Cancer

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Financial Disclosures

• I have the following financial relationships with ACCME-defined ineligible companies to report over the past 24 months:
  • Consulting for Mersana, AstraZeneca, GlaxoSmithKline
Unlabeled/Investigational Uses

• I will be discussing unlabeled or investigational uses of pharmaceutical products or medical devices
  • This is a presentation of a clinical trial of upifitamab rilsodotin (UpRi, XMT-1536), which is not FDA-approved
Upifitamab Rilsodotin (UpRi) – First-in-Class ADC Targeting NaPi2b

**Antibody:** Humanized monoclonal anti-NaPi2b

**Linker:** Polymer scaffold; cleavable ester linker

**Payload:** AF-HPA (DolaLock-controlled bystander effect)

**Drug-to-Antibody Ratio:** ~10

Upon ADC internalization into tumor cells and efficient release of payload, AF-HPA payload is metabolized to AF that remains highly potent but loses the ability to cross the cell membrane, locking it in the tumor, controlling the bystander effect, and consequently limiting impact on adjacent healthy cells.

**NaPi2b** is a Sodium-Dependent Phosphate Transporter Broadly Expressed in Ovarian Cancer With Limited Expression in Healthy Tissues

- NaPi2b expressed by tumor cells in two-thirds of patients with high-grade serous ovarian cancer
- NaPi2b is a lineage antigen (not an oncogene)

**NaPi2b IHC assay in development** – an optimal diagnostic assay would be robust, predictive, reproducible, easily able to distinguish a wide range of expression using TPS scoring method

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UpRi Phase 1b Study – Ovarian Cancer Expansion Cohort Study Design

Study Closed for Enrollment

**Patient Population:** HGSOC\(^a\) progressing after standard treatments; measurable disease per RECIST v1.1; ECOG PS 0 or 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-refractory disease

**UpRi IV Q4W until disease progression or unacceptable toxicity**

- 36 mg/m\(^2\) cohort initiated in August 2019
- 43 mg/m\(^2\) to a max of ~80 mg cohort initiated in December 2019

**Primary Objectives**
- Evaluate safety and tolerability of MTD or RP2D
- Assess preliminary efficacy (ORR, DCR)

**Secondary Objectives**
- Association of tumor NaPi2b expression and objective tumor response using an IHC assay with a broad dynamic range to distinguish tumors with high and low NaPi2b expression
- Further assessment of preliminary anti-neoplastic activity (DoR)

**Assessment:** Tumor imaging (MRI or CT) at baseline and every 2nd cycle; response assessed per RECIST v1.1

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\(^a\) HGSOC including fallopian tube and primary peritoneal cancer.

CT, computed tomography; DCR, disease control rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; HGSOC, high-grade serous ovarian cancer; IHC, immunohistochemistry; IV, intravenous; MRI, magnetic resonance imaging; MTD, maximum tolerated dose; NaPi2b, sodium-dependent phosphate transport protein 2B; ORR, overall response rate; PS, performance score; Q4W, every 4 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended phase 2 dose; UpRi, upifitamab rilsodotin.

Expansion Cohort Experience Across a Range of Doses Allowed for Further Optimization of UpRi Profile

Updated Analysis of Phase 1b PROC Expansion Cohort to Evaluate Safety and ORR Based on UpRi Dose Levels\(^a\)

Dose Group 36 (33–38 mg/m\(^2\)) (n=29)

- 12 patients at 36 mg/m\(^2\) starting dose (all BSA levels)
- 17 patients at ~80 mg starting dose with BSA ≥1.8 who received an actual dose of 33 to 38 mg/m\(^2\)

Dose Group 43 (>38–43 mg/m\(^2\)) (n=66)

- 39 patients at 43 mg/m\(^2\) starting dose with BSA <1.8
- 27 patients at ~80 mg starting dose with BSA ≥1.8 who received an actual dose of >38 mg/m\(^2\)

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\(^a\) Two patients received <30 mg/m\(^2\) and therefore were not included in either dose group.

BSA, body surface area; ORR, overall response rate; PROC, platinum-resistant ovarian cancer; UpRi, upifitamab rilsodotin.
Patient Demographics and Disease Characteristics

Phase 1b Expansion Study in Ovarian Cancer Included 97 Patients in Safety Analysis Set

Data cut: June 10, 2021. Two patients received <30 mg/m² and therefore were not included in either dose group.

<table>
<thead>
<tr>
<th>Median Age, years (range)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>68 (33, 87)</td>
<td>66 (33, 85)</td>
<td>69 (38, 87)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline ECOG PS, n (%)</th>
<th>0</th>
<th>1</th>
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</thead>
<tbody>
<tr>
<td>33 (34)</td>
<td>6 (21)</td>
<td>27 (41)</td>
</tr>
<tr>
<td>64 (66)</td>
<td>23 (79)</td>
<td>39 (59)</td>
</tr>
</tbody>
</table>

| Median Baseline BSA, m² (range) | 1.82 (1.34, 2.78) | 2.12 (1.58, 2.30) | 1.77 (1.34, 2.02) |

<table>
<thead>
<tr>
<th>Primary Tumor Type, n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian</td>
<td>72 (74)</td>
<td>22 (76)</td>
<td>48 (73)</td>
</tr>
<tr>
<td>Fallopian Tube</td>
<td>15 (15)</td>
<td>2 (7)</td>
<td>13 (20)</td>
</tr>
<tr>
<td>Primary Peritoneal</td>
<td>8 (8)</td>
<td>5 (17)</td>
<td>3 (5)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Prior Lines of Therapy, n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–3</td>
<td>65 (67)</td>
<td>21 (72)</td>
<td>42 (64)</td>
</tr>
<tr>
<td>4+</td>
<td>32 (33)</td>
<td>8 (28)</td>
<td>24 (36)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior Therapy, n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td>68 (70)</td>
<td>17 (59)</td>
<td>49 (74)</td>
</tr>
<tr>
<td>PARPi</td>
<td>57 (59)</td>
<td>13 (45)</td>
<td>43 (65)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Platinum-free Interval, b n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–3 mos</td>
<td>34 (35)</td>
<td>11 (38)</td>
<td>22 (33)</td>
</tr>
<tr>
<td>&gt;3–6 mos</td>
<td>46 (47)</td>
<td>14 (48)</td>
<td>31 (47)</td>
</tr>
<tr>
<td>&gt;6 mos c</td>
<td>10 (10)</td>
<td>2 (7)</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Unknown d</td>
<td>7 (7)</td>
<td>2 (7)</td>
<td>5 (8)</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>BRCA1/2 Mutation, n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>15 (15)</td>
<td>3 (10)</td>
<td>11 (17)</td>
</tr>
<tr>
<td>No</td>
<td>65 (67)</td>
<td>21 (72)</td>
<td>43 (65)</td>
</tr>
<tr>
<td>Unknown e</td>
<td>17 (18)</td>
<td>5 (17)</td>
<td>12 (18)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NaPi2b Expression by TPS, n (%)</th>
<th>All Dose Levels (N=97)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determined</td>
<td>78 (80)</td>
<td>24 (83)</td>
<td>52 (79)</td>
</tr>
<tr>
<td>High (TPS ≥75)</td>
<td>50 (64)</td>
<td>18 (75)</td>
<td>32 (62)</td>
</tr>
<tr>
<td>Low (TPS &lt;75)</td>
<td>28 (36)</td>
<td>6 (25)</td>
<td>20 (38)</td>
</tr>
<tr>
<td>Not Yet Determined</td>
<td>19 (20)</td>
<td>5 (17)</td>
<td>14 (21)</td>
</tr>
</tbody>
</table>

BSA, body surface area; BRCA1/2, breast cancer susceptibility gene 1 or 2; ECOG, Eastern Cooperative Oncology Group; NaPi2b, sodium-dependent phosphate transport protein 2B; PARPi, poly (ADP-ribose) polymerase inhibitor; PS, performance status; TPS, tumor proportion score.

* Three patients enrolled with 5 prior lines of systemic therapy.
* Platinum-free interval defined as the time between the last cycle of most recent platinum-containing regimen and evidence of disease progression; determined from treatment dates and/or clinic notes.
* All patients had received 4 or 5 lines of prior therapy.
* Treatment dates missing/not provided; unable to determine.
* BRCA1/2 mutation status not available/not reported.
* NaPi2b expression not yet determined or tissue unavailable.
**Treatment-Related AEs by UpRi Dose Group**

**Dose Group 36 Had a More Favorable Safety Profile Compared to Dose Group 43**

- No severe ocular toxicity, neutropenia, or peripheral neuropathy in either dose group
- 4 (14%) patients had treatment-related SAEs in Dose Group 36 vs 18 (27%) in Dose Group 43
- Lower frequencies and lower grade pneumonitis occurred in Dose Group 36 (with no Grade 3+) vs Dose Group 43

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**TRAEs ≥20%**

<table>
<thead>
<tr>
<th>AE</th>
<th>CTCAE Grade 3+</th>
<th>CTCAE Grade All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose Group 36 (n=29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST Increased</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased Appetite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood ALP Increased</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dehydration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose Group 43 (n=66)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Percentage (%) of Patients**

Data cut: June 10, 2021. Analysis with 95 patients. Two patients received <30 mg/m² and therefore were not included in either dose group.

* Dose Group 36 pneumonitis: Grade 1–2 (n=2); Grade 3+ (n=0); Dose Group 43 pneumonitis: Grade 1–2 (n=5), Grade 3+ (n=4).

AE, adverse event; ALP, alkaline phosphatase; AST, aspartate aminotransferase; CTCAE, Common Terminology Criteria for Adverse Events; SAE, serious adverse event; TRAE, treatment-related adverse event; UpRi, upifitamab rilsodotin.
## Dose Modification by UpRi Dose Group

**Dose Group 36 Had Fewer Treatment-Related Dose Modifications and Treatment Discontinuations Compared to Dose Group 43**

<table>
<thead>
<tr>
<th>Any Dose Modification d/t TRAE (Reduction, Delay, Discontinuation), n (%)</th>
<th>Dose Group 36 (n=29)</th>
<th>Dose Group 43 (n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 (34)</td>
<td>32 (48)</td>
<td></td>
</tr>
<tr>
<td>Dose Reduction d/t TRAE, n (%)</td>
<td>6 (21)</td>
<td>20 (30)</td>
</tr>
<tr>
<td>Dose Delay d/t TRAE, n (%)</td>
<td>4 (14)</td>
<td>12 (18)</td>
</tr>
<tr>
<td>Dose Discontinuation d/t TRAE, n (%)</td>
<td>2 (7)</td>
<td>8 (12)</td>
</tr>
</tbody>
</table>

Data cut: June 10, 2021. Analysis with 95 patients. Two patients received <30 mg/m² and therefore were not included in either dose group. d/t, due to; TRAE, treatment-related adverse event; UpRi, upifitamab rilsodotin.
Best Response by UpRi Dose Group

Similar Tumor Reduction in Both Dose Groups: Two-thirds of Patients Had Reductions in Target Tumor Lesions by RECIST 1.1

49/73 (67%) Patients Had a Target Lesion Reduction From Baseline

Data cut: June 10, 2021. Analysis with 73 evaluable patients. Two patients excluded as post-baseline tumor measurement shows “Not Measurable”, yet “PD” was assigned by investigator in response dataset. There were 22 unevaluable patients: 4 in Dose Group 36, 2 patient withdrawals (1 enrolled in hospice), 2 patient deaths; 16 in Dose Group 43, 5 patient withdrawals, 1 clinical progression, 3 due to adverse events, 8 deaths; 1 had not reached first scan.

CR, complete response; H, high; L, low; ND, not yet determined; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; TPS, tumor proportion score; uPR, unconfirmed partial response; UpRi, upifitamab rilsodotin.
## Confirmed ORR by UpRi Dose Group and NaPi2b Level, Duration of Response

### 44% ORR in Dose Group 36 for Patients With NaPi2b-High Ovarian Cancer

<table>
<thead>
<tr>
<th>NaPi2b-High (TPS ≥75)</th>
<th>All Dose Levels</th>
<th>Dose Group 36</th>
<th>Dose Group 43</th>
</tr>
</thead>
<tbody>
<tr>
<td>NaPi2b-High</td>
<td>N</td>
<td>38</td>
<td>16</td>
</tr>
<tr>
<td>ORR, n (%)</td>
<td>13 (34)</td>
<td>7 (44)</td>
<td>6 (27)</td>
</tr>
<tr>
<td>CR, n (%)</td>
<td>2 (5)</td>
<td>2 (13)</td>
<td>0</td>
</tr>
<tr>
<td>PR, n (%)</td>
<td>11 (29)</td>
<td>5 (31)</td>
<td>6 (27)</td>
</tr>
<tr>
<td>DCR, n (%)</td>
<td>33 (87)</td>
<td>12 (75)</td>
<td>21 (95)</td>
</tr>
</tbody>
</table>

| All NaPi2b Levels      | N              | 75            | 25            | 48            |
| NaPi2b-High            | ORR, n (%)     | 17 (23)       | 9 (36)        | 8 (17)        |
| CR, n (%)              | 2 (3)          | 2 (8)         | 0             |
| PR, n (%)              | 15 (20)        | 7 (28)        | 8 (17)        |
| DCR, n (%)             | 54 (72)        | 18 (72)       | 35 (73)       |

- Median DoR in patients (all dose levels) with NaPi2b-high ovarian cancer (n=13): 5 months
- No obvious difference in median DoR observed between Dose Groups 36 and 43

Data cut: June 10, 2021. Two patients received <30 mg/m² and therefore were not included in either dose group. All responses are confirmed. There were 75 evaluable patients. There were 22 unevaluable patients: 4 in Dose Group 36, 2 patient withdrawals (1 enrolled in hospice), 2 patient deaths; 18 in Dose Group 43, 5 patient withdrawals, 1 clinical progression, 3 due to adverse events, 8 deaths, 1 had not reached first scan. Of 4 unevaluable patients in Dose Group 36, 2 were NaPi2b-high; of 18 unevaluable in Dose Group 43, 10 were NaPi2b-high.

CR, complete response; DCR, disease control rate; DoR, duration of response; NaPi2b, sodium-dependent phosphate transport protein 2B; ORR, overall response rate; PR, partial response; TPS, tumor proportion score; UpRi, upifitamab rilsodotin.
Data cut: June 10, 2021. Median follow-up time for all patients was 21.3 weeks.

NaPi2b, sodium-dependent phosphate transport protein 2B; ND, not yet determined; UpRi, upifitamab rilsodotin.
UPLIFT (ENGOT-ov67 / GOG-3048)

UpRi Single-Arm Registrational Trial in Platinum-Resistant Ovarian Cancer

**Patient Population:** HGSOC* progressing after standard treatments; measurable disease per RECIST v1.1; ECOG PS 0 or 1; enrolling regardless of NaPi2b expression

**Key Inclusion Criteria**
- Platinum-resistant ovarian cancer (PROC)
- 1–4 prior lines of therapy
- Grade ≤2 peripheral neuropathy
- Archival or fresh tissue required for biomarker evaluation

**Key Exclusion Criteria**
- 1–2 prior lines bevacizumab-naive
- Primary platinum-refractory disease

**UpRi** 36 mg/m² up to max 80 mg; IV Q4W

**Primary Endpoint**
- Confirmed ORR in NaPi2b-high (N = ~100)

**Secondary Endpoint**
- Confirmed ORR in overall population (N = up to ~180 including 100 NaPi2b-high)

**Other Secondary Endpoints**
- DoR
- Safety

Prospectively-defined retrospective analysis to validate NaPi2b biomarker cutoff

NCT03319628: Trial Currently Enrolling Patients

* HGSOC including fallopian tube and primary peritoneal cancer.

HGSOC, high-grade serous ovarian cancer; IV, intravenous; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; FPD, first patient dosed; NaPi2b, sodium-dependent phosphate transport protein 2B; ORR, overall response rate; PROC, platinum-resistant ovarian cancer; PS, performance score; Q4W, every 4 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; UpRi, upifitamab rilsodotin.
UP-NEXT (GOG-3049 / ENGOT-OV71-NSGO-CTU)

Phase 3 Study of UpRi Monotherapy Maintenance vs Placebo in Recurrent Platinum-Sensitive Ovarian Cancer

Key Enrollment Criteria
- CR, PR, or SD as best response following platinum in recurrent disease
- 2–4 prior lines of platinum (including the immediately preceding platinum)
- NaPi2b-high (TPS ≥75)
- Prior PARPi therapy only required for BRCAmut

Primary Endpoint
- PFS by BICR

Secondary Endpoints
- PFS by Investigator
- ORR
- OS

UpRi IV Q4W

Randomize 2:1
N=350

Placebo

Informed by FDA Feedback and CHMP Scientific Advice; Plans to Initiate in 2022

BICR, blinded independent central review; BRCAmut, breast cancer susceptibility gene mutated; CHMP, Committee for Medicinal Products for Human Use; CR, complete response; FDA, Food and Drug Administration; IV, intravenous; NaPi2b, sodium-dependent phosphate transport protein 2B; ORR, overall response rate; OS, overall survival; PARPi, poly (ADP-ribose) polymerase inhibitor; PFS, progression-free survival; PR, partial response; Q4W, every 4 weeks; SD, stable disease; TPS, tumor proportion score; UpRi, upifitamab rilsodotin.
Conclusions

• UpRi, a first-in-class ADC targeting NaPi2b, showed clinically meaningful activity in a population of heavily pre-treated patients with ovarian cancer, without severe ocular toxicity, neutropenia, or neuropathy
• UpRi had notable activity in patients with NaPi2b-high tumors
• Based on analysis of reported UpRi expansion data, Dose Group 36 had a more favorable safety profile while maintaining similar efficacy compared to Dose Group 43
• At the optimized dose of 36 mg/m², UpRi demonstrated robust clinical activity with a differentiated safety profile
• These data support the design of UPLIFT and UP-NEXT registrational studies

ADC, antibody drug conjugate; NaPi2b, sodium-dependent phosphate transport protein 2B; UpRi, upifitamab rilsodotin.
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We Thank the Patients, Their Families, and Caregivers for Their Contribution to This Study

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University of Florida, Gainesville, FL
University of Miami, Miami, FL
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University of Tennessee, Knoxville, TN
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Virginia Cancer Specialists, Fairfax, VA
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