

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 10, 2021**

**MERSANA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation)

**001-38129**

(Commission File Number)

**04-3562403**

(IRS Employer  
Identification No.)

**840 Memorial Drive  
Cambridge, MA 02139  
Cambridge, MA**

(Address of principal executive offices)

**02139**

(Zip Code)

(Registrant's telephone number, including area code): **(617) 498-0020**

**Not Applicable**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	MRSN	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

Mersana Therapeutics, Inc. intends to use a corporate presentation, dated September 10, 2021, in connection with a webcast presentation to the investment community.

A copy of the corporate presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a> 104	<a href="#">Corporate presentation, dated September 10, 2021</a> The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**MERSANA THERAPEUTICS, INC.**

By: /s/ Brian DeSchuytner  
Brian DeSchuytner  
Senior Vice President, Finance & Product Strategy

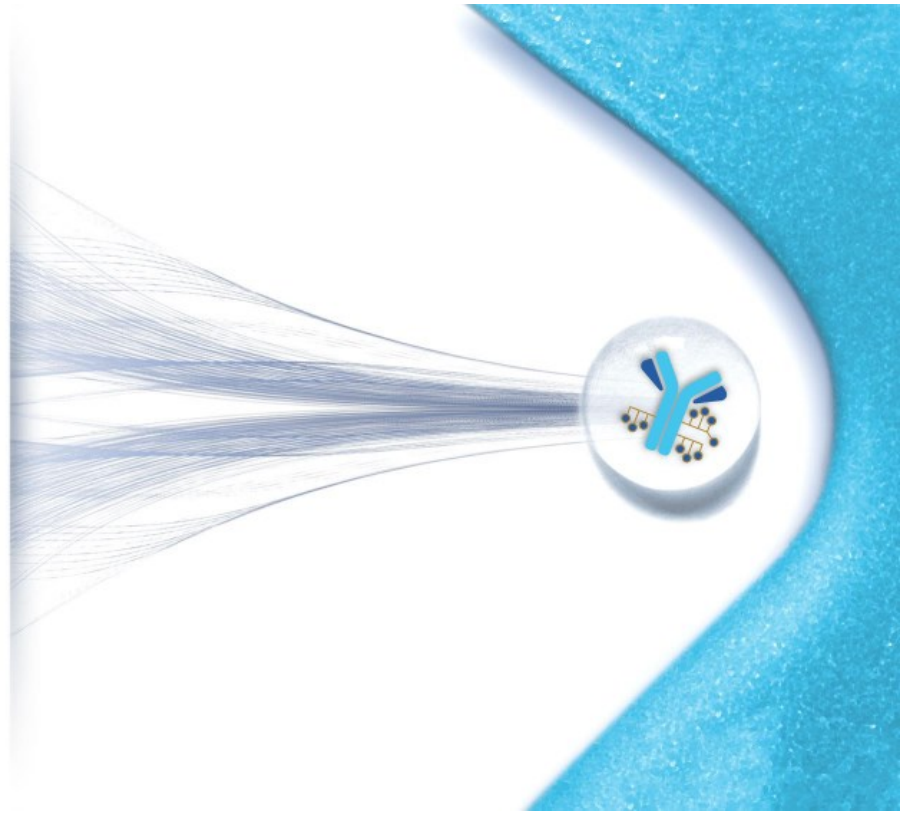
Date: September 10, 2021

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**Interim Data from the  
Ovarian Cancer  
Expansion Cohort  
and  
Next Steps for UpRi  
Development Plan**

September 10, 2021



# Legal Disclaimer



This presentation contains "forward-looking" statements within the meaning of federal securities laws. These forward-looking statements are not statements of historical facts and are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include information concerning the Company's clinical strategy for its product candidates, progression, design and timing of its clinical studies, including the Company's UP-NEXT trial, and data from its ongoing clinical study, the ability of the single-arm UPLIFT cohort to enable registration, and expectations regarding future clinical trial results. Forward-looking statements generally can be identified by terms such as "aims," "anticipates," "believes," "contemplates," "continues," "could," "estimates," "expects," "goal," "intends," "may," "on track," "opportunity," "plans," "poised for," "possible," "potential," "predicts," "projects," "promises to be," "seeks," "should," "target," "will," "would" or similar expressions and the negatives of those terms. Forward-looking statements represent management's beliefs and assumptions only as of the date of this presentation. The Company's operations involve risks and uncertainties, many of which are outside its control, and any one of which, or combination of which, could materially affect its results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that may materially affect the Company's results of operations and whether these forward-looking statements prove to be correct include, among other things, that preclinical testing or early clinical results may not be predictive of the results or success of ongoing or later preclinical or clinical studies, that results of the Company's ongoing or future clinical studies may be inconclusive with respect to the efficacy of the Company's product candidates, that the Company may not meet clinical endpoints with statistical significance or there may be safety concerns or adverse events associated with product candidates, that the identification, development and testing of the Company's product candidates and new platforms will take longer and/or cost more than planned, and that the Company's clinical studies may not be initiated or completed on schedule, if at all, as well as those listed in the Company's Quarterly Report on Form 10-Q filed on August 6, 2021, with the Securities and Exchange Commission ("SEC"), and subsequent SEC filings. In addition, while we expect that the COVID-19 pandemic may adversely affect the Company's preclinical and clinical development efforts, business operations and financial results, the extent of the impact on the Company's operations and the value of and market for the Company's common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, the spread of variants of COVID-19, including the Delta variant, travel restrictions, quarantines, physical distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Copies of the Company's Quarterly Report on Form 10-Q and our other SEC filings are available by visiting EDGAR on the SEC website at <http://www.sec.gov>.

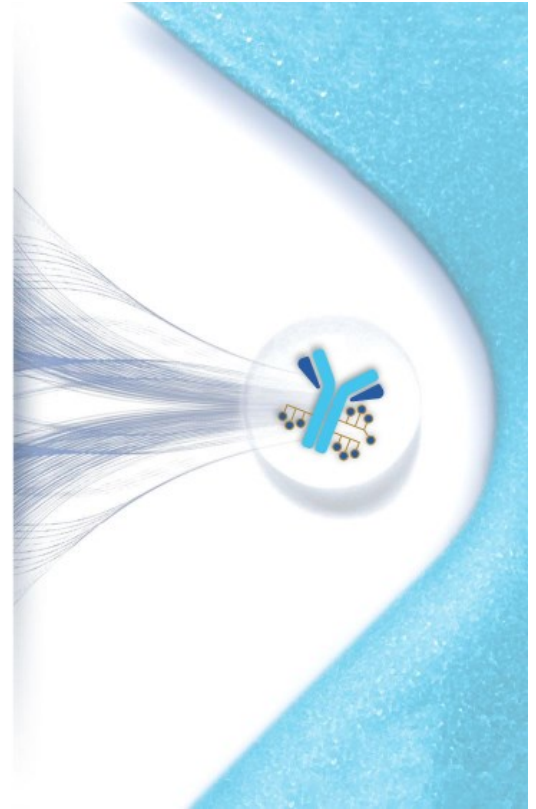
# Today's Agenda

Topic	Speaker
<ul style="list-style-type: none"><li>Opening Remarks</li></ul>	Anna Protopapas, President & CEO
<ul style="list-style-type: none"><li>Interim Data from the Ovarian Cancer Expansion Cohort of the UpRi Phase 1 Study</li></ul>	Debra L. Richardson, MD, Associate Professor and Section Chief, Division of Gynecological Oncology at OU Health Stephenson Cancer Center and the Sarah Cannon Research Institute
<ul style="list-style-type: none"><li>UpRi Development Plan:<ul style="list-style-type: none"><li>UPLIFT Update</li><li>UP-NEXT Phase 3 Maintenance Study</li></ul></li></ul>	Arvin Yang, MD, PhD, Chief Medical Officer
<ul style="list-style-type: none"><li>Closing Remarks</li></ul>	Anna Protopapas, President & CEO
<ul style="list-style-type: none"><li>Q&amp;A</li></ul>	

# **UpRi: First-in-Class Dolaflexin ADC Targeting NaPi2b**

Interim Data from the Ovarian Cancer  
Expansion Cohort of the UpRi Phase 1 Study

Debra L. Richardson, MD  
*Associate Professor and Section Chief, Division of  
Gynecological Oncology at OU Health Stephenson Cancer  
Center and the Sarah Cannon Research Institute*



# Significant Unmet Medical Need in Platinum-Resistant Ovarian Cancer

With PARPi and bevacizumab increasingly used in earlier lines,  
the current standard of care is single agent chemotherapies

Study	Demographics	Control Arm	Control Arm Performance
Forward I ESMO 2019 <small>Annals of Oncology 2021; 32(6):757-765</small>	1 – 3 Prior Median 2 Prior Prior PARPi: 10% Prior Bev: 47%	PLD, Topotecan, Weekly Paclitaxel	ORR 12%
Javelin 200 SGO 2019	1 – 3 Prior Median 2 Prior	PLD	ORR 4%
Corail ESMO 2018	1 – 3 Prior Median 2 Prior Prior PARPi: 5% Prior Bev: 46%	PLD or Topotecan	ORR 12%



# Design for the Ovarian Cancer Expansion Cohort of the UpRi Phase 1 Study

## 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 therapy

**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/m<sup>2</sup> cohort initiated in August 2019 and enrollment closed
- 43 mg/m<sup>2</sup> cohort initiated in December 2019 and enrollment is closed; 43 mg/m<sup>2</sup> up to a maximum of ~80 mg total evaluated in EXP\*

### 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 immunohistochemistry (IHC) assay with a broad dynamic range to distinguish tumors with high and low NaPi2b expression
- Further assessment of preliminary anti-neoplastic activity (DOR)

### Assessments:

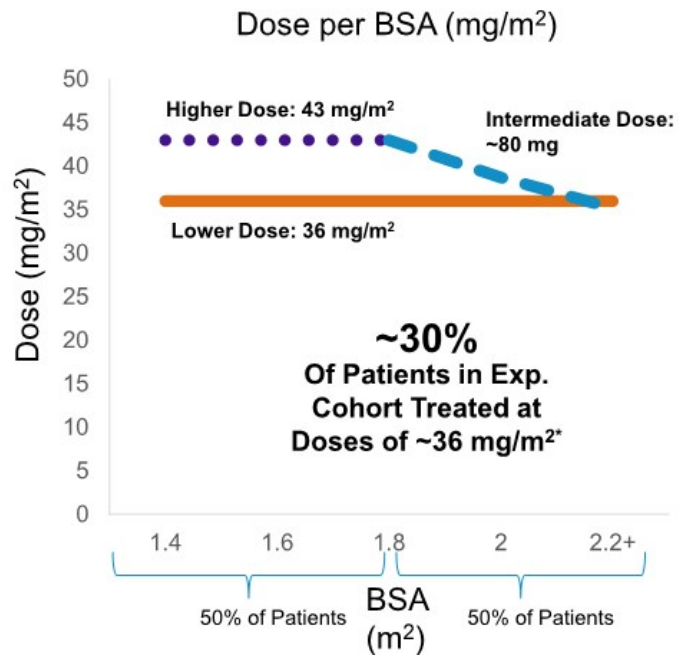
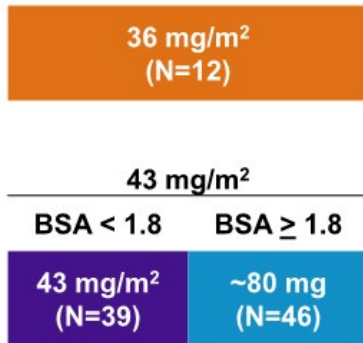
- Tumor imaging (MRI or CT): baseline and every 2<sup>nd</sup> cycle; response assessed per RECIST v1.1

\*Maximum Doses are Common in Oncology Drug Development (e.g., ADCETRIS<sup>®</sup>, PADCEV<sup>®</sup>, Mylotarg<sup>™</sup>)

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

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

## Doses Studied in Expansion



# Patient Demographics and Disease Characteristics

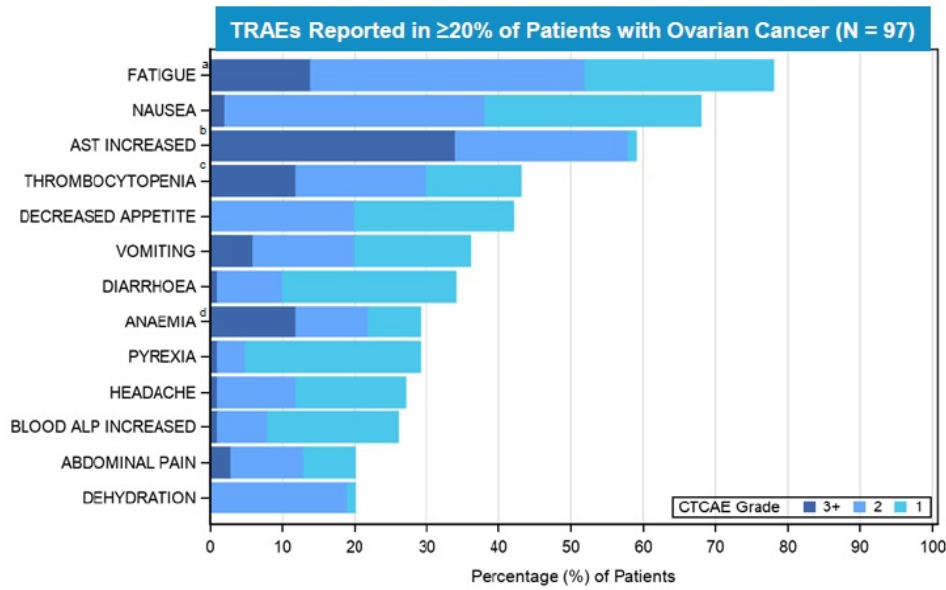
Data Cut: June 10, 2021

Ovarian Cancer Expansion Patients (N = 97)		
Age; years	Median (range)	68 (33, 87)
ECOG Performance Status; n (%)	0	33 (34)
	1	64 (66)
Baseline BSA	≥ 1.8 m <sup>2</sup>	51 (53)
	≥ 2.2 m <sup>2</sup>	5 (5)
Primary Tumor Type; n (%)	Ovarian	72 (74)
	Fallopian Tube	15 (15)
	Primary Peritoneal	8 (8)
Prior Lines of Therapy; n (%)	1-3	65 (67)
	4+ <sup>a</sup>	32 (33)
Prior Therapy; n (%)	Bevacizumab	68 (70)
	PARP inhibitor	57 (59)
Platinum-free Interval <sup>b</sup> ; n (%)	0-3 mos	34 (35)
	>3-6 mos	46 (47)
	>6 mos <sup>c</sup>	10 (10)
	Unknown <sup>d</sup>	7 (7)
BRCA1/2 Mutation; n (%)	Yes	15 (15)
	No	65 (67)
	Unknown <sup>e</sup>	17 (18)
NaPi2b TPS <sup>f</sup> ; n (%)	Determined	78 (80)
	High	50 (64)
	Low	28 (36)
	Not Yet Determined (ND)	19 (20)

<sup>a</sup> Three patients enrolled with 5 prior lines of systemic therapy. <sup>b</sup> 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. <sup>c</sup> All patients had received 4 or 5 lines of prior therapy. <sup>d</sup> Treatment dates missing/not provided; unable to determine. <sup>e</sup> BRCA1/2 mutation status not available/not reported. <sup>f</sup> High NaPi2b Expression: Tumor Proportion Score (TPS) ≥75; Low NaPi2b Expression: TPS <75; ND = NaPi2b Expression not yet determined or tissue not available

# UpRi Continues to Have a Consistent Tolerability Profile

No grade  $\geq 3$  (severe) TRAEs of neutropenia, peripheral neuropathy, or ocular toxicity have been reported



Data Cut: June 10, 2021

<sup>a</sup>Fatigue includes preferred terms of asthenia and fatigue; <sup>b</sup>AST increase is transient in nature, recovers to baseline or to Grade 1 prior to the next dose, no instances are associated with elevated bilirubin or cases of Hy's law; <sup>c</sup>Thrombocytopenia includes preferred terms of platelet count decreased and thrombocytopenia. Thrombocytopenia is transient in nature, nadirs at Day 8 and recovers prior to the next dose; <sup>d</sup>Anaemia includes preferred terms of anaemia of chronic disease, blood loss anaemia and iron deficiency anaemia

# Decreased Grade 3+ Treatment Related AEs with Lower Dose

	Lower Dose 36 mg/m <sup>2</sup>	Intermediate Dose ~80 mg	Higher Dose 43 mg/m <sup>2</sup>
≥ Grade 3 Fatigue	1 (8%)	6 (13%)	9 (23%)
≥ Grade 3 Increased AST	1 (8%)	16 (35%)	16 (41%)
≥ Grade 3 Pneumonitis	0 (0%)	0 (0%)	4* (10%)

\* 2 cases of Grade 5 pneumonitis including 1 previously reported; most recent case was in a 75-year-old 4<sup>th</sup> line recurrent ovarian cancer patient treated at higher dose of 43 mg/m<sup>2</sup> (BSA 1.47 m<sup>2</sup>, 105 lb) with past medical history of poor pulmonary reserve: asthma and chronic obstructive pulmonary disease requiring intermittent supplemental oxygen at baseline, coronary artery disease and congestive heart failure

# Observed Consistent Tolerability Profile with Limited Discontinuations due to TRAE

## **Dose modification due to Treatment-Related Adverse Events (TRAEs):**

- Of the 97 patients, 43 (44%) had dose delay, reduction, and/or discontinuation due to a TRAE
  - Dose reductions due to TRAEs occurred in 27 (28%) patients
  - Dose delays due to TRAEs occurred in 16 (16%) patients
  - Dose discontinuation (withdrawn) due to TRAEs occurred in 10 (10%) patients

## **Treatment-Emergent Severe Adverse Events (SAEs) reported in $\geq 5\%$ of Patients:**

- Out of 97 patients, 47 (48%) reported Treatment-Emergent SAEs. The most frequent of which were Gastrointestinal Obstruction 7 (7%), 5 (5%) each for Pyrexia, Pneumonitis, and Abdominal Pain
- 22 (23%) of the SAEs were deemed by the investigator to be treatment-related

# Consistent Activity Observed in Heavily-Pretreated Ovarian Cancer

## Best Response in Evaluable Patients with Ovarian Cancer (n = 75)

	NaPi2b High (TPS $\geq$ 75)	NaPi2b Low (TPS<75)	Not Yet Determined NaPi2b	All Patients
<b>N</b>	<b>38</b>	<b>23</b>	<b>14</b>	<b>75</b>
CR	2 (5)	0	0	2 (3)
PR	11 (29)	2 (9)	2 (14)	15 (20)
uPR	1 (3)	0	2 (14)	3 (4)
SD	19 (50)	8 (35)	7 (50)	34 (45)
PD	5 (13)	13 (57)	3 (21)	21 (28)
<b>Confirmed ORR</b>	<b>13 (34)</b>	<b>2 (9)</b>	<b>2 (14)</b>	<b>17 (23)</b>
<b>DCR</b>	<b>33 (87)</b>	<b>10 (43)</b>	<b>11 (79)</b>	<b>54 (72)</b>

Data Cut: June 10, 2021

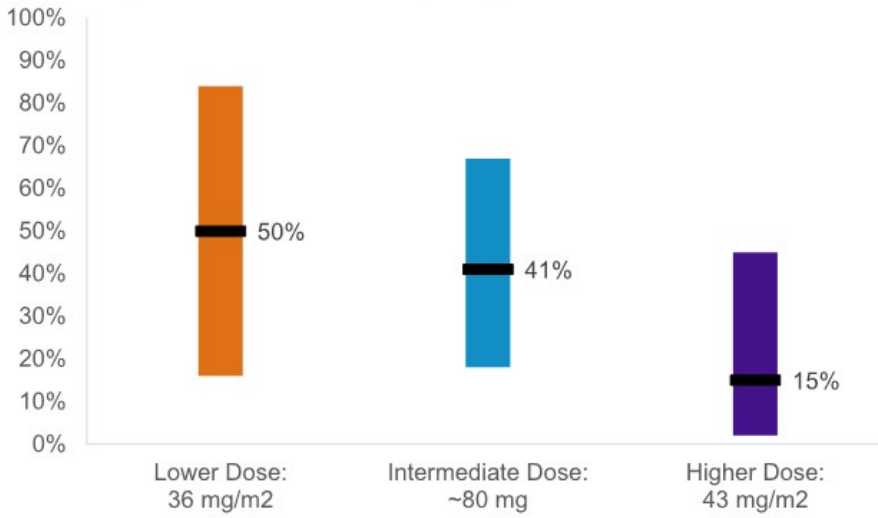
CR = complete response; PR = partial response; uPR = unconfirmed PR; confirmatory scan pending at the time of the data cut

ORR = Objective Response Rate; DCR = Disease Control Rate

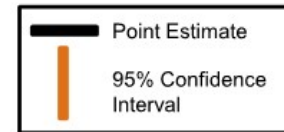
22 patients were not evaluable by RECIST 1.1: 10 deaths (4 disease progression, 2 pneumonitis, 2 sepsis, 1 viral pneumonia, 1 unknown); 5 patient withdrawals; 1 enrolled in hospice; 1 clinical progression; 4 discontinued treatment; 1 had not yet reached first scan

# Similar Efficacy Across the Three Dose Levels, with Trend to Higher Efficacy with Lower Dose

Confirmed ORR with 95% Confidence Interval  
NaPi2b High, RECIST-Evaluable (N=38)



- Data trends consistent in the overall population



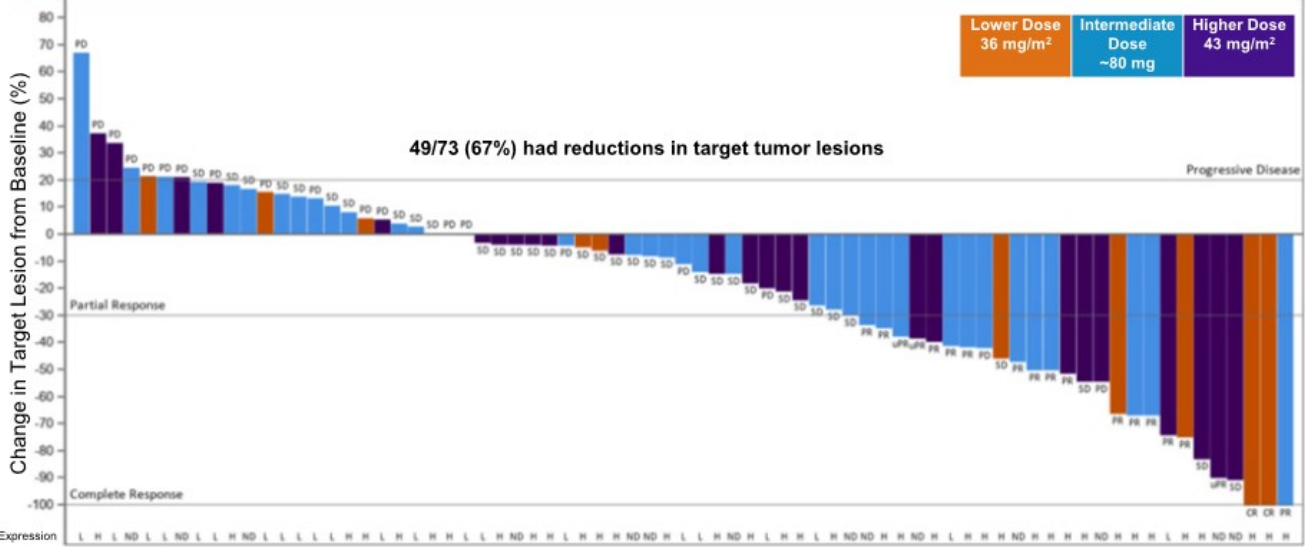
Data Cut: June 10, 2021  
NaPi2b High based on TPS<sub>≥</sub>75



# Two-Thirds of Patients Had Reductions in Target Tumor Lesions



Maximum % Change from Baseline in Target Lesions in Evaluable Patients with Ovarian Cancer (n=73\*)

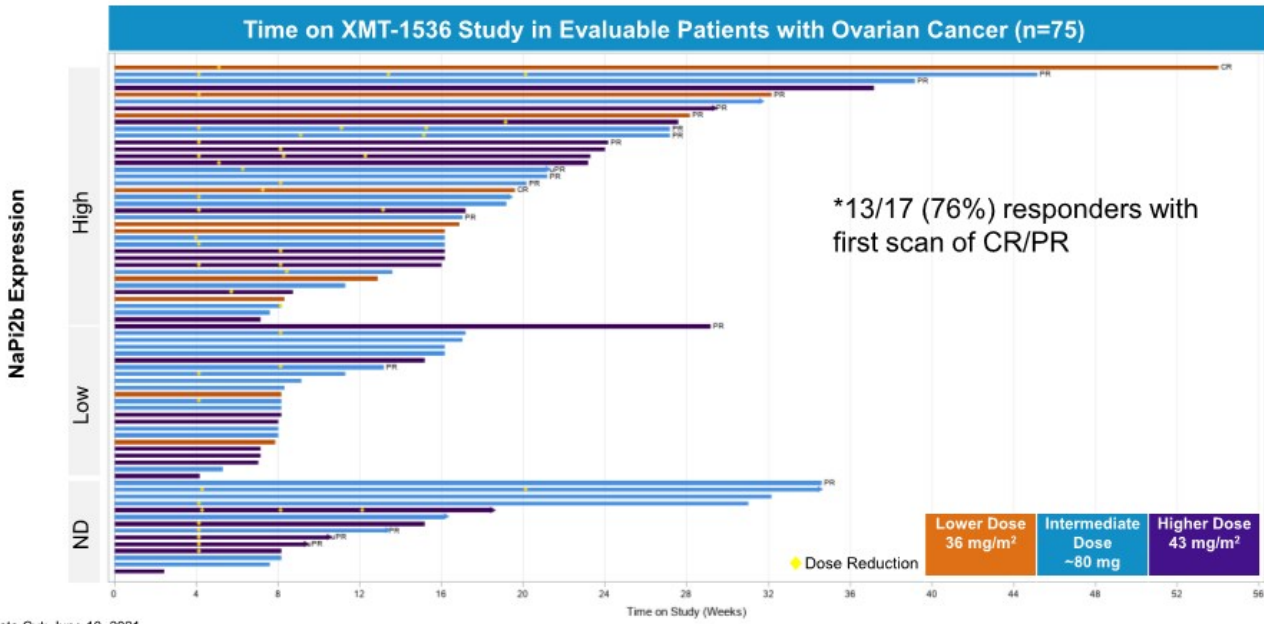


Data Cut: June 10, 2021

2 pts excluded as post-baseline tumor measurement shows "Not Measurable", yet "PD" was assigned by Investigator in the response dataset

Abbreviations: CR = complete response; PR = partial response; uPR = unconfirmed PR; H = High NaPi2b Expression; L = Low NaPi2b Expression; ND = NaPi2b Expression not yet determined or tissue not available

# Trend to Longer Time on Study with High NaPi2b Expression

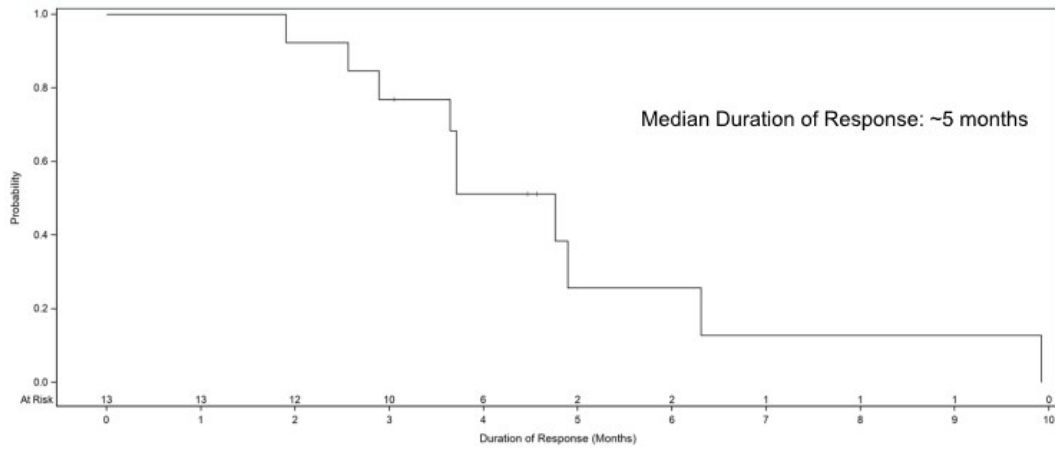


Data Cut: June 10, 2021

Abbreviations: CR = complete response; PR = partial response; uPR = unconfirmed PR; High = High NaPi2b Expression; Low = Low NaPi2b Expression; ND = NaPi2b Expression not yet determined or tissue not available

# Median Duration of Response Consistent at ~5 Months in Patients with High NaPi2b Expression

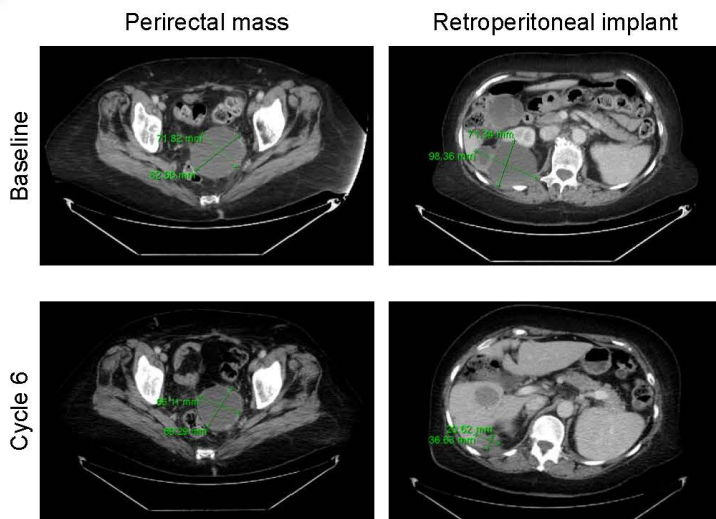
Duration of Response in Patients with NaPi2b High Ovarian Cancer (n=13)



Data Cut: June 10, 2021

\*The median duration of response for NaPi2b Low and NaPi2b not yet determined expression is 3.9 months and 3.7 months, respectively.

# Partial Response in a Patient with Ovarian Cancer Dosed at 36 mg/m<sup>2</sup> for a Total of 9 Cycles



- 66-year-old patient with BRCA1/2 negative high-grade serous ovarian cancer
- NaPi2b High (TPS<sub>≥</sub>75)
- 4 prior lines of systemic therapies including carboplatin/taxol/bevacizumab; carboplatin/doxil with PARP inhibitor maintenance; and cisplatin/paclitaxel
- Received 36 mg/m<sup>2</sup> (maximum dose of approximately 80 mg with a BSA of 2.16 m<sup>2</sup>)
- Received 9 Cycles of UpRi
- Confirmed PR by RECIST v1.1 with -41.4% tumor reduction

# Conclusions: UpRi Expansion in Ovarian Cancer

- In this updated analysis of patients with heavily-pretreated ovarian cancer, UpRi continued to be generally well-tolerated with a consistent profile – no severe neutropenia, peripheral neuropathy, or ocular toxicity
- Consistent antitumor activity observed with UpRi, including patients previously treated with bevacizumab and PARPi
  - Complete response observed in 2 patients with platinum-resistant ovarian cancer at the lower dose
  - Confirmed ORR of 34% and DCR of 87% in NaPi2b High population
  - Median duration of response ~5 months in NaPi2b High population
- This larger data set provides important observations to support the potential of UPLIFT as a registration strategy and to inform next steps in the UpRi development plan
  - Decreased grade 3+ Treatment Related AEs, including pneumonitis, with lower dose
  - Similar efficacy across the three dose levels, with trend toward higher efficacy with lower dose

# Acknowledgements

**We thank the patients, their families and caregivers for their contribution to this study**

## **UNITED STATES**

Allegheny Health Network, Pittsburgh, PA  
Arizona Oncology Associates, Tucson, AZ  
Avera Cancer Institute – Sioux Falls, SD  
Billings Clinic, Billings, MT  
Dana Farber Cancer Institute, Boston, MA  
Emory University, Atlanta, GA  
Fox Chase Cancer Center, Philadelphia, PA  
H. Lee Moffitt Cancer Center, Tampa FL  
Henry Ford Medical Center, Detroit, MI  
Greenville Hospital System University Medical Center, Greenville, SC  
Lahey Clinic, Burlington, MA  
Levine Cancer Center, Charlotte, NC  
Mary Crowley Cancer Research Center, Dallas, TX  
Maryland Oncology and Hematology, Rockville, MD  
Massachusetts General Hospital, Boston, MA  
Mount Sinai, New York City, NY  
NEXT Oncology, San Antonio, TX  
Ohio State University Wexner Medical Center, Hilliard, OH  
Oncology and Hematology Assoc. of SW VA, Inc., Roanoke, VA  
QUEST Research Institute, Royal Oak, MI  
Rocky Mountain Cancer Centers, LLP, Denver, CO  
Sarah Cannon Research Institute, Nashville, TN  
START, San Antonio, TX

## **UNITED STATES**

START Midwest, Grand Rapids, MI  
Stephenson Cancer Centre, Oklahoma City, OK  
Texas Oncology, Austin, TX  
Texas Oncology Fort Worth, Fort Worth, TX  
Texas Oncology, Tyler, TX  
University of Alabama at Birmingham, Birmingham, AL  
University of Colorado, Aurora, CO  
University of Florida, Gainesville, FL  
University of Miami, Miami, FL  
University of Pittsburgh Medical Center, Pittsburgh, PA  
University of Tennessee, Knoxville, TN  
University of Utah Huntsman Cancer Institute, Salt Lake City, UT  
Virginia Cancer Specialists, Fairfax, VA  
Virginia Commonwealth University Massey Cancer Center, Richmond, VA  
Washington University, St. Louis, MO  
Willamette Valley Cancer Institute, Eugene, OR  
Women's Cancer Care Associates, LLC – Albany, NY

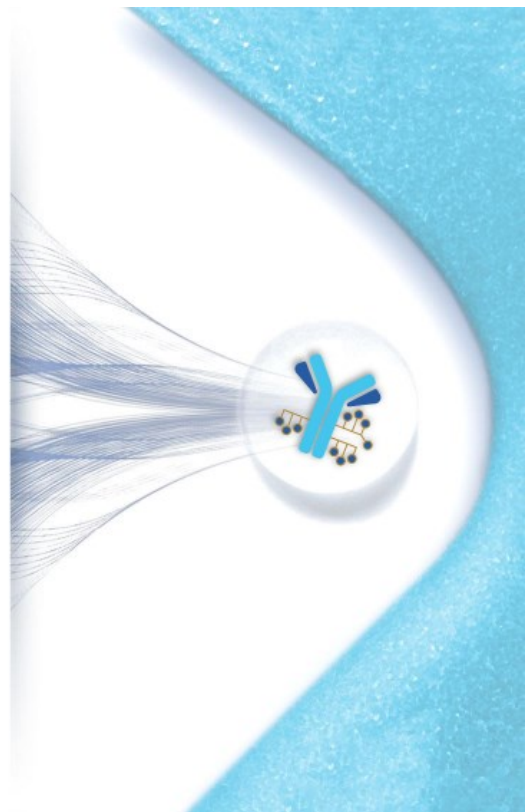
## **CANADA**

McGill University (Glen-Cedars Cancer Center), Montreal  
British Columbia Cancer Agency, Vancouver

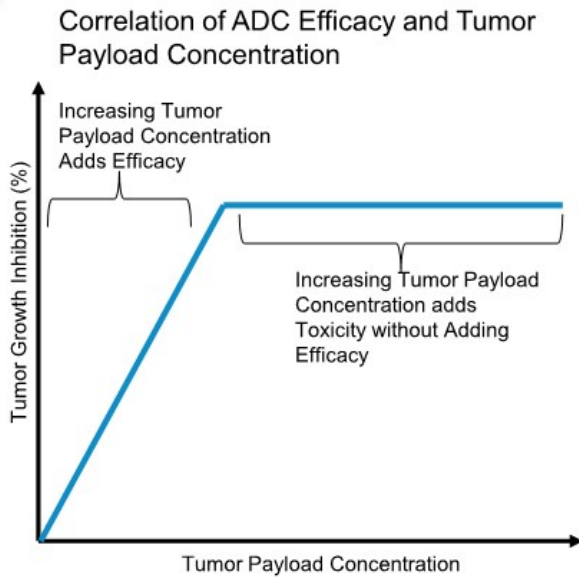
## **AUSTRALIA**

Lifeshouse Australia as trustee for the Lifeshouse Australia Trust, Camperdown  
Peter MacCallum Center, Melbourne, Victoria  
Austin Health, Heidelberg, Victoria

## **Next Steps for UpRi Development Plan**



# Increasing Dose Beyond the Optimal Threshold May Add Incremental Toxicity without Incremental Efficacy



Source: Drug Metab Dispos 47:1146–1155, October 2019

- Further analysis utilizing population PK models confirmed the efficacy and safety findings showing the association between increasing exposure and G3+ adverse events, including pneumonitis
- Preclinically, ADCs have a well-characterized exposure / response relationship
  - ADC efficacy increases with payload tumor concentration up to a plateau
  - Beyond this plateau, additional drug can decrease tolerability without improving efficacy
  - Preclinical data confirm relationship appears regardless of target, payload, linker, or platform

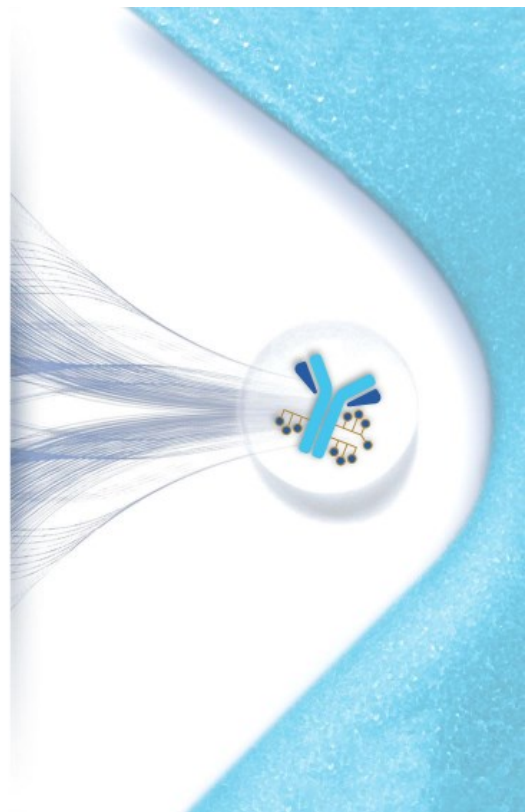
The Dose that Optimizes Therapeutic Index May Not be the Maximum Tolerated Dose



# Action Plan to Implement Learnings from Expansion Cohort Data Set

- Data set from expansion cohort supports differentiated efficacy and tolerability profile
- Analysis of data combined with population PK modeling identifies the opportunity to further improve UpRi profile
- New UPLIFT Dose: 36 mg/m<sup>2</sup> up to a maximum of ~80 mg
  - ~15% or less change to dose
  - Potential to improve the therapeutic index of UpRi and the probability of success of UPLIFT
  - Implemented as amendment to the UPLIFT protocol with the support of investigators and cooperative groups
  - Proactively informed FDA
- Amendment is designed to optimize eligibility for management of pneumonitis
  - Exclude patients with severe uncontrolled pulmonary disease or cardiovascular disease, history of or suspected pneumonitis or interstitial lung disease, oxygen saturation or room air below 93%

**UP-NEXT: UpRi Monotherapy vs.  
Placebo as Maintenance in Platinum-  
Sensitive Recurrent Ovarian Cancer**



# Despite Bevacizumab and PARPi Options, Significant Unmet Need Remains for New Maintenance Agents



## UpRi Differentiation

Activity against Bev and PARPi Pre-Treated Disease

Bevacizumab and PARP Moving into Earlier Lines and Combinations

- A population previously treated with bevacizumab and PARPi maintenance sequentially or in combination is emerging, with no standard of care upon relapse

Watch & Wait Remains a Standard of Care for Some Patients

- Patients poorly served by current maintenance agents need additional options. Watch & wait remains an option in guidelines
  - 80% of patients without BRCA mutation (e.g., HRP, HRD)
  - Co-morbidities (e.g., hypertension, risk for bowel obstruction)
  - Tolerability (e.g., thrombocytopenia)

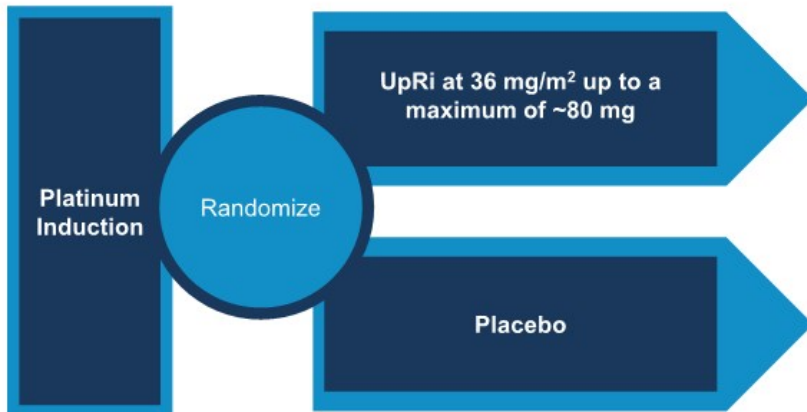
Optimized Dose with Differentiated Tolerability Profile and Biomarker Enrichment

PARPi Maintenance not Indicated for Stable Disease following Platinum

- PARPi activity is predicted by platinum responsiveness, patients that achieve stable disease to platinum were not included in PARPi maintenance studies
- Emerging evidence of poor outcomes with platinum following PARPi may increase proportion achieving SD

Activity, including CRs, in Heavily Pre-Treated Patients

# UP-NEXT/GOG-3049: Phase 3 Study of UpRi Monotherapy Maintenance vs Placebo in Platinum-Sensitive Recurrent OC



## Key Enrollment Criteria:

- Platinum-sensitive recurrence, following platinum induction
- NaPi2b High biomarker selection by  $TPS \geq 75$
- 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

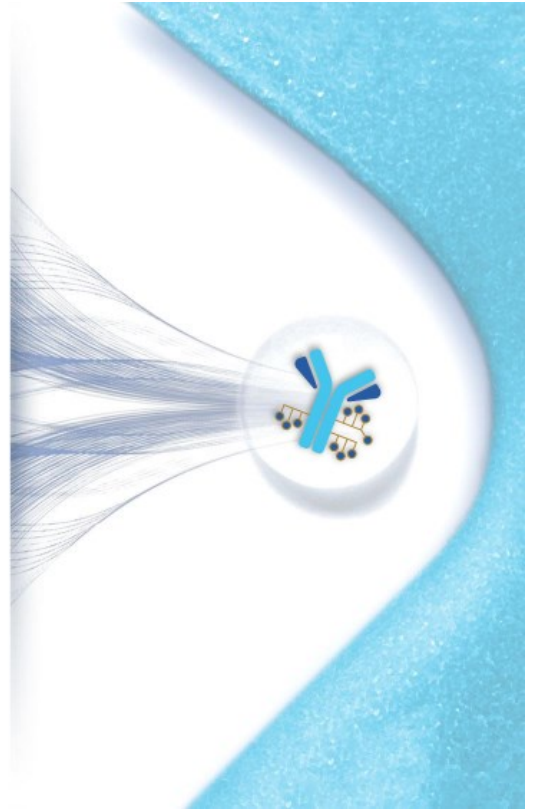
Informed by FDA Feedback, Final Design Pending CHMP Scientific Advice  
Plans to Initiate in 2022

# UP-NEXT Key Differentiators



- **Platinum-Sensitive Population**
  - Earlier in disease than UPLIFT population
  - Opportunity to be first ADC in earlier lines and platinum-sensitive disease
- **UpRi Monotherapy**
  - Randomized vs. placebo, potential for higher probability of success
- **Broader Population than Existing Maintenance Options**
  - Enrolls patients who have achieved stable disease to platinum doublet in addition to patients who achieve partial or complete responses
  - Enrolls patients with prior bevacizumab, prior PARPi, both, or neither
- **Registration Intent**
  - Intended to support global launches
  - If positive, could serve as confirmation of UPLIFT

## Closing Remarks

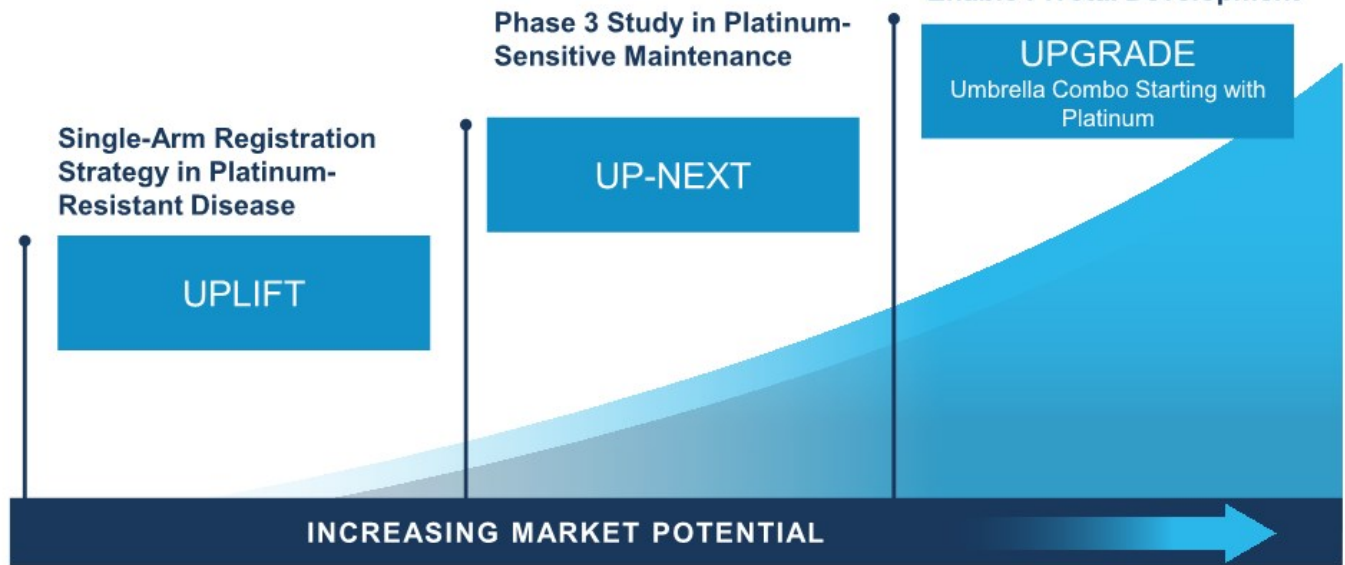


# Data Set Supports UpRi Profile and UPLIFT Registration Strategy

UpRi Profile	<p><u>Meaningful and Durable Activity in Heavily-Pretreated Patients</u></p> <p>&gt;30% ORR with CRs in NaPi2b High Ovarian Cancer</p>	<p><u>Consistent Tolerability Profile</u></p> <p>No Severe Neutropenia, Ocular Toxicity, or Peripheral Neuropathy</p>
	<p><u>Robust, Predictive, and Reproducible Diagnostic</u></p> <p>Tumor Proportion Score <math>\geq 75</math> Present in Two-Thirds of Patients Enriches for Improved Outcomes</p>	<p><u>36 mg/m<sup>2</sup></u> <u>Up to a Maximum of ~80 mg</u></p> <p>Potential to Further Improve Safety while Maintaining Efficacy</p>

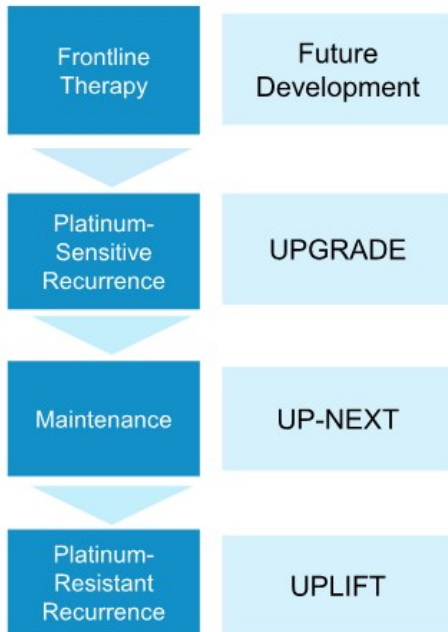
# An Opportunity to Deliver a Potentially Foundational Medicine for Ovarian Cancer

Phase 1 / 2 Combinations to Enable Pivotal Development





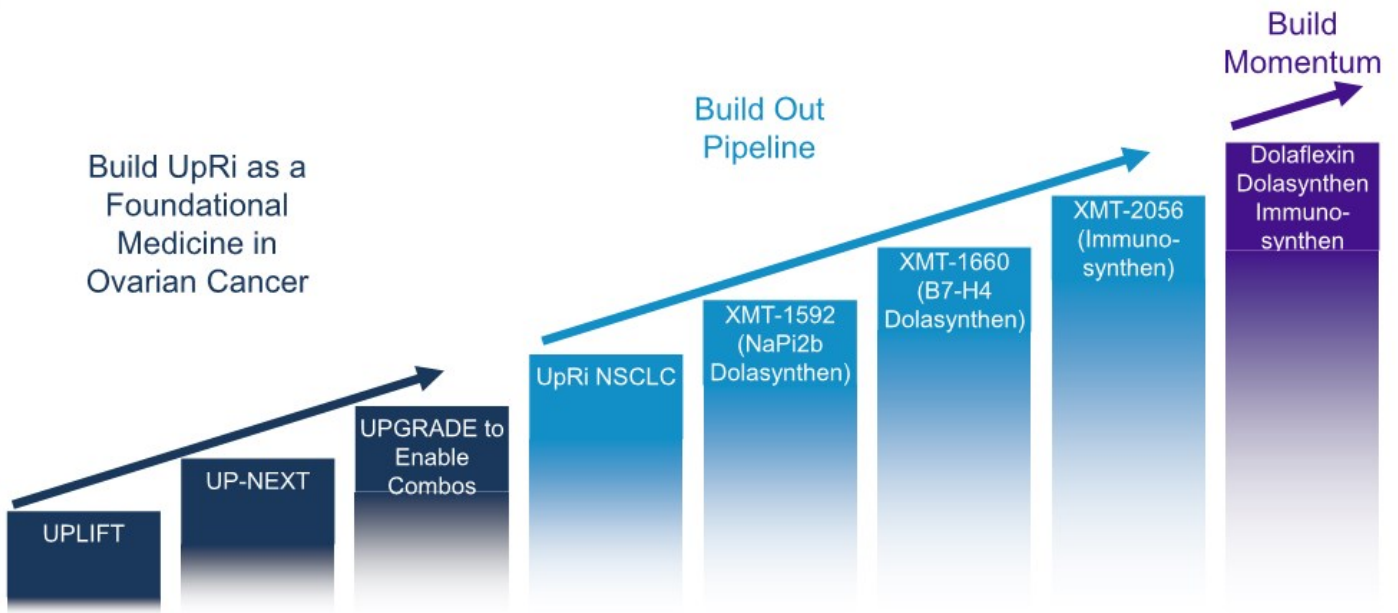
# Opportunities in Platinum-Sensitive, Platinum-Resistant, Monotherapy, Combination, Treatment, and Maintenance



- 22,000 newly diagnosed ovarian cancer patients annually
- Plus, fallopian tube and primary peritoneal cancers treated in the same algorithm
- With a median survival 5 years from diagnosis
- 80% relapse following frontline therapy
- And 14,000 deaths per year

Source: SEER

# Multiple Value-Drivers Across UpRi, Pipeline, and Platforms



**Q&A**

