## **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): January 5, 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)

(Registra	ant's telephone number, including area code):	: (617) 498-0020
(For	Not Applicable mer name or former address, if changed since	e last report)
Check the appropriate box below if the Form 8-K file provisions:	ing is intended to simultaneously satisfy the f	filing obligation of the registrant under any of the following
☐ Written communications pursuant to Rule 425 und	der 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 C	CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to	Rule 13e-4(c) under the Exchange Act (17 C	FR 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
or Rule 12b-2 of the Securities Exchange Act of 193- Emerging growth company □	4 (§240.12b-2 of this chapter).  nark if the registrant has elected not to use the	e 405 of the Securities Act of 1933 (§230.405 of this chapter)  e extended transition period for complying with any new or

## Item 2.02 Results of Operations and Financial Condition.

On January 5, 2021, Mersana Therapeutics, Inc. (the "Company") issued a press release announcing corporate and pipeline updates and 2021 goals and anticipated milestones. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The Company is also furnishing, as Exhibit 99.2 to this Current Report on Form 8-K, an analyst and investor presentation, which the Company intends to use on January 5, 2021 in connection with a presentation to the investment community (the "Analyst Presentation").

The information included in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Item 8.01 Other Events.

The Company is filing the Analyst Presentation as Exhibit 99.2 to this Current Report on Form 8-K, which is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
<u>99.1</u>	Press release issued by Mersana Therapeutics, Inc. on January 5, 2021
<u>99.2</u>	Analyst & Investor Presentation, dated January 5, 2021
99.1 99.2 104	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: January 5, 2021

#### Mersana Therapeutics Announces Corporate and Pipeline Updates and 2021 Goals and Anticipated Milestones

- Following successful FDA meeting, the Company plans to initiate UPLIFT, a single-arm registrational strategy to evaluate XMT-1536 in platinum-resistant ovarian cancer, in Q1 2021
- Data from the ovarian cancer expansion cohort of the XMT-1536 Phase 1 study continued to show consistent activity and tolerability in a heavily-pretreated population
- XMT-1660, a first-in-class ADC targeting B7-H4, expected to complete IND-enabling studies in Q4 2021
- Ended Q4 2020 with approximately \$255 million in cash, funding the Company's anticipated operating plan commitments for at least the next two vears

**CAMBRIDGE, Mass., January 5, 2021** -- Mersana Therapeutics, Inc. (NASDAQ:MRSN), a clinical-stage biopharmaceutical company focused on discovering and developing a pipeline of antibody-drug conjugates (ADCs) targeting cancers in areas of high unmet medical need, today provided corporate and pipeline updates and announced its goals and anticipated milestones for 2021.

The Company will host a virtual Analyst and Investor event today at 10:00 a.m. ET, during which members of the Mersana executive team will provide an update on the XMT-1536 registration pathway informed by FDA feedback and further studies planned to evaluate XMT-1536 in earlier lines of ovarian cancer. The Company will also present preclinical data for XMT-1660, a first-in-class ADC targeting B7-H4, and outline the Company's goals and anticipated milestones for 2021. The Company will be joined by investigator Debra L. Richardson, MD, Associate Professor and Section Chief, Division of Gynecologic Oncology at the OU Health Stephenson Cancer Center and the Sarah Cannon Research Institute, who will review the updated data from the ovarian cancer expansion cohort of the XMT-1536 Phase 1 expansion study.

"2021 promises to be another transformative year for Mersana's pipeline. Our focus will be to initiate the UPLIFT single-arm registration strategy for XMT-1536 in platinum-resistant ovarian cancer and to initiate the UPGRADE combination umbrella study with the goal of informing the path into earlier lines of ovarian cancer therapy. The updated data being presented today show encouraging response rates in late-stage ovarian cancer patients and tolerability further supporting the potential of this therapy to be foundational for the treatment of ovarian cancer," said Anna Protopapas, President and CEO of Mersana Therapeutics. "Additionally, both the non-small cell lung cancer cohort of the Phase I expansion study of XMT-1536 and the XMT-1592 Phase 1 dose escalation study continue to actively enroll patients with interim data for both studies expected in the second half of this year. We will also work to advance XMT-1660, our first-in-class ADC targeting B7-H4, and XMT-2056, our first Immunosynthen STING-agonist ADC development candidate, through IND-enabling studies."

"We are very pleased with the continued activity and tolerability of XMT-1536 in heavily-pretreated patients with ovarian cancer without the severe neutropenia, peripheral neuropathy and ocular toxicity seen in other ADCs," said Arvin Yang, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Mersana Therapeutics. "Based on these data and feedback from the FDA we plan to initiate a single-arm registrational strategy this quarter through an amendment to the ongoing Phase I study protocol. We believe this study design will allow for significant operational efficiencies and leverages continued momentum in patient enrollment."

## UPLIFT Single-Arm Registration Strategy Studying XMT-1536 in Platinum-Resistant Ovarian Cancer

Informed by feedback from a meeting with the FDA, the Company plans to initiate UPLIFT, a single-arm registration strategy, to evaluate the safety and efficacy of XMT-1536 in platinum-resistant ovarian cancer patients who have received up to four lines of therapy. Platinum-resistant ovarian cancer patients previously treated with three or four lines of therapy may enroll without regard to prior bevacizumab treatment. Platinum-resistant ovarian cancer patients who received one or two lines of therapy will be required to have had prior bevacizumab treatment. Patients may enroll without regard to NaPi2b expression; however, the role of the biomarker will be evaluated. The primary endpoint will be the objective response rate (ORR) in the higher NaPi2b patient population and the secondary endpoints will be the ORR regardless of NaPi2b expression, as well as duration of response and safety. The single-arm registration strategy will be initiated as an amendment to the ongoing multinational, multi-center, open label study protocol and the Company expects to enroll approximately 180 patients.

#### **Updated Expansion Study Data for XMT-1536**

Today's update focuses on the ovarian cancer expansion cohort of the XMT-1536 Phase 1 study which is enrolling heavily pre-treated patients with ovarian cancer who have received up to four prior lines of therapy. With a data cutoff of December 3, 2020, these data include 72 patients evaluable for safety and 47 patients evaluable for RECIST response.

#### Key findings include:

- Adverse event profile consistent with previously reported expansion data
  - o The most frequently reported treatment-related adverse events (TRAEs) were generally Grade 1-2 fatigue, nausea, transient AST elevation without associated changes in bilirubin or cases of Hy's law, and transient thrombocytopenia.
  - o 31% of patients experienced a dose reduction, delay, or discontinuation due to a treatment-related adverse event.
  - o Serious adverse events occurred in 39% of patients regardless of relatedness with the most common related SAEs occurring in more than 2 patients of pyrexia (4), vomiting (3), abdominal pain (2), pneumonitis (2).
  - o There were no reported cases of severe neutropenia, peripheral neuropathy or ocular toxicity.
- · Anti-tumor activity in platinum-resistant and platinum-refractory ovarian cancer previously treated with bevacizumab, PARP inhibitors, or both.

### Activity observed in higher NaPi2b expressing population

- o 31 patients with higher NaPi2b expression were evaluable for response, with 2 achieving confirmed complete responses (CRs) and 8 achieving confirmed partial responses (PRs) for an ORR of 32% (10/31). Additionally, 13 patients achieved stable disease (SD) for a disease control rate (DCR) of 74% (23/31).
- o The median duration of response was estimated at 5 months in patients with higher NaPi2b expression.
- o A trend toward higher response rate as well as deeper and more durable responses in patients with higher NaPi2b expression supports the continued development of a NaPi2b diagnostic assay.

## Activity observed in overall population, regardless of NaPi2b expression

- o Among all 47 patients evaluable for response, 3 additional patients achieved PRs for an ORR of 28% (13/47). 6 additional patients achieved SD for a DCR of 68% (32/47).
- o 69% of responses were observed by the first scan.
- o 67% of patients showed reduction in target lesions.

### Corporate

Cash and cash equivalents as of December 31, 2020, were approximately \$255 million. The Company expects that its current cash and cash equivalents will enable it to fund its current anticipated operating plan commitments for at least the next two years. In addition, the Company has the option to draw additional funds through the debt financing agreement with Silicon Valley Bank.

#### 2021 Goals and Anticipated Milestones

#### XMT-1536, first-in-class Dolaflexin ADC targeting NaPi2b:

- UPLIFT single-arm registration strategy studying XMT-1536 in platinum-resistant ovarian cancer expected to initiate in first quarter of 2021: The single-arm cohort, informed by FDA feedback, will evaluate the safety and efficacy of XMT-1536 in approximately 180 patients with platinum-resistant ovarian cancer. This study is intended to support the initial registration of XMT-1536.
- UPGRADE umbrella combination study in ovarian cancer expected to initiate in the third quarter of 2021: The Company plans to initiate the UPGRADE study to evaluate the combination of XMT-1536 with other agents, starting with a platinum chemotherapy combination dose escalation cohort. This study is designed to inform the lifecycle management strategy for XMT-1536 in earlier lines of ovarian cancer, including platinum-sensitive disease.
- The Company plans to report updated interim data from the NSCLC adenocarcinoma expansion cohort of the XMT-1536 Phase 1 study in the second half of 2021: The Company has increased enrollment in parallel with the opening of international sites that had been delayed because of COVID-19 and continues to recruit patients in the expansion phase of the study.

### XMT-1592, first Dolasynthen ADC targeting NaPi2b:

The Company plans to report interim XMT-1592 Phase 1 dose escalation data in the second half of 2021: XMT-1592 is the Company's first clinical candidate created using its new Dolasynthen ADC platform. In preclinical studies, XMT-1592 showed four times greater efficacy in a patient-derived lung tumor model in comparison to XMT-1536, the Company's Dolaflexin ADC that has already shown promising activity when targeted to NaPi2b in the clinic. The Company continues to dose escalate and plans to disclose interim dose escalation data in the second half of 2021 and outline the XMT-1592 development plan in the fourth quarter of 2021.

## XMT-1660, first-in-class Dolasynthen ADC targeting B7-H4:

Completion of XMT-1660 IND-enabling studies expected in the fourth quarter of 2021: Investigational New Drug (IND)-enabling studies are ongoing for XMT-1660, a first-in-class B7-H4 ADC candidate. B7-H4 is expressed on both tumor cells and immunosuppressive tumor-associated macrophages (TAMs). This expression provides the potential for both a direct, cytotoxic antitumor effect as well as for additional payload delivery to the tumor microenvironment that can further contribute to immunogenic cell death, dendritic cell activation, and stimulation of an immune response consistent with the features of the Company's unique DolaLock payload. The Company plans to initiate a Phase 1 dose escalation study of XMT-1660 in 2022.

#### XMT-2056, first Immunosynthen STING-agonist ADC candidate:

• Completion of XMT-2056 IND-enabling studies expected in the fourth quarter of 2021: In November 2020, the Company introduced XMT-2056 and presented preclinical data that supported the potential differentiation of the Immunosynthen platform from other innate immune stimulatory approaches and its potential applicability across multiple targets. The Company plans to disclose the target for this program in the fourth quarter of 2021 and initiate a Phase 1 dose escalation study in 2022.

#### **Webcast and Conference Call Details**

A live webcast of the presentation will be available on the Investors & Media section of the Mersana website at <a href="https://ir.mersana.com/events-and-presentations">https://ir.mersana.com/events-and-presentations</a>. Analyst and Investors may ask a question during the live Q&A by dialing (855) 940-5308 (toll-free domestic) or (929) 517-9745 (international) and providing the Conference ID 6265117.

### **About Mersana Therapeutics**

Mersana Therapeutics is a clinical-stage biopharmaceutical company using its differentiated and proprietary ADC platforms to rapidly develop novel ADCs with optimal efficacy, safety and tolerability to meaningfully improve the lives of people fighting cancer. Mersana's lead product candidate, XMT-1536, is in the expansion portion of a Phase 1 proof-of-concept clinical study in patients with ovarian cancer and NSCLC adenocarcinoma. XMT-1592, Mersana's second ADC product candidate targeting NaPi2b-expressing tumors, was created using Mersana's customizable and homogeneous Dolasynthen platform and is in the dose escalation portion of a Phase 1 proof-of-concept clinical study. The Company's early-stage programs include XMT-1660, a first-in-class B7-H4 targeting ADC, as well as XMT-2056, a STING-agonist ADC developed using the Company's Immunosynthen platform. In addition, multiple partners are using Mersana's Dolaflexin platform to advance their ADC pipelines.

## Forward-Looking Statements

This press release 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 business strategy and the design, progression and timing of its clinical trials, the ability of the single-arm UPLIFT cohort to enable registration, and expectations regarding future clinical trial results based on data achieved to date, and the sufficiency of the Company's cash on hand. 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 press release. 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 may not be predictive of the results or success of ongoing or later preclinical or clinical trials, that the development and testing of the Company's product candidates and new platforms will take longer and/or cost more than planned, and that the identification of new product candidates will take longer than planned, as well as those listed in the Company's Annual Report on Form 10-K filed on February 28, 2020, with the Securities and Exchange Commission ("SEC"), the Company's Quarterly Report on Form 10-Q filed on May 8, 2020, with the SEC and subsequent SEC filings. In addition, while we expect that the COVID-19 pandemic might 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, 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.

## **Contact:**

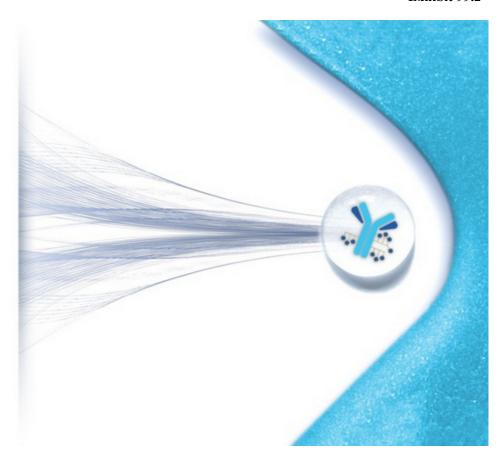
Investor & Media Contact Sarah Carmody, 617-844-8577 <a href="mailto:scarmody@mersana.com">scarmody@mersana.com</a>



## Accelerating ADC Innovation

...because patients are waiting

Virtual Analyst & Investor Day January 5, 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 Mersana Therapeutics, Inc.'s (the "Company's") business strategy and the design, progression and timing of its clinical trials, the ability of the single-arm UPLIFT cohort to enable registration, expectations regarding future clinical trial results based on data achieved to date, and the sufficiency of the Company's cash on hand.

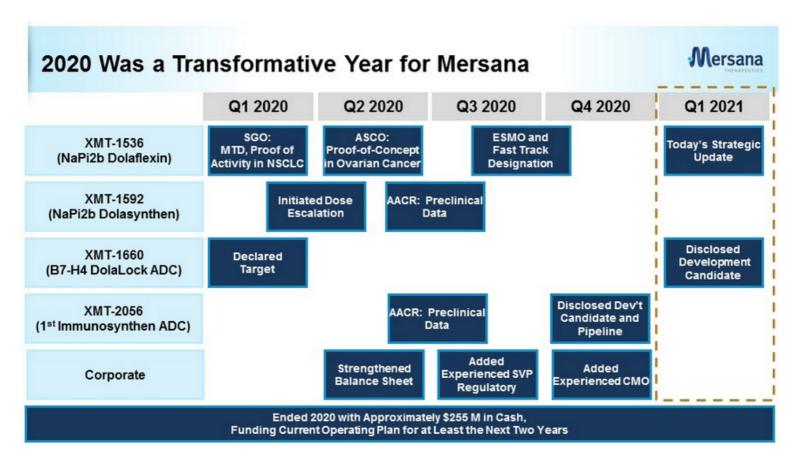
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Copies of the Company's Annual Report on Form 10-K and our other SEC filings are available by visiting EDGAR on the SEC website at http://www.sec.gov.

## Today's Agenda



Topic	Speaker
Opening Remarks	Anna Protopapas, President & CEO
XMT-1536 Pivotal Registration Strategy in Ovarian Cancer	Arvin Yang, MD, PhD, Chief Medical Officer
XMT-1536 Phase 1 Ovarian Cancer Expansion Study Data Update	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
Ovarian Cancer Market Dynamics and XMT-1536 Opportunities	Brian DeSchuytner, SVP Finance & Product Strategy
XMT-1660 B7-H4 ADC Development Candidate	Tim Lowinger, PhD, Chief Science & Technology Officer
Closing Remarks: 2021 Corporate Goals & Anticipated Milestones	Anna Protopapas, President & CEO
Q&A	



## Poised for Significant Value Inflection Points and Continued Momentum in 2021



1 XMT-1536 in Ovarian	Initiate Single-Arm Registration Strategy	Initiate Lifecycle Management Studies / Combinations
2 XMT-1536 In NSCLC	Seek to Achieve Proof-of-Concept	Select Lead in NSCLC
3 XMT-1592	Complete Dose Escalation	SCIECT LOUG III 1150 LO
4 XMT-1660 (B7-H4)	IND-Enabling Studies	IND Submission Q1 2022
5 XMT-2056 (Immunosynthen)	IND-Enabling Studies	IND Submission Q1 2022

## XMT-1536 Has a New Name



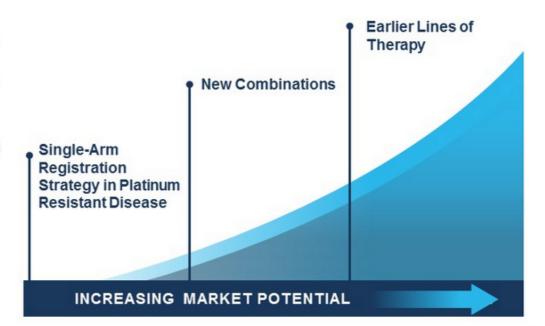


## upifitamab rilsodotin or UpRi, for short

## UpRi (XMT-1536): An Opportunity to Deliver a Potentially Foundational Therapy for Ovarian Cancer



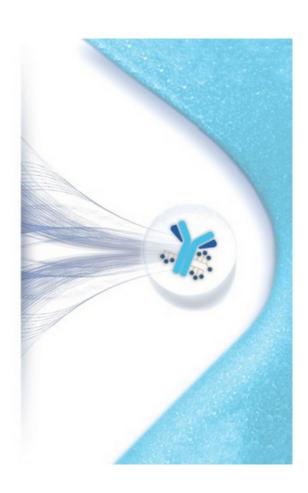
- In a heavily-pretreated ovarian cancer population:
  - Proof of concept, >30%
     ORR in ovarian cancer with higher NaPi2b expression
  - Activity, including CRs, in patients failing platinum, bevacizumab, and/or PARPi
  - No severe neutropenia, peripheral neuropathy or ocular toxicity
  - Biomarker identification for improved patient outcomes



## UpRi (XMT-1536): First-in-Class Dolaflexin ADC Targeting NaPi2b

Single-Arm Registration Strategy in Ovarian Cancer

Arvin Yang, MD, PhD Chief Medical Officer



## **UPLIFT Strategy: Key Areas Discussed with FDA**



Strategy Informed by End of Phase Meeting and Meeting Minutes

- Population with high unmet medical need
- Performance of current standard of care
- Design of single-arm registration cohort
- Primary and secondary endpoints
- Biomarker validation strategy

## Appropriate Benchmarks for Current Standard of Care in Platinum-Resistant Ovarian Cancer



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

			Historical Comparison for UPLIFT Population
Study	Demographics	Control Arm	Control Arm Performance
Forward I ESMO 2019	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%

## **UPLIFT: Single-Arm Registration Strategy in Platinum Resistant Ovarian Cancer**



## Patient Population:

No Pre-Selection for NaPi2b

Inclusion Criteria: **Platinum Resistant Ovarian Cancer** 1 - 4 Prior Lines

**Exclusion Criteria:** 1 - 2 Prior Lines Bev-naïve **Primary Platinum Refractory Disease** 

Global: US, Europe, Australia, Canada

Dose: 43 mg/m<sup>2</sup> q4w ~180 Patients

## **Primary Endpoint:**

Confirmed ORR in higher NaPi2b

## **Key Secondary Endpoint:**

Confirmed ORR in overall population

## Other Secondary Endpoints:

- Duration of Response
- Safety

# Significant Time Advantage in Amending with the Single-Arm UPLIFT Cohort



UPLIFT will be operationalized as an amendment as opposed to initiating a new study

## **Objective**

- Determine safety and MTD: 43 mg/m<sup>2</sup>
- Proof of concept achieved June 2020
- Expansion cohort serves as training set for NaPi2b biomarker
- Demonstrate clinically meaningful outcome
- Validate NaPi2b Biomarker

First in Human to Pivotal Cohort in One Study

Dose Escalation Cohort (Enrollment Complete in March 2020)



Ovarian Cancer Expansion Cohort (Enrollment August 2019 – Q1 2021)



## Strategy to Deliver a Robust and Reproducible Commercial Diagnostic Assay



Ovarian Cancer Expansion Cohort and Relevant Doses from Escalation Cohort

- NaPi2b expression assessed with clinical assay in >80 patients
- "Train" proposed commercial assay
  - Repeat assessment on all samples
  - Ensures same read regardless of lab and pathologist
- Determine cutoff for UPLIFT Pivotal Cohort based on full data set

UPLIFT: Single-Arm Registration Strategy in Platinum-Resistant Ovarian Cancer

- Prospectively-defined retrospective analysis validates NaPi2b biomarker cutoff with proposed commercial assay
- Enroll without NaPi2b biomarker selection
  - Evaluate both NaPi2b biomarker higher and overall population
  - Optionality for either companion diagnostic or complementary diagnostic assay

## UPLIFT Registration Strategy Creates Potential for Speed and Label Differentiation



## Streamlined Execution

Leverages expansion cohort enrollment momentum in high unmet need population for single-arm registration path

## Broad Target Population

- Includes patients with 4 prior lines of therapy, a broader population than historical studies in platinum-resistant ovarian cancer
- Includes bevacizumab-naïve patients with 3 4 prior lines of therapy, accommodating differences in bevacizumab use in early disease
- No pre-selection accelerates enrollment and provides potential upside opportunity for broad label regardless of NaPi2b expression level

## Assay Validation Process

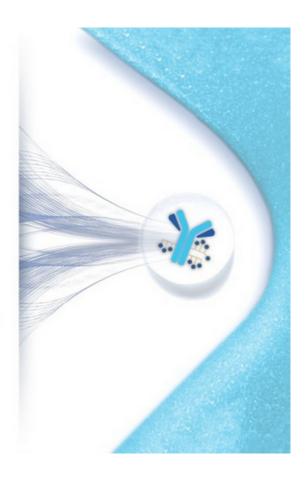
Training and validation method designed to support a commercial assay

## Planning to Initiate UPLIFT Patient Dosing in Q1 2021

## UpRi (XMT-1536): First-in-Class Dolaflexin ADC Targeting NaPi2b

Phase 1 Ovarian Cancer Expansion Cohort Data Update

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



The following information is from an ongoing study and based on December 3, 2020 data cut

## **Acknowledgements**



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

### UNTED STATES

Allegheny Health Network, Pittsburgh, PA Arizona Oncology Associates, Tucson, AZ 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

CANADA

McGill University (Glen-Cedars Cancer Center), Montreal

British Columbia Cancer Agency, Vancouver

AUSTRALIA

Lifehouse Australia as trustee for the Lifehouse Australia Trust, Camperdown

Peter MacCallum Center, Melbourne, Victoria

Austin Health, Heidelberg, Victoria

## Design for the Ovarian Cancer Cohort of the XMT-1536 (UpRi) Phase 1 Expansion 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

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

\*Tolicher TW et al. J Clin Oncol 37, 2019 (suppl; abstr 3010)
\*Richardson DL et al. Presented at SGO Annual Meeting 2020; LBAS
\*Hamilton E et al. Presented during the 2020 <u>European Society of Medical Oncology</u> (ESMO) Virtual Congress

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 reported1.2.3)
- 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

## **Patient Demographics and Disease Characteristics**



Data cut off: 03 December 2020

Age; years	Median (range)	68 (33, 87)
ECOG Performance Status; n (%)	0	26 (36) 46 (64)
Primary Tumor Type <sup>a</sup> ; n (%)	Ovarian Fallopian Tube Primary Peritoneal	55 (76) 11 (15) 6 (8)
Prior Lines of Therapy; n (%)	1-3 4+ <sup>5</sup>	47 (65) 25 (35)
Prior Therapy; n (%)	Bevacizumab PARP inhibitor	48 (67) 42 (58)
Platinum-free Interval <sup>c</sup> ; n (%)	0-3 mos >3-6 mos >6 mos <sup>d</sup> Unknown <sup>e</sup>	26 (36) 39 (54) 6 (8) 1 (1)
BRCA1/2 Mutation; n (%)	Yes No Unknown <sup>r</sup>	11 (15) 52 (72) 9 (13)
NaPi2b H-score®; n (%)	Determined Higher Lower Not Yet Determined (ND)	54 (75) 37 (69) 17 (31) 18 (25)

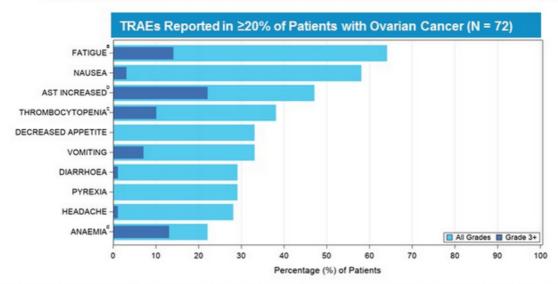
\*Includes 1 Endometriold, 1 Low Grade, 1 Serous / Endometroid, and 1 Carcinosarcoma histology, \* Three patients enrolled with 5 prior lines of systemic therapy, \* Platinum-free Interval defined as the time between the last cycle of most recent platinum-containing regimen and exidence of disease progression; determined from treatment dates and/or clinic notes. \*All patients are platinum-sensitive and had receive 4 or 5 lines of prior therapy.

\*Treatment dates missing/inct provided, unable to determine. \*SRCA1/2 mutation status not available into response conserved («110); Lower NuPIZD Expression: as defined in dose escalation as below the lowest H-score at which response observed («110); ND = NuPIZD Expression not yet determined or tissue not available.

# XMT-1536 (UpRi) Continues to Have a Consistent Tolerability Profile



- 63 (88%) patients reported at least 1 treatment-related adverse event (TRAE)
- No Grade ≥ 3 (severe) TRAEs of neutropenia, peripheral neuropathy, or ocular toxicity have been reported



Fatigue includes preferred terms of asthenia and riskipue. NAST inconsesse is transient in nature, recovers to baseline not to Grade 1 prior to the next dose, no instances are associated with elevated billiubilior or cases of Hys Bury. "Intrombookpopenia is bransient and Europe and Europe in the next dose," As when the includes preferred terms of assential and blood loss anaemia.

# Safety Summary of XMT-1536 (UpRi) in Patients with Ovarian Cancer (N = 72)



Dose Modifications	Patients, n (%)	
Any dose reduction, delay, or discontinuation due to TRAE	22 (31%)	
Dose reductions due to TRAE	17 (24%)	
Dose delays due to TRAE	8 (11%)	
Discontinuations due to TRAE	5 (7%)	

SAEs	Patients, n (%)	Notes
Any SAEs*	28 (39%)	<ul> <li>SAEs reported in ≥2 (3%) patients included:</li> <li>5 patients: Gastrointestinal obstruction (0 related)</li> <li>4 patients each: Abdominal pain (2 related), pyrexia (4 related), and vomiting (3 related)</li> </ul>
Treatment- Related SAEs	11 (15%)	<ul> <li>2 patients each: Cerebrovascular accident/transient ischemic attack (0 related), pneumonitis (2 related, Grade 2 and Grade 5**), pneumonia (0 related), respiratory failure (0 related), renal impairment (1 related), fatigue (1 related), and atrial fibrillation (0 related)</li> </ul>

<sup>&</sup>quot;includes both related and unrelated SAEs as assessed by the linvestigator." One grade 5 pneumonitis assessed by the investigator as related to study drug.

Abbreviations: SAEs = serious adverse events; TRAE = treatment related adverse event.

## Case History of G5 Pneumonitis Case and Program Level Review and Modifications



## Heavily Pre-Treated 87-Year-Old Patient with Recurrent Ovarian Cancer and 4 Prior Lines of Chemotherapy

(carboplatin, paclitaxel, pegylated liposomal doxorubicin, niraparib)

## Cycle 2 Day 14

#### Initial Presentation: Admitted to Non-Study Hospital

- · Moderate weakness, fatigue, dyspnea, and dizziness
- · Treated empirically with diuresis
- Discharged to home in stable condition with some improvement

## Cycle 2 Day 20

#### Re-admitted

- Admitted to cancer hospital with severe fatigue, weakness, and dyspnea
- · Treated empirically with diuresis and antibiotics with transient improvement

## Cycle 2 Day 24

#### Diagnosed and Treated for Pneumonitis

- · With worsening symptoms, pulmonary consultation suspected pneumonitis
- Started on corticosteroids, complicated by altered mental status and persistent requirement for high-flow oxygen



#### Transitioned to Palliative Care

- · Family concerned respiratory status would not improve
- Determined patient would not want more aggressive care
- Patient was transitioned to comfort care only and died 6 days later

- Safety Review Committee identified a low frequency of pneumonitis cases which were generally low grade and resolved with dose delays, reductions, and/or treatment with steroids
  - 8 additional cases out of 145 treated patients
  - Grade 1/2 n=7, Grade 3 n=1
- Modifications to protocol
  - Enhanced guidance on identification and management of pneumonitis
  - Enhanced Dose delay / reduction guidelines
- No further recommendations received from FDA

## Continued Robust Activity Observed in Heavily-Pretreated Mersana **Ovarian Cancer**



Best Response in Evaluable Patients with Ovarian Cancer (n = 47)				
	All (n = 47)	Higher NaPi2b <sup>o</sup> (n = 31)	Lower NaPi2b <sup>00</sup> (n = 13)	NaPi2b Not Yet Determined (n = 3)
CR; n(%)	2 (4)	2 (6)	0	0
PR; n(%)	11 (23)	8 (26)	2 (15)	1 (33)
SD; n(%)	19 (40)	13 (42)	5 (38)	1 (33)
PD; n(%)	15 (32)	8 (26)	6 (46)	1 (33)
ORR; n (%)	13 (28)	10 (32)	2 (15)	1 (33)
DCR; n (%)	32 (68)	23 (74)	7 (54)	2 (67)

## All Responses are Confirmed

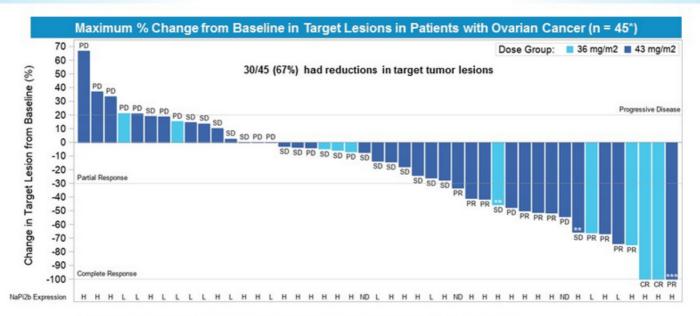
<sup>&</sup>quot;25 patients were not evaluable for RECIST response: 10 patients discontinued prior to first scans: 1 clinical progression; 1 related SAE (G5 pneumonitis); 3 unrelated SAEs; 5 withdrew consent; 15 patients did not yet have RECIST assessment as of the data out

<sup>9</sup> Higher NaPi2b Expression: defined in dose escalation as at / above lowest H-score at which response observed (x110)

<sup>00</sup> Lower NaPi2b Expression: defined in dose escalation as below the lowest H-score at which response observed (<110)

## Deep Responses Observed in Heavily-Pretreated Ovarian Cancer

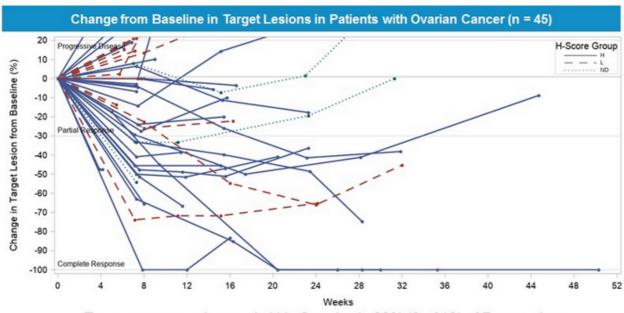




<sup>&</sup>quot;2 patients not included in waterfall plot as tumor measurement data missing in the database as of data cut, both patients had BOR of PD due to new lesions "Unconfirmed response, BOR per RECIST v1.1 is SD ""O R of target lesions and non-CRition-PD of non-target lesions, BOR per RECIST v1.1 is PR H = Higher NaPi2b Expression; L = Lower NaPi2b Expression; ND = NaPi2b Expression not yet determined or tissue not available

# Responses with XMT-1536 (UpRi) Occur Early and Appear to Deepen Over Time



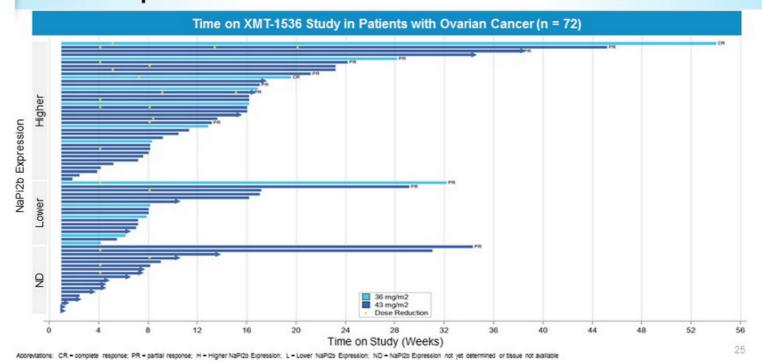


Tumor response observed within 2 cycles in 69% (9 of 13) of Responders

H = Higher NaPi2b Expression: L = Lower NaPi2b Expression: ND = NaPi2b Expression not yet determined or tissue not available

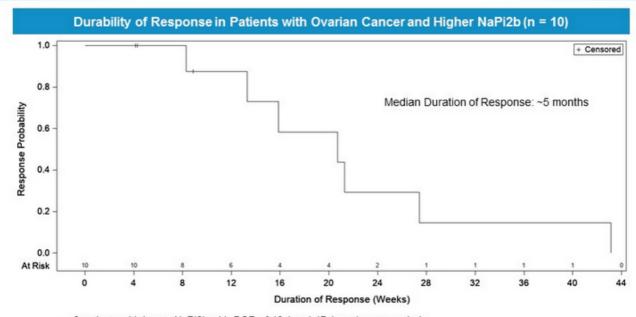
# Clear Trend to Longer Time on Study with Higher NaPi2b Expression





## Median Duration of Response Estimated to be ~5 Months in Patients with Higher NaPi2b Expression





- 2 patients with Lower NaPi2b with DOR of 16.1 and 17.1 weeks, respectively
- 1 patient with NaPi2b ND with DOR 16.1 weeks

## Conclusions: UpRi (XMT-1536) Expansion in Ovarian Cancer

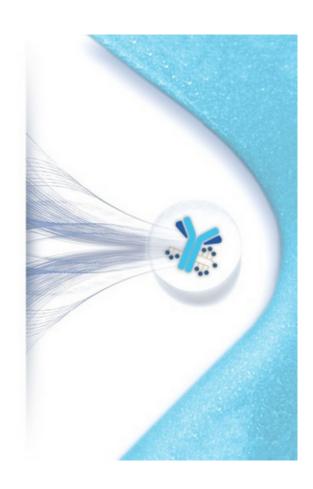


- In this updated analysis of patients with ovarian cancer, UpRi (XMT-1536) continued to be generally welltolerated with a consistent profile – no severe neutropenia, peripheral neuropathy, or ocular toxicity
- Consistent antitumor activity observed with UpRi (XMT-1536), including patients previously treated with bevacizumab and PARPi
  - Complete response observed in 2 patients with platinum-resistant ovarian cancer
  - Confirmed ORR of 32% and DCR of 74% in higher NaPi2b population
  - Median duration of response ~5 months in higher NaPi2b population
- Trend toward higher response rate as well as deeper and more durable responses in patients with higher NaPi2b expression supports the continued development of NaPi2b diagnostic assay
- These data support the continued development of UpRi (XMT-1536) for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received 1 to 4 prior lines of systemic therapy

## UpRi (XMT-1536): First-in-Class Dolaflexin ADC Targeting NaPi2b

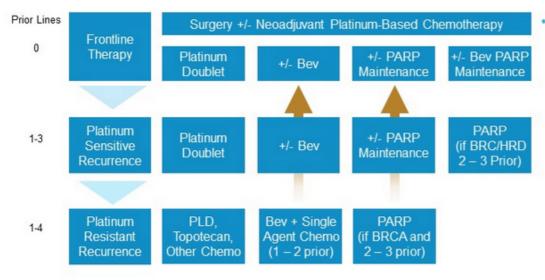
Ovarian Cancer Market Dynamics and UpRi Opportunities

Brian DeSchuytner SVP Finance & Product Strategy



### Early Use of Bevacizumab and PARP Inhibitors is Changing the Ovarian Cancer Landscape



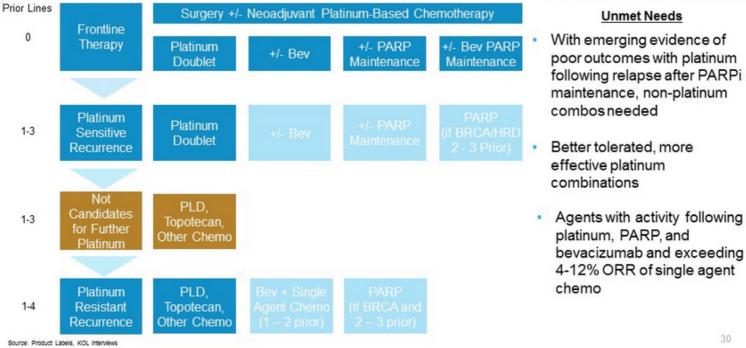


- Key approvals moving targeted therapy into the frontline
  - PAOLA-1 (Bevacizumab + Olaparib maintenance vs Bevacizumab)
  - PRIMA (niraparib maintenance vs placebo)
  - GOG-218 (Bevacizumab + platinum doublet vs platinum doublet)

Source: Product Labels, KOL Interviews 29

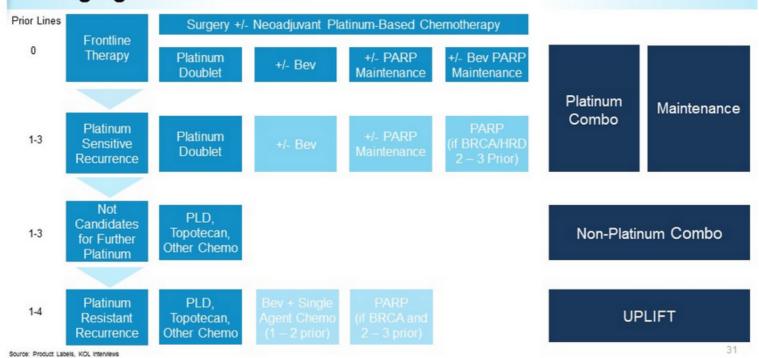
#### **Creating New Unmet Needs and Patient Populations**





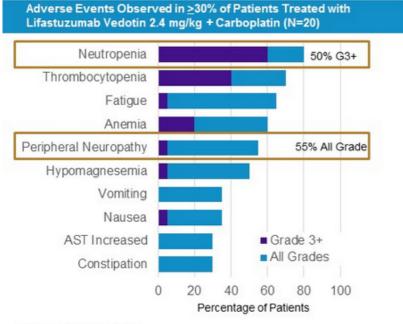
## And Opportunities to Evaluate UpRi in Practice Changing Clinical Studies





### UpRi Profile May Offer Potential Advantages in Combination





- Roche's lifastuzumab vedotin demonstrated significant overlapping toxicities in combination with platinum
- To date, UpRi has demonstrated activity without severe neutropenia, neuropathy, or ocular toxicity
- Platinum doublets remain the backbone of ovarian cancer therapy in earlier lines, but tolerability limits platinum treatment duration

Moore, K. et al Gynecologic Oncology (2020)

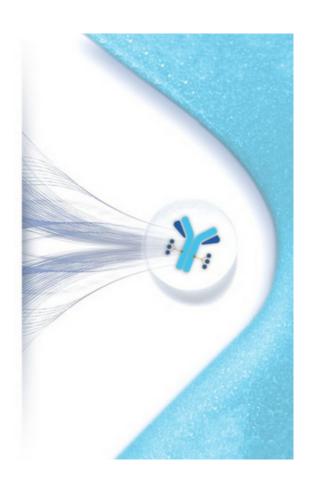
# UpRi (XMT-1536): An Opportunity to Deliver a Potentially Foundational Therapy for Ovarian Cancer



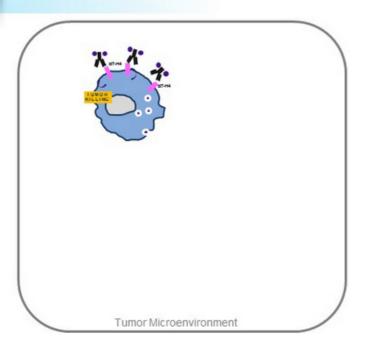


### XMT-1660: First-in-Class B7-H4 ADC

Timothy B. Lowinger, PhD Chief Science & Technology Officer

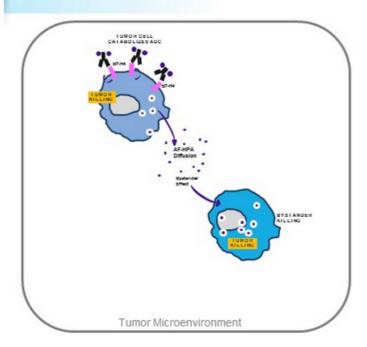






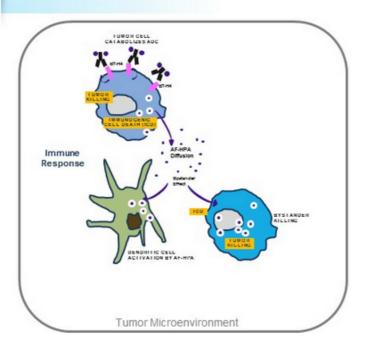
- B7-H4 is selectively expressed on tumor cells in multiple indications
  - Limited expression in normal tissues
- A DolaLock ADC targeting B7-H4 has the potential to exert its effect through multiple mechanisms of action:
  - Uptake by tumor cells and direct cytotoxicity





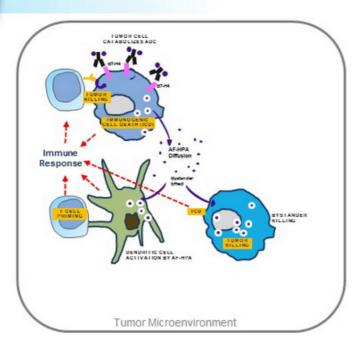
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  - Released payload can also diffuse to antigen negative tumor cells via the DolaLock controlled bystander effect





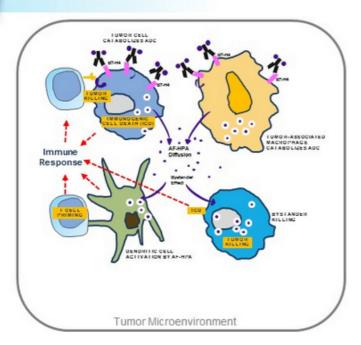
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  - Tumor cell killing results in immunogenic cell death, and the DolaLock payload activates dendritic cells





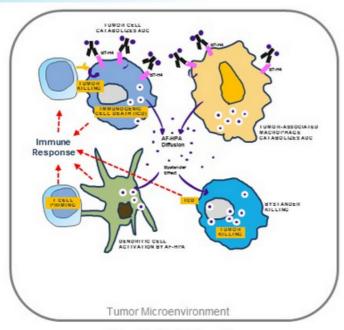
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  - The DolaLock ADC can provide a combined cytotoxic and immune-based anti-tumor effect





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  - The DolaLock ADC can provide a combined cytotoxic and immune-based anti-tumor effect
- B7-H4 is also expressed on tumor-associated macrophages which can potentially further contribute to the effect



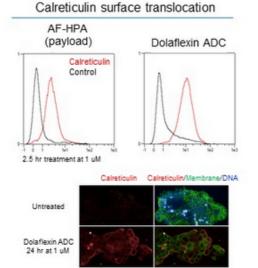


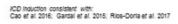
"The Perfect Storm"

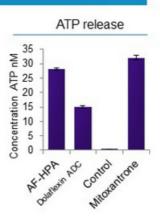
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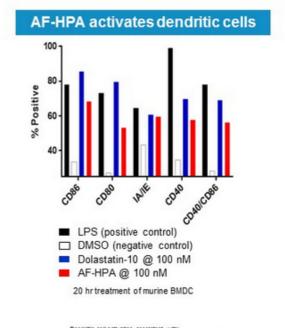
### Our DolaLock Payload is Both Cytotoxic and Immunostimulatory Mersana

#### AF-HPA induces immunogenic cell death





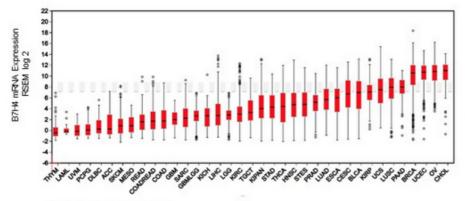




Dendritic cell activation consistent with: Martin et al. 2014; Mueller et al. 2014; Mueller et al. 2015

## B7-H4 is Expressed in Multiple Cancer Indications with High Unmet Medical Need





Based on mRNA expression data (cBioPortal), high expression in:

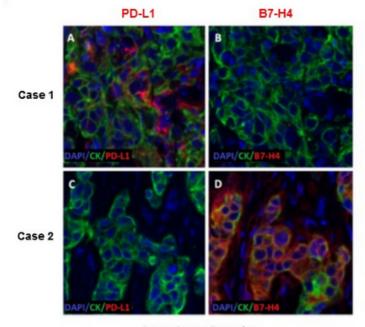
- Bile duct carcinoma
- Ovarian
- Uterine
- Breast
- Pancreatic Lung squamous
- Bladder
- · Etc.

#### Protein expression data:

- 2-3+ IHC B7-H4 staining/H>50 in >50% of samples in TNBC, uterine, ovarian cancer (Sachdev et al. ASCO, 2019) n= not stated
- B7-H4 Expression (aggregate 1-3+ immunoreactivity) in 77%TNBC, and ~60% HER2+ and HR+ (Leong et al., 2015) n=202
- B7-H4 Expression "High" in ~ 45% of Breast Cancers (Altan et al., 2018) (two cohorts n=561, 444)
- B7-H4 Expression detected in 12.8 and 22.6 % of NSCLC (two cohorts), with higher frequency in SCC (Schalper et al., 2017)

## Targeting B7-H4 Creates Opportunities to Potentially Address Patients Poorly Served by Checkpoint Inhibitors





PD-L1 and B7-H4 expression are essentially mutually exclusive

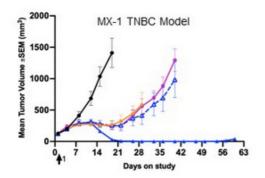
 No co-expression in >95% of breast cancer and lung cancer samples\*

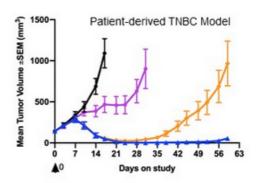
**Breast Cancer Examples** 

\*Altan et al. 2018 Breast Cancer, Schalper et al. 2016 Clin.Canc.Res.

## XMT-1660 Selected Candidate Based on Direct Comparison Across Multiple In Vivo Models, including PDX Models







Solid lines indicate equivalent dose by payload; dashed line = 0.5x dose Non-binding control ADCs and unconjugated B7-H4 mAb were all inactive; data omitted for clarity







### Preclinical Profile of XMT-1660 Supports Advancement



- Pharmacokinetic profile displays long half life (~5 days in NHPs) and dosedependent exposure
  - Highly stable with very low (<0.1%) free payload detected in circulation
- Well tolerated in NHPs after multiple doses
- Demonstrated therapeutic index based on well-tolerated exposure in NHPs and efficacious exposures in mouse

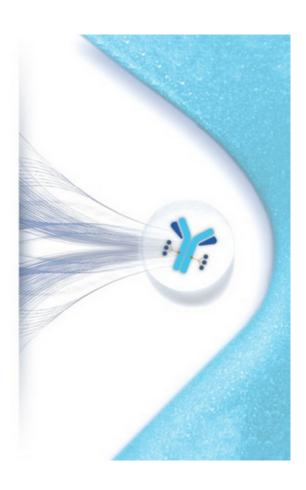
### **Summary of the Opportunity**



- Potential first-in-class opportunity with compelling target biology and unique fit to DolaLock payload
- Clinical candidate was optimized on multiple parameters
  - DAR, site specific bioconjugation, selection of optimal antibody
  - Dolasynthen DAR-6 consistently outperformed stochastic Dolaflexin DAR-12 and site specific Dolasynthen DAR-2 across multiple tumor models
- Expression in areas of high unmet medical need: TNBC, ER+ BC, Endometrial cancer and others
  - Opportunity for accelerated development path in key indications of interest
- Expected to enter the clinic in Q1 2022

### **Corporate Update**

Anna Protopapas President & CEO



#### UpRi (XMT-1536): Compelling Efficacy and Tolerability Data with Broad Potential in Ovarian Cancer



#### >30% ORR with CRs in Ovarian Cancer Patients with Higher NaPi2b Expression

- Majority of patients pre-treated with PARP inhibitors or bevacizumab;
   35% with 4 or more prior lines
  - Complete response observed in 2 patients with platinum-resistant ovarian cancer
  - ORR of 32% and DCR of 74% in patients with higher NaPi2b expression
  - Median duration of response: 5 months in higher NaPi2b Population
- Biomarker selects for enhanced outcomes, but responses and stable disease observed in lower NaPi2b population as well

#### No Severe Neutropenia, Ocular Toxicity, or Peripheral Neuropathy

- Most common treatment-related adverse events (TRAEs) were generally Grade 1-2 fatigue, nausea, transient AST elevation without associated changes in bilirubin or cases of Hy's law, transient thrombocytopenia
- Enhanced dose modification and management guidelines for pneumonitis

#### Single-Arm Registration Strategy and Expansion Potential in Combos and Earlier Lines

- UPLIFT includes key differentiators
  - Leverages expansion cohort momentum and no biomarker pre-selection for enrollment speed
  - Broad population up to 4 prior lines, with no prior bevacizumab required for 3 – 4 prior lines
  - -Assay validation strategy
- UPGRADE umbrella combination study, with initial platinum cohort, informs strategy in earlier lines

Data as of December 3,2020. Complete ESMO 2020 disclosure available here: <a href="https://www.mersana.com/wp-content/uploads/2020/09/Mersana">https://www.mersana.com/wp-content/uploads/2020/09/Mersana</a> ESMO-2020 Poster FINAL.pdf Complete ASCO 2020 disclosure available here: <a href="https://www.mersana.com/wp-content/uploads/2020/05/2020-ASCO">https://www.mersana.com/wp-content/uploads/2020/05/2020-ASCO</a> XMT-1536 Poster FINAL-14May2020.pdf

# UpRi (XMT-1536): An Opportunity to Deliver a Potentially Foundational Therapy for Ovarian Cancer





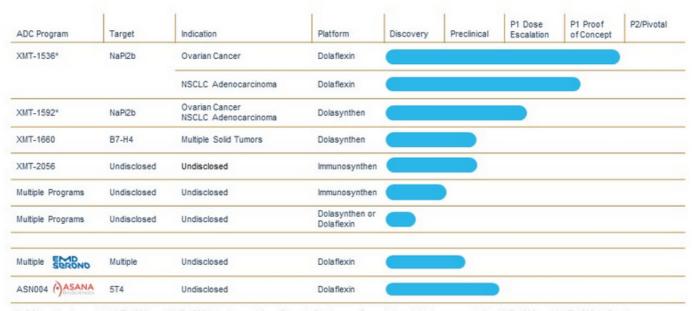
### Goals and Anticipated Milestones for 2021



Upifitamab Rilsodotin UpRi (XMT-1536)	<ul> <li>Q1 2021: Initiate UPLIFT single-arm registration strategy as amendment</li> <li>Q3 2021: Initiate UPGRADE combination dose escalation umbrella study</li> <li>2H 2021: Report updated interim data from NSCLC expansion cohort</li> </ul>
XMT-1592	<ul> <li>2H 2021: Report dose escalation data</li> <li>Q4 2021: Outline further development path</li> </ul>
XMT-1660	Q4 2021: Complete IND-enabling studies to initiate Phase I dose escalation in 2022
XMT-2056	<ul> <li>Q4 2021: Complete IND-enabling studies to initiate Phase I dose escalation in 2022</li> <li>Q4 2021: Disclose target</li> </ul>
Corporate	<ul> <li>Continue to leverage proprietary platforms to expand pipeline</li> <li>Proactively evaluate potential for collaborations that maximize value</li> </ul>

### We are Leveraging our Novel ADC Platforms to Generate Differentiated Product Candidates





\*NaPi2b antibody used in XMT-1536 and XMT-1592 is in-licensed from Recepta Biopharma. Recepta has rights to commercialize XMT-1536 and XMT-1592 in Brazil

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### **Question & Answer Session**

