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Update on the overall safety and efficacy of the combination PKMYT1-inhibitor lunresertib and ATR-inhibitor camonsertib in patients with ovarian and endometrial cancers: Phase 1 MYTHIC study (NCT04855656)

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Disclosure information

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Alison M. Schram, M.D.

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Lunre BM are prevalent in and contribute to poor outcomes in endometrial and ovarian cancers

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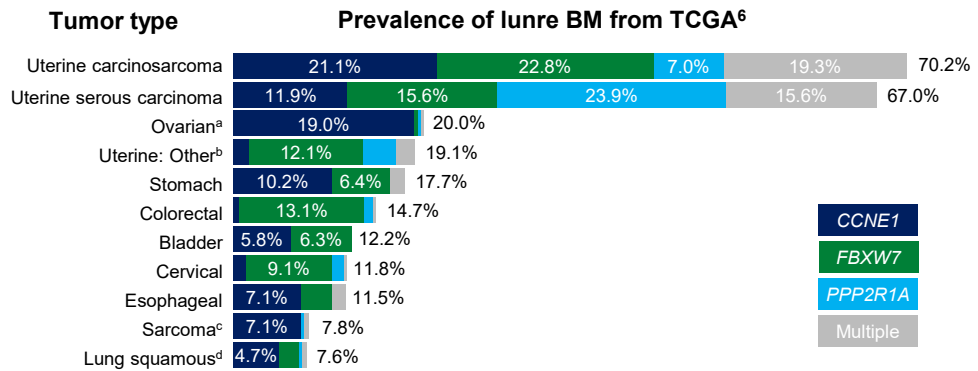
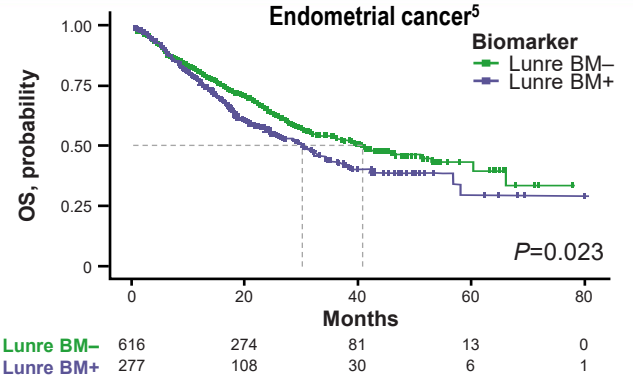
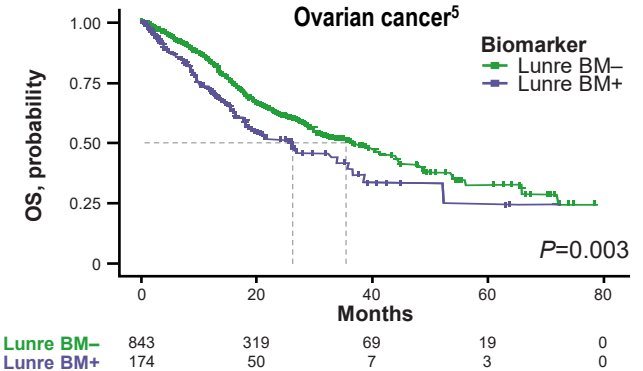
Lunre, a first-in-class PKMYT1i, is synthetically lethal in tumors harboring lunre BM including *CCNE1*^{amp} and deleterious mutations in *FBXW7* and *PPP2R1A*[1-4]

Lunre BM are enriched in gynecological malignancies and are associated with worse prognoses compared to lunre BM– tumors[5]







[a] Includes only high-grade serous ovarian patients. [b] Uterine endometrioid carcinoma and uterine mixed endometrial carcinoma. [c] Soft-tissue sarcoma only. [d] Squamous histology of non-small cell lung cancer only.

[1] Gallo D, et al. Nature. 2022;604(7907):749–756. [2] Gallo D, et al. Poster B057 presented at AACR-NCI-EORTC (ANE) 2023. [3] Xu H, et al. Nat Commun. 2025;16(1):3112. [4] Yap TA, et al. Plenary presentation at AACR-NCI-EORTC (ANE); 2023. [5] Schram A, et al. Poster 89 presented at AACR Ovarian Symposium; 2024. [6] Cancer Genome Atlas Research Network. Nature. 2011;474(7353):609–615. amp, amplification; *CCNE1*, cyclin E1; *FBXW7*, F-box and WD repeat domain containing 7; lunre, lunresertib; lunre BM, lunre-sensitizing biomarkers; OS, overall survival; PKMYT1i, protein kinase, membrane-associated tyrosine/threonine inhibitor; *PPP2R1A*, serine/threonine-protein phosphatase 2A; TCGA, The Cancer Genome Atlas.

Combination lunre + camo synergize to promote antitumor activity

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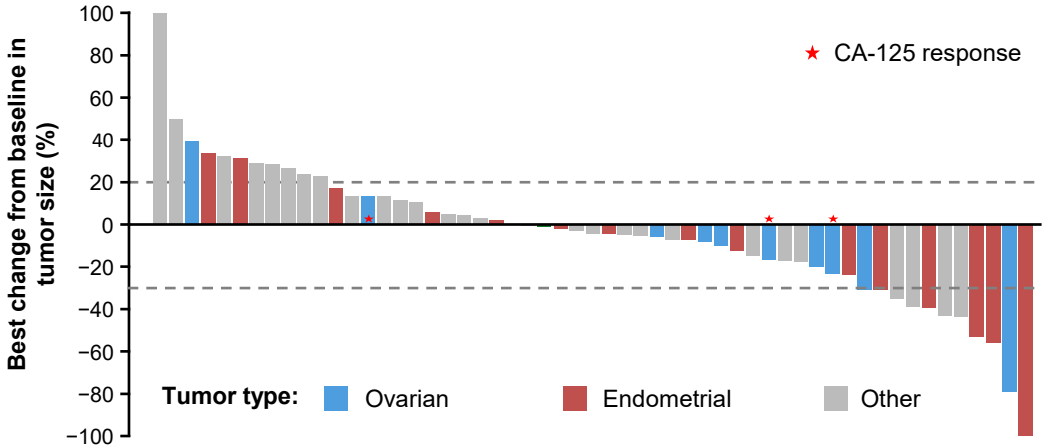
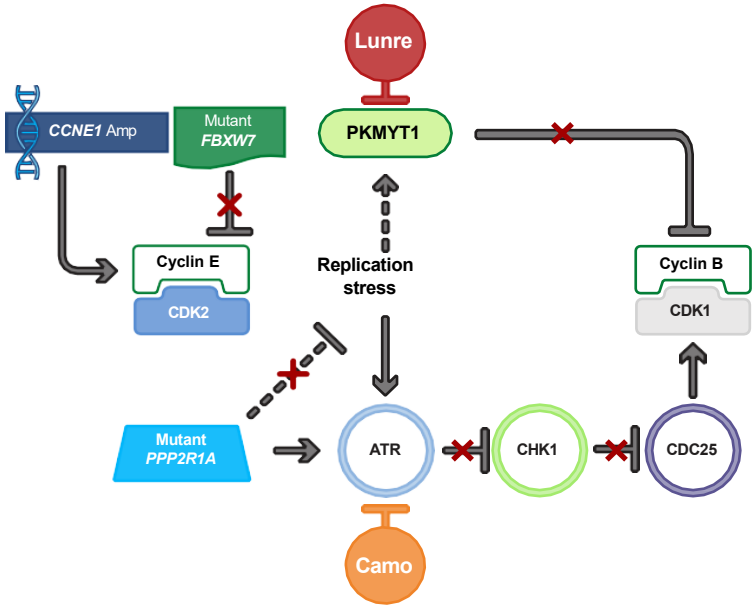
- Camo, an ATRi, synergizes with PKMYT1 inhibition to enhance antitumor activity[2-4]
- Combination lunre + camo is well tolerated with promising clinical activity in molecularly selected patients across multiple tumor types[3,4]
- Preliminary signal observed in ovarian and endometrial cancer[4]





Data from Yap *et al.* 2023 and represent best change from baseline in tumor size for patients treated with combination lunre + camo (any dose) where dashed lines represent RECIST change from baseline of +20% and –30%, respectively.
[2] Gallo D, et al. Poster B057 presented at AACR-NCI-EORTC (ANE) 2023. [3] Xu H, et al. Nat Commun. 2025;16(1):3112. [4] Yap TA, et al. Plenary presentation at AACR-NCI-EORTC (ANE) 2023.
Amp, amplification; ATR, ataxia telangiectasia and Rad3-related; ATRi, ATR inhibitor; CA-125, cancer antigen-125; camo, camonsertib; *CCNE1*, cyclin E1; CDC25, cell division cycle-25; CDK, cyclin-dependent kinase; CHK1, checkpoint kinase 1; *FBXW7*, F-box and WD repeat domain containing 7; lunre, lunresertib; lunre BM, lunresertib-sensitizing biomarkers; PKMYT1, protein kinase, membrane-associated tyrosine/threonine; *PPP2R1A*, serine/threonine-protein phosphatase 2A; RECIST, Response Evaluation Criteria in Solid Tumours. 24020448b

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MYTHIC module 2: Study design

Key inclusion criteria

Module 2: Lunre with camo

- Patients ≥12 years with solid tumors resistant/intolerant to standard therapy
- Tumors with ***CCNE1*** amplifications[a], or deleterious alterations in ***FBXW7*** or ***PPP2R1A*** by local NGS report (tissue or plasma)[b]
- ECOG PS of 0–1
- Hemoglobin ≥10 g/dL
- Platelets ≥100 K/μL
- ANC ≥1.5 K/μL

Study ongoing, closed to enrollment
NCT04855656

Study timeline and objectives

✓ **Primary endpoints:**
- Safety, tolerability, RP2D, schedule

✓ **Other endpoints:**
- Pharmacokinetics
- Preliminary antitumor activity
- Pharmacodynamics in paired tumor biopsies
- Kinetics of ctDNA

[a] *CCNE1* amplification (copy number ≥6). [b] NGS report centrally reviewed and annotated by Precision Oncology Decision Support Group at MD Anderson Cancer Center.
ANC, absolute neutrophil count; camo, camonsertib; *CCNE1*, cyclin E1; ctDNA, circulating tumor DNA; ECOG PS, Eastern Cooperative Oncology Group Performance Status; *FBXW7*, F-box and WD repeat domain containing 7; lunre lunresertib; NGS, next-generation sequencing; *PPP2R1A*, serine/threonine-protein phosphatase 2A; RP2D, recommended phase 2 dose.

RP2D schedule optimization improved the rate and severity of anemia

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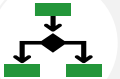
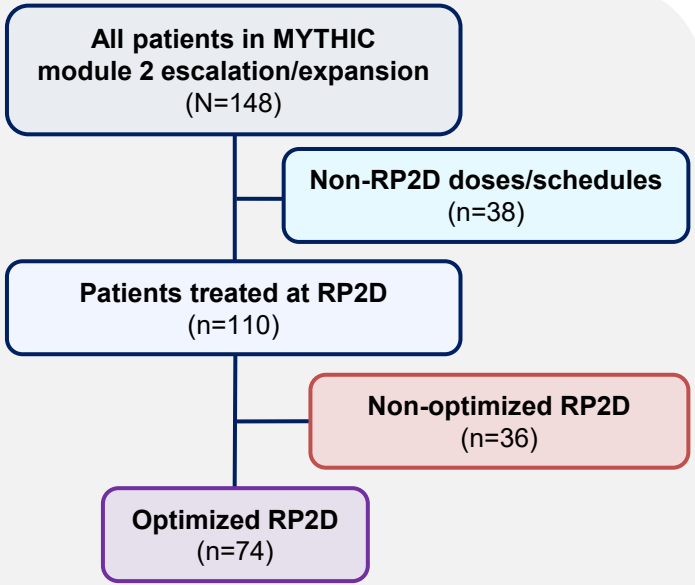
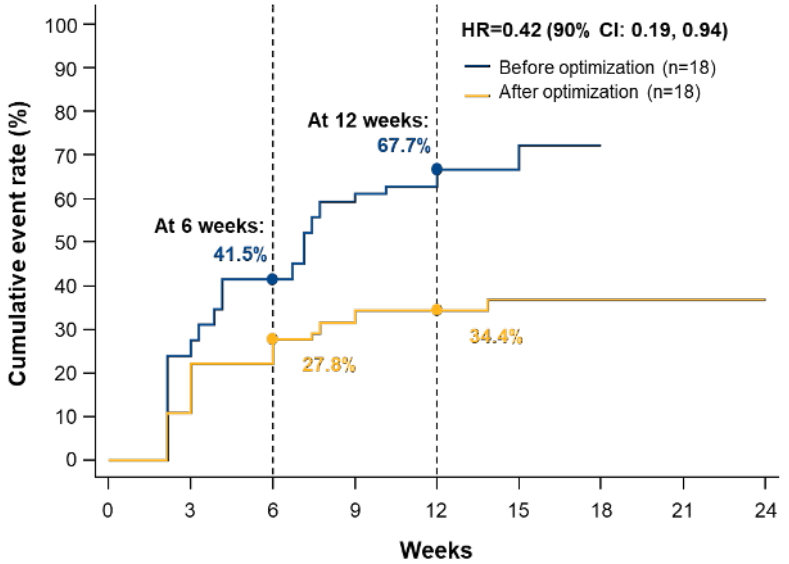




- Patients with initial hemoglobin <11 g/dL were dosed at 2/1w
- Patients with initial hemoglobin >11 g/dL were dosed at 3w

Time to first grade 3 anemia event in patients with baseline hemoglobin <11 g/dL[7]



- Individualized schedule optimization reduced the risk of grade 3 anemia by 58% in patients with baseline hemoglobin <11 g/dL[7]

Cumulative event rates of grade 3 anemia in patients with baseline hemoglobin <11 g/dL for patients before optimization (blue) and after optimization (yellow). Dashed lines represent landmarks of 6 and 12 weeks.

[7] Højgaard M, et al. Poster presented at EORTC-NCI-AACR (ENA) 2024; Barcelona, Spain.

2/1w, 2 weeks on/1 week off; 3w, 3 weeks continuous; CI, confidence interval; HR, hazard ratio; RP2D, recommended phase 2 dose.

Safety and tolerability profile at RP2D after schedule optimization

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TRAEs in ≥10% of patients	All patients at RP2D after schedule optimization (N=74)		
	All grade n (%)	Grade 3 n (%)	Grade 4 n (%)
Any event	73 (98.6)	37 (50.0)	2 (2.7)
Anemia	58 (78.4)	24 (32.4)	0
Nausea/vomiting	46 (62.2)	1 (1.4)	0
Rash pooled[a]	36 (48.6)	4 (5.4)	0
Fatigue	28 (37.8)	3 (4.1)	0
Stomatitis	25 (33.8)	3 (4.1)	0
Neutropenia	20 (27.0)	8 (10.8)	1 (1.4)[b]
Decreased appetite	15 (20.3)	0	0
PPE syndrome	15 (20.3)	3 (4.1)	0
Diarrhea	14 (18.9)	0	0
Leukopenia	13 (17.6)	1 (1.4)	2 (2.7)[b]
Pain in extremity	9 (12.2)	0	0
Dizziness	8 (10.8)	0	0
Pyrexia	8 (10.8)	0	0

All patients at RP2D after schedule optimization (N=74)	n (%)
Serious TRAE	5 (6.8)
TRAE leading to dose reduction	41 (55.4)
TRAE leading to dose interruption	43 (58.1)
TRAE leading to treatment discontinuation	4 (5.4)
TRAE leading to death	0

- Rash and mucocutaneous events were generally brief and low grade
- Consistent tolerability and safety profile in patients with gynecologic cancers
- ~5% patients discontinued due to AEs

[a] Rash terms included dermatitis contact, eczema, erythema, flushing, pruritis, rash, rash erythematous, rash maculopapular, rash pruritic, and skin exfoliation. [b] One patient had both grade 4 neutropenia and grade 4 WBC count decrease reported, concomitant with a viral infection and allergic reaction to cephalosporin (unrelated).

AE, adverse event; PPE, palmar-plantar erythrodysesthesia; RP2D, recommended phase 2 dose; TRAE, treatment-related adverse events.

Efficacy analysis subsets: endometrial and ovarian populations

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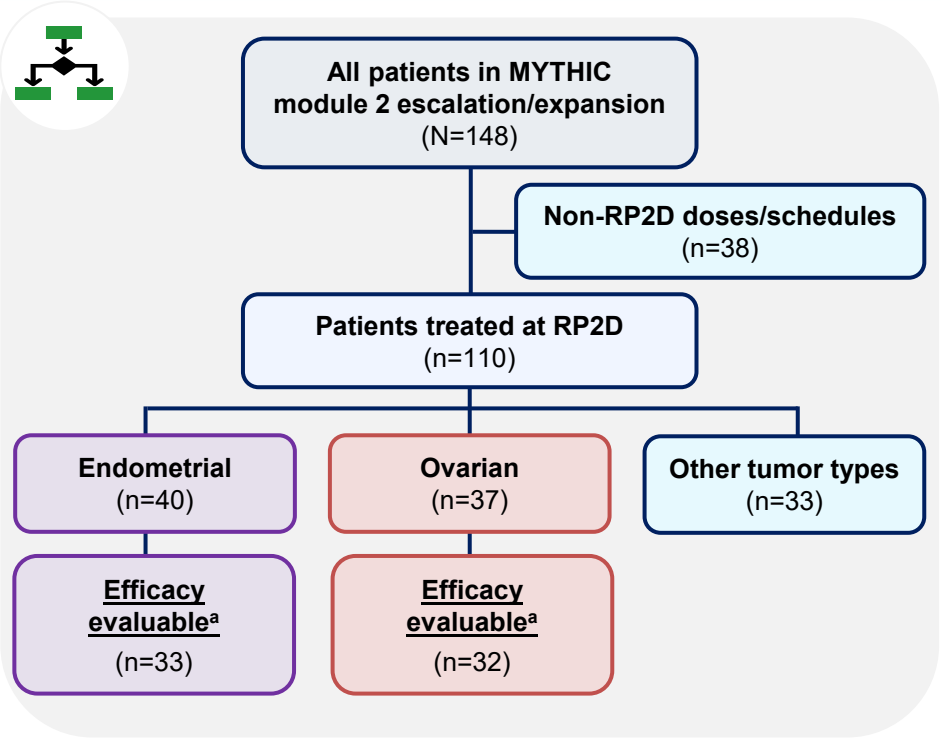

Parameter, %	Endometrial (N=33)	Ovarian (N=32)
Age (years)		
Median (range)	67.0 (48-82)	64 (44-79)
≥65 years	70%	50%
ECOG performance status		
0	40%	47%
1	60%	53%
Prior lines of therapy		
Median (range)	3.0 (1-10)	3.0 (1-10)
1–2	39%	41%
≥3	61%	59%
Prior platinum	100%	97%
Prior PARPi	3%	47%
Prior PD1/L1	82%	19%
Histological subtypes		
Carcinosarcoma	15%	–
Clear cell	3%	–
Endometrioid	27%	–
Serous	55%	72%
Non-serous	–	28%
Enrollment gene		
CCNE1	15%	91%
FBXW7	21%	3%
PPP2R1A	49%	3%
Multiple	15%[b]	3%[c]
TP53 mutation	88%	100%
MSI high	0	ND

[a] Efficacy evaluable defined as treated patients with measurable disease and at least one post-baseline scan. [b] Included five patients with tumors harboring co-alterations: *CCNE1/FBXW7* (n=2), *CCNE1/PPP2R1A* (n=2), and *FBXW7/PPP2R1A* (n=1). [c] Included one patient with a tumor harboring *CCNE1/FBXW7*.
CCNE1, cyclin E1; ECOG, Eastern Cooperative Oncology Group; *FBXW7*, F-box and WD repeat domain containing 7; MSI, microsatellite instability; ND, not determined; PARPi, poly (ADP-ribose) polymerase inhibitor; *PPP2R1A*, serine/threonine-protein phosphatase 2A; RP2D, recommended phase 2 dose.

Target and pathway engagement confirmed in gynecological malignancies

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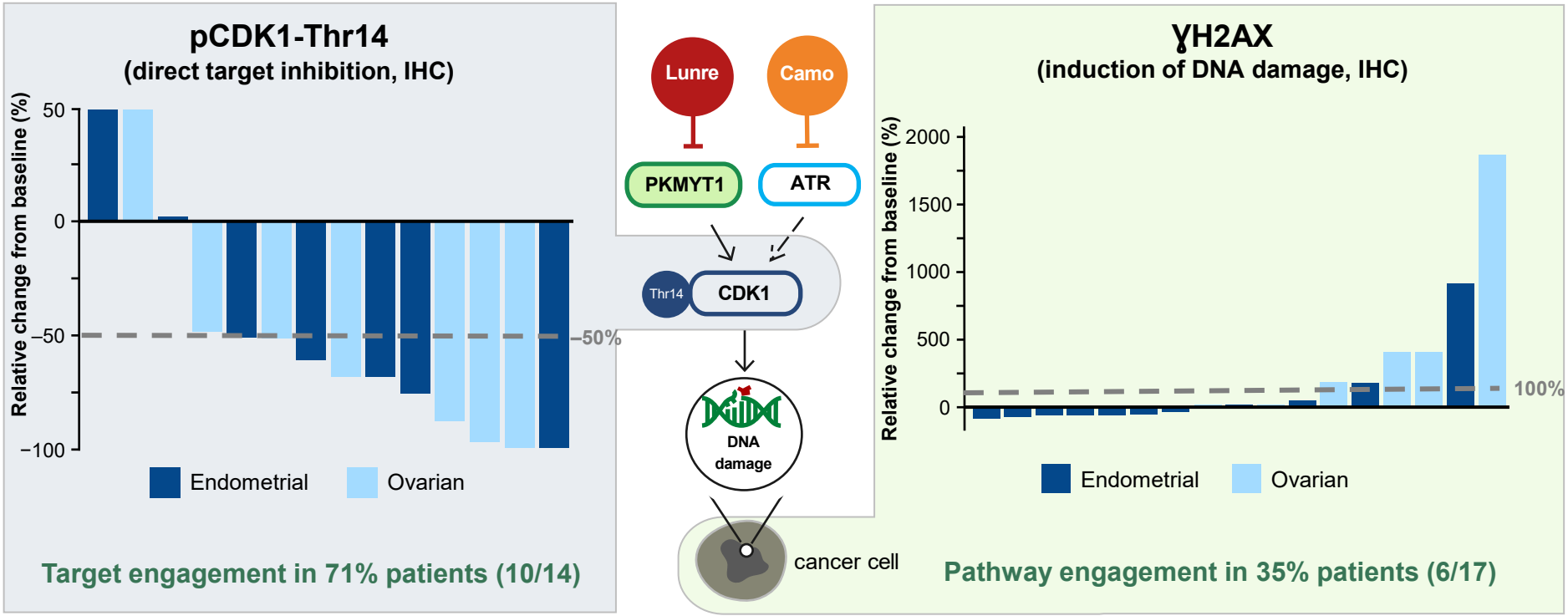

Paired biopsies collected from patients receiving 80 mg twice daily lunre at the time of on-treatment tumor tissue collection. Relative changes are calculated comparing +3% pCDK1- and γH2AX-positive cells pretreatment vs on-treatment for each patient. pCDK1 increase is capped at 50% value for visualization purposes.
ATR, ataxia telangiectasia and Rad3-related; camo, camonsertib; CDK1, cyclin-dependent kinase 1; IHC, immunohistochemistry; lunre, lunresertib; pCDK1, phosphorylated CDK1; PKMYT1, protein kinase, membrane associated tyrosine/threonine 1; Thr, threonine.

Clinical benefit observed across endometrial cancer histological subtypes and genotypes

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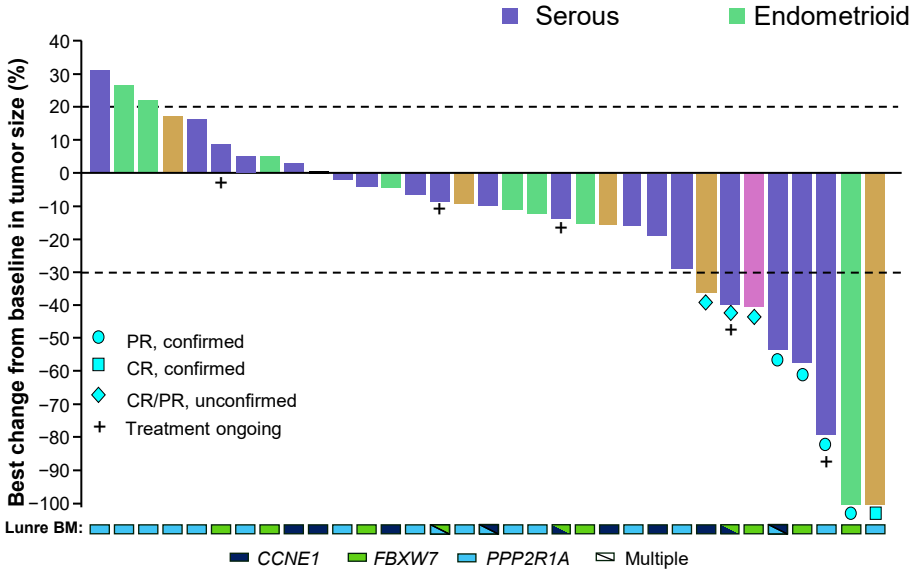

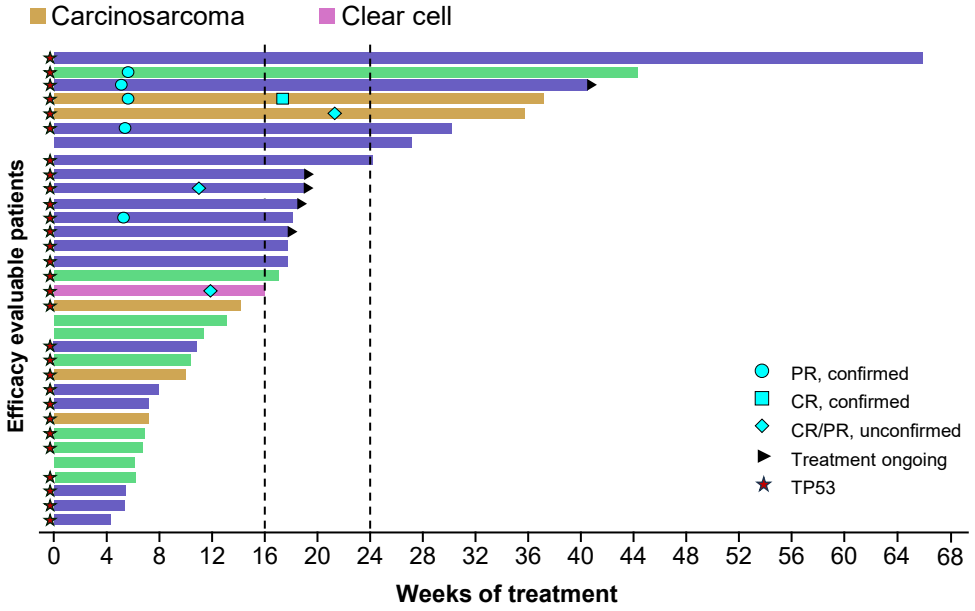

RECIST confirmed + unconfirmed, % (95% CI)	24.2% (11.1–42.3)
RECIST confirmed, % (95% CI)	15.2% (5.1–31.9)

CBR[a], % (95% CI)	48.5% (30.8–66.5)
Time to response (w), median (range)	5.6w (5.1–21.3)
PFS at 24w, % (95% CI)	38.3% (18.5–57.9)

[a] CBR was defined as the best overall response of confirmed or unconfirmed, CR or PR, according to RECIST 1.1 criteria or duration of treatment ≥16w without progressive disease (denoted by dashed line).
CBR, clinical benefit rate; *CCNE1*, cyclin E1; CI, confidence interval; CR, complete response; *FBXW7*, F-box and WD repeat domain containing 7; lunre BM, lunresertib-sensitizing biomarker; PFS, progression-free survival; *PPP2R1A*, serine/threonine-protein phosphatase 2A; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours; w, week.

Patients with ovarian cancer had clinical benefit despite being heavily pretreated

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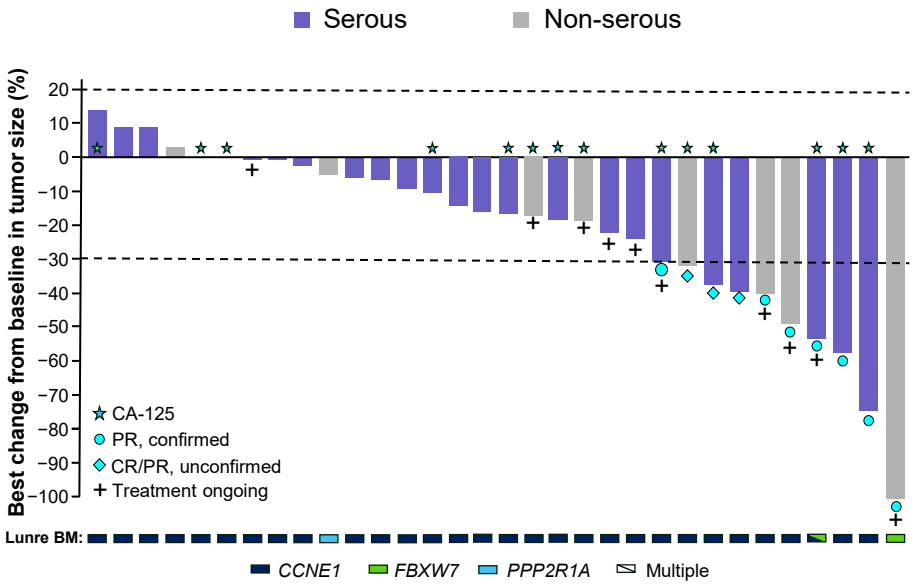

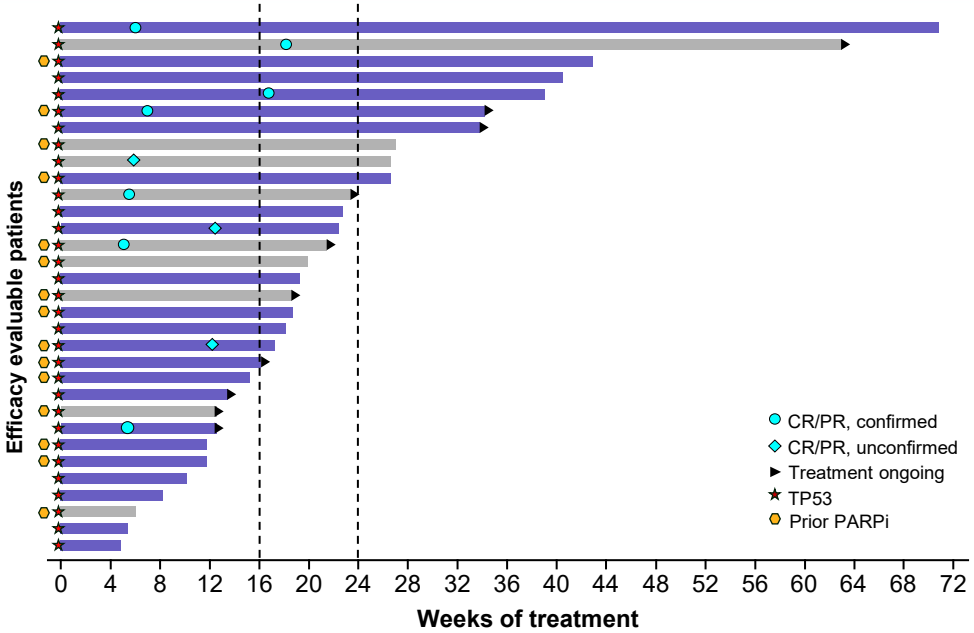

RECIST confirmed + unconfirmed, % (95% CI)	31.3% (16.1–50.0)
RECIST confirmed, % (95% CI)	21.9% (9.3–40.0)

CBR[a], % (95% CI)	68.8% (50.0–83.9)
Time to response (w), median (range)	6.9w (5.1–18.1)
PFS at 24w, % (95% CI)	41.2% (21.8–59.7)

[a] CBR was defined as the best overall response of CR or PR according to RECIST 1.1 criteria or duration of treatment ≥16 weeks without disease progression (denoted by dashed line).
CA-125, cancer antigen-125; CBR, clinical benefit rate; *CCNE1*, cyclin E1; CI, confidence interval; CR, complete response; *FBXW7*, F-box and WD repeat domain containing 7; lunre BM, lunresertib-sensitizing biomarker; PARP, poly (ADP-ribose) polymerase; PFS, progression-free survival; *PPP2R1A*, serine/threonine-protein phosphatase 2A; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours; w, week.

MRs were observed in patients with ovarian and endometrial cancers

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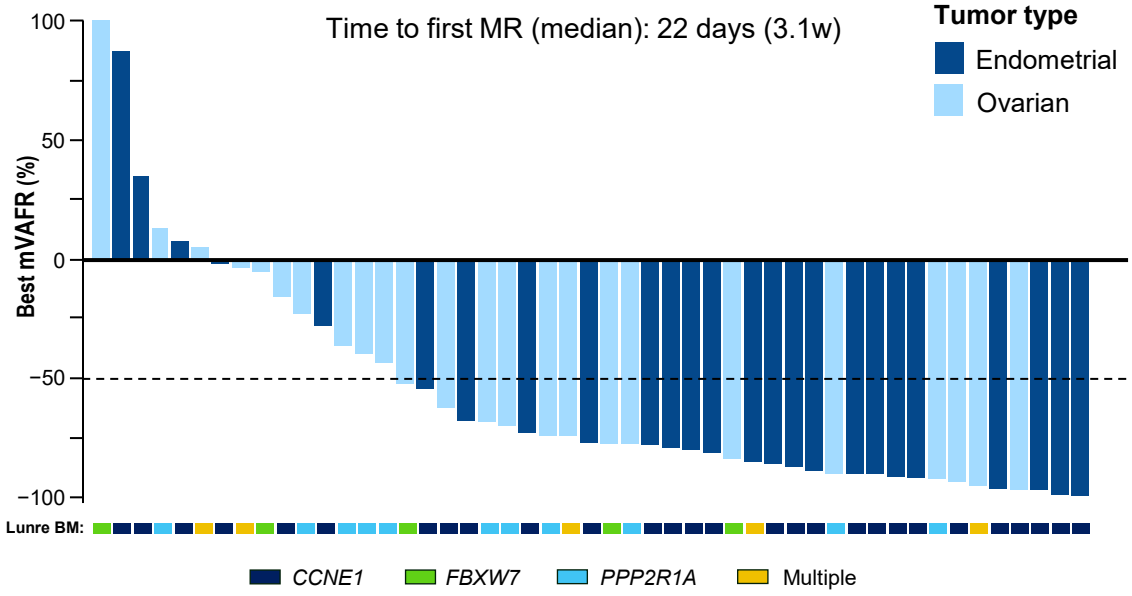
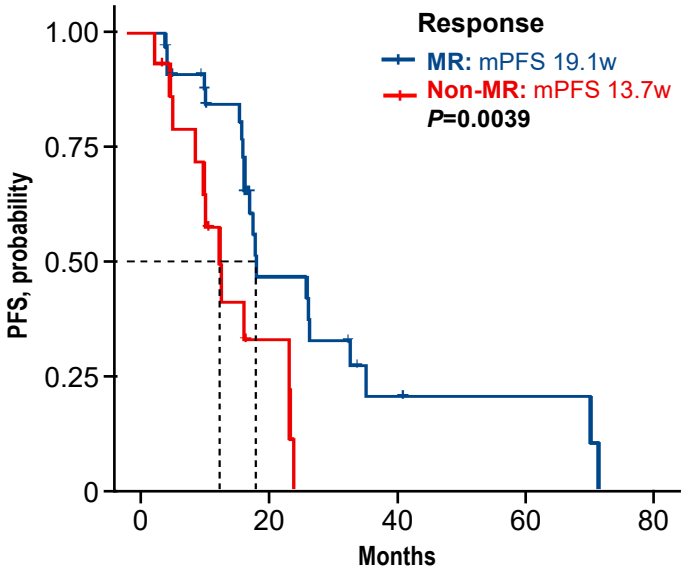
MRs were observed in 69% (34/49) of patients



Early MRs are associated with improved PFS



Waterfall plot summarizes ctDNA dynamics in efficacy-evaluable patients with ovarian and endometrial cancer enrolled at RP2D. ctDNA samples were collected at baseline, cycle 2 day 1, or cycle 3 day 1. MR was defined as –50% or greater decrease in mean VAF compared to baseline.

CCNE1, cyclin E1; ctDNA, circulating tumor DNA; *FBXW7*, F-box and WD repeat domain containing 7; lunre BM, lunresertib-sensitizing biomarker; MR, molecular response; MRR, MR rate; mPFS, median PFS; mVAF, mean variant allele frequency; mVAFR, mVAF ratio; PFS, progression-free survival; *PPP2R1A*, serine/threonine-protein phosphatase 2A; RP2D, recommended phase 2 dose; w, weeks.

Conclusions

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- **Lunre is a, first-in-class, potent PKMYT1i that is synthetically lethal in tumors harboring *CCNE1* amplifications, and/or deleterious *FBXW7* or *PPP2R1A* mutations**
- **Lunre plus camo is an oral combination therapy of two novel targeted agents that are tolerable and effective in molecularly selected recurrent endometrial and ovarian cancers**
  - Antitumor activity, clinical benefit, and durable responses observed across histologies in this heavily pretreated population with poor prognosis
- **Favorable safety and tolerability profile**
  - Most frequent, on-target grade 3 event was anemia mitigated by implementation of an individualized schedule based on hemoglobin level
- **Pharmacodynamic analyses in tumor tissue confirmed mechanism of action in gynecological malignancies**
- **Early ctDNA molecular responses correlate with clinical outcomes, and were observed across indications and enrollment alterations, providing additional evidence of antitumor activity**
- **This oral combination may provide a therapeutic option in areas of high clinical unmet need and further supports continued late-stage clinical development**

Camo, camonsertib; *CCNE1*, cyclin E1; ctDNA, circulating tumor DNA; *FBXW7*, F-box and WD repeat domain containing 7; lunre, lunresertib; PKMYT1i, protein kinase, membrane associated tyrosine/threonine 1 inhibitor; *PPP2R1A*, serine/threonine-protein phosphatase 2A.

Thank you
Any questions?

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- Patricia LoRusso is a study investigator.
- Linda R. Duska has participated on a scientific advisory board for Aadi Bioscience; received research funding paid to their institution from Merck; has acted as an expert advisor (unpaid) for Merck; received writing fees for expert content for UpToDate; and has served on the Editorial Board of the British Journal of Obstetrics and Gynaecology.
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- Mia C. Weiss is a study investigator.
- Victoria Mandilaras has received honoraria for lectures and advisory boards for AstraZeneca, Esai, Merck, Novartis, and Pfizer; and has received research funding or contracts paid to their institution from AstraZeneca, Merck, Pfizer Inc., Repare Therapeutics, Roche, and Seagen.
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- Joan R. Tymon-Rosario is a study investigator.
- Xizi Sun, Elia Aguado-Fraile, Sunantha Sethuraman, Isabel Soria-Bretones, and Nathan Hawkey are employees of Repare Therapeutics and may hold stock and/or stock options.
- Emeline S. Bacqué, Paul A. Basciano, and Maria Koehler are former employees of Repare Therapeutics and may hold stock and/or stock options.
- Stephanie Lheureux has received grants or contracts paid to their institution from AstraZeneca, GlaxoSmithKline, Merck, Regeneron, Repare Therapeutics, Roche, and Seagen; consulting fees from AstraZeneca, GlaxoSmithKline, Eisai, Merck, Novocure, and Shattuck Labs; payment or honoraria for lectures, presentations, speaker's bureaus, manuscript writing, or educational events from AstraZeneca, GlaxoSmithKline, and Eisai/Merck; and participation on a data safety monitoring board or advisory board from AstraZeneca.
- Timothy A. Yap is an employee of The University of Texas MD Anderson Cancer Center, where he is Vice President, Head of Clinical Development in the Therapeutics Discovery Division, which has a commercial interest in DNA damage response and other inhibitors (IACS30380/ART0380 was licensed to Artios); has received funding paid to their institution from Acrivon, Artios, AstraZeneca, Bayer, Beigene, BioNTech, Blueprint, Bristol Myers Squibb, Boundless Bio, Clovis, Constellation, Cyteir, Eli Lilly, EMD Serono, Forbius, F-Star, GlaxoSmithKline, Genentech, Haihe, Ideaya ImmuneSensor, Insilico Medicine, Ionis, Ipsen, Jounce, Karyopharm, KSQ, Kyowa, Merck, Mirati, Novartis, Pfizer, Ribon Therapeutics, Regeneron, Repare, Rubius, Sanofi, Scholar Rock, Seattle Genetics, Tango, Tesaro, Vivace, and Zenith; has received consultancy funding from AbbVie, Acrivon, Adagene, Almac, Aduro, Amphista, Artios, Astex, AstraZeneca, Athena, Atrin, Avenzo, Avoro, Axiom, Baptist Health Systems, Bayer, Beigene, BioCity Pharma, Blueprint, Boxer, Bristol Myers Squibb, C4 Therapeutics, Calithera, Cancer Research UK, Carrick Therapeutics, Circle Pharma, Clovis, Cybrexa, Daiichi Sankyo, Dark Blue Therapeutics, Diffusion, Duke Street Bio, 858 Therapeutics, EcoR1 Capital, Ellipses Pharma, EMD Serono, Entos, F-Star, Genesis Therapeutics, Genmab, Glenmark, GLG, Globe Life Sciences, GSK, Guidepoint, Ideaya Biosciences, Idience, Ignyta, I-Mab, ImmuneSensor, Impact Therapeutics, Institut Gustave Roussy, Intellisphere, Jansen, Kyn, MEI pharma, Merck, Mereo, Merit, Monte Rosa Therapeutics, Natera, Nested Therapeutics, Nexys, Nimbus, Novocure, Odyssey, OHSU, OncoSec, Ono Pharma, Onxeo, PanAngium Therapeutics, Pegascy, PER, Pfizer, Piper-Sandler, Pliant Therapeutics, Prolynx, Radiopharma Theranostics, Repare, resTORbio, Roche, Ryvu Therapeutics, SAKK, Sanofi, Schrodinger, Servier, Synnovation, Synthis Therapeutics, Tango, TCG Crossover, TD2, Terremoto Biosciences, Tessellate Bio, Theragnostics, Terns Pharmaceuticals, Tolremo, Tome, Thryv Therapeutics, Trevarx Biomedical, Varian, Veeva, Versant, Vibliome, Voronoi Inc, Xinthera, Zai Labs, and ZielBio; and is a stockholder in Seagen; he was supported by the NCI Cancer Center Support Grant CA016672 to The University of Texas MD Anderson Cancer Center, DOD grants W81XWH2210504_BC211174 and W81XWH-21-1-0282_OC200482, V Foundation Scholar Grant VC2020-001, and NIH R01 grant 1R01CA255074.

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