

**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, 2025

PMV Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39539
(Commission
File Number)

46-3218129
(IRS Employer
Identification No.)

400 Alexander Park Drive, Suite 301
Princeton, NJ
(Address of Principal Executive Offices)

08540
(Zip Code)

Registrant's Telephone Number, Including Area Code: (609) 642-6670

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, \$0.00001 par value per share	PMVP	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 7.01 Regulation FD Disclosure.

The webinar presentation used in connection with the webinar described in Item 8.01 below is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing, whether made before or after the date hereof, regardless of any general incorporation language in such a filing.

The webinar presentation attached as Exhibit 99.1 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are “forward-looking” rather than historical.

Item 8.01 Other Events.

On September 10, 2025, PMV Pharmaceuticals, Inc. (the “Company”) issued a press release announcing rezatapopt monotherapy interim data from its PYNNALE Phase 2 trial across multiple solid tumors with a TP53 Y220C mutation and hosted an investor webinar to review the Phase 2 interim clinical data. The press release is attached hereto as Exhibit 99.2 and incorporated by reference herein.

The press release attached as Exhibit 99.2 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are “forward-looking” rather than historical.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Investor Webinar dated September 10, 2025
99.2	Press Release issued by PMV Pharmaceuticals, Inc., dated September 10, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

PMV Pharmaceuticals, Inc.

Date: September 10, 2025

By: /s/ Michael Carulli

Michael Carulli
Chief Financial Officer
(Principal Financial Officer)

PYNNACLE Phase 2 Clinical Data Update Investor Webinar

September 10, 2025



Disclaimer

Forward-Looking Statements

This presentation contains forward looking statements. Such statements include, but are not limited to, statements regarding our research, preclinical and clinical development activities, plans and projected timelines for rezatapopt, including the timing of disclosures regarding clinical data updates of its current clinical trial for rezatapopt, expected therapeutic benefits of rezatapopt including potential efficacy and tolerability, plans regarding regulatory filings and approvals, including targeted dates for our NDA submission and initial FDA approval for platinum-resistant or refractory ovarian indication, ongoing safety and response rate of participants in our PYNACLE study, as well as the overall timing and success of our current and future clinical trials for rezatapopt, and the adequacy of the data to support its regulatory approval, and our expectations regarding the therapeutic, addressable patient populations, timing for approval and commercial potential of rezatapopt, as well as our cash runway forecast. The words "believe," "may," "should," "will," "estimate," "promise," "plan," "continue," "anticipate," "intend," "expect," "potential" and similar expressions (including the negative thereof), are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: our preclinical studies and clinical trials may not be successful; the U.S. Food and Drug Administration (FDA) may not agree with our interpretation of the data from clinical trials of our product candidates; we may decide, or the FDA may require us, to conduct additional clinical trials or to modify our ongoing clinical trials, which could result in enrollment or other delays to our anticipated timelines; we may experience delays in the commencement, enrollment, completion or analysis of clinical testing for our product candidates, or significant issues regarding the adequacy of our clinical trial designs or the execution of our clinical trials may arise, which could result in increased costs and delays, or limit our ability to obtain regulatory approval; the commencement, enrollment and completion of clinical trials and the reporting of data; a global pandemic, other public health emergencies or geopolitical tensions or conflicts may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; our product candidates may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates could delay or prevent regulatory approval or commercialization; we may not be able to obtain additional financing on terms acceptable to us or at all; as well as those risks and uncertainties set forth in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 3, 2025, the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, filed with the SEC on May 9, 2025, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, filed with the SEC on August 7, 2025, and its other filings filed with the SEC.. Additional risks and uncertainties may emerge from time to time, and it is not possible for PMV Pharma's management to predict all risk factors and uncertainties.

All forward-looking statements contained in this presentation speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This presentation does not constitute an offer to sell or a solicitation of an offer to buy securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Today's Objectives

- 01** Rezatapopt background

- 02** Ovarian cancer treatment landscape

- 03** PYNACLE Phase 2 interim data update
Initial NDA strategy informed by FDA feedback

- 04** Q&A



Panel



David Mack, PhD
President and Chief
Executive Officer



Ramez N. Eskander, MD
Professor, Department of
Obstetrics, Gynecology, and
Reproductive Sciences
UC San Diego



Deepika Jalota, PharmD
Chief Development
Officer

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David Mack, PhD
President and Chief
Executive Officer

PMV Pharma is Harnessing the Power of p53 to Treat Cancer



PMV's lead candidate is rezatapopt, a first-in-class, investigational p53 Y220C reactivator

The p53 Y220C mutation, a previously undruggable target, is found in 2.9% of ovarian cancer and 1% of all solid tumors



Phase 1 PYNACLE study has achieved proof of concept data for rezatapopt

Pivotal Phase 2 PYNACLE study interim clinical data demonstrates favorable efficacy and safety across multiple tumor types



NDA submission planned in 1Q2027 in platinum-resistant/refractory ovarian cancer patients



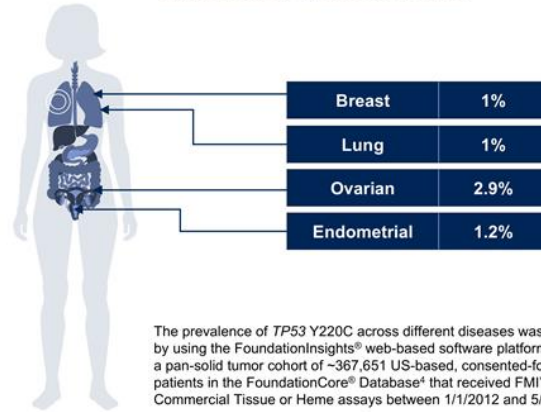
Strong balance sheet with \$148M as of June 30, 2025, with cash runway through 1Q2027

Rezatapopt Targets TP53 Y220C Hotspot Mutation Detected Across Solid Tumors

- *TP53* mutations are the most common genomic alterations across all human cancers¹
- Most *TP53* mutations occur in the central DNA-binding domain and ten of them are referred to as 'hot-spot' mutations, accounting for ~30% of the *TP53* mutations observed in human cancer¹⁻²
- p53 Y220C is a key hot-spot *TP53* missense mutation that destabilizes p53^{1,3}
- **p53 Y220C present in ~1% of solid tumors⁴**
- **Addressable 2L+ U.S. & EU4/UK patients ~12K^{4,5}**

Frequency of *TP53* Y220C Across Common Solid Tumors

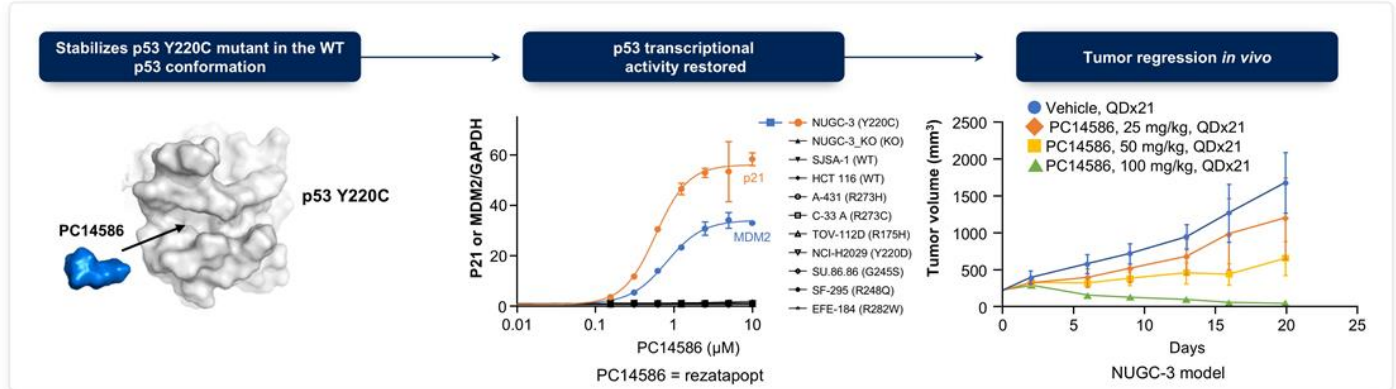
Foundation Medicine Tissue and Heme assay test results collected between 1/1/2012 and 5/31/2024



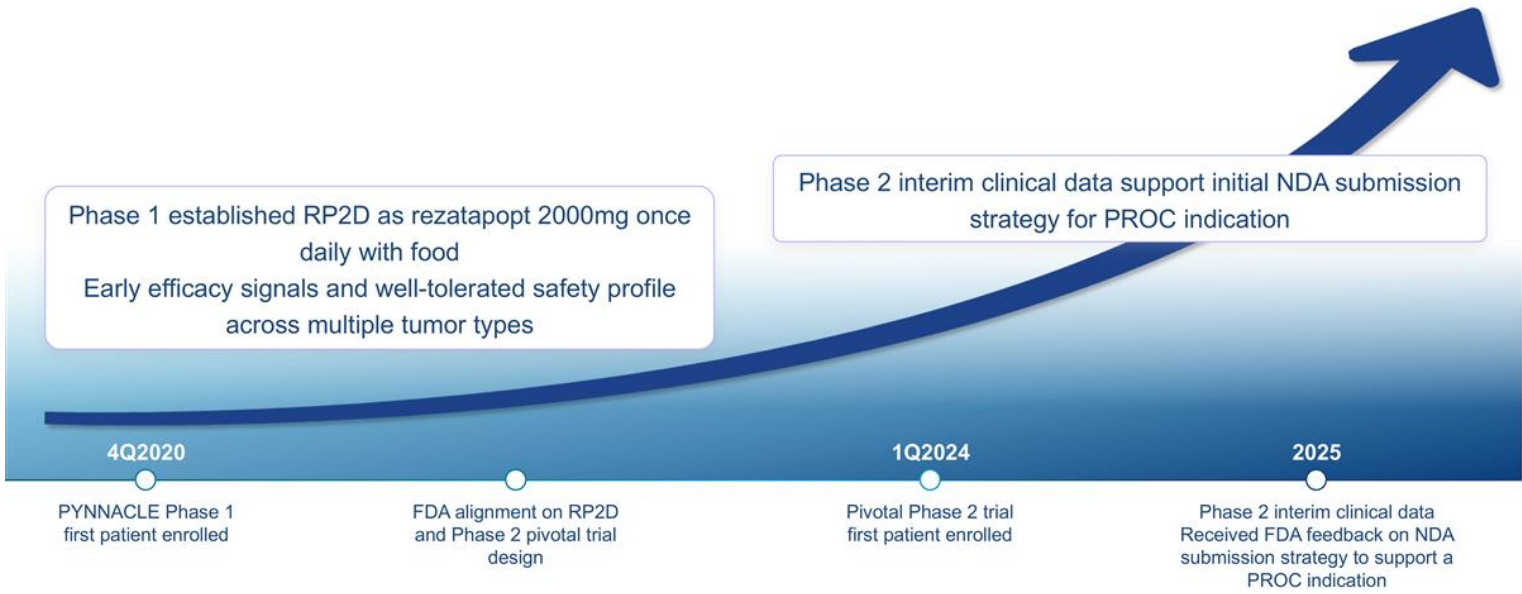
Deoxyribonucleic acid. ¹Baugh EH, et al. *Cell Death Differ.* 2018;25:154–160. ²Roszkowska KA, et al. *Int J Mol Sci.* 2020;21:1334. ³Bouaoun L, et al. *Hum Mutat.* 2016;37:865–876. ⁴Foundation Insights, Schram et al. AACR-NCI-EORTC Conference 2023. ⁵DRG Epidemiology Estimates 2028.

Rezatapopt is a p53 Y220C-Selective First-in-Class p53 Reactivator

- Orally available small molecule designed to selectively bind to the pocket contained in the p53 Y220C mutant protein¹
- Stabilizes the p53 Y220C mutant protein in the wild-type p53 conformation, thereby restoring transcription and tumor-suppressor function¹
- Inhibits proliferation across all Y220C-expressing cell lines



Seamless Phase 1/2 PYNNACLE Clinical Trial: Rapid Rezatapopt Monotherapy Development Towards NDA Submission



RP2D, recommended Phase 2 dose; FDA, Food and Drug Administration; PROC, platinum-resistant/refractory ovarian cancer; NDA, New Drug Application

Compelling Rezatapopt Monotherapy Phase 2 Interim Data

Across All Cohorts:

- Encouraging efficacy in heavily pre-treated patients with a *TP53* Y220C mutation with poor prognoses¹
- Promising rate of tumor responses observed across multiple tumor types
 - ORR: 33%
 - Median duration of response: 6.2 months
- Differentiated safety and tolerability profile compared to standard of care

Ovarian Cancer:

- Significant unmet medical need
- Strong response rate and benefit
 - ORR: 43%
 - Median duration of response: 7.6 months
- Initial registrational opportunity in platinum-resistant or refractory ovarian cancer (PROC) informed by FDA feedback

- *TP53* Y220C mutation leads to a worse prognosis¹
- Emerging clinical data supports rezatapopt as an effective, well-tolerated, oral option
- Opportunity to deliver a novel, biomarker-selected chemo-alternative

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02 Ovarian cancer treatment landscape

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04 Q&A



Ramez N. Eskander, MD
Professor, Department of
Obstetrics, Gynecology, and
Reproductive Sciences
UC San Diego

Disclosures

Consultant/Advisory Board:

- AstraZeneca
- Clovis Oncology
- Daiichi Sankyo, Inc.
- Eisai Inc.
- Elevar Therapeutics
- GSK
- ImmunoGen, Inc.
- Mersana Therapeutics
- Myriad Genetics, Inc.
- Novocure GmbH
- Onconova Therapeutics
- Nuvectis
- PMV Pharmaceuticals
- Regeneron
- Lilly
- AbbVie
- Pfizer

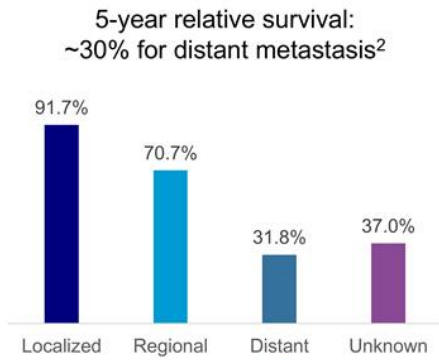
Other Financial or Material Support for GOG Associate Clinical Trial Advisor

Ovarian Cancer is a Leading Cause of Cancer Death Among Women

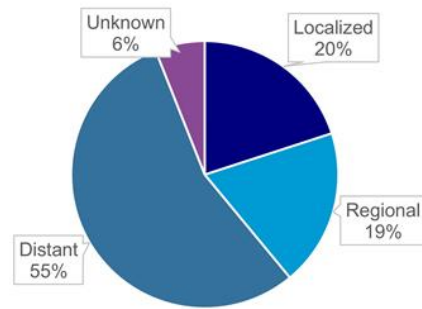
Estimated new US cases in 2025: 20,890^{1,2}

Estimated deaths in 2025: 12,730^{1,2}

5-year relative survival: 51.6%^{1,2}



>70% present with advanced disease²



Up to 80% with advanced disease will relapse within 12–18 months^{3,5–9}

Recurrent ovarian cancer 5-year survival rate: <30%⁵

Platinum-sensitive:
mOS ≤4 years^{a,3,4,10}

Platinum-resistant:
mOS <1 year^{3,4,8–10}



^a mOS in patients with recurrent PSOC can vary widely based on time since last platinum-based chemotherapy / length of time to recurrence, stage at initial diagnosis, and the presence of specific mutations. mOS, median overall survival. Full citations for footnotes 1-10 are provided in the References slide.

TP53 Mutations are Present in >75% of Ovarian Cancer Cases and are Associated with Poor Prognosis



HGSOC accounts for 70–75% of epithelial ovarian cancer cases^{11–14}

Most common subtype, often diagnosed at advanced stages^{11–14}

TP53 mutations

- In >75% of ovarian cancers^{15,a}
- In >95% of HGSOC cases^{15,a}
- TP53 dysfunction in fallopian tubal cells initiates HGSOC^{13,16}

Mutated p53^{16,17}



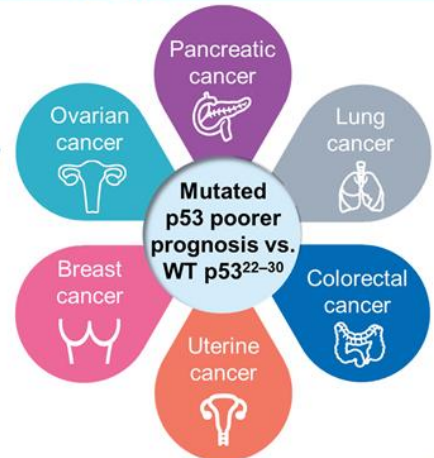
High frequency in more aggressive and invasive tumor subtypes^{15,19–22}

TP53 mutations and prognosis

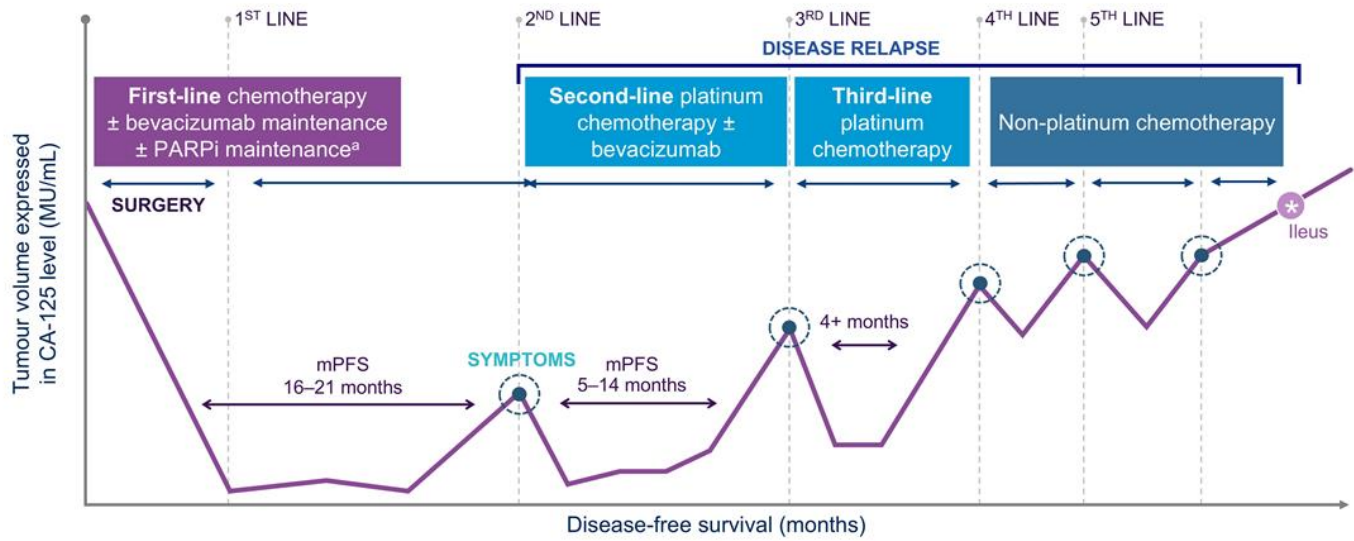


Retrospective studies

TP53 mutation: Negative prognostic indicator of survival and outcomes across several tumor types, including ovarian cancer^{22–30}

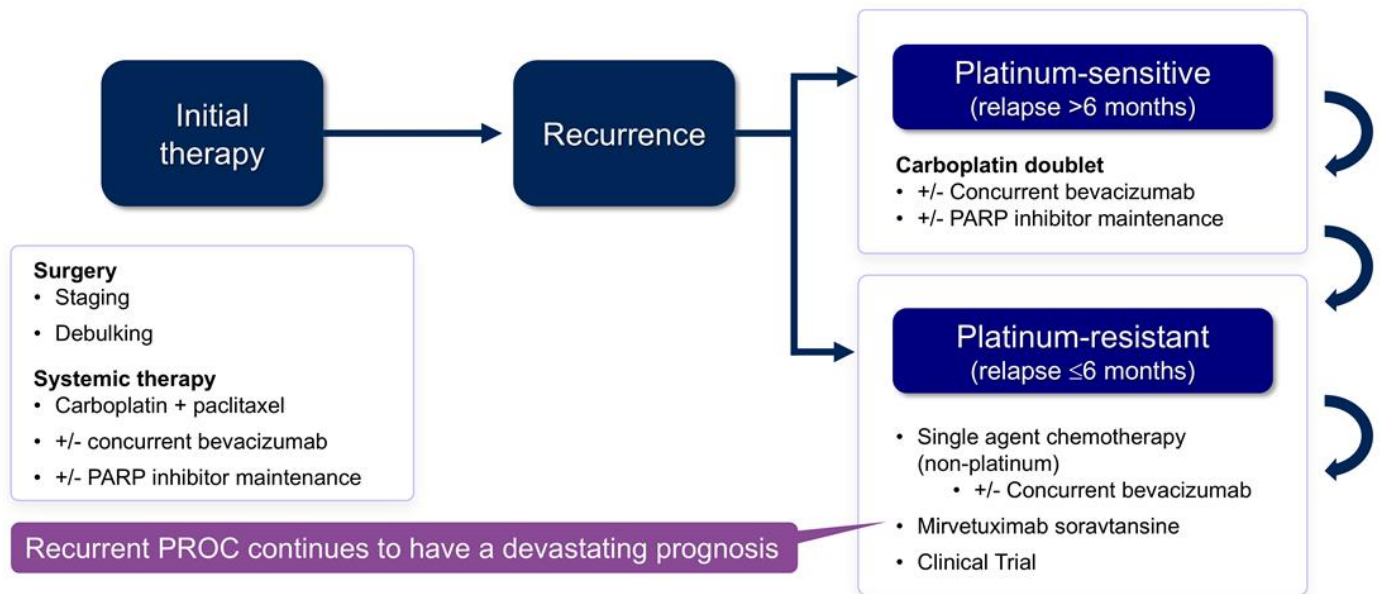


The Benefit of Treatment Decreases with Multiple Lines of Therapy^{9, 31-52}



^a Niraparib should only be used in patients with an HRD+ status. CA-125, cancer antigen 125; HRD+, homologous recombination deficiency-positive status; mPFS, median progression-free survival; PARPi, PARP inhibitor; SOC, standard of care. Slide courtesy of and adapted from Kathleen Moore. References 9,31-52. Full citations for footnotes 9, 31-52 are provided in the References slide.

Patients will Eventually Develop PROC Reflecting a High Unmet Medical Need⁵³⁻⁵⁴

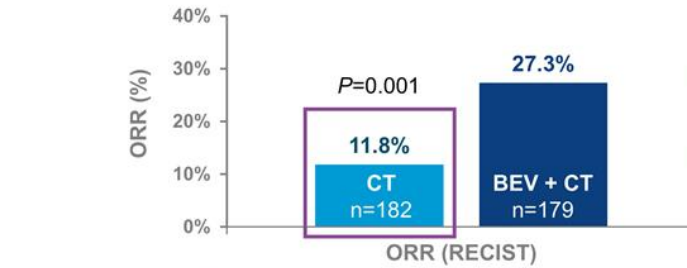
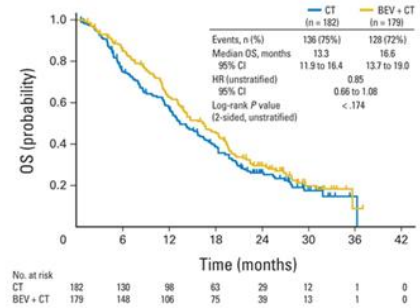
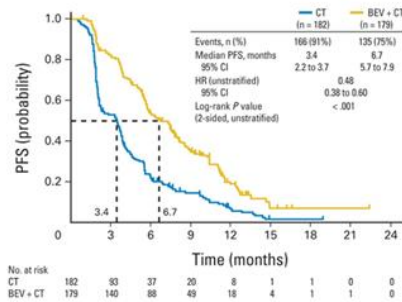


Adding Bevacizumab to Chemotherapy has Provided Benefit in PROC

AURELIA Phase 3⁶⁹
(N=358)

CT + BEV vs CT

ORR: 27.3% vs 11.8%
mPFS: 6.7 vs 3.4 mo
mOS: 16.6 vs 13.3 mo



FDA approved
for PROC
Nov 2014

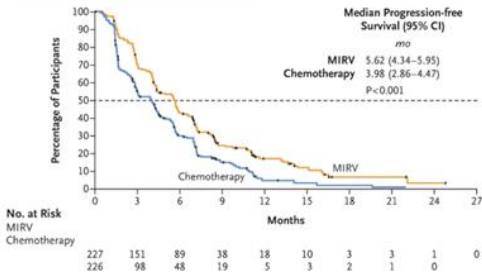
Mirvetuximab Soravtansine (ADC) is Approved for FR α -Positive PROC



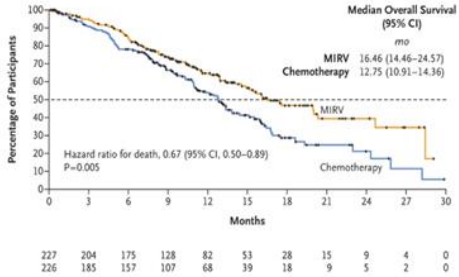
30–40% of patients with PROC are FR α -positive ($\geq 75\%$ cells with $\geq 2+$ intensity staining)⁵⁶⁻⁵⁹

MIRASOL Phase 3 (N=453)⁵⁶ Mirvetuximab soravtansine vs chemotherapy

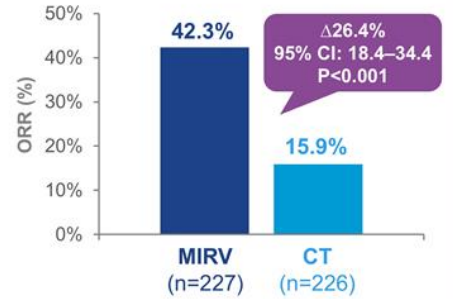
FDA approved for FR α -positive PROC
Nov 2022



mPFS: 5.6 vs 4.0 months



mOS: 16.5 vs 12.8 months



ORR: 42.3% vs 15.9%
mDoR: 6.8 vs 4.5 months



ADC, antibody-drug conjugate; CI, confidence interval; CT, chemotherapy; FR α , folate receptor alpha; mDoR, duration of response; MIRV, mirvetuximab soravtansine; mo, months; mOS, median overall survival; mPFS, median progression-free survival; ORR, overall response rate; PROC, platinum-resistant ovarian cancer. Full citations for footnotes 56-59 are provided in the References slide.

ADCs and Chemotherapy have some Overlapping and Distinct Toxicities

ADCs: Designed to be more targeted, leading to fewer and less severe side effects; however, they can still cause significant toxicity

Chemotherapy and ADCs⁶⁰⁻⁶⁶

- Hematologic: anemia, neutropenia, thrombocytopenia
- Peripheral neuropathy
- Pneumonitis
- Cardiac
- Hepatic
- Renal
- GI: nausea, abdominal pain, diarrhea, vomiting, constipation
- Skin reactions
- Fatigue
- Alopecia



Some events, such as ocular events or pneumonitis, can be more severe or more difficult to manage

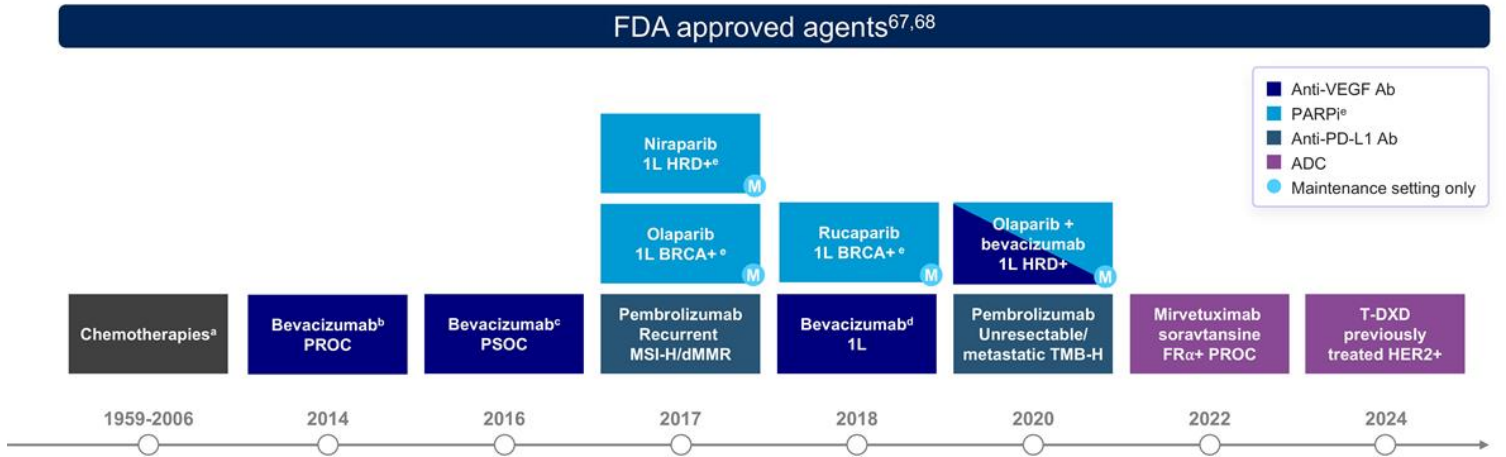
ADCs⁶⁰⁻⁶²

- Interstitial lung disease
- Ocular (vision impairment, keratopathy, dry eye, conjunctivitis)
- Vascular leak syndrome
- Immune responses

Chemotherapy⁶²⁻⁶⁶

- Increased risk of infection
- Mouth sores, dry mouth
- Incontinence
- Cognitive impairment
- Edema
- Dyspnea

Ovarian Cancer Treatment Landscape has Evolved to be More Molecularly Focused Over the Years



^aCyclophosphamide, melphalan, cisplatin, etoposide (oral), carboplatin, altretamine, paclitaxel, docetaxel, topotecan, pegylated liposomal doxorubicin (PLD), gemcitabine + carboplatin; ^bPlus weekly paclitaxel, PLD or topotecan; ^cPlus paclitaxel/carboplatin; gemcitabine/carboplatin; ^dPlus paclitaxel/carboplatin; ^eNiraparib, rucaparib, and olaparib have been withdrawn as maintenance therapy for platinum-sensitive recurrent *BRCA*wt ovarian cancer. 1L, first-line; Ab, antibody; ADC, antibody-drug conjugate; *BRCA*m, *BRCA* mutation; dMMR, deficient mis-match repair; *FR*α, folate receptor alpha; *HER2*, human epidermal growth factor receptor 2; *HRD*, homologous recombination deficiency; *MSI-H*, microsatellite instability – high; *PARPi*, *PARP* inhibitor; *PD-L1*, programmed death receptor – ligand 1; *PLD*, pegylated liposomal doxorubicin; *PROC*, platinum-resistant ovarian cancer; *PSOC*, platinum-sensitive ovarian cancer; *SGRM*, selective glucocorticoid receptor modulator; *T-DXD*, trastuzumab deruxtecan; *TMB-H*, tumor mutational burden – high; *VEGF*, vascular endothelial growth factor. Full citations for footnotes 67,68 are provided in the References slide.

The Unmet Medical Need is High for PROC

Despite advances in therapeutic options there is still an unmet need in advanced ovarian cancer, particularly in PROC

Patients with PROC often experience rapid progression of disease and have a median overall survival of <12 months

There is a lack of effective and durable treatment options, leading to poor prognosis and limited survival outcomes

Current treatments, primarily chemotherapy, are often ineffective, highlighting the urgent need for new tolerable therapies that can improve progression-free and overall survival

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Deepika Jalota, PharmD
Chief Development
Officer

Overview of PYNNACLE Phase 2 Interim Data



Overall results across all cohorts



Ovarian cohort results



NDA submission strategy



Looking ahead

PYNNACLE Phase 2 Study Design

Ongoing Phase 2 study actively enrolling patients across ~60 sites globally

		Cohorts	
Patient Population <ul style="list-style-type: none"> Aged ≥ 12 years Locally advanced or metastatic solid tumors, excluding primary CNS tumors Documented <i>TP53</i> Y220C and <i>KRAS</i> WT only Prior standard therapy or ineligible for appropriate standard of care therapy 	Basket N = 114 Rezatapopt at 2000mg QD	Cohort 1: Ovarian cancer	n = 42
		Cohort 2: Lung cancer	n ~18
		Cohort 3: Breast cancer	n ~18
		Cohort 4: Endometrial cancer	n ~18
		Cohort 5: All other solid tumors	n ~18

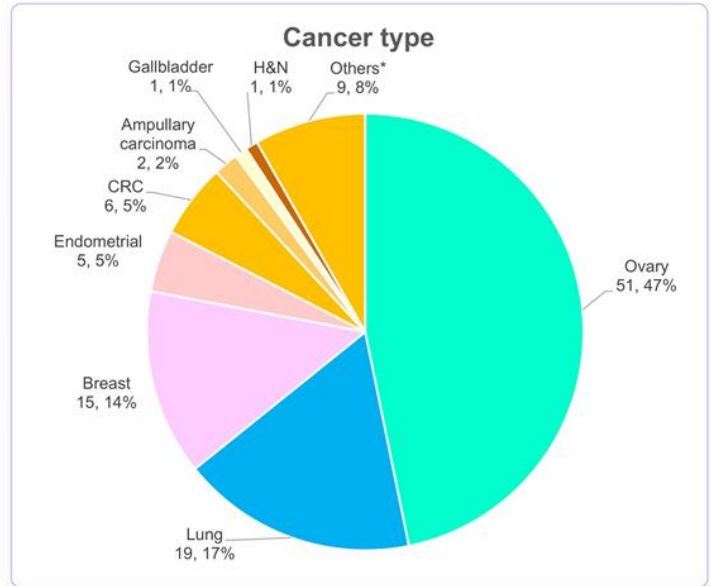
Primary endpoint:
 ORR per BICR
 - Across all cohorts
 - Ovarian cancer cohort

Accelerating development in key tumor types via a streamlined single-arm pivotal study design

Demographics and Baseline Characteristics (All Cohorts)

Heavily pre-treated patients across broad spectrum of tumor types

	Total N=109
Age (years)	Median 65
Sex	Female 72%, Male 28%
ECOG PS	0: 42%, 1: 54%
Prior line of systemic therapy	Median of 3 prior lines (range 1-10) 3 or more prior lines 57%
TP53 Y220C mutation status	100%
KRAS status	Wild type 100%



*Others include 2 gastric cancer, 2 sarcoma, 1 small intestine cancer, 1 HCC, 1 pancreatic cancer, 1 thymic carcinoma and 1 esophagus carcinoma;
ECOG PS, Eastern Cooperative Oncology Group Performance Status

Data Cutoff 04Aug2025

Responses Observed Across All Cohorts in Eight Tumor Types

TP53 Y220C / KRAS WT Efficacy Population ^a (n=97)

Across All Cohorts	ORR n (%)	By Cohort	ORR n (%)
ORR per Investigator assessment	32 (33%)	Ovarian	19/44 (43%) ^b
Confirmed Complete Response (CR)	1	Breast	2/11 (18%)
Confirmed Partial Response (PR)	26	Lung	4/18 (22%) ^b
Unconfirmed Partial Response (uPR)	5 ^b	Endometrial	3/5 (60%) ^b
		Other Solid Tumors	4/19 (21%)

Data Cutoff 04Aug2025

Post-data cutoff:

- 5 uPR patients
 - 2 lung uPRs and 1 ovarian uPR had a confirmed PR
 - Remaining 2 uPRs (1 lung and 1 endometrial) continue on treatment
- Additionally, 1 new ovarian uPR (20/44; 45% ORR) was observed

Overall
33% Overall ORR (including 5 uPRs)
6.2 months median Duration of Response ^c

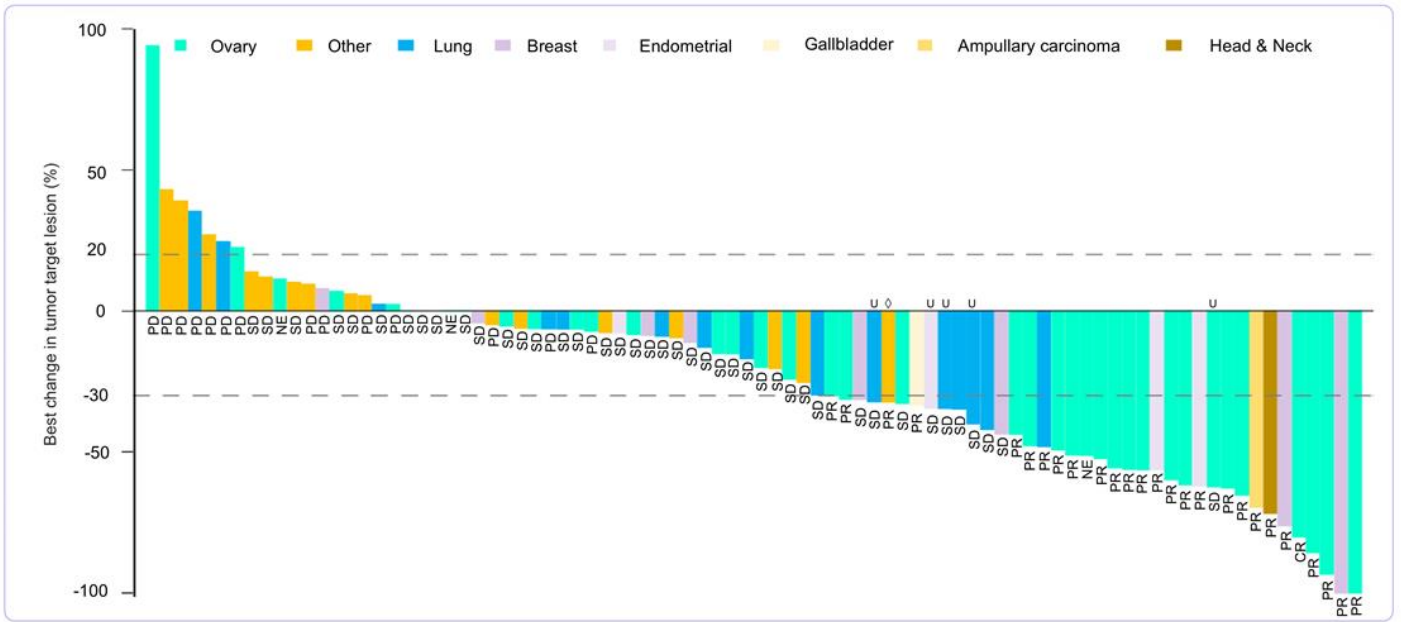
Ovarian Cancer
43% ORR (including 1 uPR)
7.6 months median Duration of Response ^c

^a Patients with the opportunity to reach first post-baseline scan. Patients discontinuing before the first post-baseline scan are included in the efficacy population.

^b As of 04Aug2025, uPRs were observed in 3 lung cancer patients, 1 ovarian cancer patient and 1 endometrial cancer patient.

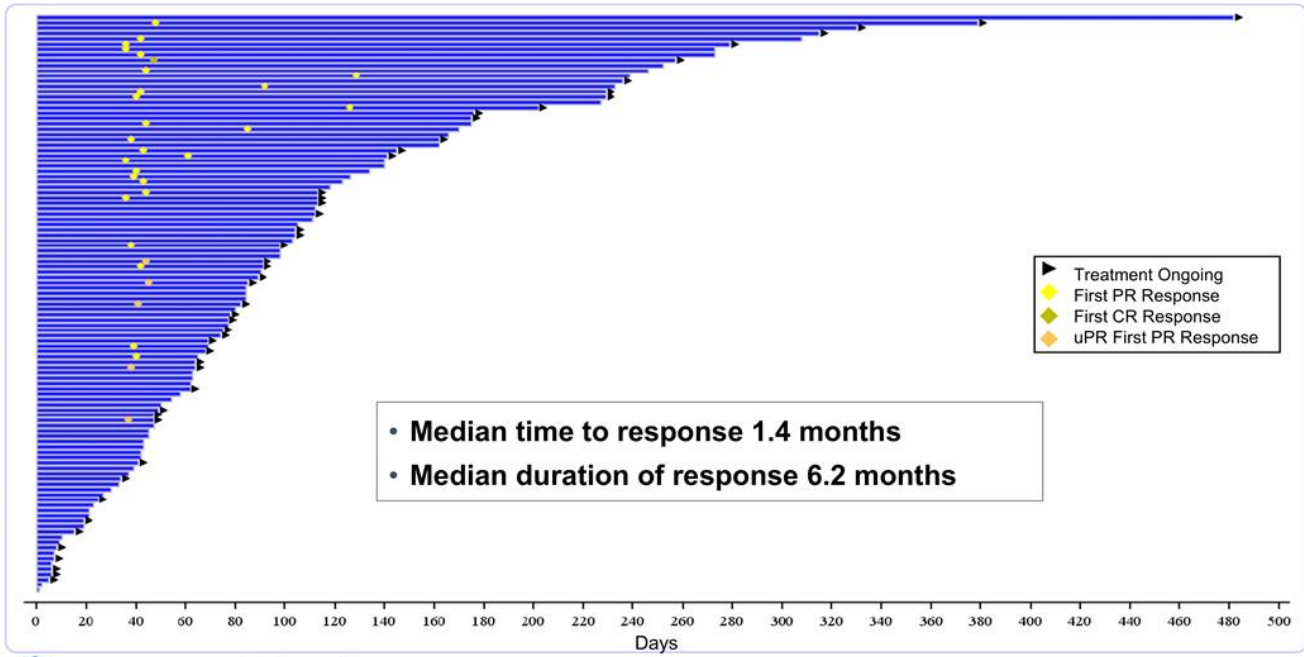
^c DoR accounts only for confirmed responses.

Target Lesion Reduction Observed in the Majority of Patients



Post data cutoff: Among the 5 uPRs, 2 lung cancer patients and 1 ovarian cancer patient had a confirmed PR and the remaining 2 uPR patients continue to be on treatment. In addition, 1 new uPR was observed in the ovarian cancer cohort within the efficacy population.
^u As of 04Aug2025, uPRs were observed in 3 lung cancer, 1 ovarian cancer and 1 endometrial cancer patients. ^o CRC patient.

Rapid Time to Response and Long Duration of Treatment



Post data cutoff:
Among the 5 uPRs, 2 lung cancer patients and 1 ovarian cancer patient had a confirmed PR and the remaining 2 uPR patients continue to be on treatment.
In addition, 1 new uPR was observed in the ovarian cancer cohort within the efficacy population.

Data Cutoff 4Aug2025

Favorable Safety and Tolerability

All TRAEs* (≥ 10% of Patients Preferred Term, n (%))	Overall N = 109	Grade 1	Grade 2	Grade 3	Grade 4
Any TRAE	84 (77.1)	20 (18.3)	36 (33.0)	24 (22.0)	4 (3.7)
Nausea	36 (33.0)	24 (22.0)	12 (11.0)	-	-
Blood creatinine increased	22 (20.2)	6 (5.5)	14 (12.8)	2 (1.8)	-
Fatigue	22 (20.2)	10 (9.2)	11 (10.1)	1 (0.9)	-
Alanine aminotransferase increased	19 (17.4)	7 (6.4)	5 (4.6)	6 (5.5)	1 (0.9)
Anemia	14 (12.8)	5 (4.6)	5 (4.6)	4 (3.7)	-
Aspartate aminotransferase increased	14 (12.8)	5 (4.6)	3 (2.8)	6 (5.5)	-
Decreased appetite	14 (12.8)	11 (10.1)	3 (2.8)	-	-
Vomiting	13 (11.9)	7 (6.4)	6 (5.5)	-	-

* No Grade 5 TRAEs observed

Data Cutoff 04Aug2025

- TRAEs were mostly Grade 1/2
- Most frequent TRAEs were nausea, blood creatinine increased, fatigue, and ALT increased
- Administration of rezatapopt with food decreased incidence of GI TRAEs compared to Phase 1
- Lab abnormalities are manageable/monitorable with the majority of cases being reversible and transient
- Low rate (3.7%) of drug discontinuation due to a TRAE



TRAEs, treatment-related adverse events; GI, gastrointestinal

Demographics and Baseline Characteristics (Ovarian Cancer)

Heavily pre-treated population with poor prognostic features

	n=51
Age (years)	Median 67
ECOG Performance Status	0: 47%, 1: 51%
Prior lines of systemic therapy	Median 4 prior lines (range 1-10) 3 or more prior lines: 73%
Prior therapies	Platinum-based tx: 100% Bevacizumab: 78% PARPi: 59%
Platinum status at study entry	Platinum-resistant: 59% Platinum-refractory: 35%* Platinum-sensitive 6%
Histology	High grade serous: 96%
Somatic BRCA1/2 mutation	BRCA1: 8%, BRCA2: 4%

* Including 14% (n=7) primary platinum-refractory

Data Cutoff 04Aug2025

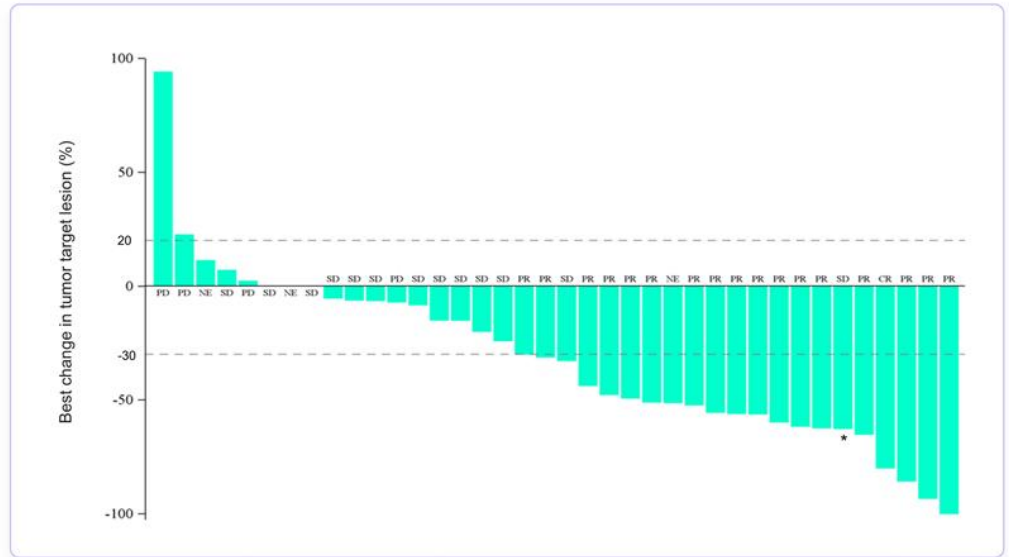
Heavily pre-treated patients:



- **94%** platinum-resistant or refractory
- **78%** received prior bevacizumab
- **73%** with three or more prior lines of therapy

Deep Tumor Shrinkage Leading to High Response Rate

Ovarian Cancer	
	ORR n (%)
Platinum-resistant or refractory	18*/41 (44%)
Platinum-sensitive	1/3 (33%)
Overall	19*/44 (43%)

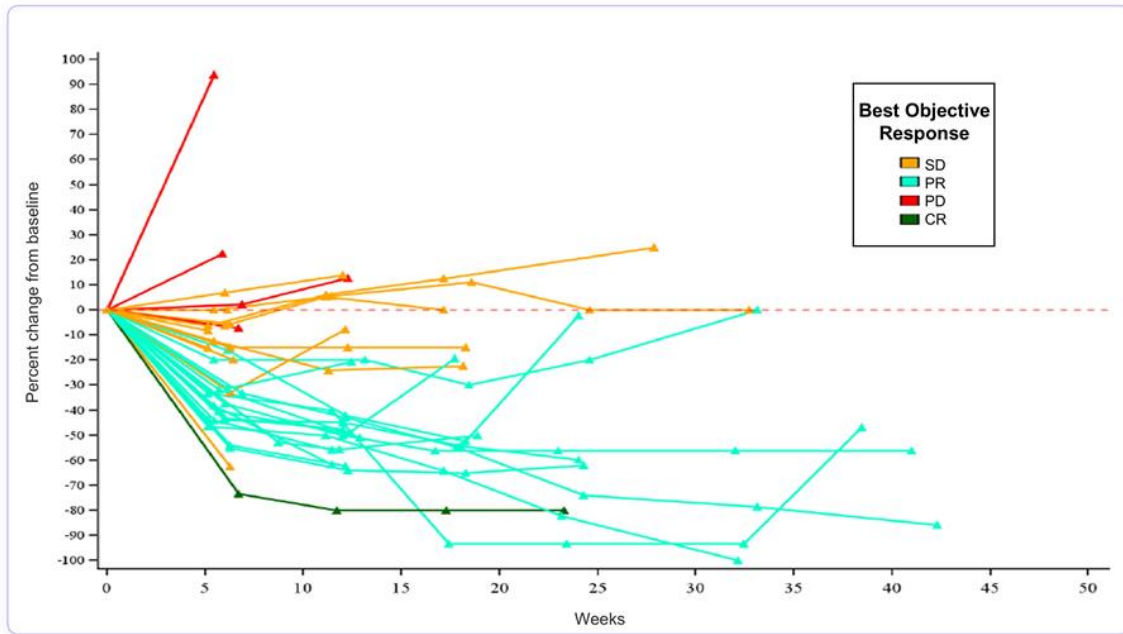


Data Cutoff 04Aug2025

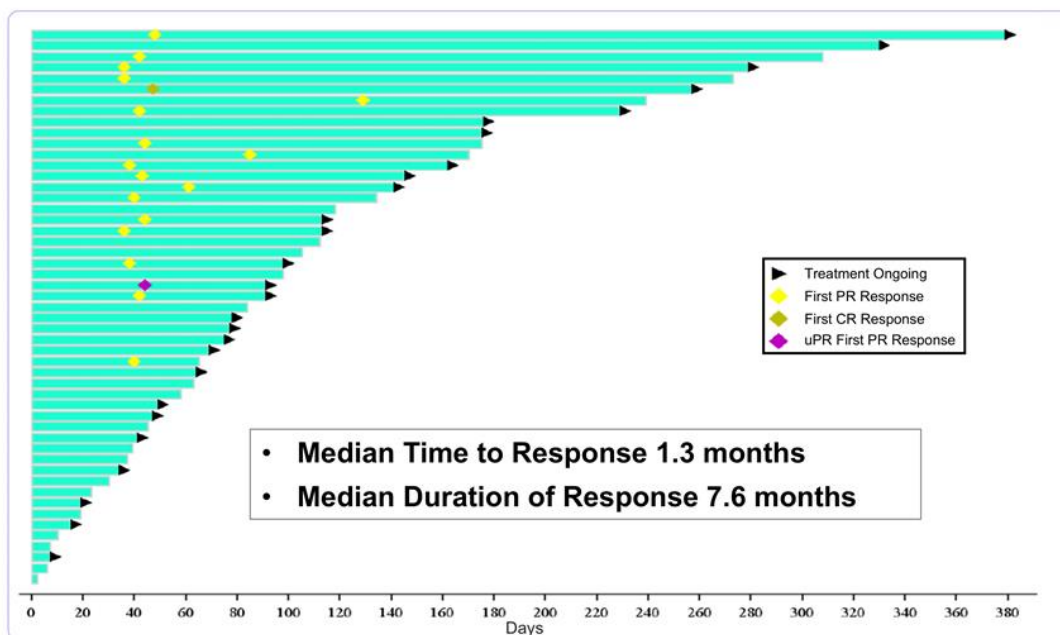


* 1 Unconfirmed partial response – confirmed after data cutoff date
 Post data cutoff, 1 new uPR (20/44; 45% ORR) was observed in the ovarian cancer cohort within the efficacy population (n=44).
 † NE (not evaluable) as the scan was performed outside of the protocol-defined window.
 ORR, overall response rate

Deep and Sustained Tumor Reduction



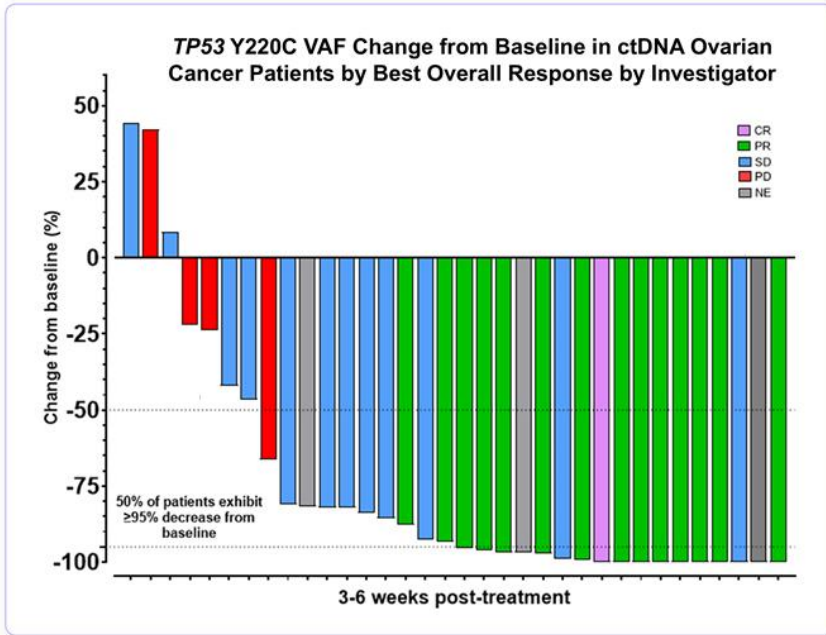
Rapid and Durable Responses



Post data cutoff:
 - 1 uPR was confirmed.
 - In addition, 1 new uPR (20/44; 45% ORR) was observed in the ovarian cancer cohort within the efficacy population.

Data Cutoff 04Aug2025

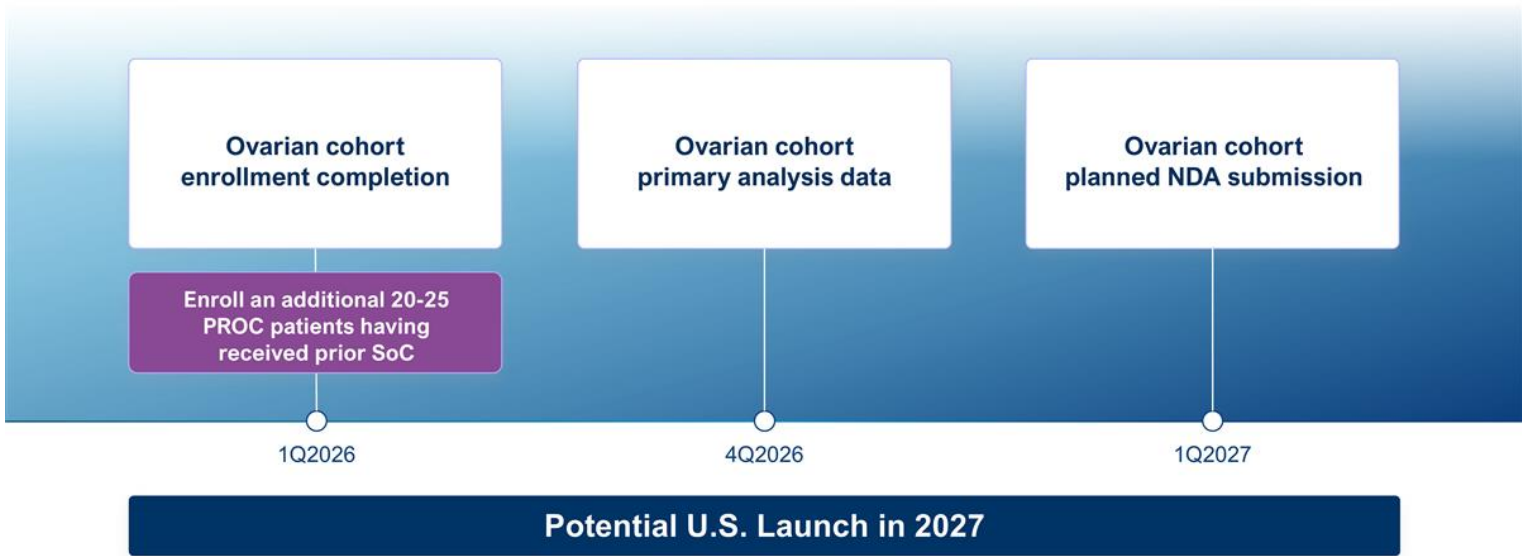
On Target Activity Supported by Significant Decreases in ctDNA TP53 Y220C Mutation VAF



- 34 ovarian cancer patients had ctDNA TP53 Y220C Variant Allele Frequency (VAF) at baseline and on treatment
- 91% experienced a TP53 Y220C VAF decrease supporting on target activity
- 79% exhibited a ≥50% reduction from baseline
- 32% achieved complete clearance of TP53 Y220C, including a patient with a CR

Ovarian Cancer as Lead Indication Informed by FDA Feedback

Targeting 1Q2027 NDA submission seeking accelerated approval



Rezatapopt Offers Compelling Commercial Opportunity

Commercial Opportunity:

- De-risked opportunity in PROC as lead indication with projected 2027 launch
- Potential to expand label beyond PROC
- Clear value proposition for rezatapopt relative to existing and emerging treatments
- TP53 Y220C mutation broadly identifiable

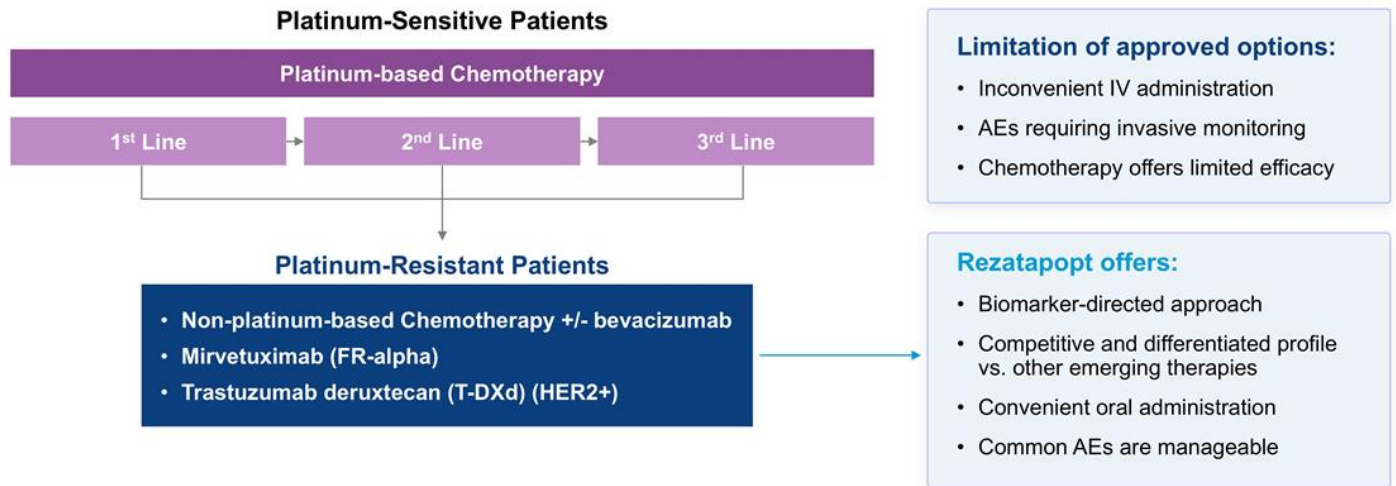
Market Research Feedback

*I would think this is going to be the **go-to agent** [for ovarian cancer]. With this current data, **this beats everything in the market**—if the patient does carry the mutation." Community Oncologist, TX*

It's meaningful if a patient doesn't have to come in for an infusion all the time. PO [oral] is attractive..." Community Gynecologic Oncologist, GA



Rezatapopt Well-Positioned for Success in Ovarian Cancer and Beyond



TP53 Y220C Mutation is Broadly Identifiable on Existing NGS Panels

- Molecular testing is now recommended by NCCN and ESMO across many cancer types including ovarian cancer, breast cancer, NSCLC, endometrial and others
- Reimbursement of NGS testing is widely covered by Medicare and private insurance for qualifying patients



TEMPUS



Memorial Sloan Kettering
Cancer Center



NGS, next-generation sequencing; NCCN, National Comprehensive Cancer Network; ESMO, European Society for Medical Oncology; NSCLC, non-small cell lung cancer

TP53 Y220C 2L+ Ovarian Cancer Offers Meaningful Market Potential

Total 2L+ TP53 Y220C Ovarian Cancer



~1,700

Addressable 2L+
U.S. & EU4/UK Patients¹



~\$350 - 420M

U.S. Market
Potential²



~\$520 - 630M

Global Market
Potential³

- Ovarian cancer patient population will be pursued as initial NDA submission
- Label expansion potential in other tumors

Future Opportunities to Grow Rezatapopt Beyond Ovarian Cancer

Monotherapy

Endometrial

- Monotherapy data continues to be generated in Phase 2 PYNNAACLE
- 2L+ endometrial cancer has the potential to add ~350 patients in U.S. and EU4/UK

Breast

- Monotherapy data continues to be generated in Phase 2 PYNNAACLE
- 2L+ Breast cancer has the potential to add ~2,000 patients in U.S. and EU4/UK

Combination

Solid Tumors

- Bevacizumab (PSOC)
- KRAS inhibitors (NSCLC, Pancreatic, CRC)

Hematologic

- R/R AML/MDS in combination with azacitidine (ongoing IIT)
- Newly diagnosed AML/MDS in combination with azacitidine and venetoclax

Compelling Efficacy and Defined Registrational Path for Rezatapopt



In the Phase 2 PYNACLE trial interim data, rezatapopt demonstrated an ORR of 43% in ovarian cancer with a median DoR of 7.6 months



NDA submission planned in 1Q2027 in platinum-resistant/refractory ovarian cancer patients



Strong balance sheet with \$148M as of June 30, 2025, with cash runway through 1Q2027

Today's Objectives

- 01** Rezatapopt background
- 02** Ovarian cancer treatment landscape
- 03** PYNNACLE Phase 2 interim data update
Initial NDA strategy informed by FDA feedback
- 04** Q&A



Panel



David Mack, PhD
President and Chief
Executive Officer



Ramez N. Eskander, MD
Professor, Department of
Obstetrics, Gynecology, and
Reproductive Sciences
UC San Diego



Deepika Jalota, PharmD
Chief Development
Officer

Thank You



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68. WAGO 2025 Highlights.

PMV Pharmaceuticals Announces Promising Rezatapopt Monotherapy Interim Data From PYNNAACLE Phase 2 Trial Across Multiple Solid Tumors With a TP53 Y220C Mutation

- PYNNAACLE Phase 2 pivotal clinical trial interim data include confirmed responses observed in eight tumor types spanning ovarian, lung, breast, endometrial, head and neck, colorectal, gallbladder, and ampullary carcinoma
- 33% overall response rate (ORR) observed among 97 evaluable patients across all cohorts with a median duration of response of 6.2 months
- 43% ORR observed among 44 evaluable patients in ovarian cancer cohort with a median duration of response of 7.6 months
- Rezatapopt New Drug Application submission for platinum resistant/refractory ovarian cancer planned in first quarter of 2027
- Company to host investor webinar at 8:00 AM ET today to review Phase 2 interim clinical data

PRINCETON, N.J., September 10, 2025 (GLOBE NEWSWIRE) — PMV Pharmaceuticals, Inc. (“PMV Pharma” or the “Company”; Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53, today announced interim data from the Phase 2 pivotal portion of the PYNNAACLE clinical trial. The ongoing Phase 1/2 PYNNAACLE clinical trial is evaluating rezatapopt in patients with advanced solid tumors harboring a TP53 Y220C mutation.

The Phase 2 clinical trial data below are summarized as of an August 4, 2025 data cutoff date:

- The safety population consisted of 109 patients treated with at least one dose of rezatapopt 2000 mg daily as monotherapy.
 - Median number of prior lines of systemic therapy was three (range: 1-10)
- The efficacy population consisted of 97 patients treated with at least one dose of rezatapopt as of the data cutoff date and either had ≥ 1 post-baseline tumor assessment or discontinued early.

Efficacy

- Confirmed responses were observed in patients whose tumors were TP53 Y220C mutated and KRAS wild-type in eight tumor types including ovarian, lung, breast, endometrial, head and neck, colorectal, gallbladder, and ampullary carcinoma.
- Overall response rate (ORR) of 33% (32/97 patients) per investigator assessment according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, including confirmed and unconfirmed responses.
- The cohort-specific ORRs were as follows:
 - Ovarian cancer: 43% ORR (19/44 patients, including one confirmed complete response, 17 confirmed partial responses, and one unconfirmed partial response [uPR])
 - Breast cancer: 18% ORR (2/11 patients)
 - Endometrial cancer: 60% ORR (3/5 patients, including one uPR)
 - Lung cancer: 22% ORR (4/18 patients, including three uPRs)
 - Other solid tumors: 21% ORR (4/19 patients)
- Across all cohorts, the median time to response was 1.4 months and the median duration of response was 6.2 months.
- In the ovarian cancer cohort, the median time to response was 1.3 months and median duration of response was 7.6 months.
- Post the August 4, 2025 data cutoff date, the patients with uPRs remain on treatment.

Safety

- Treatment-related adverse events (TRAEs) were mostly Grade 1-2 with the most frequent TRAEs observed (>15%) being nausea, fatigue, blood creatinine increased, and alanine aminotransferase increased. The rates of individual Grade 3 TRAEs were <6%. All Grade 3 TRAEs resolved on treatment and there were no discontinuations due to Grade 3 AST/ALT elevations.

- Rezatapopt administration with food led to an improvement in gastrointestinal tolerability relative to Phase 1 data.
- Lab abnormalities were manageable, with the majority of cases being transient and reversible.
- The rate of drug discontinuations due to a TRAE was 3.7%.

Regulatory Update

- During a recent meeting with the U.S. Food and Drug Administration (FDA), PMV Pharma received feedback regarding the initial New Drug Application (NDA) submission strategy for platinum resistant/refractory ovarian cancer. PMV Pharma plans to enroll an additional 20-25 platinum resistant/refractory ovarian cancer patients who have received prior standard of care by the end of the first quarter of 2026. The Company plans to submit an NDA for platinum resistant/refractory ovarian cancer by the end of the first quarter of 2027.

“These Phase 2 PYNACLE interim trial data illustrate that rezatapopt, a first-in-class therapy, has the potential to harness the power of p53 to address cancers with high unmet need,” said Deepika Jalota, Pharm.D., Chief Development Officer of PMV Pharma. “Since PMV Pharma’s inception, leveraging more than four decades of research experience, we have pioneered the discovery and development of small molecule therapeutics that are designed to selectively address this historically undruggable target. Today, we are one step closer to realizing our vision of developing therapies that reactivate specific mutant p53 proteins to restore their wild-type function. Looking ahead, we expect to complete enrollment in the Phase 2 portion of the PYNACLE study by the first quarter of 2026 and plan to submit an NDA to the FDA for rezatapopt in the first quarter of 2027.”

Investor Webinar

PMV Pharma will host an investor webinar via webcast today at 8:00 AM ET to review the PYNACLE Phase 2 interim data and provide a regulatory update. The event will feature presentations by PMV Pharma management and Ramez N. Eskander, M.D., Professor of Obstetrics, Gynecology, and Reproductive Sciences at University of California, San Diego.

To register for the event please click [here](#).

About Rezatapopt

Rezatapopt (PC14586) is a first-in-class, small molecule, p53 reactivator designed to selectively bind to the pocket in the p53 Y220C mutant protein, restoring the wild-type tumor-suppressor function. The U.S. Food and Drug Administration granted Fast Track designation to rezatapopt for the treatment of patients with locally advanced or metastatic solid tumors with a p53 Y220C mutation.

About the PYNACLE Clinical Trial

The ongoing Phase 1/2 PYNACLE clinical trial is evaluating rezatapopt in patients with advanced solid tumors harboring a *TP53* Y220C mutation. The primary objective of the Phase 1 portion of the clinical trial was to determine the maximum tolerated dose and recommended Phase 2 dose (RP2D) of rezatapopt when administered orally to patients. Safety, tolerability, pharmacokinetics and effects on biomarkers were also assessed. The Phase 2 portion is a registrational, single arm, expansion basket clinical trial comprising five cohorts (ovarian, lung, breast, and endometrial cancers, and other solid tumors) with the primary objective of evaluating the efficacy of rezatapopt at the RP2D in patients with *TP53* Y220C and *KRAS* wild-type advanced solid tumors. For more information about the Phase 1/2 PYNACLE clinical trial, refer to www.clinicaltrials.gov (NCT trial identifier NCT04585750).

About PMV Pharma

PMV Pharma is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. TP53 mutations are found in approximately half of all cancers. The Company's co-founder, Dr. Arnold Levine, established the field of p53 biology when he discovered the p53 protein in 1979. Bringing together leaders in the field to utilize more than four decades of p53 biology, PMV Pharma combines unique biological understanding with a pharmaceutical development focus. PMV Pharma is headquartered in Princeton, New Jersey. For more information, please visit www.pmvpharma.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the Company's clinical development activities, plans and projected timelines for rezatapopt, including expectations regarding the timing and completion of patient enrollment and ultimate completion of the Phase 2 portion of the PYNACLE study, the timing of disclosures regarding clinical data updates of its current clinical trial for rezatapopt, expected therapeutic benefits of rezatapopt including potential efficacy and tolerability, plans regarding regulatory filings and approvals, including targeted timelines for the Company's New Drug Application submission and initial U.S. Food and Drug Administration (FDA) approval for platinum-resistant or refractory ovarian indication, ongoing safety and response rate of participants in the PYNACLE study, as well as the overall timing and success of the Company's current and future clinical trials for rezatapopt, the adequacy of the data to support the Company's pursuit of regulatory approval, and the Company's expectations regarding the therapeutic, addressable patient populations, timing for approval, and commercial potential of rezatapopt. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the Company's preclinical studies and clinical trials may not be successful; the FDA may not agree with the Company's interpretation of the data from clinical trials of its product candidates; the Company may decide, or the FDA may require the Company, to conduct additional clinical trials or to modify its ongoing clinical trials, which could result in enrollment or other delays to the Company's anticipated timelines; the Company may experience delays in the commencement, enrollment, completion, or analysis of clinical testing for its product candidates, or significant issues regarding the adequacy of the Company's clinical trial designs or the execution of its clinical trials may arise, which could result in increased costs and delays, or limit the Company's ability to pursue or obtain regulatory approval; the commencement, enrollment, and completion of clinical trials and the reporting of data; a global pandemic, other public health emergencies or geopolitical tensions or conflicts may disrupt the Company's business and that of the third parties on which the Company is dependent on, including delaying or otherwise disrupting the Company's clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; the Company's product candidates may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of the Company's product candidates could delay or prevent regulatory approval or commercialization; the Company may not be able to obtain additional financing on terms acceptable or at all; as well as those risks and uncertainties set forth in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 3, 2025, the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, filed with the SEC on May 9, 2025, and the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025, filed with the SEC on August 7, 2025, and its other filings filed with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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