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): October 12, 2023

PMV Pharmaceuticals, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39539**	**46-3218129**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Research Way **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 8.01 Other Events.

On October 12, 2023, the Company issued a press release announcing updated Phase 1 results from its ongoing Phase 1/2 PYNNACLE clinical trial with a September 5, 2023 cutoff date that showed PC14586 achieved efficacy in heavily pretreated patients across multiple tumor types and was well tolerated with a favorable safety profile. The updated results were also presented at a late-breaking poster session at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Also on October 12, 2023, the Company hosted a virtual KOL webinar to discuss the updated Phase 1 results from the study, as well as other regulatory updates.

A copy of the press release and KOL webinar presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and incorporated by reference herein.

The press release and KOL webinar presentation attached as Exhibits 99.1 and 99.2, respectively, 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:

Exhibit Number	Description
99.1	Press Release issued by PMV Pharmaceuticals, Inc., dated October 12, 2023.
99.2	Presentation: KOL Webinar for Phase 1/2 PYNNACLE Study of PC14586 from the 2023 AACR-NCI-EORTC International Conference, dated October 12, 2023.
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: October 12, 2023

By: /s/ Winston Kung

Winston Kung
Chief Operating Officer and
Chief Financial Officer
(Principal Financial Officer)

PMV Pharmaceuticals Updated PC14586 Phase 1 Data
Demonstrated Anti-Tumor Activity Across Multiple Solid Tumor
Types With a TP53 Y220C Mutation

- *Updated PC14586 Phase 1 data presented today as a late-breaking poster at 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics*
- *Confirmed responses observed in multiple tumor types including ovarian, breast, prostate, lung, and endometrial cancer with median duration of response of seven months*
- *Confirmed overall response rate of 38% at Recommended Phase 2 Dose of 2000 mg daily (6/16 evaluable patients) reflective of the planned Phase 2 patient population (TP53 Y220C and KRAS wild-type)*
- *Company to host KOL webinar at 4:00 PM ET today to review updated PC14586 Phase 1 clinical data*

PRINCETON, N.J., October 12, 2023 (GLOBE NEWSWIRE) — PMV Pharmaceuticals, Inc. (Nasdaq: PMVP), a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53, today announced updated Phase 1 results from its ongoing Phase 1/2 PYNNACLE clinical trial that showed PC14586 achieved efficacy in heavily pretreated patients across multiple tumor types and was well tolerated with a favorable safety profile. Results are being presented in a late-breaking poster session today by Alison M. Schram, M.D., Medical Oncologist at Memorial Sloan Kettering Cancer Center and PYNNACLE Study Investigator, at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics taking place in Boston, Massachusetts.

Dr. Schram commented, “Patients with a solid tumor harboring a TP53 Y220C mutation are in need of new treatment options, as currently there are no approved therapies targeting p53. The safety and efficacy data presented today demonstrate the potential of PC14586 to address a high unmet need in patients with TP53 Y220C-positive advanced solid tumors.”

Study highlights include:

Patient Characteristics

- As of the September 5, 2023 data cutoff, 67 safety evaluable patients were treated in the efficacious dose range (1150 mg daily and above).
- Median age was 63 years (32-84); 61% of patients were female.
- Median number of prior lines of systemic therapy was three (range: 1-9).

Efficacy

- Confirmed responses were observed in patients whose tumors were TP53 Y220C and KRAS wild-type in the efficacious dose range, in multiple tumor types including ovarian, breast, prostate, small-cell lung, and endometrial cancer.
- Median duration of response was seven months.
- Overall response rate (ORR) per RECIST version 1.1 was 38% (6/16 evaluable patients) at the Recommended Phase 2 Dose (RP2D) of 2000 mg daily and 34% (13/38) in the efficacious dose range.

Safety

- Treatment-related adverse events (TRAEs) were mostly Grade 1-2 with the most frequent TRAEs observed (>20%) being nausea, vomiting and blood creatinine increased, with a low rate of discontinuations due to a TRAE (3%).
- Gastrointestinal toxicity improved when PC14586 was administered with food.

Phase 2 Plans

- A RP2D of 2000 mg once daily was selected based on overall safety, pharmacokinetics (PK), and efficacy in alignment with the U.S. Food and Drug Administration at an End of Phase 1 meeting held in Q3 2023.
- The planned Phase 2 patient population includes TP53 Y220C and KRAS wild-type patients.
- PMV plans to initiate a registrational Phase 2 trial in early 2024.

“These updated data from our ongoing Phase 1/2 PYNNACLE clinical trial showed that PC14586, a first-in-class precision oncology investigational therapy, continues to demonstrate clinical benefit in a patient population of high unmet need. The emerging Phase 1 data have guided us in designing our Phase 2 registrational trial to enroll a TP53 Y220C and KRAS wild-type patient population. This represents approximately 90% of patients with TP53 Y220C-positive tumors and the patient population most likely to derive benefit from PC14586,” said Leila Alland, M.D., Chief Medical Officer of PMV Pharma. “We are excited to initiate our registrational Phase 2 trial in early 2024.”

KOL Webinar

PMV will host a KOL webinar via webcast today at 4:00 PM ET to review the data and provide a regulatory update. The event will feature presentations by Aparna Parikh, M.D., M.S., Director of the Global Cancer Care Program at Mass General Hospital Cancer Center, and PYNNACLE Study Investigator, and PMV management.

To register for the event please click here.

Additional PMV Presentations at AACR-NCI-EORTC Conference

The updated PYNNACLE clinical trial data will also be discussed by Dr. Alland during the Chemistry in Cancer Research Town Hall at 6:00 PM ET on Friday, October 13, 2023, and by Dr. Parikh at 10:00 AM ET on Saturday, October 14, 2023.

About the PYNNACLE Clinical Trial

The ongoing Phase 1/2 PYNNACLE study is evaluating PC14586 in patients with advanced solid tumors harboring a TP53 Y220C mutation. The primary objective of the Phase 1 portion of the trial is to determine the maximum tolerated dose (MTD), and Recommended Phase 2 dose (RP2D) of PC14586 when administered orally to patients. Safety, tolerability, pharmacokinetics and effects on biomarkers will also be assessed. Phase 2 will be an expansion study with the primary objective of evaluating the efficacy of PC14586 at the RP2D in patients with TP53 Y220C advanced solid tumors. For more information about the Phase 1/2 PYNNACLE clinical trial, refer to www.clinicaltrials.gov (NCT study identifier NCT04585750).

About PC14586

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

About PMV Pharma

PMV Pharma is a precision oncology company pioneering the discovery and development of small molecule, tumor-agnostic therapies targeting p53. p53 mutations are found in approximately half of all cancers. The field of p53 biology was established by our co-founder Arnold Levine, Ph.D., 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 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, expectations regarding timing of the Phase 2 portion of its current clinical trial for PC14586, expected therapeutic benefits of PC14586 including potential efficacy and tolerability, statements regarding the Company’s future plans or expectations for PC14586, including expectations regarding ongoing safety and response rate of participants in our clinical trials, as well as the overall success of the current and future clinical trials for PC14586, and the adequacy of the data to support its regulatory approval, and any future commercialization plans for the product candidate; and the future plans or expectations for the Company’s discovery platform for its other early-stage and clinical candidates. 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 success, cost, and timing of the Company’s product candidate development activities and planned clinical trials, the Company’s ability to execute on its strategy and operate as an early clinical stage company, the potential for clinical trials of PC14586 or any future clinical trials of other product candidates to differ from preclinical, preliminary or expected results, the Company’s ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company’s clinical trials, supply chain, and operations, as well as those risks and uncertainties set forth in the section entitled “Risk Factors” in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 1, 2023 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.

Contacts

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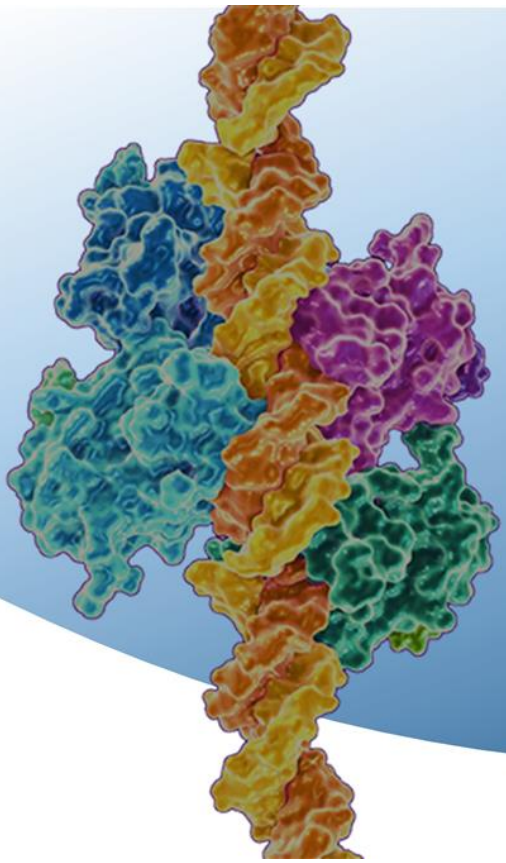
Exhibit 99.2



KOL Webinar for Phase 1/2 PYNNACLE study of PC14586 from the 2023 AACR-NCI-EORTC International Conference

October 12, 2023

PMVPharma

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 PC14586, including the timing of disclosures regarding clinical data updates of its current clinical trial for PC14586, expected therapeutic benefits of PC14586 including potential efficacy and tolerability, and our pipeline programs, plans regarding regulatory filings and approvals, including initiation of the potentially pivotal Phase 2 portion of the study, ongoing safety and response rate of participants in our clinical trials, as well as the overall success of its the current and future clinical trials for PC14586, and the adequacy of the data to support its regulatory approval, and our expectations regarding the therapeutic and commercial potential of our product candidates, 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; 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; the COVID-19 pandemic 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; and we may not be able to obtain additional financing. 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. Other risks and uncertainties affecting us are described more fully in our filings with the Securities and Exchange Commission. 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.

Agenda

01	02	03	04
Introduction	AACR-NCI-EORTC 2023 Update and Clinical Experience	Looking Ahead Phase 2	Q&A Session
David Mack, PhD	Aparna Parikh, MD	Deepika Jalota, PharmD	All

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Panel

David Mack, PhD
President and Chief Executive Officer

Aparna Parikh, MD
Director Global Cancer Care Program, Mass General Hospital

Deepika Jalota, PharmD
Chief Development Officer

Leila Alland, MD
Chief Medical Officer

PMV Pharma is Harnessing the Power of p53 to Treat Cancer

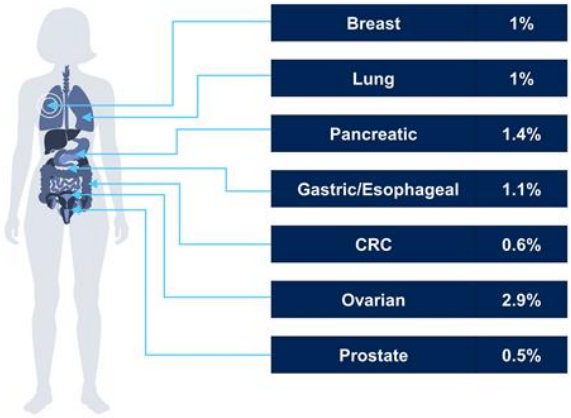
- PMV's lead candidate is PC14586, a first-in-class p53 Y220C reactivator
  The p53 Y220C mutation, a previously undruggable target, is found in 1% of solid tumors
- PC14586 has achieved clinical proof of concept with favorable safety and preliminary efficacy observed across multiple tumor types
- FDA End of Phase 1 meeting confirmed the RP2D, and a path for a single arm, tumor agnostic Phase 2 study to be initiated in early 2024 and plan to file an NDA in 2026
- Favorable safety profile opens the opportunity to combine PC14586 with multiple standard of care regimens, including anti-PD1
- Strong balance sheet ~$219MM as of June 30, 2023 with a cash runway into year end 2025

TP53 Y220C Hotspot Mutation is Detected across Solid Tumor Types

- *TP53* mutations are the most common genomic events across all human cancers[1]
- 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 cancer[1–2]
- p53 Y220C is a key hot-spot TP53 missense mutation that destabilizes p53[1,3]
- **p53 Y220C is present in ~1% of all solid tumors[4]**

Frequency of *TP53 Y220C* Across Common Solid Tumors

Foundation Medicine Tissue and Heme assay test results collected between 1/1/12 and 12/31/2020



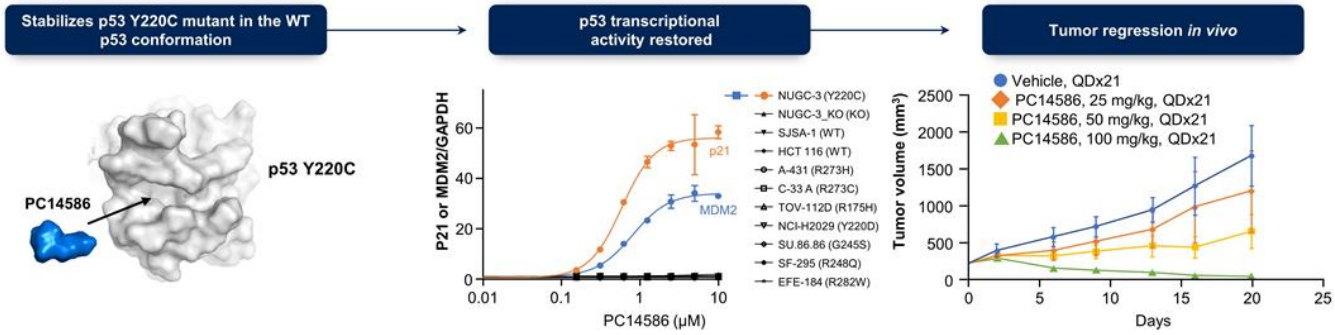
CRC, colorectal cancer; DNA, deoxyribonucleic acid.

1. Baugh EH, et al. *Cell Death Differ*. 2018;25,154–160.
2. Roszkowska KA, et al. *Int J Mol Sci*. 2020;21:1334.
3. Bouaoun L, et al. *Hum Mutat*. 2016;37:865–876.
4. Westphalen CB, et al. *NPJ Precis Oncol*. 2021;20;5(1):69.

The prevalence of TP53 Y220C across different diseases was analyzed by using the FoundationInsights® web-based software platform to query a pan-solid tumor cohort of ~367,651 US-based, consented-for-research patients in the FoundationCore® Database[4] that received FMI's Commercial Tissue or Heme assays between 1/1/12 and 12/31/2020

PC14586 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 protein[1]
- Stabilizes the p53 Y220C mutant protein in the wild-type p53 conformation, thereby restoring transcription and tumor-suppressor function[1]
- Inhibits proliferation across all Y220C-expressing cell lines; increased sensitivity to PC14586 correlates with the absence of RAS pathway mutation



MDM2, mouse double minute 2 homolog; KO, knockout; WT, wild-type.

1. Dumble M, et al. *Cancer Res.* 2021;81(13_Suppl):Abstract LB006.

PYNNACLE

Updated Phase 1 results from the PYNNACLE Phase 1/2 study of PC14586, a selective p53 reactivator, in patients with advanced solid tumors harboring a *TP53 Y220C* mutation

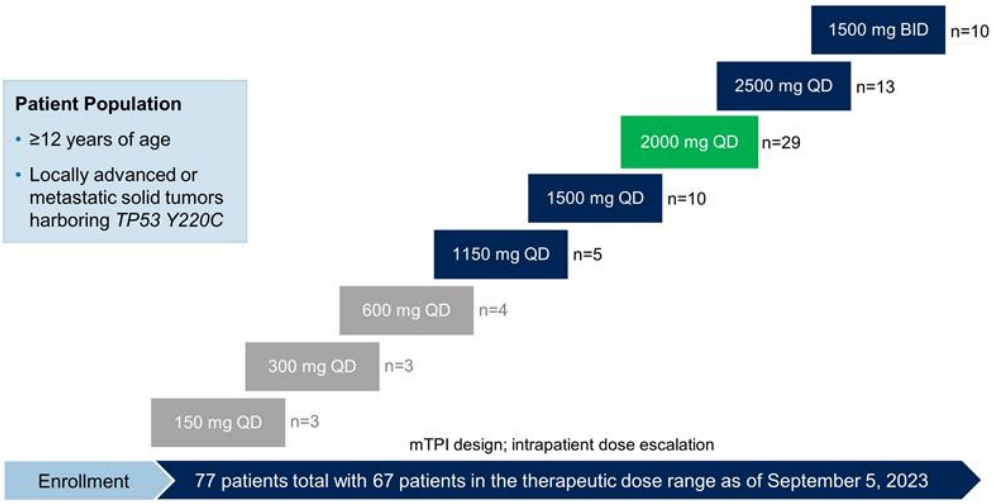
Aparna Parikh, M.D., M.S.
Director of the Global Cancer Care Program at
Mass General Hospital Cancer Center

PYNNACLE Phase 1/2 Trial – Phase 1 Study Design

Patients With Advanced Solid Tumors Harboring TP53 Y220C Mutation

Patient Population

- ≥12 years of age
- Locally advanced or metastatic solid tumors harboring *TP53 Y220C*



Primary objective	• Determine MTD, select RP2D, and evaluate safety and tolerability
Secondary objectives	• PK • Preliminary efficacy
Exploratory objectives	• Biomarkers/PD

BID, twice daily; MTD, maximum tolerated dose; mTPI, modified toxicity probability interval design; QD, once daily

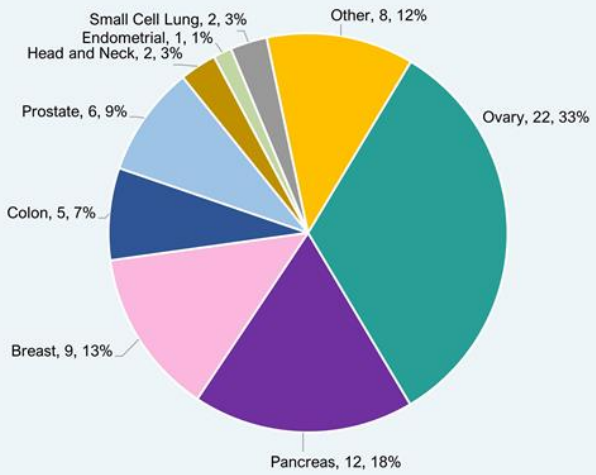
NCT study identifier: NCT04585750

Patient Demographics and Disease Characteristics

Efficacious dose range (1150 mg QD to 1500 mg BID)

	n=67
Age, years	
Median (min–max)	63 (32–84)
Sex, n (%)	
Female	41 (61)
Male	26 (39)
Race, n (%)	
White	51 (76)
Asian	5 (7)
Black or African American	6 (9)
Other	1 (1)
Not Reported/Unknown	4 (6)
ECOG status, n (%)	
0	22 (33)
1	45 (67)
Prior systemic therapies, n (%)	
1	6 (9)
2	19 (28)
≥3	37 (55)
Not reported	5 (6)
Median (min–max)	3 (1-9)
Germline TP53 Y220C, n (%)	
Negative	66 (99)
Positive	1 (1)
KRAS status, n (%)	
Wild type	50 (75)
KRAS Single Nucleotide Variant (SNV)	17* (25)

Cancer Type, n (%)



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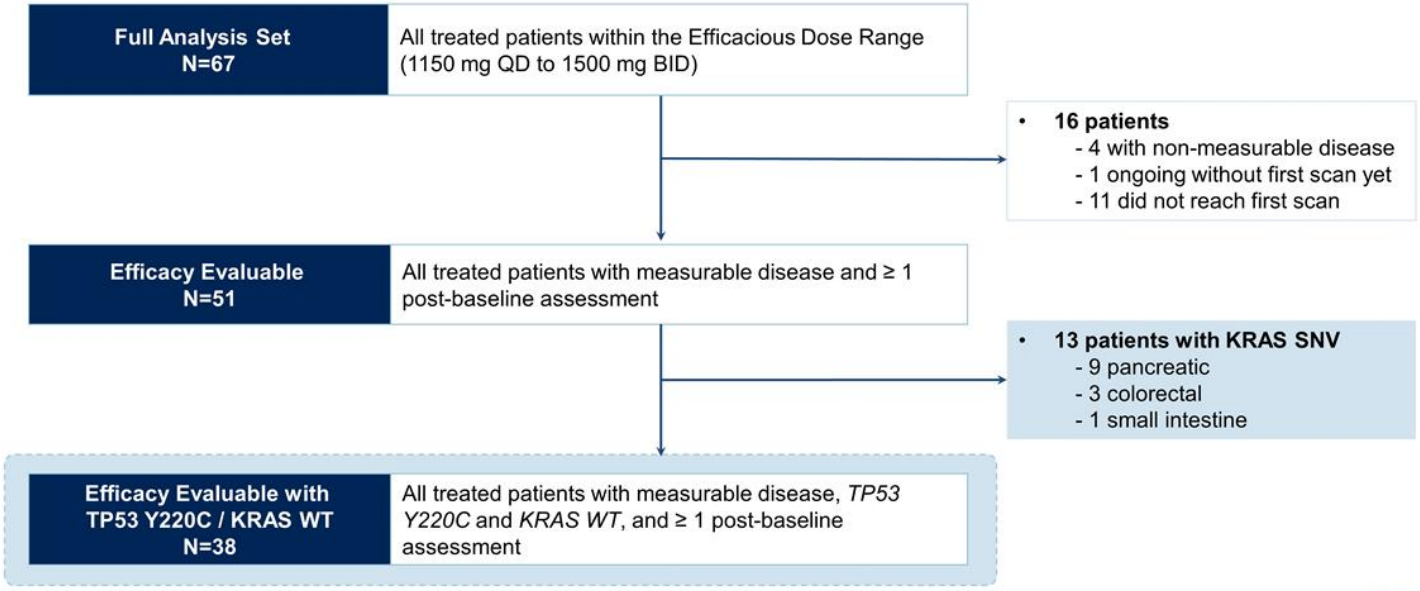
* 12 pancreas, 3 colon, 1 small intestine, 1 cholangiocarcinoma

"Other" include sarcoma, cholangiocarcinoma, esophageal cancer, gastro-esophageal cancer, germ cell tumor, pleomorphic rhabdomyosarcoma, small intestine cancer, and urothelial cancer

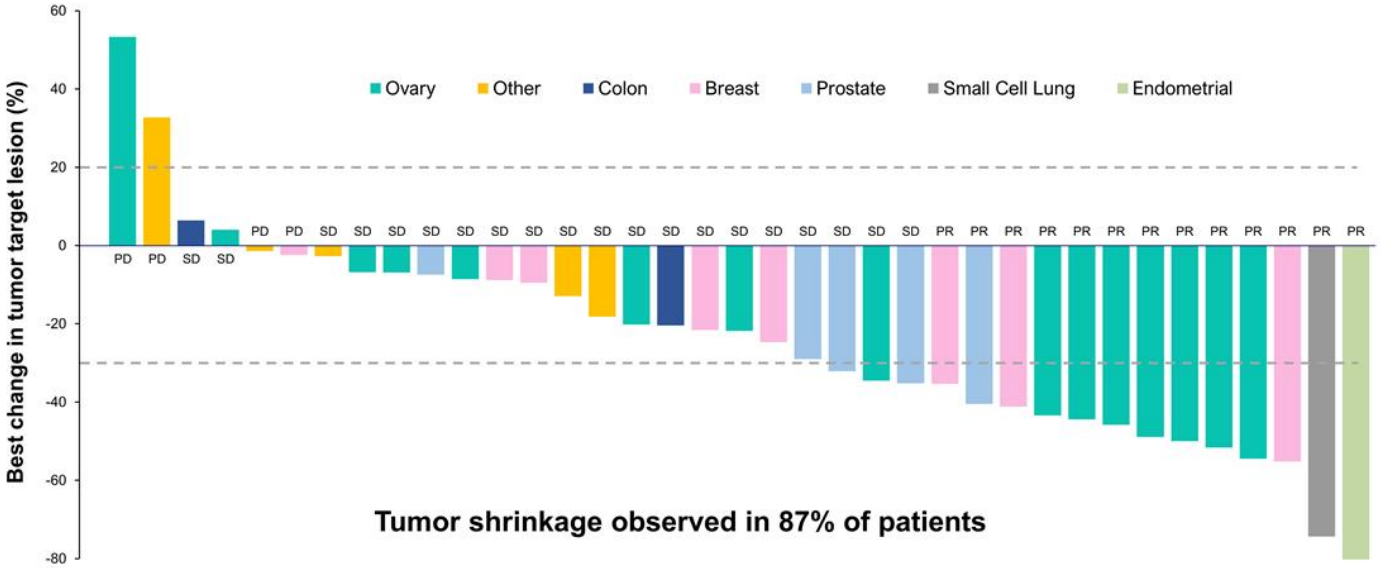
PMV-586-101 Phase 1: Efficacy Evaluable Population

Efficacious Dose Range (1150 mg QD to 1500 mg BID)



Target Lesion Reduction Across Tumor Types

Efficacious dose range TP53 Y220C / KRAS WT (1150 mg QD to 1500 mg BID)



Includes patients with measurable disease at baseline and ≥ 1 post-baseline assessment. One SCLC patient without tumor measurement at 1st scan is not represented
Other tumor types include sarcoma, esophageal cancer, germ cell tumor, pleomorphic rhabdomyosarcoma, and urothelial cancer

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Confirmed Responses at RP2D And Across Efficacious Dose Range In Multiple Tumor Types

PYNNACLE

TP53 Y220C / KRAS WT Patients

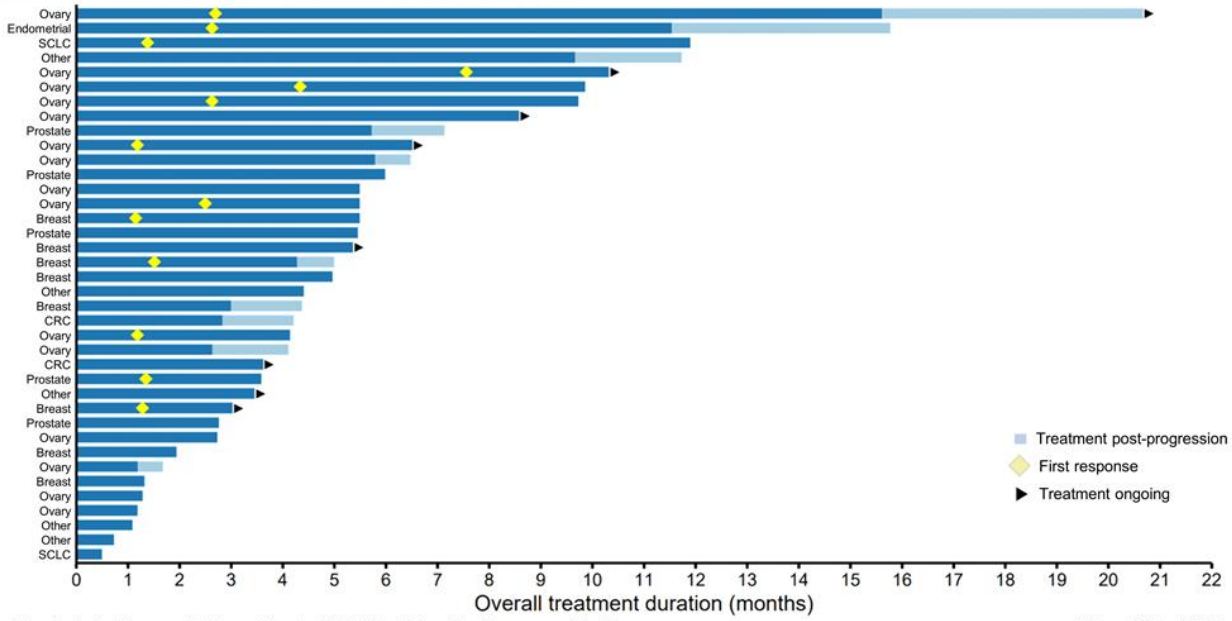
	RP2D 2000 mg QD N=16	Efficacious Dose Range 1150 mg QD – 1500 mg BID N=38
	ORR n (%)	ORR n (%)
Overall	**6 (38%)**	**13 (34%)**
Partial Response (PR)	**6**	**13**
Stable Disease (SD)	**8**	**20**
Progressive Disease (PD)	**2**	**5**

Tumor type	RP2D 2000 mg QD N=16	Efficacious Dose Range 1150 mg QD – 1500 mg BID N=38
	ORR n (%)	ORR n (%)
Ovary	2/5 (40)	7/15 (47)
Breast	2/3 (67)	3/8 (38)
Small cell lung	0/1 (0)	1/2 (50)
Endometrial	1/1 (100)	1/1 (100)
Other solid tumors	1/6 (17)	1/12 (8)

38% confirmed ORR at the RP2D
7 months median Duration of Response

Time to Response & Duration of Treatment

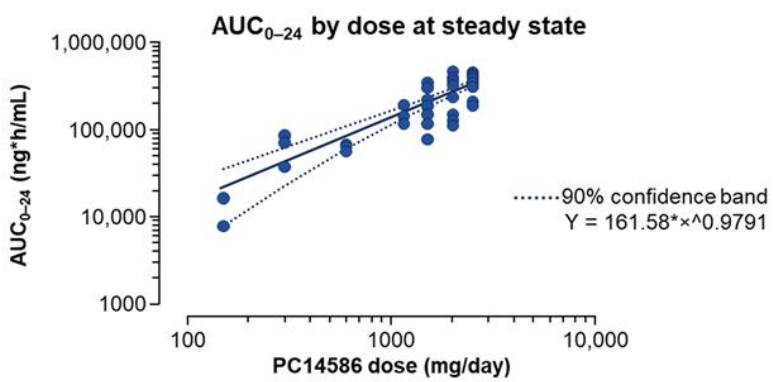
Efficacious Dose Range – TP53 Y220C/KRAS WT



Includes all patients with measurable disease at baseline, KRAS WT and ≥ 1 post-baseline assessment (n=38)

Data cut-off Sep 5, 2023

PC14586 Displays Linear and Dose Proportional PK



Median PC14586 $T_{1/2}$ of 19 hours at steady state across all patients allowing for QD dosing

PC14586 Demonstrated a Favorable Safety Profile

Efficacious dose range (1150 mg QD to 1500 mg BID)

All TRAEs (≥ 5% of Patients) Preferred Term, n (%)	Max CTCAE				
	Overall n=67	1	2	3	4
Any TRAE	**60 (89.6)**	**16 (23.9)**	**27 (40.3)**	**16* (23.9)**	**1**(1.5)**
Nausea	34 (50.7)	22 (32.8)	11 (16.4)	1 (1.5)	
Vomiting	29 (43.3)	16 (23.9)	12 (17.9)	1 (1.5)	
Blood creatinine increased	18 (26.9)	10 (14.9)	8 (11.9)		
Diarrhea	13 (19.4)	12 (17.9)		1 (1.5)	
Fatigue	13 (19.4)	8 (11.9)	5 (7.5)		
ALT increased	12 (17.9)	4 (6.0)	5 (7.5)	3 (4.5)	
AST increased	11 (16.4)	7 (10.4)	2 (3.0)	2 (3.0)	
Anemia	10 (14.9)	1 (1.5)	6 (9.0)	3 (4.5)	
Decreased appetite	7 (10.4)	2 (3.0)	4 (6.0)	1 (1.5)	
Proteinuria	6 (9.0)	1 (1.5)	5 (7.5)		
Rash maculo-papular	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	
Headache	5 (7.5)	4 (6.0)	1 (1.5)		
Lipase increased	5 (7.5)	4 (6.0)		1 (1.5)	
Platelet count decreased	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	
Amylase increased	4 (6.0)	3 (4.5)	1 (1.5)		
Dehydration	4 (6.0)		4 (6.0)		

TRAEs were mostly grade 1/2

Most frequent TRAEs were nausea and vomiting which improved when PC14586 was given with food

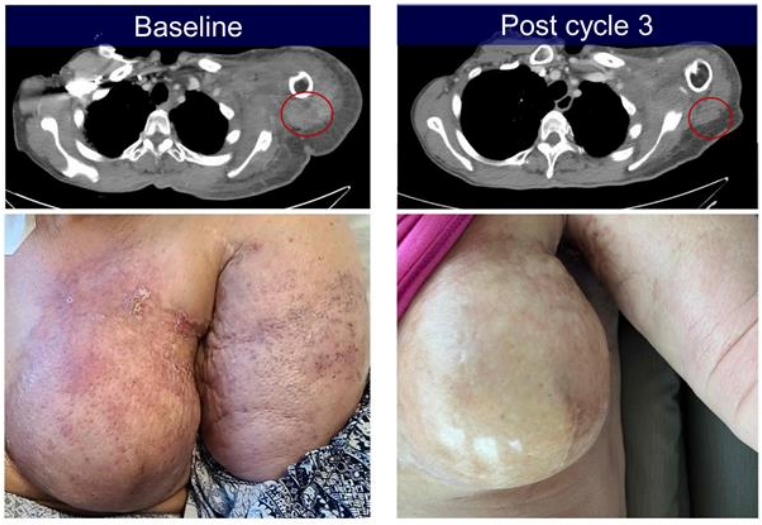
Low rate (3%) of drug discontinuation due to a TRAE

*Includes 5 additional grade 3 treatment-related adverse events: neutrophil count decreased, acute kidney injury, pancreatitis, pneumonitis, and rash erythematous
** Includes 1 patient with grade 4 immune thrombocytopenia. AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BID, twice daily; CTCAE, Common Terminology Criteria for Adverse Events; QD, once daily.

Patient with Triple Negative Breast Cancer with Rapid Onset of Response

51-year-old woman with metastatic TNBC

- Prior treatment course:
  - Neoadjuvant therapy (carbo + pac + pembro followed by cp + dox + pembro)
  - Bilateral mastectomy followed by pembro maintenance, radiotherapy, and breast reconstruction
  - Pegylated liposomal doxorubicin for disease recurrence
  - Progressive disease in axilla with extensive skin lesions on adjacent breast and arm, limiting mobility
- *TP53 Y220C* detected by NGS
- PC14586 2000 mg QD was started
  - Rapid, visible reduction in arm swelling and improved mobility of arm and fingers within the 1st week
  - PR at 6 weeks (41% reduction in axilla lesion) confirmed at 12 weeks and ongoing



Images courtesy of Dr. Shivaani Kummar, OHSU

carbo, carboplatin; pac, paclitaxel; pembro, pembrolizumide; cp, cyclophosphamide; dox, doxorubicin; NGS, next-generation sequencing; PR, partial response; QD, once daily; TNBC, triple negative breast cancer.

Conclusion

- PC14586 demonstrated single agent clinical efficacy in heavily pre-treated patients across multiple *TP53* Y220C and *KRAS* WT tumor types.
- A favorable safety profile was observed, with improvement in gastrointestinal adverse events when PC14586 is taken with food.
- Based on the overall data, 2000 mg QD was selected as the RP2D.
- The PYNNACLE registrational Phase 2 trial will assess PC14586 as monotherapy at the RP2D of 2000 mg QD in patients with *TP53* Y220C mutation and *KRAS* WT advanced solid tumors.

Looking Ahead & Phase 2

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Defined Registration Paths in Ovarian and Tumor Agnostic Patient Populations

PYNNACLE

FDA alignment on RP2D, patient population and pivotal single arm Phase 2 study design obtained at EOP1 Meeting

Patient Population

- Aged ≥ 12 years
- Locally advanced or metastatic solid tumors, excluding primary CNS tumors
- Documented *TP53 Y220C* and *KRAS* WT only
- Prior standard therapy or ineligible for appropriate standard of care therapy

Basket
N = 114

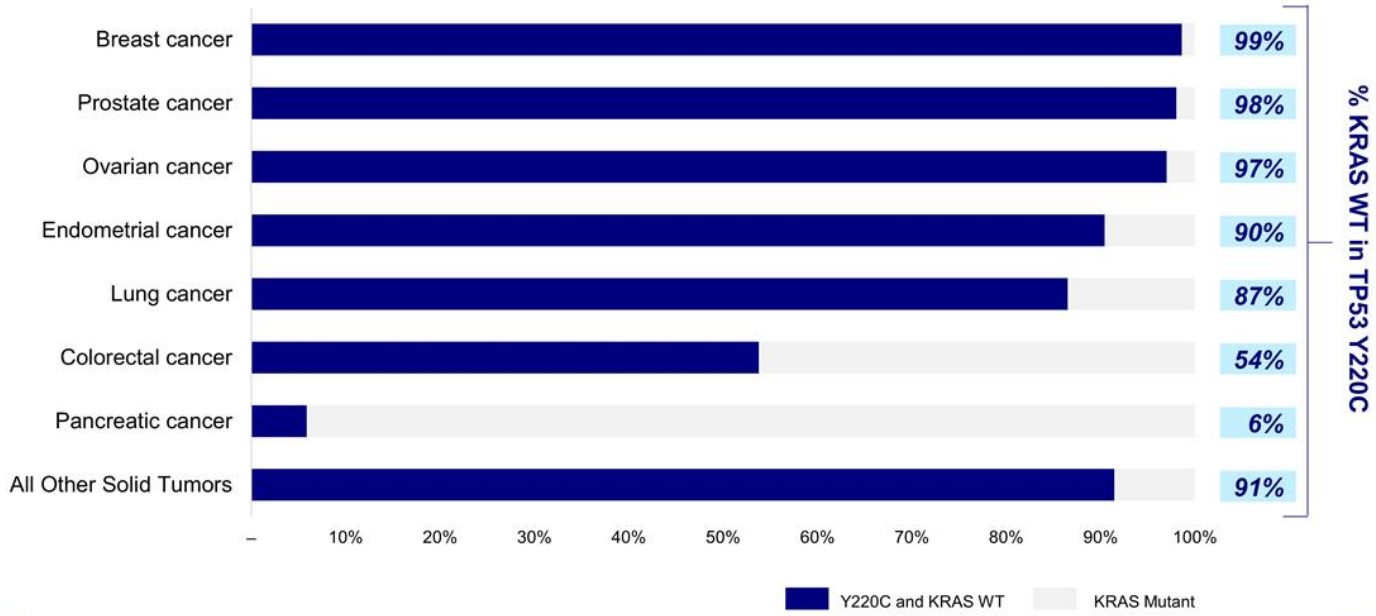
PC14586 at 2000mg QD

Cohorts		
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

Opportunity to accelerate development of specific tumor types while also pursuing a tumor-agnostic strategy

Most TP53 Y220C Patients are KRAS WT

Overall, approximately 90% TP53 Y220C patients are KRAS WT



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Source: The prevalence of TP53 Y220C and KRAS across different diseases was analyzed by using the FoundationInsights® web-based software platform to query a pan-solid tumor cohort of ~367,651 US-based, consented-for-research patients in the FoundationCore® Database[4] that received FMI's Commercial Tissue or Heme assays between 1/1/12 and 12/31/2020

PC14586 May Benefit 14,000+ patients/yr with solid tumors in the US

Favorable Preliminary Efficacy Relative to Standard of Care (SOC) in 2L+

Tumor Type	TP53 Y220C Frequency (%)[1]	Patients (US) *TP53 Y220C / KRAS WT* [1,2]	SOC ORR (%) *all-comer, 2L+* [3-8]
All Solid Tumors	**~1**	**14,000+**	**<15**
Ovarian	2.9	1,200	12 (platinum-resistant)
Breast	1	2,800	12 (3L+, all subtypes)
Lung	1	1,800	<15 (NSCLC 3L) 7 (SCLC 2L)
Endometrial	1.1	700	<15 (3L)

TP53 MUTATED TUMORS
Have correlated with **poor clinical survival and** outcomes across multiple tumor types[9-12]

HIGH UNMET NEED
Phase 2 will enable the generation of additional patient data **across multiple tumor types** to support a **tumor agnostic approach**

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[1] Foundation Insights, Schram *et al.* AACR-NCI-EORTC Conference 2023 [2] Incidence based on Cancer Facts & Figures, 2021; Ovarian Cancer: DRG Epidemiology Report 2021 [3] Pujade-Lauraine, E. *et al.* 2014 [4] Cortes, J. *et al.* 2011 [5] Herbst, R.S. *et al.* 2016 [6] Fehrenbacher, L. et al. 2018 [7] O'Brien, M. *et al.* 2006 [8] Makker, V. *et al.* 2022 [9] Donehower *et al.* 2019 [10] Sadighi *et al.* 2017 [11] Li *et al* 2019 [12] Tuna *et al 2019*

PC14586 – Advancing to a Phase 2 Single Arm Pivotal Study

Single-agent clinical activity observed across multiple tumor types supporting continued tumor agnostic development

Acceptable safety profile with Grade 1 / 2 adverse events most frequently observed

Successful FDA EOP1 meeting completed in Q3 2023

Confirmed RP2D with a single-arm Phase 2 design to support a potential accelerated approval

PC14586: On a Path to NDA Submission in 2026

Key Upcoming Milestones

Program	Update	Timing
PC14586 Monotherapy	Initiate Phase 2 trial	2024
	Initial Phase 2 data	2025
	Planned NDA submission	2026
PC14586 + PD1 Combination Study	Initial Phase 1b data	2024
Cash Balance	As of June 30, 2023	$219mm

Q&A Session

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