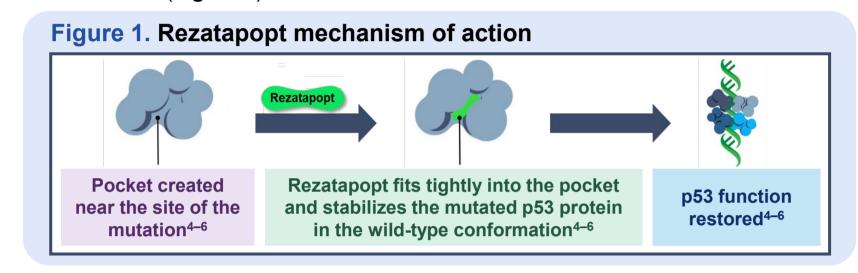
# Rezatapopt for locally advanced or metastatic solid tumors with a TP53 Y220C mutation: Initial analysis of the pivotal **PYNNACLE Phase 2 trial**

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#### BACKGROUND

- TP53, encoding the p53 protein, is the most frequently mutated gene across all cancers1
- TP53 mutations destabilize the p53 protein, causing loss of p53 tumor suppressor function<sup>2</sup>
- TP53 Y220C is a key hotspot TP53 missense mutation present in ~1% of all solid tumors<sup>3</sup>
- This mutation creates a pocket on the surface of the p53 protein, destabilizing the protein structure and causing loss of tumor suppressor function<sup>2,3</sup>
- Rezatapopt is an investigational, first-in-class, selective p53 reactivator specific to the TP53 Y220C mutation (Figure 1)4-6



• In the Phase 1 portion of the PYNNACLE clinical trial (NCT04585750), rezatapopt demonstrated efficacy and manageable safety in heavily pretreated patients with advanced or metastatic solid tumors harboring a TP53 Y220C mutation<sup>7–9</sup>

#### **OBJECTIVE**

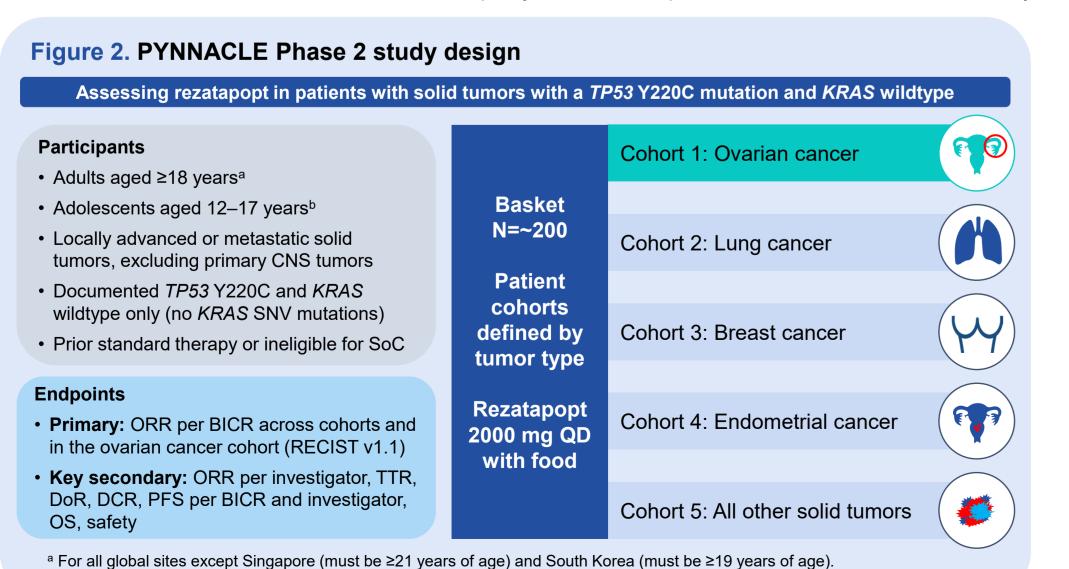
 Here, we present initial data from the pivotal PYNNACLE Phase 2 clinical trial assessing rezatapopt in patients with solid tumors harboring a TP53 Y220C mutation

#### **METHODS**

- PYNNACLE Phase 2 is a pivotal, global, single-arm, multi-cohort clinical trial assessing rezatapopt in patients with locally advanced or metastatic solid tumors with a TP53 Y220C mutation, excluding those with a *KRAS* single nucleotide variant (**Figure 2**)
- Patient cohorts are defined by tumor type
- Eligible patients receive oral rezatapopt 2000 mg QD with food for 21-day cycles

<sup>b</sup> If weighing ≥40 kg (in Australia, South Korea [12–18 years of age], and the USA only).

- The primary endpoint is ORR per BICR across cohorts and in the ovarian cancer cohort (RECIST v1.1)
- Secondary endpoints include investigator-assessed ORR, other efficacy endpoints, OS, PFS, and safety
- Patients are followed until death, loss to follow-up, 2 years after last patient discontinuation, or end of study



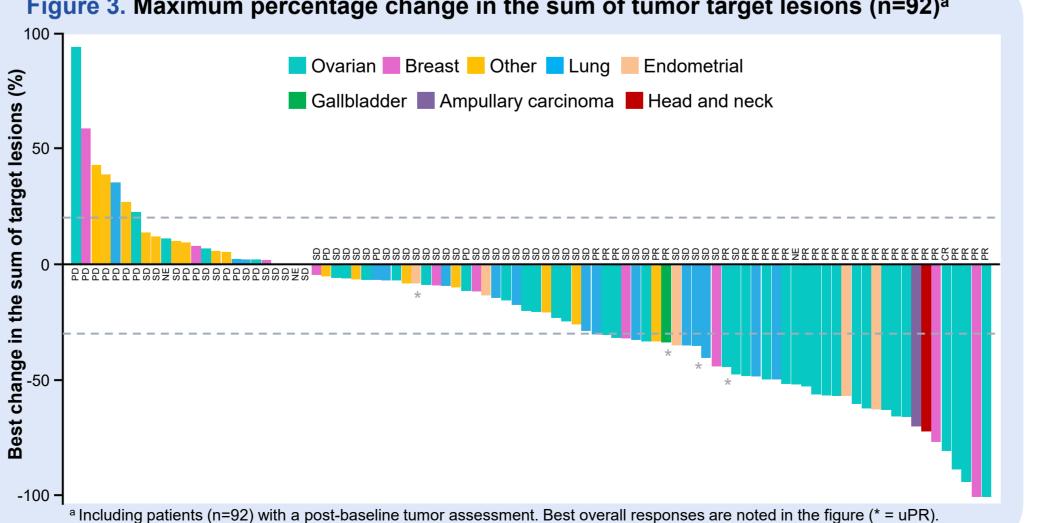
- In the Phase 2 PYNNACLE trial, by data cutoff (Sept 4, 2025), 112 patients had received rezatapopt
- Patients were heavily pretreated across a broad spectrum of tumors (Table 1)
- 64% of patients had received ≥3 prior lines of systemic therapy
- Of 51 patients with ovarian cancer, 49 (96%) had high-grade serous ovarian cancer, 1 (2%) had clear cell ovarian cancer, and 1 (2%) had sex cord-stromal ovarian cancer

#### Table 1. Patient baseline characteristics

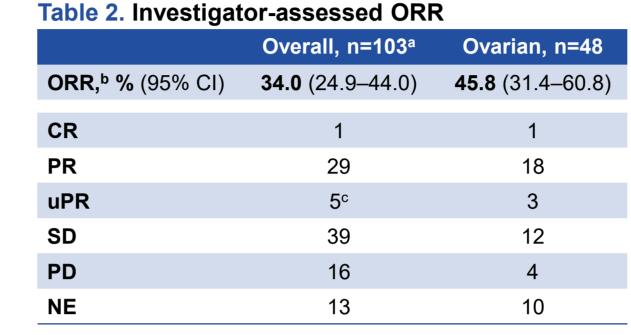
	Overall N=112	Ovarian n=51	Lung n=19	Breast n=17	Endometrial n=6	Other <sup>a</sup> n=19
Median age, years (min-max)	65 (37–91)	67 (46–91)	63 (48–81)	55 (37–77)	71 (65–73)	58 (45–85)
Sex, n (%) Female Male	82 (73) 30 (27)	51 (100) 0	4 (21) 15 (79)	17 (100) 0	6 (100) 0	4 (21) 15 (79)
Race, n (%) White Asian American Indian or Alaska Native Black or African American Other Not reported	n=108 81 (75) 14 (13) 1 (1) 1 (1) 1 (1) 10 (9)	n=51 40 (78) 5 (10) 0 0 0 6 (12)	n=19 13 (68) 3 (16) 0 0 1 (5) 2 (11)	n=14 10 (71) 3 (21) 0 0 0 1 (7)	n=5 4 (80) 1 (20) 0 0 0	n=19 14 (74) 2 (11) 1 (5) 1 (5) 0 1 (5)
ECOG status, n (%) 0 1	n=108 47 (44) 61 (56)	n=50 24 (48) 26 (52)	n=19 2 (11) 17 (89)	n=15 8 (53) 7 (47)	n=5 4 (80) 1 (20)	n=19 9 (47) 10 (53)
Prior lines of systemic therapy, n (%)	n=107	n=51	n=19	n=13	n=5	n=19
1 2 ≥3 Median (min–max)	9 (8) 29 (27) 69 (64) 3 (1–10)	1 (2.0) 11 (22) 39 (76) 4 (1–10)	5 (26) 7 (37) 7 (37) 2 (1–4)	0 2 (15) 11 (85) 4 (2–9)	2 (40) 0 3 (60) 4 (1–7)	1 (5) 9 (47) 9 (47) 2 (1–7)

- <sup>a</sup> Includes colorectal cancer (n=6), ampullary carcinoma (n=2), gastric cancer (n=2), sarcoma (n=2), gallbladder cancer (n=1), head and neck cancer (n=1), small intestine cancer (n=1), HCC (n=1), pancreatic cancer (n=1), thymic carcinoma (n=1), and esophagus carcinoma (n=1)
- Reductions in tumor target lesions (Figure 3) and confirmed responses (Table 2) were seen across the different tumor types; among efficacy-evaluable patients:
- Across all cohorts (n=103), investigator-assessed ORR was 34.0% In the ovarian cancer cohort (n=48), investigator-assessed ORR was 45.8%
- Rapid and durable responses were observed (Figure 4)
- TRAEs were mostly Grade 1/2; no Grade 5 TRAEs were observed (**Table 3**)
- Nausea, fatigue, blood creatinine increased, and ALT increased were the most frequent
- Laboratory abnormalities were manageable / monitorable; most cases were transient and reversible
- Four patients (4%) discontinued treatment due to TRAEs
- Administration of rezatapopt with food decreased incidence of gastrointestinal TRAEs vs Phase 1<sup>8,10</sup>

#### Figure 3. Maximum percentage change in the sum of tumor target lesions (n=92)<sup>a</sup>



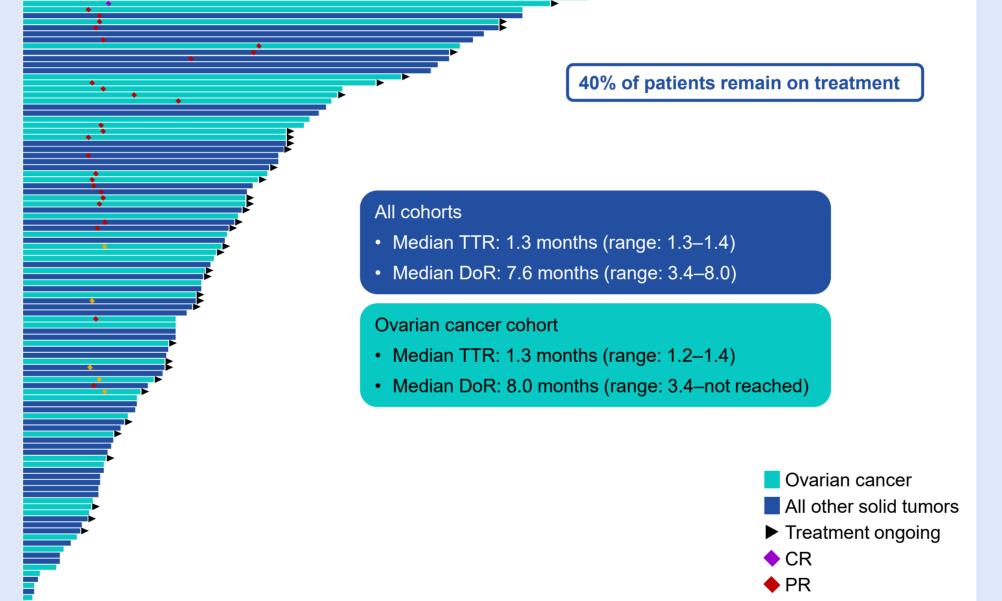
At the time of data extraction, an additional uPR was recorded without tumor measurements reported as of yet.



	ORR, <sup>b</sup> n (%)			
<b>Lung</b> , n=19	4 (21.1)			
Breast, n=12	2 (16.7)			
Endometrial, n=5	3 (60.0)			
Other, n=19	4 (21.1)			
<sup>a</sup> Efficacy-evaluable population includes all enrolled				

patients with a first post-baseline tumor assessment and patients who discontinued early. b ORR is calculated using CR, PR, and uPR. c Four uPRs were confirmed and one uPR remains on treatment after the





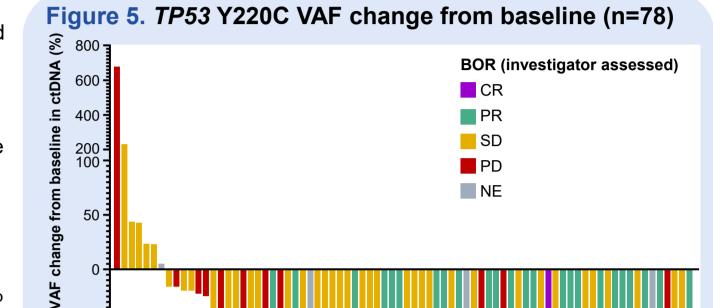
RESULTS

#### **Table 3. TRAEs in ≥5% of patients**

	Patricina					
Patients, n (%)	All patients	Max CTCAE toxicity grade				
	N=112	1	2	3	4	
At least one TRAE	86 (77)	18 (16)	37 (33)	26 (23)	5 (4)	
Nausea	38 (34)	24 (21)	13 (12)	1 (1)	0	
Fatigue	26 (23)	11 (10)	13 (12)	2 (2)	0	
Blood creatinine increased	22 (20)	5 (4)	16 (14)	1 (1)	0	
ALT increased	20 (18)	8 (7)	5 (4)	6 (5)	1 (1)	
AST increased	16 (14)	6 (5)	3 (3)	7 (6)	0	
Anemia	16 (14)	5 (4)	6 (5)	5 (4)	0	
Decreased appetite	14 (13)	11 (10)	3 (3)	0	0	
Vomiting	13 (12)	7 (6)	6 (5)	0	0	
Diarrhea	10 (9)	8 (7)	1 (1)	1 (1)	0	
Platelet count decreased	8 (7)	3 (3)	1 (1)	2 (2)	2 (2)	
Pruritus	8 (7)	6 (5)	2 (2)	0	0	
Constipation	7 (6)	6 (5)	1 (1)	0	0	
Dry mouth	7 (6)	7 (6)	Ô	0	0	
Rash maculo-papular	7 (6)	1 (1)	2 (2)	4 (4)	0	
Asthenia	6 (5)	2 (2)	4 (4)	0	0	

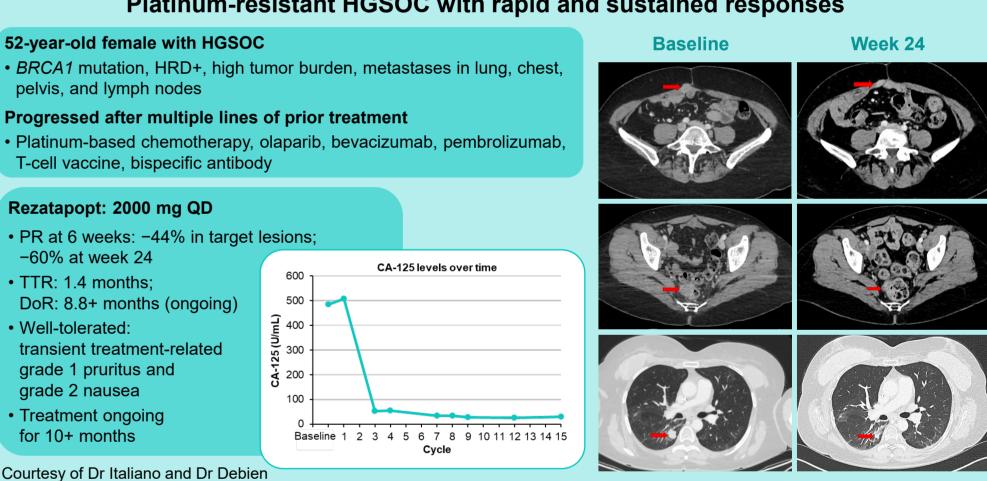
**Months** 

- On-target activity was supported by decreases in ctDNA TP53 Y220C VAF (Figure 5)
- In total, 78 patients had ctDNA TP53 Y220C VAF data available at baseline and on treatment (3–6 weeks)
- Of 78 patients, 71 (91%) had a reduction in TP53 Y220C VAF
- 73% had a reduction of ≥50%
- All patients experiencing a response had a reduction in *TP53* Y220C VAF



3-6 weeks post-treatment

#### Platinum-resistant HGSOC with rapid and sustained responses



#### CONCLUSIONS

- In this initial analysis of the pivotal PYNNACLE Phase 2 clinical trial, rezatapopt showed single-agent efficacy and manageable safety
- Clinical efficacy was achieved in heavily pretreated patients across multiple tumor types
- Rezatapopt offers a promising targeted treatment for solid tumors with a TP53 Y220C mutation

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Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BICR, blinded independent central review; BOR, best overall response; CI, confidence interval; CNS, central nervous system; CR, complete response; ctDNA, circulating tumor DNA; CTCAE, Common Terminology Criteria for Adverse Events; DCR, disease control rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; HCC, hepatocellular carcinoma; HGSOC, high-grade serous ovarian cancer; HRD, homologous recombination deficiency; NE, non-evaluable; ORR, overall response rate; OS, overall survival;

RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease; SNV, single nucleotide variant; SoC, standard of care;

TRAE, treatment-related adverse event; TTR, time to response; uPR, unconfirmed partial response; VAF, variant allele frequency.

research funding/grant, attended advisory boards, and provided a speaker role.

PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once daily;

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