

Rezatopopt, a selective p53 reactivator, in advanced or metastatic solid tumours with a TP53 Y220C mutation: Interim efficacy results from patients with ovarian cancer in the Phase 2 PYNNALE trial

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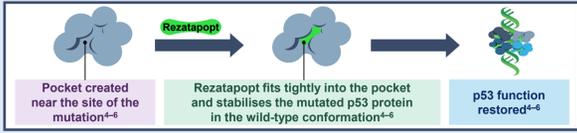
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BACKGROUND

- The *TP53* gene, encoding the p53 protein, is the most frequently mutated gene across all cancers¹
- TP53* mutations destabilise the p53 protein, causing loss of p53 tumour suppressor function²
- TP53* Y220C is a key hotspot *TP53* missense mutation present in ~1% of all solid tumours, ~3% of ovarian cancers, and >3% of high-grade serous ovarian cancers (HGSOC)³
 - This mutation creates a pocket on the surface of the p53 protein, destabilising the protein structure and causing loss of tumour suppressor function^{2,3}
- Rezatopt is an investigational, first-in-class, selective p53 reactivator specific to the *TP53* Y220C mutation (Figure 1)⁴⁻⁶
 - Rezatopt stabilises the mutated Y220C-p53 protein in the wild-type p53 conformation by binding to the pocket created by the tyrosine-to-cysteine substitution in the p53 protein; this restores p53 function

Figure 1. Rezatopt mechanism of action



- In the Phase 1 portion of the PYNNALE clinical trial (NCT04585750), rezatopt demonstrated efficacy and manageable safety in heavily pretreated patients with advanced or metastatic solid tumours harbouring a *TP53* Y220C mutation⁷⁻⁹

OBJECTIVE

- Here we present initial data from patients with ovarian cancer harbouring a *TP53* Y220C mutation treated with rezatopt in the pivotal PYNNALE Phase 2 clinical trial

METHODS

- PYNNALE Phase 2 is a pivotal, global, single-arm, multi-cohort clinical trial assessing rezatopt in patients with locally advanced or metastatic solid tumours with a *TP53* Y220C mutation (Figure 2)
- Eligible patients receive oral rezatopt 2000 mg QD with food for 21-day cycles
- The primary endpoint is ORR per BICR across all 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

Figure 2. PYNNALE Phase 2 study design

Assessing rezatopt in patients with solid tumours with a *TP53* Y220C mutation and *KRAS* wild-type

Participants

- Adults aged ≥18 years^a
- Adolescents aged 12–17 years^b
- Locally advanced or metastatic solid tumours, excluding primary CNS tumours
- Documented somatic *TP53* Y220C mutation and *KRAS* wild-type only (no *KRAS* SNV mutations) – test results confirmed from tissue analysis
- Prior standard therapy or ineligible for SoC

Endpoints

- Primary:** ORR per BICR across cohorts and in the ovarian cancer cohort (RECIST v1.1)
- Key secondary:** ORR per investigator, TTR, DoR, DCR, PFS per BICR and investigator, OS, safety

Basket N=200	Cohort 1: Ovarian cancer (platinum resistant/refractory)
Patient cohorts defined by tumour type	Cohort 2: Lung cancer
Rezatopt 2000 mg QD with food	Cohort 3: Breast cancer
	Cohort 4: Endometrial cancer
	Cohort 5: All other solid tumours

^a For all global sites except Singapore (must be ≥21 years of age) and the Republic of Korea (must be ≥19 years of age).
^b If weighing ≥40 kg (in Australia, the Republic of Korea [12–18 years of age] and the USA only).

RESULTS

- In the Phase 2 PYNNALE trial, by data cut-off (4 Sept 2025), 112 patients with solid tumours had received rezatopt including 51 patients with ovarian cancer (Table 1)
- Of the 51 patients with ovarian cancer, 49 (96%) had HGSOC, one (2%) had clear cell ovarian cancer, and one (2%) had sex cord-stromal ovarian cancer

Table 1. Patient demographics and baseline characteristics

	Ovarian cancer cohort, n=51
Median age, years (min–max)	67 (46–91)
ECOG status, n (%)	n=50 0 / 1 24 (48) / 26 (52)
Prior lines of systemic therapy, n (%)	
1 / 2	1 (2) / 11 (22)
≥3	39 (77)
Median (min–max)	4 (1–10)
Prior therapies, n (%)	
Bevacizumab	40 (78)
Platinum status, n (%)	
Sensitive	3 (6)
Resistant	30 (59)
Refractory	18 (35)
Primary platinum refractory	7 (14)
FRα / FOLR1 status, ^a n (%)	n=44
Positive / Negative	21 (48) / 23 (52)
Germline <i>TP53</i> Y220C mutation, n (%)	n=49
Yes / No	0 / 49 (100)
<i>BRCA</i> status, n (%)	n=48
Somatic <i>BRCA</i> 1/2 mutation	6 (13)
HRD status, ^a n (%)	n=41
Positive / Negative	15 (37) / 26 (63)

^a Status was reported post data cut-off.

- Reductions in tumour target lesions (Figure 3) and confirmed responses (Table 2) were seen amongst the efficacy-evaluable patients with ovarian cancer (n=48)
 - Investigator-assessed ORR (RECIST v1.1) was 46%
- Rapid and durable responses were observed amongst patients with ovarian cancer (Figure 4)
- Reduction in CA-125 levels were reported in most patients with available data (Figure 5)
- Across all patient cohorts (N=112), TRAEs were mostly Grade 1/2; no Grade 5 TRAEs were observed (Table 3)
 - Laboratory abnormalities were manageable / monitorable; most cases were transient and reversible
 - A similar safety profile was observed in patients with ovarian cancer
 - Four patients (4%) discontinued treatment due to TRAEs, including one patient with ovarian cancer who discontinued due to blood creatinine increase

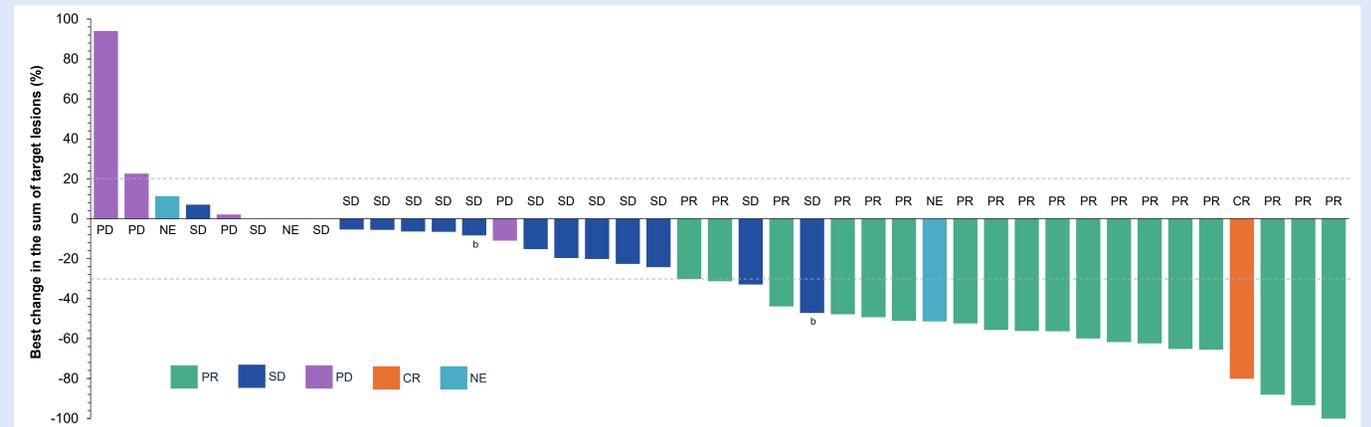
RESULTS

Table 2. Investigator-assessed ORR in efficacy-evaluable patients with ovarian cancer^a

	Total ovarian cancer cohort n=48	Platinum resistant n=27	Platinum refractory ^b n=18	Prior bevacizumab ^c n=37	Prior PARPI n=29	FRα positive ^d n=21	FRα negative ^e n=20
ORR, ^f % (95% CI)	46 ^g (31–61)	48 (29–68)	44 ^h (22–69)	46 (30–63)	52 (33–71)	48 (26–70)	40 (19–64)
BOR, n (%)							
CR	1 (2)	0 (0)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)
PR	18 (38)	12 (44)	6 (33)	14 (38)	13 (45)	9 (43)	6 (30)
uPR	3 (6)	1 (4)	2 (11)	2 (5)	1 (3)	1 (5)	2 (10)
SD	14 (29)	8 (30)	5 (28)	10 (27)	7 (24)	9 (43)	4 (20)
PD	4 (8)	2 (7)	2 (11)	4 (11)	2 (7)	1 (5)	2 (10)
NE	8 (17)	4 (15)	3 (17)	6 (16)	5 (17)	1 (5)	6 (30)

Data cut-off: 4 Sept 2025.
^a Patients with the opportunity to reach first post-baseline scan. Patients discontinuing before the first post-baseline scan are included in the efficacy-evaluable population.
^b Platinum refractory: relapse during platinum therapy or within 1 month of the last dose of a platinum agent.
^c Prior bevacizumab unless medically contraindicated.
^d FRα positive: FRα expression in ≥75% of viable tumour cells.
^e FRα negative: FRα expression in <75% of viable tumour cells.
^f ORR is calculated from confirmed CR, confirmed PR, and uPR.
^g Since the 4 Sept 2025 data cut-off, a total of 24/48 patients (ORR: 50%) experienced a response, which includes one confirmed CR, 22 confirmed PRs and one uPR (pending confirmation).
^h In the primary platinum-refractory population (n=7), three patients experienced a confirmed PR as of 4 Sept 2025.

Figure 3. Target lesion reduction in patients with ovarian cancer (n=41)^a



Data cut-off: 4 Sept 2025. Dotted line shows RECIST v1.1 criteria for PD (20%) and PR (-30%).
^a Includes patients with ovarian cancer and a post-baseline target tumour measurement (n=41). Best overall responses are noted in the figure.
^b uPR. An additional patient had an uPR at the time of data cut-off, but this was not reported in the electronic data capture. As of 4 Sept 2025 data cut-off, three patients had uPRs.

Figure 4. Overall duration of treatment (n=51)

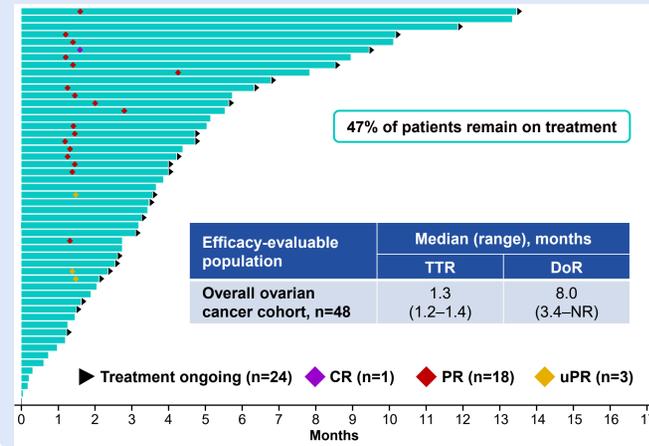
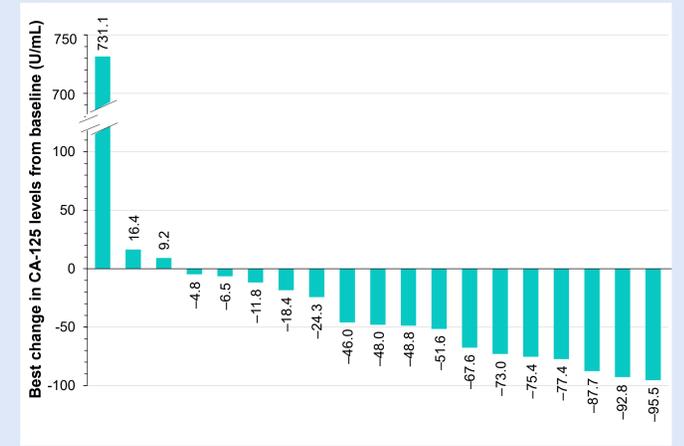


Figure 5. Reduction in CA-125 levels (n=19)



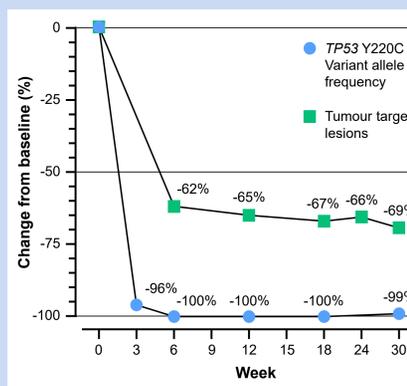
Case study

- 59-year-old white woman with platinum-resistant HGSOC
- FRα positive, MSS, high tumour burden of metastases in liver, peritoneum, pleural cavity and spleen
- Other known functional co-alterations: *BRD4*, *KDM6A*, *MYC*, *NOTCH3*, *CHECK2*, *CREBBP*, *SMARCA4*
- Heavily pretreated with three lines of prior therapy in the advanced setting and no prior responses:
 - Carboplatin / paclitaxel / bevacizumab
 - Carboplatin / caelyx → niraparib
 - Mirvetuximab soravtansine

Treatment with rezatopt

- Started on 2000 mg QD
- Treatment ongoing for 9.8 months+
- Well tolerated with transient treatment-related Grade 1 hyperlipasaemia
 - No SAEs, dose reductions or treatment interruptions
- Rapid and sustained PR

Radiographic tumour shrinkage and TP53 Y220C variant allele frequency dynamics



Response to rezatopt

- Week 6 target tumour reduction: 62%
- Week 30 (nadir) target tumour reduction: 69%
- DoR: 8.6+ months
- TTR: 1.3 months

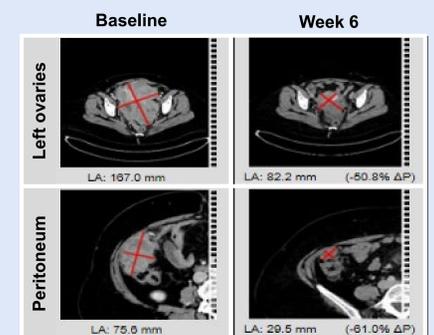


Table 3. TRAEs in >5% of patients

Preferred term	Total safety population (N=112) Patients, n (%)	Maximum CTCAE grade ^a			
		Any grade	1	2	3
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
Anaemia	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
Diarrhoea	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)	0	0	0
Rash maculo-papular	7 (6)	1 (1)	2 (2)	4 (4)	0
Asthenia	6 (5)	2 (2)	4 (4)	0	0

^a No Grade 5 TRAEs were observed.

CONCLUSIONS

- In this interim analysis of the pivotal PYNNALE Phase 2 clinical trial, rezatopt showed clinically meaningful efficacy and manageable safety in heavily pretreated patients with *TP53* Y220C-mutated advanced ovarian cancer
- Rezatopt offers a promising orally administered, targeted monotherapy for patients with ovarian cancer harbouring the *TP53* Y220C mutation

References: 1. Baugh EH, et al. *Cell Death Differ*. 2018;25:154–160; 2. Hassan O, et al. *Nat Rev Drug Discov*. 2023;22:127–144; 3. FoundationInsights™. A proprietary database used under license with review and approval from Foundation Medicine™. Available at: <https://www.foundationmedicine.com>; 4. PYNNALE Study. Available at: <https://www.pynnalestudy.com>; 5. Vu BT, et al. *ACS Med Chem Lett*. 2024;16:34–38; 6. Purohit-Kumar AN, et al. *Cancer Discov*. 2025;15:1159–1179; 7. Schram AM, et al. AACR-NCI-EORTC International Conference. 2023. Oral presentation (abstract LBA25); 8. Schram AM, et al. AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference. 2025. Oral presentation (abstract LB-0004); 9. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/study/NCT04585750>. Accessed January 2026.

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Abbreviations: AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BICR, blinded independent central review; BOR, best overall response; CA-125, cancer antigen 125; CI, confidence interval; CNS, central nervous system; CR, complete response; CTCAE, Common Terminology Criteria for Adverse Events; DCR, disease control rate; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; FOLR1, folate receptor 1; FRα, folate receptor alpha; HGSOC, high-grade serous ovarian cancer; HRD, homologous recombination deficiency; KRAS, Kirsten rat sarcoma virus; LA, longest axis; MSS, microsatellite stable; NE, non-evaluable; NR, not reached; ORR, overall response rate; OS, overall survival; PARPI, poly (ADP-ribose) polymerase inhibitor; PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once daily; RECIST, Response Evaluation Criteria in Solid Tumours; SAE, serious adverse event; SD, stable disease; SNV, single nucleotide variant; SoC, standard of care; TRAE, treatment-related adverse event; TTR, time to response; uPR, unconfirmed partial response.

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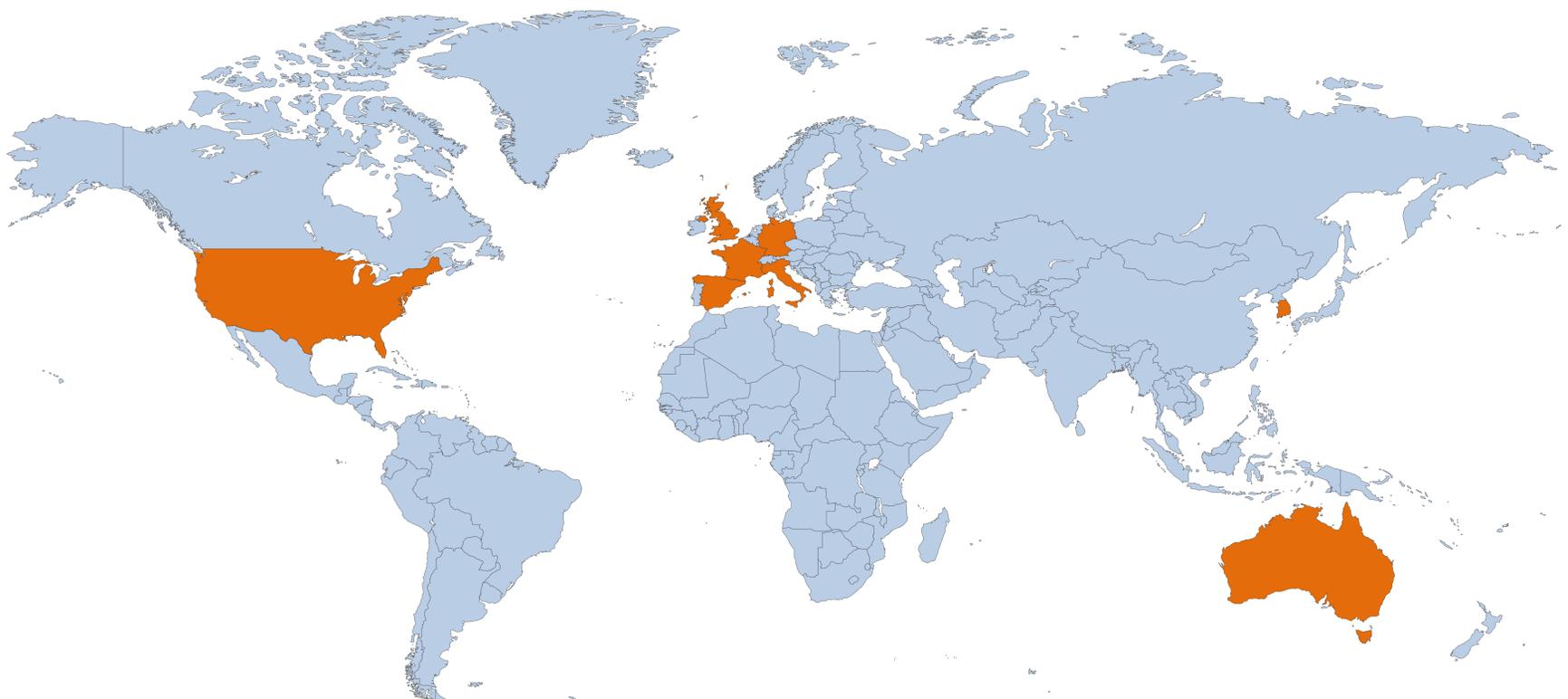
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- Local PI (institutional, financial interest): Acerta Pharma (local PI), ADC Therapeutics (local PI), Arcus Bioscience, Array Biopharma, Artios Pharma, Astellas, Astex, AstraZeneca, Basilea Pharmaceutica, Bayer, BeiGene, Bicycle Therapeutics, BioNTech SE, BluePrint, BMS, Boehringer Ingelheim, Calithera, Carrick Therapeutics, Casi Therapeutics, Clovis Oncology, Crescendo Biologics, CytomX Therapeutics, Daiichi Sankyo, Deciphera, EliLilly, Eclipsees, Exelixis, Fore Biotherapeutics, G1 Therapeutics, Genentech, Inc., Gilead Science, GSK plc, H3 Biomedicine, HUTCHMED, Immunocore, Immunomedics, Incyte, Instil Bio, Iovance, Janssen, Jiangsu Hengrui Medicine, Kronos Bio, Lupin Limited, Macrogenics, Menarini, Merck KGaA, Mereo Biopharma, Merus, Millenium Pharmaceuticals, MSD, Nerviano Medica, Nurix Therapeutics, Oncologie, Oxford Vacmedix, Pfizer, Plexxikon, PMV Pharmaceuticals, QED Therapeutics, Relay Therapeutics, Ribon Therapeutics, Roche, Sapience Pharma, Seagen, Servier, Synthon Biopharmaceuticals, Takeda, Tesaro, Turning Point Therapeutics
- Non-financial interests: ASCO (member)

Alastair Greystoke

- Consultancy and speaker fees: AstraZeneca, Amgen, Boehringer Ingelheim, BMS, Janssen/Johnson & Johnson, MSD, Novartis, Pfizer, Eli Lilly, Takeda, Roche
- Research funding: AstraZeneca
- Other role: Clinical Director (Cancer), North East England Hull and Yorkshire Genomic Medicine Service

Peter Grimison

- None

Kim LeDuke

- Employee: PMV Pharmaceuticals with stock options

Anita Schmid

- Employee: PMV Pharmaceuticals with stock options

Deepika Jalota

- Employee: PMV Pharmaceuticals with stock options

Marc Fellous

- Employee: PMV Pharmaceuticals with stock options

Alison M. Schram

- Advisory board: PMV Pharmaceuticals, Blueprint Medicines, Mersana, Endeavor Biomedicines, Revolution Medicine, Day One Biopharmaceuticals, Transcode Therapeutics and Relay Therapeutics
- Advisory role: Merus, Pfizer, PMV Pharmaceuticals, Schrodinger, Repare Therapeutics, Partner Therapeutics and Relay Therapeutics
- Research funding to institution: ArQule, AstraZeneca, BeiGene, Springworks, Black Diamond, Boehringer Ingelheim, Elevation Oncology, Kura Oncology, Eli Lilly, Merus, Northern Biologics, Pfizer, PMV Pharmaceuticals, Relay Therapeutics, Repare Therapeutics, Revolution Medicine and Surface Oncology