Incyte at ESMO 2024

September 14, 2024

Welcome & Introduction

Pablo Cagnoni
President, Head of Research & Development

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this presentation contain predictions, estimates and other forward-looking statements, including any discussion of the following: opportunities for near-term and future product and portfolio growth; the potential and progress of our pipeline and our ability to provide new treatment options for patients, including expectations for retifanlimab, tafasitamab, and our CDK2 inhibitor (INCB123667); ongoing clinical trials and clinical trials to be initiated; expectations regarding data flow/readouts; our expectations regarding regulatory filings, potential regulatory approvals and potential product launches; and our expectations regarding 2024 newsflow items.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA, EMA, and other regulatory agencies; Incyte's dependence on its relationships with and changes in the plans of its collaboration partners; the efficacy or safety of Incyte's products and the products of Incyte's collaboration partners; the acceptance of Incyte's products and the products of Incyte's collaboration partners in the marketplace; market competition; unexpected variations in the demand for Incyte's products and the products of Incyte's collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for Incyte's products and the products of Incyte's collaboration partners; sales, marketing, manufacturing and distribution requirements, including Incyte's and its collaboration partners' ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional products that become approved; greater than expected expenses, including expenses relating to litigation or strategic activities; variations in foreign currency exchange rates; and other risks detailed in Incyte's reports filed with the Securities and Exchange Commission, including its annual report on form 10-K for the year ended December 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

Incyte at ESMO 2024 Agenda

7:00-8:00 pm (CEST)	**Pablo J. Cagnoni, MD** President, Head of Research & Development	**Welcome & introduction**
	Sheela Rao, MBBS FRCP MD Medical Oncologist, Royal Marsden Hospital	**Phase 3 retifanlimab (Zynyz®) results in squamous cell carcinoma of the anal canal (SCAC)**
	Rebecca Kristeleit, BSc MBChB PhD FRCP FRSB Consultant Medical Oncologist GSTT and Adjunct Reader (Associate Professor) KCL, London	**Gynecologic Cancers**
	Ekaterine Asatiani, MD Group VP & Head of Early Development	**Phase 1 data from potential first-in-class CDK2 inhibitor in patients with CCNE1 ovarian and other advanced cancers**
	Steven Stein, MD Chief Medical Officer	**CDK2 inhibitor:** Development plan, unmet need & target patient population
	Pablo J. Cagnoni, MD President, Head of Research & Development	**Closing Remarks**
8:00-8:30 pm (CEST)	**Q&A**	

Near-Term Product Growth Opportunities and Differentiated Pipeline with First-in-Class and/or Best-in-Class Potential

Near-Term Launches and Filings

Axatilimab (anti-CSF1R)
Approved on August 14, 2024 in 3L chronic GVHD and Phase 3 1L trial planned in **2H'24**

Tafasitamab
sBLA filing in FL and MZL by **year-end 2024** and Phase 3 results in DLBCL in **2025**

Retifanlimab
sBLA filing in squamous cell carcinoma of the anal canal by **year-end 2024**

Opzelura
sNDA filing in pediatric atopic dermatitis (≥2 to <12 yrs) **by year end 2024**

IAI / Dermatology

Povorcitinib (JAK1i)
Pivotal trial data in hidradenitis suppurativa (moderate/severe) expected **1Q'25**

MRGPRX2 antagonist
Clinical proof-of-concept data in chronic urticaria, chronic inducible urticaria and atopic dermatitis expected **1Q'25**

MRGPRX4 antagonist
Clinical proof-of-concept in cholestatic pruritus expected **1Q'25**

Anti-CD122 (IL-15Rβ)
Phase 1 data expected in **2025**

Oncology

CDK2i
Phase 3 trial in ovarian cancer to start in **2025**

TGFβR2 x PD-1
Clinical proof-of-concept data in solid tumors expected in **2025**

KRASG12Di
Clinical proof concept data in solid tumors expected in **2025**

MPN / GVHD

Ruxolitinib XR (QD)
Pivotal data from BE study available **1H'25**

BETi
Phase 1 data and Phase 3 plans in myelofibrosis (MF) expected in **2H'24**

Zilurgisertib (ALK2i)
Phase 1 data in MF-associated anemia expected in **2H'24**

mCALR
Clinical proof-of-concept data in MF or essential thrombocythemia expected **2025**

JAK2V617Fi
Clinical proof-of-concept data in MF expected in **2025**

Incyte

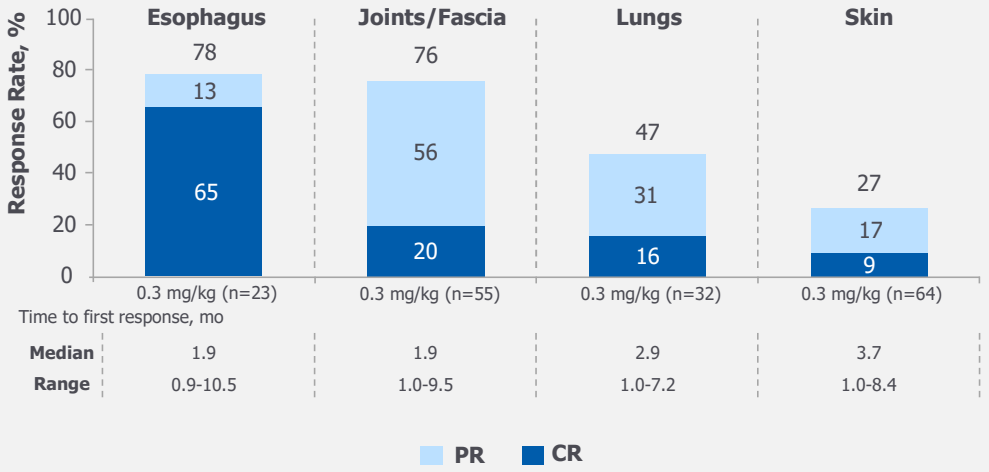
GVHD = Graft versus Host Disease

Niktimvo™ (Axatilimab-csfr) Approved for Chronic GVHD

Differentiated Mechanism of Action by targeting CSF-1R

- **The Phase 2 study (AGAVE-201) met the primary efficacy endpoint across all cohorts**
  - 75% ORR in the axatilimab 0.3 mg/kg Q2W cohort
- Responses were durable and included a reduction in symptom burden
- Well tolerated with most common AEs consistent with on target effects of CSF-1R inhibition

Responses in Fibrosis-Dominant Organs: esophagus, joints/fascia, lung and skin



CR, complete response; PR, partial response.
Differences in percentage totals are due to rounding. Denominator is the number of patients with baseline organ involvement.
* Assessed by NIH 2014 criteria.
Axatilimab for Chronic Graft-Versus-Host Disease: Responses in Fibrosis-Dominant Organs in AGAVE-201. Presented at the 50th Annual Meeting of the EBMT; 14–17 April 2024; Glasgow, Scotland

Positive Pivotal Phase 3 Trial for Tafasitamab for Patients with Follicular Lymphoma (FL)/Marginal Zone Lymphoma (MZL)

Disease Characteristics

- FL most common indolent form of B-cell NHL
- 17,000 new cases of relapsed or refractory FL annually
- Refractory patients or those whose disease progresses <24 months from diagnosis

Current SOC

- Treatment goal is to maintain quality of life and extend disease free survival
- Rituximab and other CD20-based regimens + chemo represent current standard of care

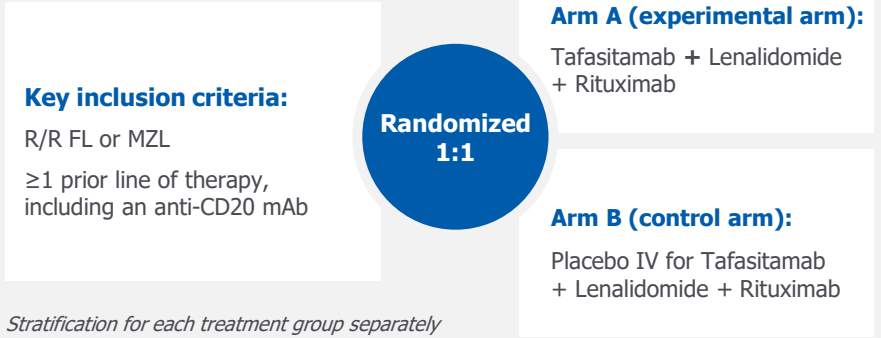
Next Steps

Full data to be presented at an upcoming scientific meeting

sBLA filing by year-end 2024

Future

- Statistically significant and clinically meaningful improvement in progression free survival (PFS)
- No new safety signals observed



Stratification for each treatment group separately

Retifanlimab: A Practice-Changing Treatment for SCAC

Featured during the Presidential Symposium at ESMO 2024

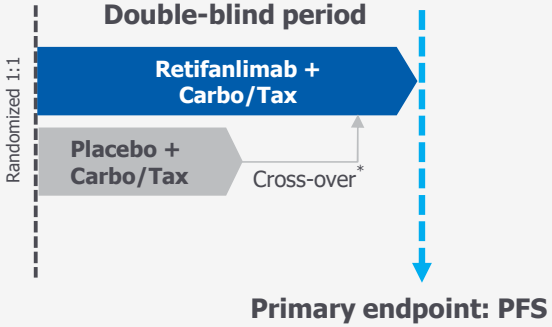
Squamous Cell Carcinoma of the Anal Canal

- Statistically significant and clinically meaningful improvement in progression free survival (PFS)
- No new safety signals observed

POD1UM-303
Key inclusion criteria:

Locally recurrent or metastatic
No prior chemo except radiosensitizing treatment and adjuvant > 6 months

HIV-positive included



* Following ICR-confirmed PD

First potential approved anti PD-1/PD-L1 inhibitor for first line treatment of locally recurrent or metastatic SCAC

Next Steps

sBLA filing by **year-end 2024**

CDK2 Inhibitor in Ovarian Cancer

Opportunity to be first-in-class

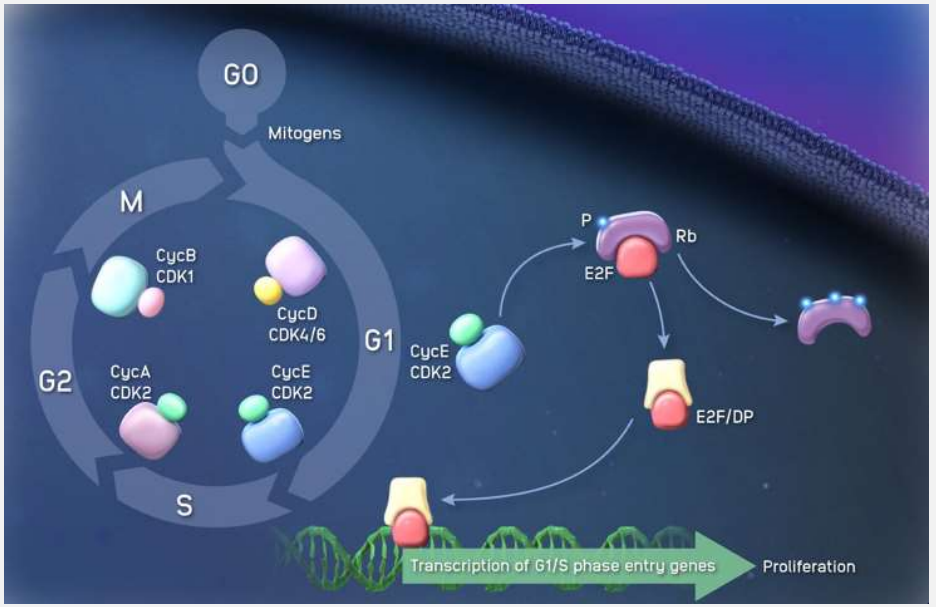
Potential to enhance outcomes and establish INCB123667 as **foundational treatment** for ovarian cancer

- Meaningful **tumor shrinkage** observed including **complete** and **partial responses** across multiple tumor types including ovarian cancer (CCNE1) patients
- AE profile aligns with CDK2 mechanism of action
- Additional opportunity in breast cancer

Next Steps

Pivotal trial in ovarian cancer
to **start in 2025**

CCNE1 amplification and cyclin E overexpression in cancer cells is predictive of CDK2 dependency



Sheela Rao, MBBS FRCP MD

Medical Oncologist specializing in gastrointestinal cancers and cancers of unknown primary within the Gastrointestinal Unit at the Royal Marsden Hospital, London, UK

Reader at The Institute of Cancer Research

Member of The International Rare Cancers Initiative - Anal Cancer

Rebecca Kristeleit, BSc MBChB PhD FRCP FRSB

Dr. Rebecca Kristeleit is Clinical Senior Lecturer and Consultant Medical Oncologist at University College London and University College London Hospitals NHS Foundation Trust

Dr. Kristeleit specializes in the treatment of gynaecological cancers, including cervical, endometrial, and ovarian cancer

Member of the Target Ovarian Cancer Scientific Advisory Board, the Oncology and Haematology Expert Advisory Group for the Commission on Human Medicines, and the ESMO Faculty from 2021 to 2025

Squamous Cell Carcinoma of the Anal Canal (SCAC)

Sheela Rao, MBBS, FRCP, MD
Medical Oncologist, Royal Marsden Hospital

Background

- SCAC is a neglected orphan disease; incidence is increasing ~3% per year mainly due to endemic HPV, the causative agent for most anogenital cancers[1-4]
  - HIV is an important amplifier of SCAC; people with HIV are 25- to 35-fold more likely to develop SCAC[5,6]
- Relapse after primary therapy (radiotherapy plus radiosensitiser) is common; standard of care treatment has not changed since the early 1980s[7]
  - Prognosis is poor for patients who relapse or with de novo metastatic disease, and quality of life is greatly diminished[8]
- The InterAACT phase 2 study established carboplatin–paclitaxel as 1L treatment. Responses were meaningful and durable, but overall PFS (8 months) and OS (20 months) remained short[9]
- HPV-driven malignancy is an attractive target for immunotherapy approaches
  - Improved survival in head and neck squamous cell carcinoma[10] and cervical cancer[11] serve as proof of concept for SCAC

1. Gondal TA, et al. *Curr Oncol*. 2023;30:3232-3250. **2.** Islami F, et al. *Int J Epidemiol*. 2017;46:924-938. **3.** Giuliano AR, et al. *Int J Cancer*. 2015;136:2752-2760. **4.** Morris V, Eng C. *J Gastrointest Oncol*. 2016;7:721-726. **5.** Wang C-CJ, et al. *Surg Oncol Clin N Am*. 2017;26:17-31. **6.** NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV. Version 1.2021. 2021. **7.** Pessia B, et al. *Ann Med Surg (Lond)*. 2020;55:36-46. **8.** Rao S, et al. *Ann Oncol*. 2021;32:1087-1100. **9.** Rao S, et al. *J Clin Oncol*. 2020;38:2510-2518. **10.** Ferris RL, et al. *N Engl J Med*. 2016;375:1856-1867. **11.** Colombo N, et al. *N Engl J Med*. 2021;385:1856-1867. **12.** Rao S, et al. *ESMO Open*. 2022;7:100529.

1L, first-line; HIV, human immunodeficiency virus; HPV, human papillomavirus; OS, overall survival; PD-1, programmed cell death protein 1; PFS, progression-free survival; SCAC, squamous cancer of the anal canal.

Epidemiology of Anal Cancer

Squamous Cell Anal Cancer (SCAC) accounts for ~ 85-90% of anal cancers[5,6]

[a] Age-adjusted/standardized. [b] 2017-2021. [c] 2024. [d] 2012-2021. [e] 2022. [f] 2018-2022. [g] 2013-2022.

1. National Cancer Institute. https://seer.cancer.gov/statfacts/html/anus.html and https://seer.cancer.gov/ 2. European Cancer Information System. https://ecis.jrc.ec.europa.eu/index.php 3. Deshmukh AA, et al. *J Natl Cancer Inst.* 2020;112:829-838. 4. Mignozzi S, et al. *Eur J Cancer Prev.* 2024;33:77-86. 5. Young AN, et al. *Surg Clin North Am.* 2020;100:629-634. 6. Gondal TA, et al. *Curr Oncol.* 2023;30:3232-3250

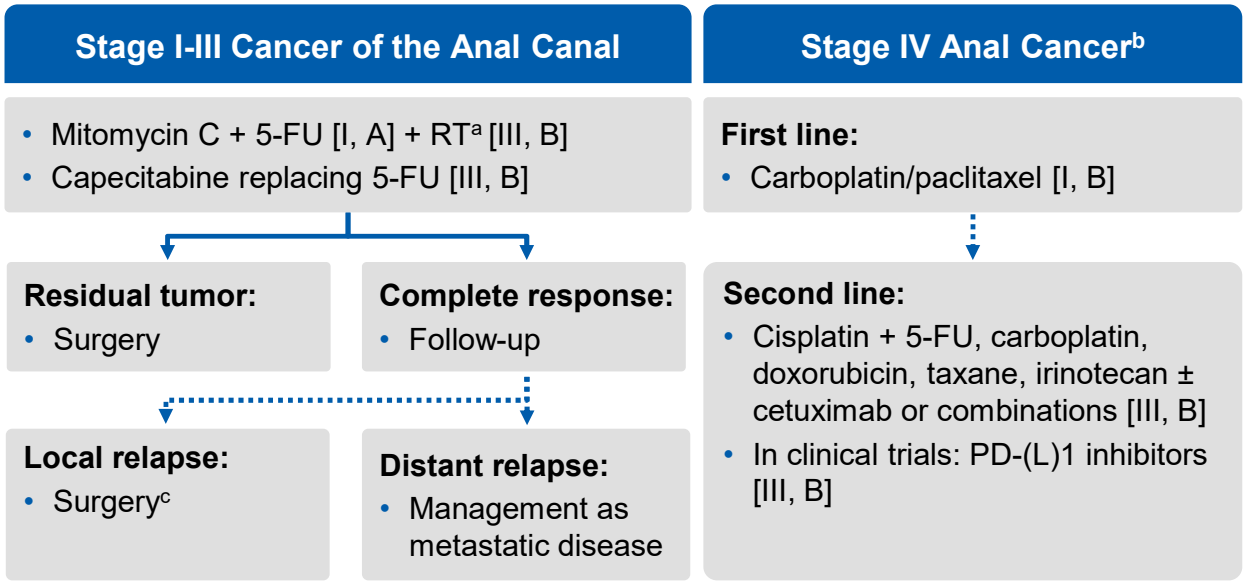
Current Treatment Landscape- U.S.

	Locoregional Disease[b]	Metastatic Disease
Primary Treatment[a]	• 5-FU/mitomycin + RT • Capecitabine/mitomycin + RT • 5-FU/cisplatin + RT (category 2B)	**Preferred regimen** • Carboplatin + paclitaxel **Other recommended regimens** • FOLFCIS, mFOLFOX6[c], 5-FU + cisplatin (category 2B), or modified DCF (category 2B) Re-evaluate and consider chemo/RT to the primary site with 5-FU or capecitabine for local control
Progressive Disease[a]	• If locally recurrent: APR[d] + groin dissection, if positive inguinal nodes – Immunotherapy[e] (nivolumab, pembrolizumab, or retifanlimab-dlwr) can be considered before proceeding to APR (category 2B) • If metastatic: see Metastatic Disease	**Preferred regimens** (if no prior immunotherapy received) • Nivolumab, pembrolizumab, or retifanlimab-dlwr **Other recommended regimens** (if not previously given) • Carboplatin + paclitaxel, FOLFCIS, mFOLFOX6[c], 5-FU + cisplatin (category 2B), or modified DCF (category 2B)

The NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) recommend platinum-based chemotherapy as a first-line treatment option for metastatic cancer of the anal canal

[a] All recommendations are category 2A unless otherwise indicated. [b] ± positive para-aortic lymph nodes that can be included in a radiation field. [c] Discontinuation of oxaliplatin should be strongly considered after 3 to 4 months of therapy (or sooner for unacceptable neurotoxicity) while maintaining other agents until time of progression. Oxaliplatin may be reintroduced if it was discontinued for neurotoxicity rather than for disease progression. [d] Consider muscle flap reconstruction. [e] Institutional experience has demonstrated that some patients received a good response and can avoid surgery.
APR, abdominoperineal resection; CRT, chemoradiotherapy; 5-FU, 5-fluorouracil; DCF, docetaxel + cisplatin + fluorouracil; FOLFCIS, cisplatin + leucovorin + 5-FU; FOLFOX, oxaliplatin + leucovorin + 5-FU; RT, radiotherapy.

Current Treatment Landscape- E.U.



The 2021 ESMO guidelines recommend carboplatin + paclitaxel as first-line treatment for metastatic anal cancer

[a] Dose of >50 Gy (optimal dose unknown). [b] Treatment algorithm applicable for patients eligible for systemic treatment. Patients not fit for systemic treatment receive best supportive care. [c] In cases in which surgery cannot be carried out, patients should be managed as if they had metastatic disease.
ESMO, European Society for Medical Oncology; PD-L, programmed cell death ligand.
Rao S, et al. *Ann Oncol*. 2021;32:1087-1100. Figure adapted from Ann Oncol, Vol 32/issue 9, Rao S, et al, Anal cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up, Pages 1087-1100

No Immunotherapy Approved

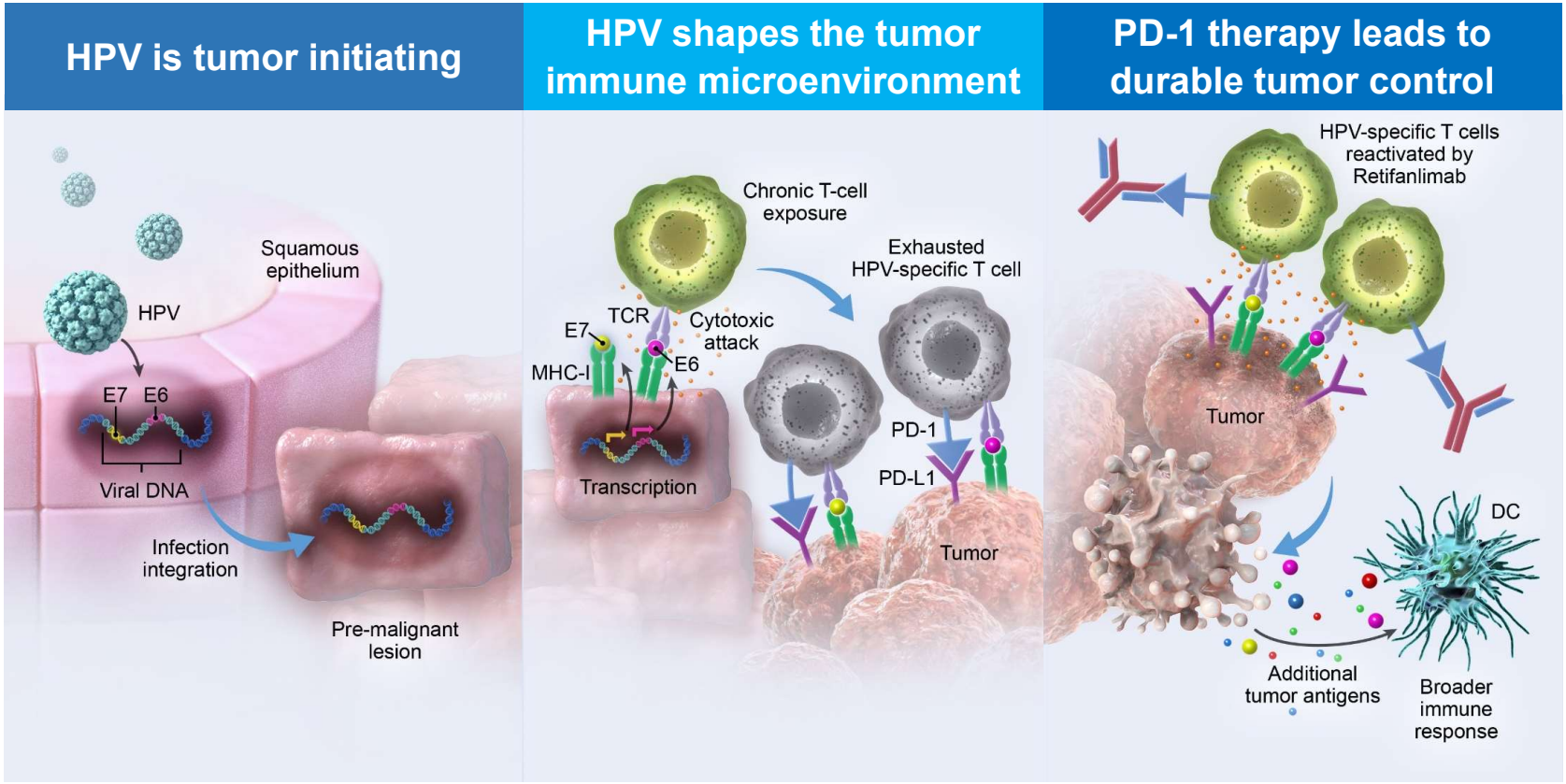
1L

- No immunotherapy approved or recommended

2L

- NCCN Guidelines® recommend the use of three PD-1–directed mAbs (pembrolizumab, nivolumab, or **retifanlimab-dlwr**) for patients with metastatic anal cancer who have progressed on 1L chemotherapy, if no prior immunotherapy was received[1]
- **However, none of these PD-1 agents are approved in this indication**

HPV-Driven Cancers are Ideal Indications for PD-1 Targeted Therapy



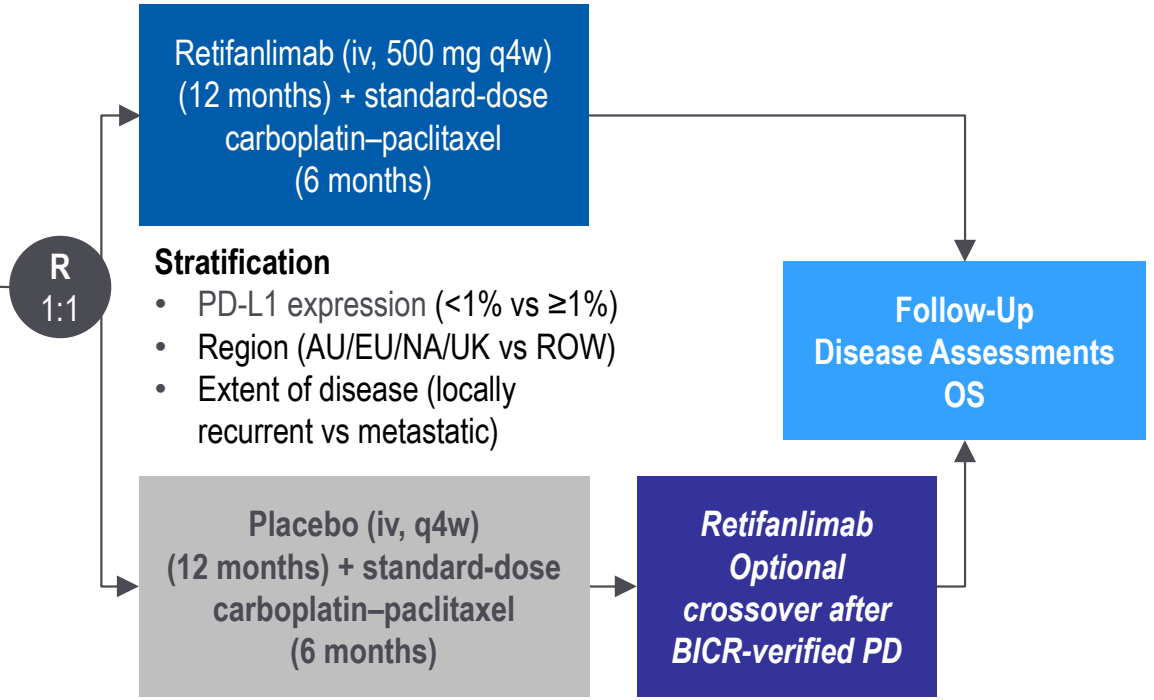
POD1UM-303/InterAACT 2: Phase 3 Study of Retifanlimab With Carboplatin-Paclitaxel in Patients With Inoperable Locally Recurrent or Metastatic Squamous Cell Carcinoma of the Anal Canal (SCAC) Not Previously Treated With Systemic Chemotherapy

POD1UM-303/InterAACT 2 Study Design

Patients with locally recurrent or metastatic SCAC

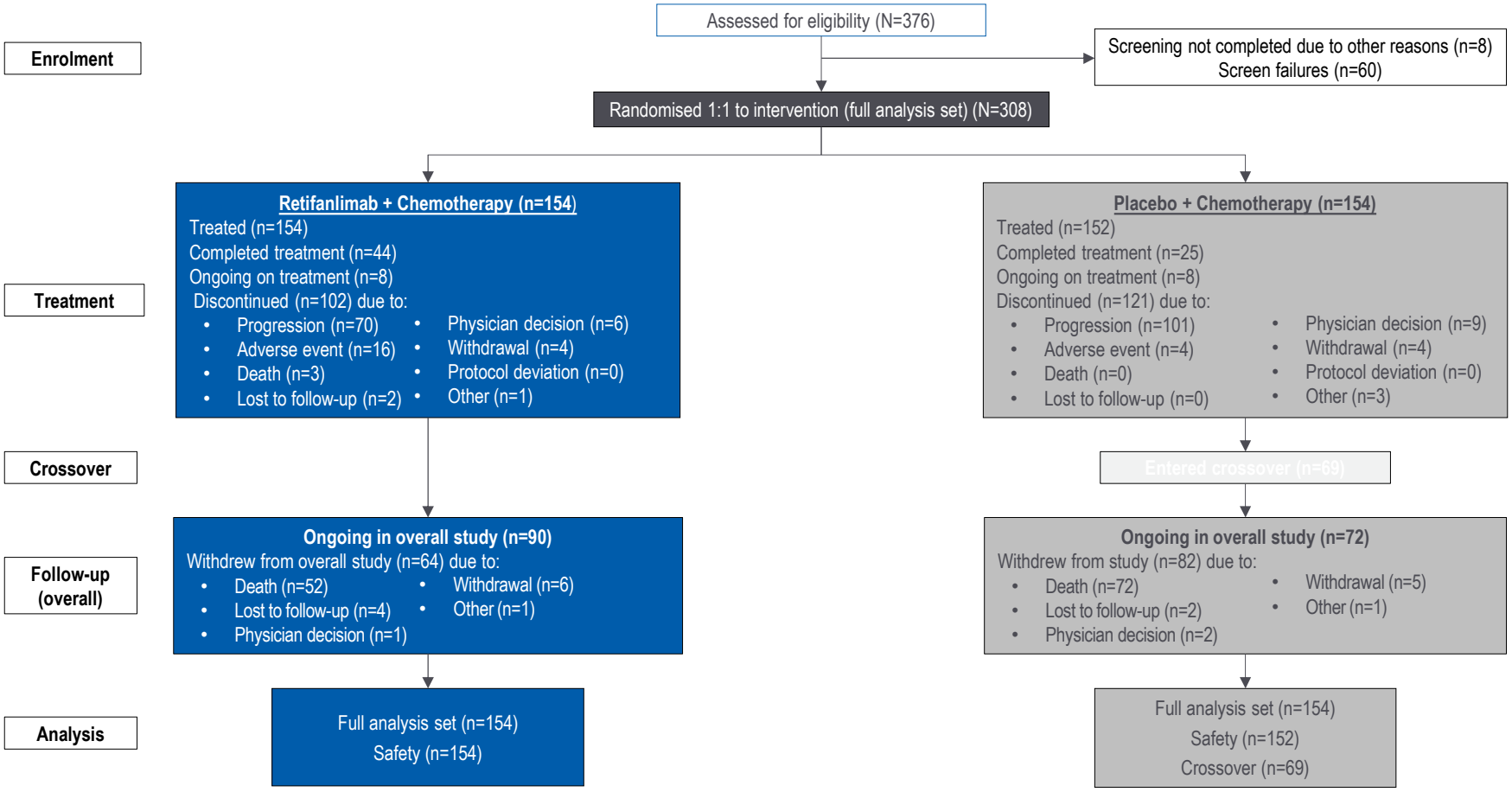
- No prior chemotherapy except as radiosensitising treatment or (neo) adjuvant therapy ≥6 months prior to study entry
- Patients with HIV and well-controlled infection were eligible
- **Planned enrolment: N=300**

Study Endpoints	
Primary	PFS by BICR (HR=0.67 at 80% power, alpha=0.025 [1-sided])
Secondary	OS (key secondary, alpha=0.025 [1-sided] if PFS is statistically significant), ORR, DOR, safety, PK
Exploratory	PFS2, PRO, HIV control, immunogenicity



Standard-dose carboplatin–paclitaxel: carboplatin AUC5 iv: day 1. Paclitaxel 80 mg/m^2 iv: days 1, 8 and 15. Each cycle = 28 days. 6 months/24 weeks (6 cycles).
AU, Australia; AUC, area under the curve; BICR, blinded independent central review; DOR, duration of response; EU, European Union; HIV, human immunodeficiency virus; HR, hazard ratio; iv, intravenous; NA, North America; ORR, overall response rate; OS, overall survival; PD, progressive disease; PD-L1, programmed cell death ligand 1; PFS, progression-free survival; PK, pharmacokinetics; PRO, patient-reported outcomes; q4w, every 4 weeks; R, randomisation; ROW, rest of the world; SCAC, squamous cancer of the anal canal; UK, United Kingdom.

Patient Flow

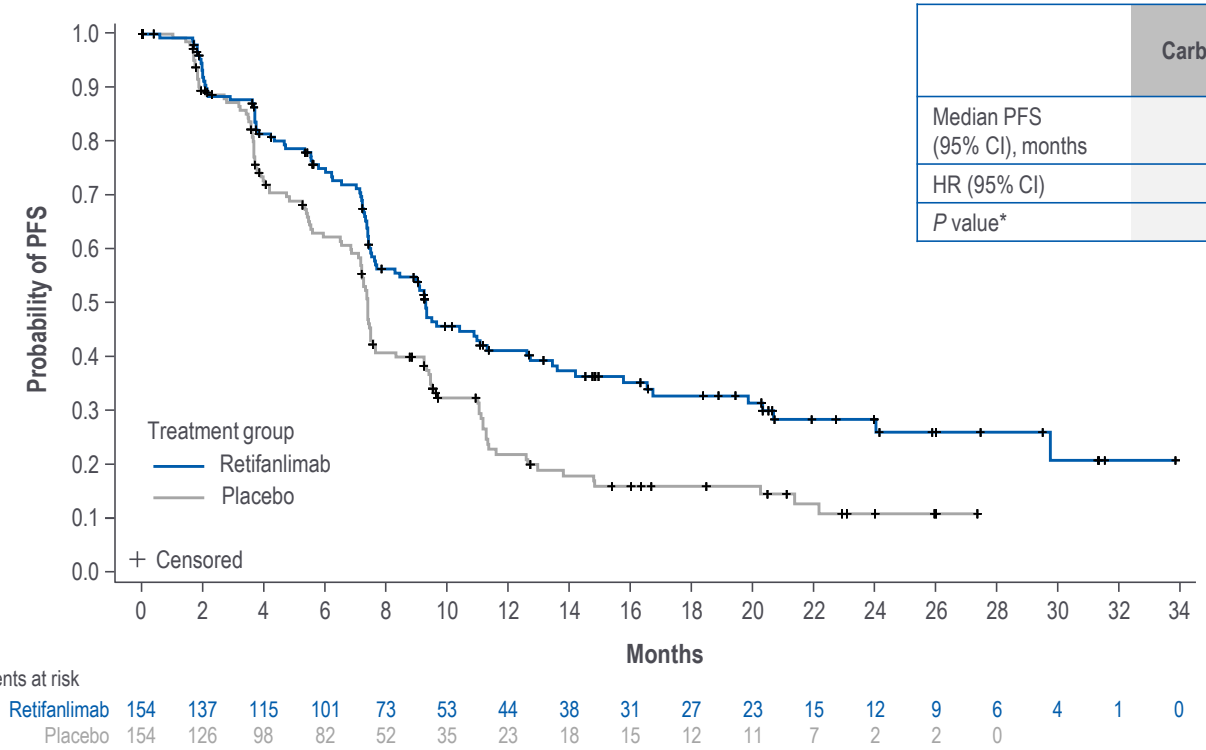


Patient Demographics and Characteristics (ITT Population)

Characteristic	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
Median age, years	61	62
Female, %	77	68
White, %	89	86
Prior RT, %	73	68
Metastatic disease, %*	**83**	**82**
Liver, %	36	36
ECOG PS 0, %	56	53
HIV+, %	3	4
PD-L1 expression status ≥1, %*,‡	**91**	**90**

*Stratification factor. †Among patients with data available. ‡PD-L1 expression <1 also includes non-evaluable patients.
ECOG PS, Eastern Cooperative Oncology Group performance status; HIV+, human immunodeficiency virus positive; ITT, intention-to-treat; PD-L1, programmed cell death ligand 1; RT, radiotherapy.

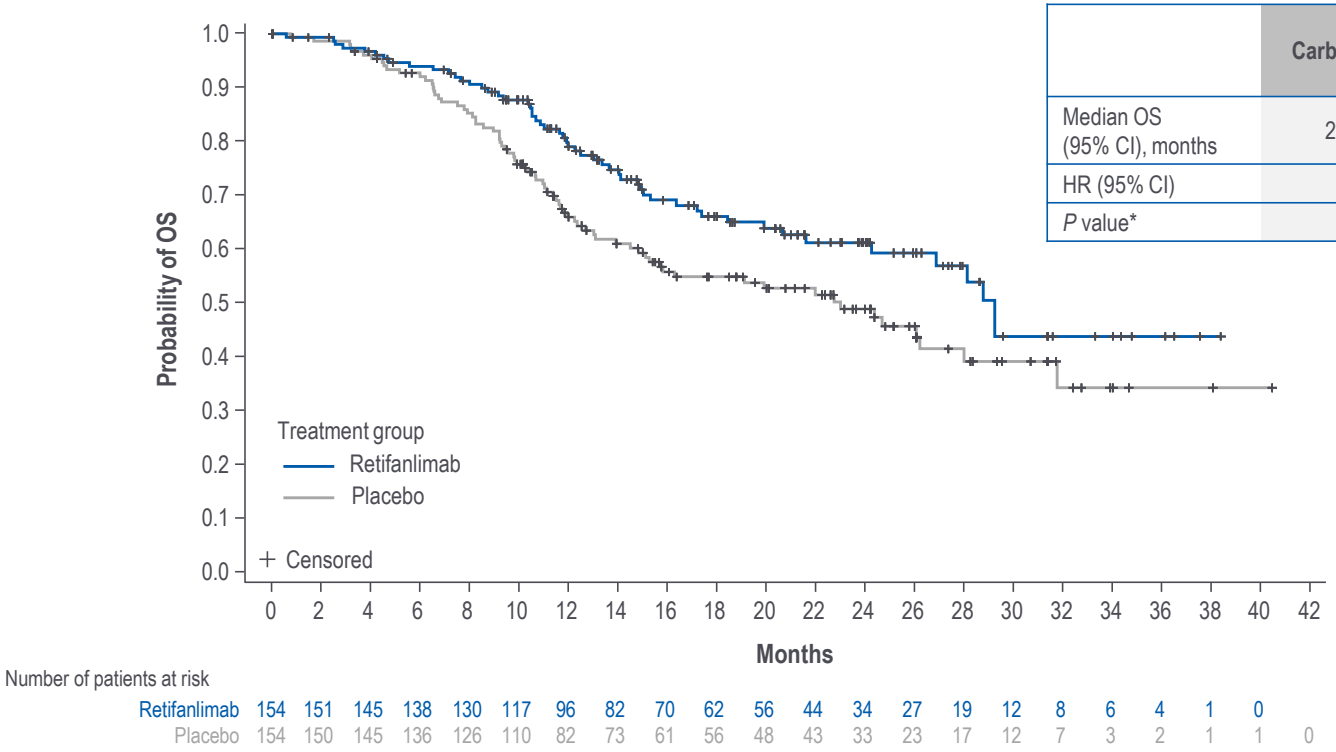
PFS by BICR (Primary Endpoint)



	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
Median PFS (95% CI), months	7.4 (7.1, 7.7)	9.3 (7.5, 11.3)
HR (95% CI)		**0.63 (0.47, 0.84)**
P value*		**0.0006**

*Stratified log-rank test with a 1-sided significance level of 2.5%. Stratification factors: region of the world, extent of disease and PD-L1 expression status.
BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; PD-L1, programmed cell death ligand 1; PFS, progression-free survival.

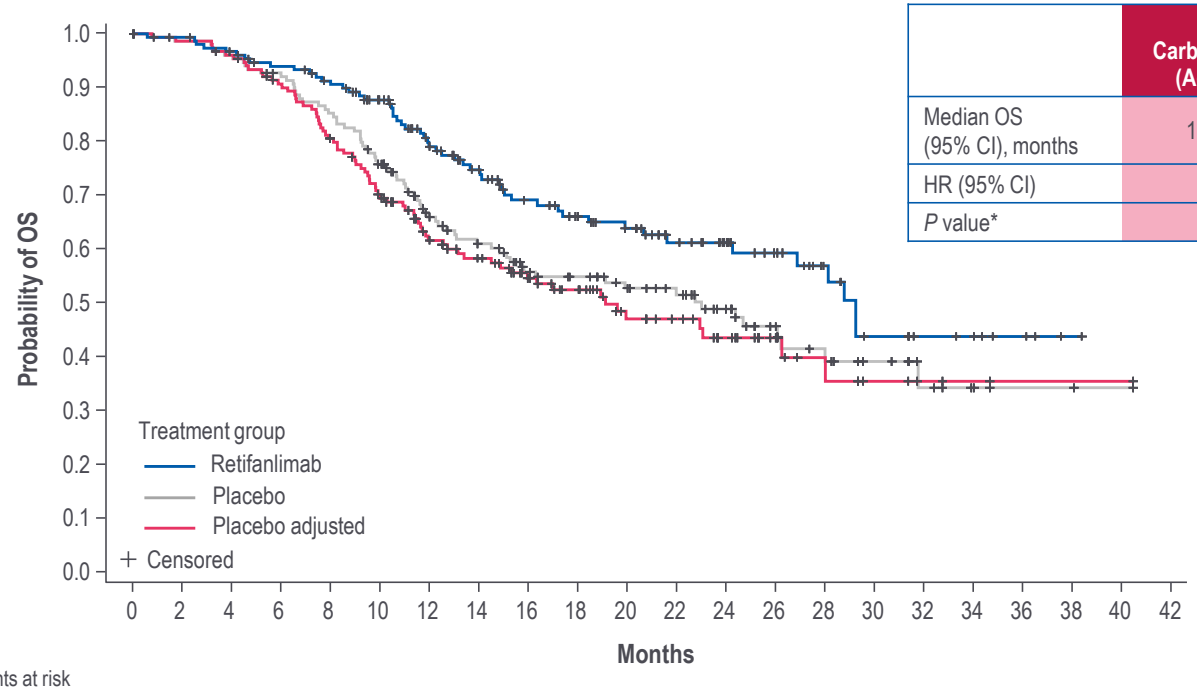
OS (Interim Analysis)



	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
Median OS (95% CI), months	23.0 (15.1, 27.9)	29.2 (24.2, NE)
HR (95% CI)		**0.70 (0.49, 1.01)**
P value*		**0.0273**

*Stratified log-rank test with a 1-sided significance level of 1.2% at this interim look. Stratification factors: region of the world, extent of disease and PD-L1 expression status.
CI, confidence interval; HR, hazard ratio; NE, not estimable; PD-L1, programmed cell death ligand 1; OS, overall survival.

OS Adjusted for Crossover



	Placebo + Carboplatin–Paclitaxel (Adjusted; n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
Median OS (95% CI), months	19.1 (13.4, 27.9)	29.2 (24.2, NE)
HR (95% CI)		**0.63 (0.44, 0.90)**
P value*		**0.0055***

Number of patients at risk

Retifanlimab	154	151	145	138	130	117	96	82	70	62	56	44	34	27	19	12	8	6	4	1	0	
Placebo	154	150	145	136	126	110	82	73	61	56	48	43	33	23	17	12	7	3	2	1	1	0
Placebo adjusted	154	150	145	133	117	99	76	67	54	45	33	29	22	14	8	5	3	2	1	1	1	0

*Nominal P value.
CI, confidence interval; HR, hazard ratio; NE, not estimable; OS, overall survival.

Secondary Endpoints by BICR*

	Placebo + Carboplatin–Paclitaxel (n=154)	Retifanlimab + Carboplatin–Paclitaxel (n=154)
ORR (95% CI), % CR, %	44 (36, 52) 14	56 (48, 64) 22 ***P*=0.0129†**
Median DOR (95% CI), months	7.2 (5.6, 9.3)	14.0 (8.6, 22.2)
DCR (95% CI), %	80 (73, 86)	87 (81, 92)

*Results by BICR. †Nominal P value for ORR.
BICR, blinded independent central review; CI, confidence interval; CR, complete response; DCR, disease control rate; DOR, duration of response; ORR, overall response rate.

InterAACT vs POD1UM-303/InterAACT 2

Treatment	InterAACT 1 (Rao, 2020)	POD1UM-303/InterAACT 2	
	Carboplatin–Paclitaxel	Placebo + Carboplatin–Paclitaxel	Retifanlimab + Carboplatin–Paclitaxel
n	91	154	154
Participating countries	UK, AU, Norway, US	EU, AU, JPN, US, PR	
Demographics and disease characteristics*			
Median age, years	61	62	
Female, %	67	72	
White/other, %	NS	87/13	
HIV+, %	5	4	
Metastatic, %	88	82	
ECOG PS 0 or 1	93	100	
Median number of chemotherapy cycles	6	6	6
ORR, % (95% CI)	59 (42, 74)	44 (36, 52)	
CR, %	13	14	
Median PFS, months (95% CI)	8.1 (6.6, 8.8)	7.4 (7.1, 7.7)	
Median OS, months (95% CI)	20 (12.7, NE)	23.0 (15.1, 27.9)	

*Entire study population.

AU, Australia, CI, confidence interval; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; EU, European Union; HIV+, human immunodeficiency virus positive; HPV+, human papillomavirus positive; JPN, Japan; NE, not estimable; NS, not shown; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, Puerto Rico; UK, United Kingdom; US, United States.

Safety Summary

Variable	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Median treatment duration, months	6.8	7.4	7.2
Patients with any TEAEs, n (%)	152 (100)	154 (100)	306 (100)
Patients with ≥ grade 3 TEAEs, n (%)	114 (75.0)	128 (83.1)	242 (79.1)
Patients with grade 5 TEAEs, n (%)	1 (0.7)*	4 (2.6)†	5 (1.6)
Patients with SAEs, n (%)	59 (38.8)	73 (47.4)	132 (43.1)
Treatment-related SAEs, n (%)	10 (6.6)	25 (16.2)	35 (11.4)
Immune-related AEs, n (%)	36 (23.7)	71 (46.1)	107 (35.0)
AEs leading to discontinuation, n (%)	4 (2.6)	17 (11.0)	21 (6.9)

- Safety of retifanlimab plus chemotherapy consistent with prior phase 2 data and known CPI literature in SCAC
- No loss of HIV control/viral load observed in patients with HIV
- At data cutoff, 90 patients (58.4%) in the retifanlimab arm remained on study

*Patient had a fatal event of pneumonia. †1 patient each had a fatal event of metastases to peritoneum, pancytopenia, pneumonia, and sepsis.
AE, adverse event; CPI, checkpoint inhibitor; HIV, human immunodeficiency virus; SAE, serious adverse event; SCAC, squamous cancer of the anal canal; TEAE, treatment-emergent adverse event.

TEAEs by Preferred Term

Most common (≥3%) grade 3 or higher TEAE

MedRA Preferred Term	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Neutropenia	45 (29.6)	54 (35.1)	99 (32.4)
Anaemia	31 (20.4)	30 (19.5)	61 (19.9)
Neutrophil count decreased	13 (8.6)	26 (16.9)	39 (12.7)
White blood cell count decreased	13 (8.6)	14 (9.1)	27 (8.8)
Diarrhoea	9 (5.9)	8 (5.2)	17 (5.6)
Leukopenia	6 (3.9)	6 (3.9)	12 (3.9)
Asthenia	5 (3.3)	6 (3.9)	11 (3.6)
Sepsis	6 (3.9)	5 (3.2)	11 (3.6)
Pulmonary embolism	5 (3.3)	5 (3.2)	10 (3.3)
Vomiting	6 (3.9)	4 (2.6)	10 (3.3)

Most common (≥2%) immune-related TEAE

MedRA Preferred Term	Placebo + Carboplatin–Paclitaxel (n=152)	Retifanlimab + Carboplatin–Paclitaxel (n=154)	Total (N=306)
Peripheral sensory neuropathy	15 (9.9)	17 (11.0)	32 (10.5)
Hypothyroidism	5 (3.3)	22 (14.3)	27 (8.8)
Hyperthyroidism	1 (0.7)	13 (8.4)	14 (4.6)
Pruritus	3 (2.0)	11 (7.1)	14 (4.6)
Adrenal insufficiency	0	8 (5.2)	8 (2.6)
Rash maculo-papular	3 (2.0)	3 (1.9)	6 (2.0)

TEAE: any AE either reported for the first time or worsening of a pre-existing event after first dose of study treatment and within 90 days of the last administration of retifanlimab/placebo, or within 30 days of the last chemotherapy.
AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

Conclusions

- This first and largest known phase 3 trial of a checkpoint inhibitor in SCAC, a disease with high unmet medical need, demonstrated benefit of addition of retifanlimab to standard of care chemotherapy
- The study met its PFS primary endpoint:
  - 9.3 months with retifanlimab vs 7.4 months with placebo (HR, 0.63 [95% CI, 0.47, 0.84]; *P*=0.0006)
- Retifanlimab improved OS vs placebo by 6 months, with a strong trend towards statistical significance at data cutoff (OS follow-up ongoing)
- ORR, DOR and DCR all showed improvement with retifanlimab vs placebo
- Treatment was generally well tolerated, and safety was consistent with other chemotherapy plus checkpoint inhibitor regimens
  - Delivery of chemotherapy was not compromised by retifanlimab administration
- Retifanlimab plus carboplatin–paclitaxel represents a new reference treatment and standard of care for patients with advanced SCAC

CI, confidence interval; DCR, disease control rate; DOR, duration of response; HR, hazard ratio; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; SCAC, squamous cancer of the anal canal.

Gynecologic Cancers

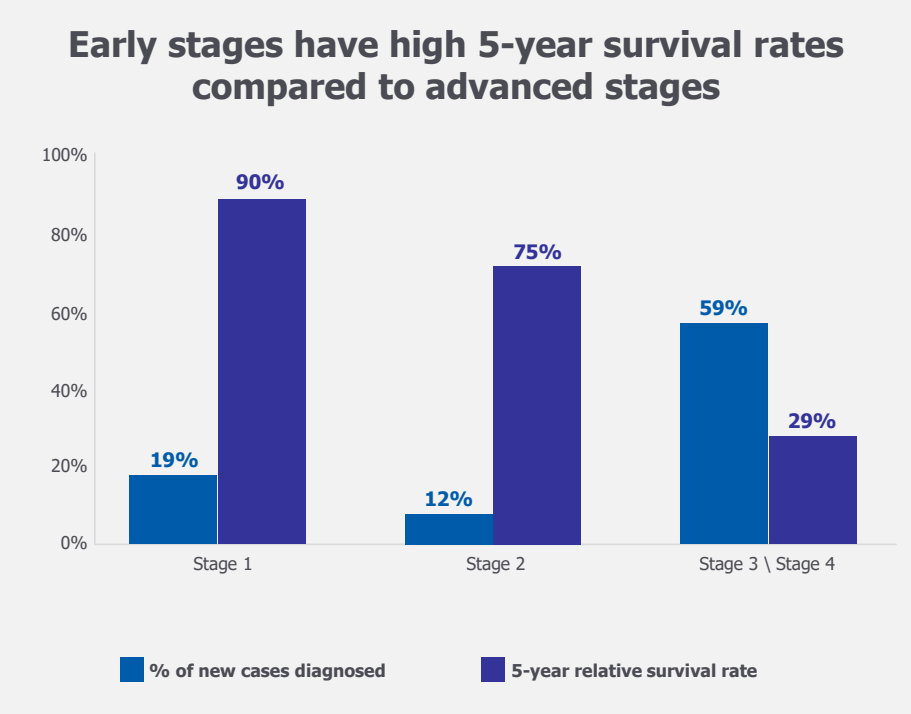
Rebecca Kristeleit, BSc MBChB PhD FRCP FRSB
Consultant Medical Oncologist GSTT and Adjunct Reader
(Associate Professor) KCL, London

Global Ovarian Cancer Epidemiology

- Ovarian Cancer is often diagnosed late/in advanced stages which shows poor survival outcomes

2022	Estimated number of new cases (Incidence)	Estimated number of death cases (Mortality)
North America	24,484	15,554
Europe	69,472	46,232
Asia	178,223	109,547

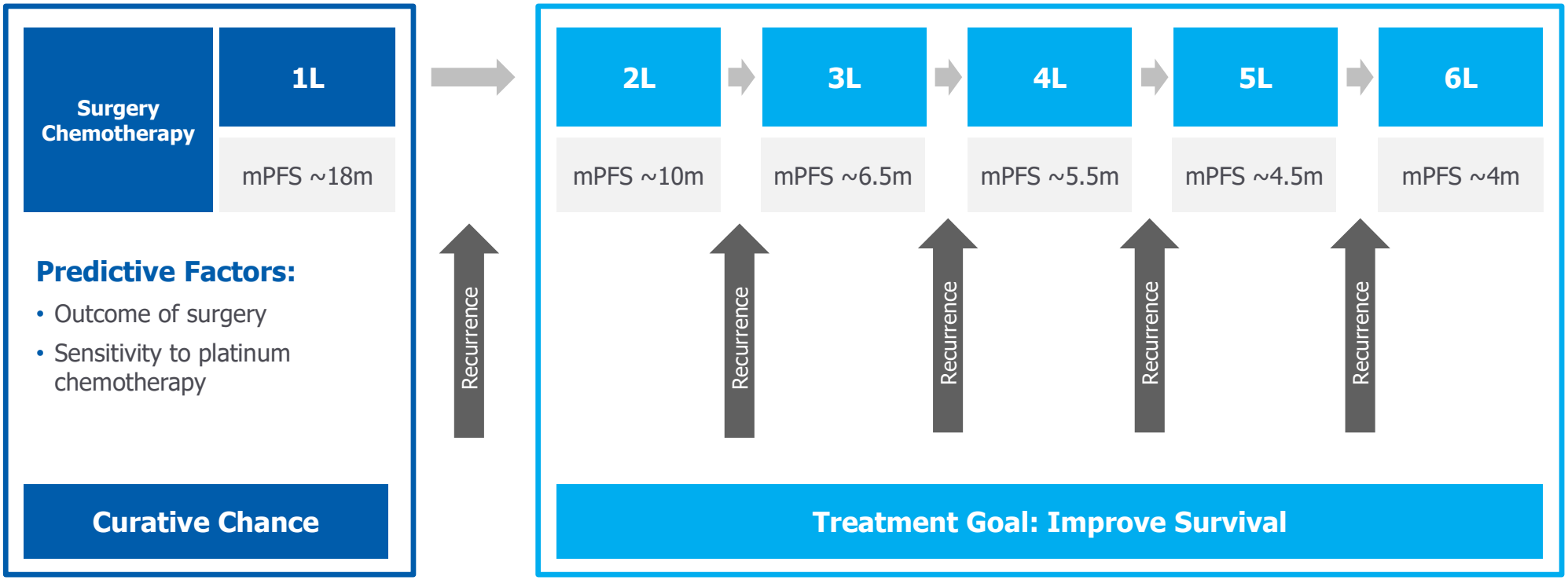
Source: Cancer Tomorrow (Globocan 2022 (version 1.1) - 08.02.2024): https://gco.iarc.fr/tomorrow/en/dataviz/tables?years=2050&cancers=25



Source: https://www.ocrf.com.au/about-us/annual-reports-publications/state-of-the-nation-in-ovarian-cancer

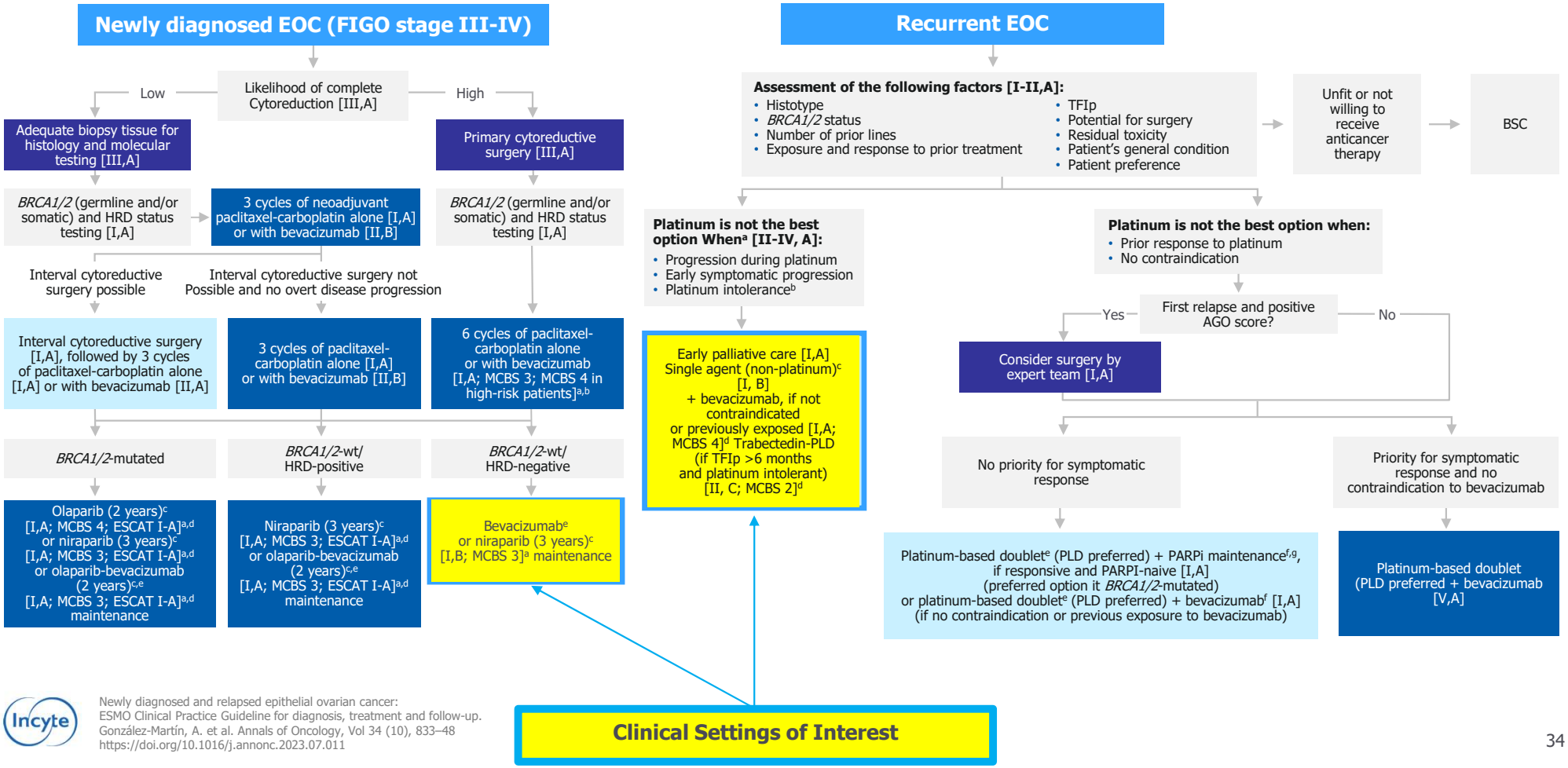
Clinical Course of Advanced Ovarian Cancer

- Treatment goal: Prevention of disease recurrence
- Median Overall Survival ~5 years



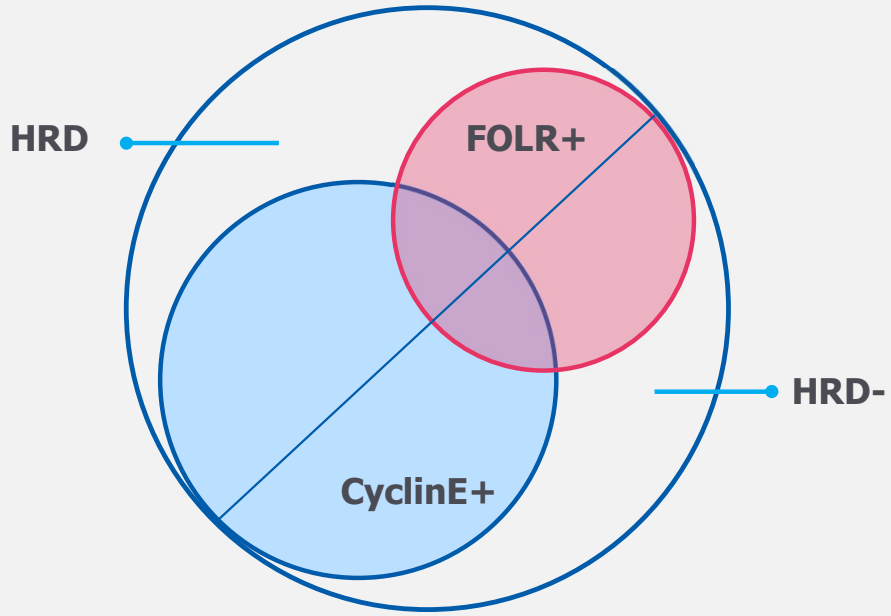
Tewari KS, J Clin Oncol. 2019 Sep 10;37(26):2317-2328
Hanker, L.C. Annals of Oncology, Volume 23, Issue 10, 2012, Pages 2605-2612

ESMO Treatment Algorithm: Newly Diagnosed & Recurrent Ovarian Cancer



Newly diagnosed and relapsed epithelial ovarian cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. González-Martín, A. et al. Annals of Oncology, Vol 34 (10), 833–48 https://doi.org/10.1016/j.annonc.2023.07.011

Cyclin E in Different Segments of Ovarian Cancer



- Approximately 50% of ovarian cancer patients have high Cyclin E protein expression [1]

- FOLR+ is 36% of PROC[2]
  - 18.5% FOLR+ overlaps Cyclin E+ high[3]
  - 32.5% of ovarian cancer is FOLR-negative and Cyclin E high[3]

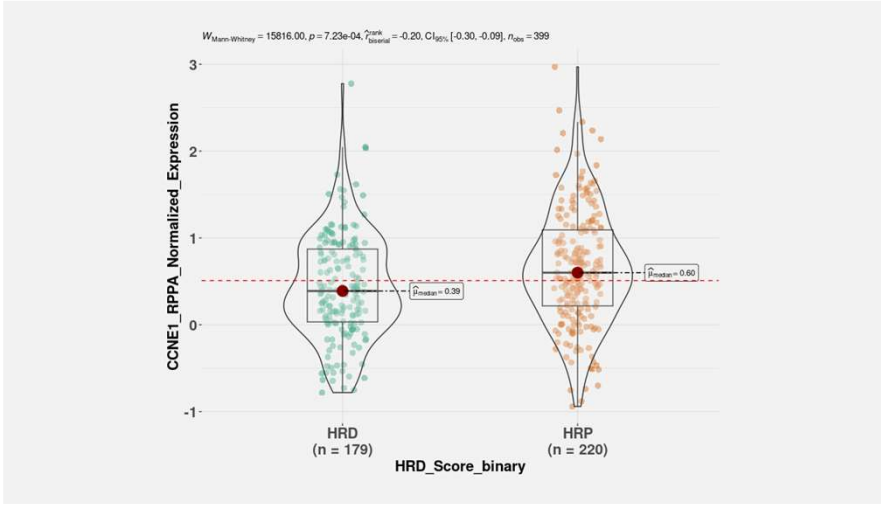
- HRD- is 52% of PSOC[4]
  - ~60% of HRD- is Cyclin E high representing 31% of PSOC[5]

1. Incyte Generated Data on file
2. Matulonis, U.A. et al Journal of Clinical Oncology 2023; 41(13)
3. Internal data on file
4. Ray-Coquard, I et al N Engl J Med 2019;381:2416-2428
5. Internal data on file derived from TCGA database

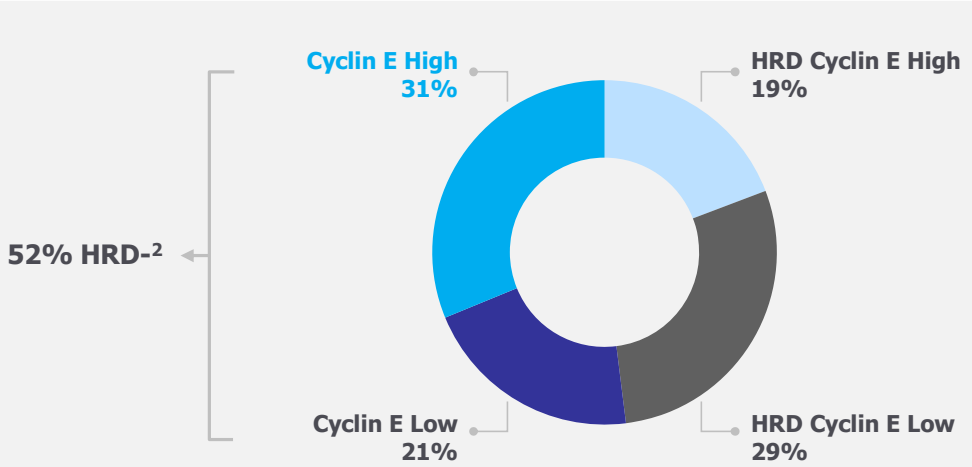
Development Opportunity in HRD- Ovarian Cancer

- In the 1L setting, most patients receive bevacizumab maintenance therapy
- HRD- patients represent ~52% of 1L maintenance patient population[1]
- PFS in 1L maintenance for HRD- patients is significantly lower than for BRCA+ or HRD+ patients
- Cyclin E protein expression is enriched in HRD- population: ~60% HRP patients are Cyclin E high[2]

HRD- represents an area of unmet need in 1L maintenance in combination with bevacizumab



High CCNE1 protein expression
(50th percentile expression across ovarian tumors)

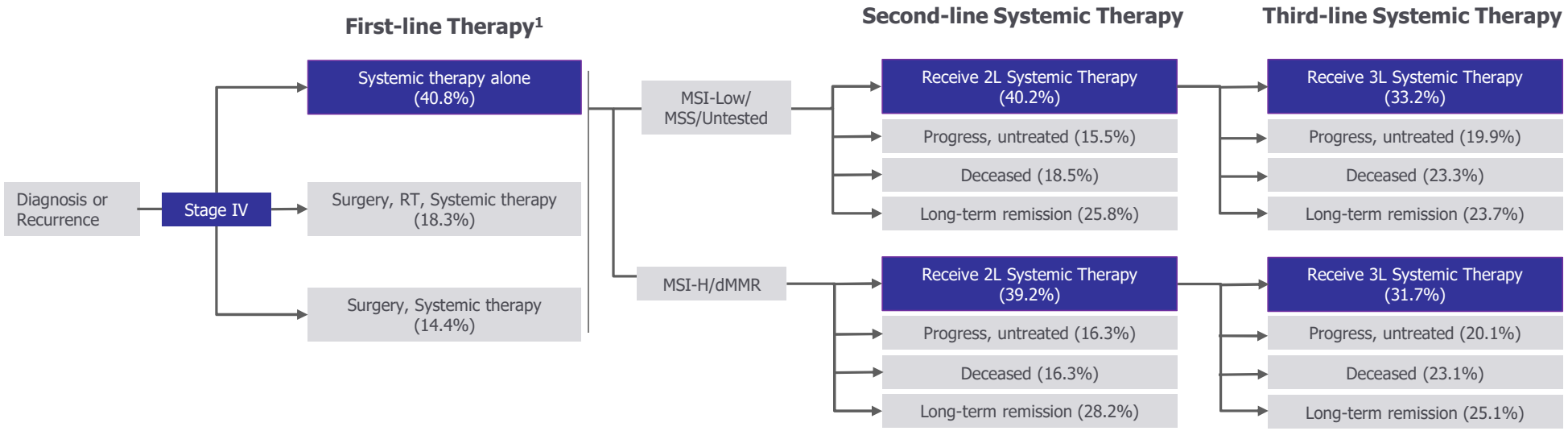


1. Ray-Coquard, I et al N Engl J Med 2019;381:2416-2428
2. Internal data on file derived from TCGA database1

Classes of Agents in Development in Ovarian Cancer

Antibody Drug Conjugates	• Multiple targets: HER2, FR-alpha (luveltamab, mirv, FZEC), TROP2, CDH6, Napi2B • GLORIOSA Phase III mirv+bev vs bev maintenance in 2L PSOC
DNA Damage Response Agents	• Next generation selective PARPi, ATRi, ATMi, Pol theta inhibition, Wee1 • Combinations including DDR agents, chemo
Bispecific Antibodies	• Various mechanisms of tumour-immune cell concurrent dual targeting – e.g., ubamatamab (Regeneron)
Cell Therapies	• Chimeric antigen receptor T-cell therapy (CAR-T)

Late-Stage Endometrial Cancer



First-line: MSI-Low/MSS/Untested	
pembrolizumab, carboplatin, paclitaxel	29.7%
carboplatin, paclitaxel	26.1%
doxorubicin, CPA, paclitaxel	10.0%

First-line: MSI-H/dMMR	
pembrolizumab, carboplatin, paclitaxel	44.3%
dostarlimab, carboplatin, paclitaxel	12.0%
carboplatin, paclitaxel	10.8%

Second-line: MSI-Low/MSS/Untested	
pembrolizumab, carboplatin, paclitaxel	13.3%
pembrolizumab, lenvatinib	12.8%
liposomal doxorubicin	11.2%

Second-line: MSI-H/dMMR	
pembrolizumab, carboplatin, paclitaxel	19.8%
pembrolizumab	11.8%
liposomal doxorubicin	10.8%

Third-line: MSI-Low/MSS/Untested	
pembrolizumab, Lenvatinib	10.2%
liposomal doxorubicin	9.5%
bevacizumab, carboplatin, paclitaxel	8.1%

Third-line: MSI-H/dMMR	
pembrolizumab, lenvatinib	9.3%
liposomal doxorubicin	9.1%
Investigational Drug	8.5%

Opportunities for Development of CDK2 Inhibitor in Cyclin E Overexpressed Gynecologic Cancers

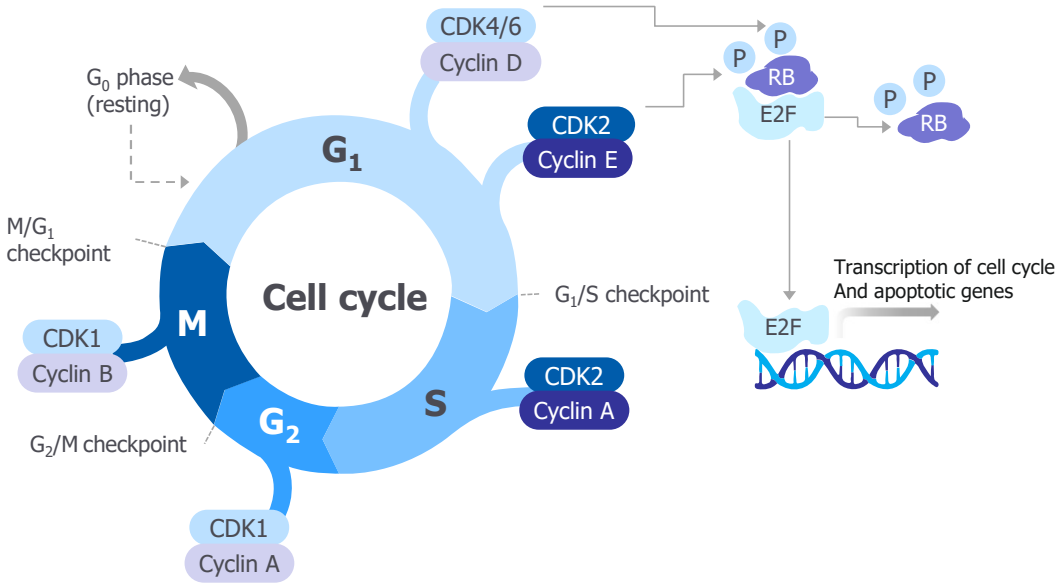
Ovarian Cancer		Endometrial Cancer
Platinum Sensitive	**Platinum Resistant**	
• 1st line maintenance • 2nd line maintenance	• Monotherapy • Future combinations	• 3rd line + • 1L/2L in combination with CPI/chemotherapy

INCB123667 – A Novel CDK2 Inhibitor

Ekaterine Asatiani
Group Vice President & Head of Early Development

Role of CDK2/Cyclin E Complex in Normal and Cancer Cells

- CDK2/cyclin E is crucial for cell cycle progression and DNA replication
- Cancer cells with *CCNE1* amplification/cyclin E1 overexpression are dependent on CDK2[1]
- *CCNE1* amplification and cyclin E overexpression are prevalent in multiple tumor types, including gynecologic malignancies,[2-3] and are associated with poor clinical outcomes[3]
  - In ovarian cancer: approximately 12% are *CCNE1* amplified[3] and 52% overexpress cyclin E1[2,4]
  - In endometrial cancer: approximately 7% are *CCNE1* amplified and 67% overexpress cyclin E1
  - High CCNE1 mRNA expression is associated with primary resistance to CDK4/6i in HR+HER2 BC (PALOMA-3 trial)[5]
- INCB123667 is a highly selective CDK2 inhibitor that showed antitumor activity in preclinical models[6]



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1. Etemadmoghadam D, et al. Clin Cancer Res. 2013;19(21):5960-5971. 2. Gorski JW et al. Diagnostics (Basel). 2020;10(5):279. 3. Chan AM, et al. J Pathol Clin Res. 2020:6(4):252-262. 4. MSK-IMPACT panel data from AACR Genie v16 public database.
5. Turner NC. Et al J Clin Oncol 2019;37;1169-78. 6. Incyte, generated data on file.
CDK2, cyclin-dependent kinase 2; CCNE1, cyclin E1.

INCB123667 has the Potential to be First-in-Class and Best-in-Class

- Incyte's CDK2i has a competitive profile of on-target potency and selectivity
- Incyte has first-in-class opportunity for CDK2i approval in Ovarian Cancer

CDK2i Asset	Company	CDK2 Potency (IC_{50})		Biochemical Selectivity					Clinical Stage
		Biochemical	Cellular	CDK1	CDK9	CDK4	CDK6	CDK5	
INCB123667	Incyte	0.87	53	220x	4177x	53X	220x	298x	Ph. 1
PF-07104091	Pfizer	1.1	20	100x	163x	218X	422x	5x	Ph. 1/2
BLU-222	Blueprint	2.6	17.7	90x	2351x	145X	105x	N/A	Ph. 1/2
INX-315	Incyclix	0.6	2.3	50x	103x	210X	580x	39x	Ph. 1/2
AZD8421	AstraZeneca	9	N/A	56x	>2000x	1000X	N/A	N/A	Ph. 1/2
AVZO-021 (ARTS-021)	Avenzo (Allorion)	1.4	N/A	N/A	N/A	N/A	N/A	N/A	Ph. 1/2

Source: Pfizer ASCO 2023 data; Blueprint Medicines ASCO 2023 data; Incyte JPM Healthcare Conference Presentation; BeiGene; Lindeman GJ, et al. J Clin Oncol. 2021; 39(suppl 15): 1004-1004
CDK(i) – cyclin dependent kinase (inhibitor); EC – endometrial cancer; GI – gastrointestinal cancer; Gr3+ AE – adverse event of grade 3 or higher; IC50 – 50% inhibitory concentration; (m)BC – (metastatic breast) cancer; mPFS – median progression-free survival; N/A – not available; OC – ovarian cancer; ORR – overall response rate; PC - ; Ph. 1/2 – phase 1/2;

Phase 1 Dose Escalation and Expansion Study (INCB123667-101)

Part 1: INCB123667 Monotherapy

1a Dose Escalation

- Advanced/ metastatic solid tumors
- Locally confirmed *CCNE1* amplification preferred

Identification of ≥1 RDE(s)

1b Dose Expansion

- Documented *CCNE1* amplification or centrally confirmed cyclin E1 overexpression (except for Group 5)

Group 1 Ovarian/fallopian/ primary peritoneal	**Group 2** Endometrial/ uterine	**Group 3** GI
Group 4 TNBC	**Group 5** $HR^+/HER2^-$ breast cancer*	**Group 6** Other tumors (except bone)

Part 2a/b: INCB123667 Combinations: palbociclib +/- fulvestrant, ribociclib +/- fulvestrant, bevacizumab, olaparib, paclitaxel

Objectives

Primary

- Safety and tolerability
- MTD and RDE(s)

Secondary

- Pharmacokinetics
- Antitumor activity

*With progression on/intolerance of a CDK4/6 inhibitor.

CCNE1, cyclin E1 gene; ECOG PS, Eastern Cooperative Oncology Group performance status; GI, gastrointestinal; HR+, hormone receptor positive; HER2−, human epidermal growth factor receptor 2 negative; MTD, maximum-tolerated dose; PO, orally; qd, once daily; RDE, recommended dose for expansion; RECIST, Response Evaluation Criteria in Solid Tumors; TNBC, triple-negative breast cancer.

Phase 1 Dose Escalation and Expansion Cohorts

- 7 dose levels were explored using QD and BID schedules and total daily dose ranging from 50 to 150 mg
- Currently 3 dose levels are expanded:
  - 50 mg BID, 100 mg QD, 125 mg QD in selected tumor types
- Enrollment in combination cohorts has started

Patient Demographics and Clinical Characteristics

	Total (N=205)
Age, median (range), years	60 (18-80)
Female, n (%)	171 (83.4)
ECOG PS status, n (%)	
0	129 (62.9)
1	76 (37.1)
Cancer type	
Ovarian cancer	89 (43.4)
Endometrial cancer	14 (6.8)
Gastrointestinal	19 (9.3)
HR+/HER2- breast cancer	35 (17.1)
Triple negative breast cancer	13 (6.3)
Others	35 (17.1)
No. of prior systemic therapy, median (range)*	
Ovarian cancer	4 (1-12)
Endometrial cancer	3 (1-5)

Data on file, Incyte Corporation (as of 26 August 2024)
*Number of prior lines currently under data cleaning

Treatment Related Adverse Events Reveal a Manageable Safety Profile

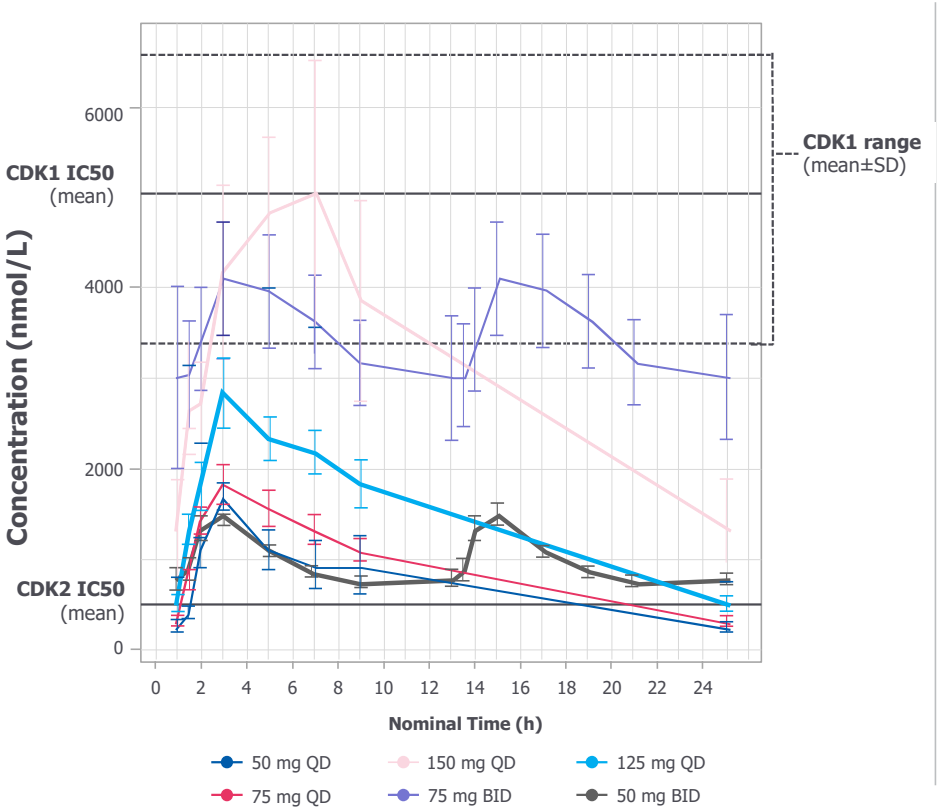
- Only 3 patients (1.5%) discontinued INCB123667 due to TRAEs (asthenia, neutropenia and vomiting)
- 11 patients (5.4%) had INCB123667 dose reductions due to TRAEs
- 75 mg BID exceeded the MTD due to hematologic DLTs; QD dosing was well tolerated up to 125 mg

Any-Grade TRAEs in ≥10% of Patients by MedDRA Preferred Term

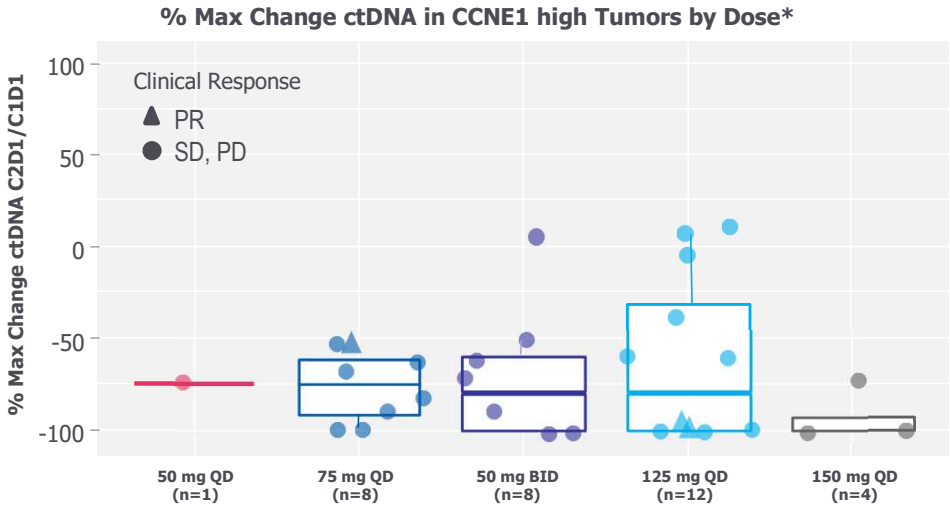
n (%)	50 mg QD (n=5)		50 mg BID (n=88)		75 mg BID (n=6)		75 mg QD (n=19)		100 mg QD (n=14)		125 mg QD (n=63)		150 mg QD (n=6)		150 mg QD intermittent* (n=4)		Total (N=205)	
	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3	All	≥Gr.3
Hematologic TRAEs																		
Thrombocytopenia	2 (40.0)	0	25 (28.4)	6 (6.8)	4 (66.7)	2 (33.3)	4 (21.1)	0	4 (28.6)	0	19 (30.2)	5 (7.9)	4 (66.7)	2 (33.3)	1 (25.0)	0	63 (30.7)	15 (7.3)
Anemia	2 (40.0)	1 (20.0)	19 (21.6)	2 (2.3)	2 (33.3)	1 (16.7)	6 (31.6)	1 (5.3)	3 (21.4)	0	24 (38.1)	4 (6.3)	3 (50.0)	1 (16.7)	0	0	59 (28.8)	10 (4.9)
Neutropenia	1 (20.0)	0	15 (17.0)	4 (4.5)	0	0	4 (21.1)	1 (5.3)	5 (35.7)	0	15 (23.8)	3 (4.8)	4 (66.7)	3 (50.0)	0	0	44 (21.5)	11 (5.3)
Leukopenia	1 (20.0)	0	11 (12.5)	0	1 (16.7)	0	3 (15.8)	0	1 (7.1)	0	14 (22.2)	2 (3.2)	2 (33.3)	1 (16.7)	1 (25.0)	0	34 (16.6)	3 (1.5)
Non-hematologic TRAEs																		
Nausea	2 (40.0)	0	17 (19.3)	1 (1.1)	1 (16.7)	0	4 (21.1)	0	5 (35.7)	0	36 (57.1)	0	4 (66.7)	0	3 (75.0)	1 (25.0)	72 (35.1)	2 (1.0)
Fatigue	1 (20.0)	0	14 (15.9)	1 (1.1)	2 (33.3)	0	2 (10.5)	1 (5.3)	2 (14.3)	0	16 (25.4)	1 (1.6)	0	0	1 (25.0)	0	38 (18.5)	3 (1.5)
Vomiting	0	0	6 (6.8)	0	2 (33.3)	1 (16.7)	1 (5.3)	0	0	0	15 (23.8)	0	1 (16.7)	0	1 (25.0)	0	26 (12.7)	1 (0.5)
Asthenia	0	0	2 (2.3)	0	1 (16.7)	0	4 (21.1)	0	0	0	8 (12.7)	1 (1.6)	5 (83.3)	3 (50.0)	1 (25.0)	0	21 (10.2)	4 (2.0)

*5 days on/2 days off; BID, twice daily; MTD, maximum tolerated dose; DLT, dose limiting toxicities; QD, once daily; MedDRA, Medical Dictionary for Regulatory Activities (v26.0); TRAE, treatment-related adverse event
Data on file, Incyte Corporation (as of 26 August 2024)

Strong Selective Inhibition of CDK2 Observed Resulting in ctDNA Reduction at All Dose Levels

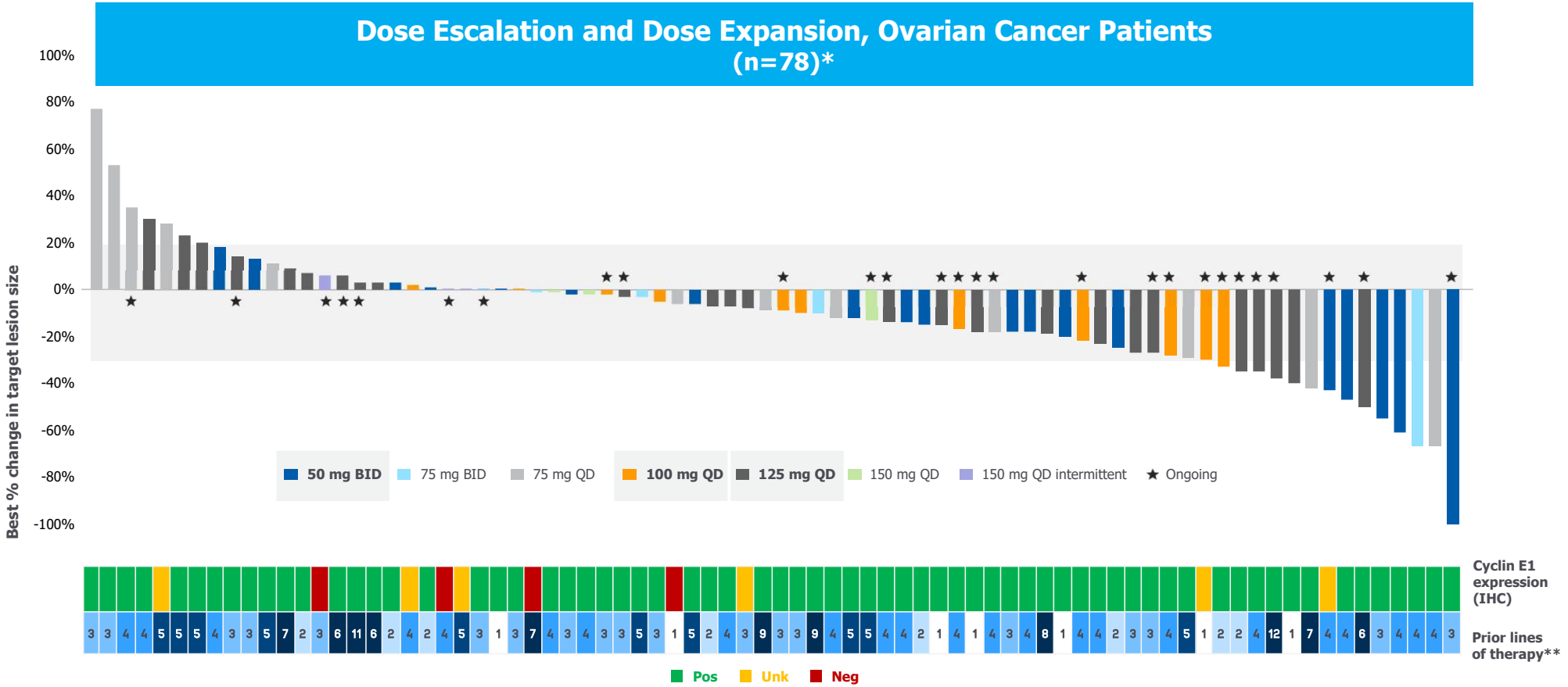


During Part 1a dose escalation, 30 out of 33 **Cyclin E-positive** patients by IHC had reductions in ctDNA between C1D1 and C2D1



Note: C1D8 PK data were collected from 0-8 hrs for BID and from 0-24 hrs for QD. Pre-dose samples for BID were used again at the 12-h time point. For BID, data after the first dose were plotted between 0-12 hrs and then again from 12-24 hrs to replicate the profile after the second dose. 50 mg QD (n=5); 50 mg BID (n=19); 75 mg QD (n=19); 125 mg QD (n=20); 150 mg QD (n=5).
*Copy number burden estimated by PredicineSCORETM.
BID, twice daily; C1D1, cycle 1 day 1; C2D1, cycle 2 day 1; ctDNA, circulating tumor DNA; QD, once daily; PD, progressive disease.

Tumor Shrinkage Observed in Platinum-Resistant Ovarian Cancer Patients



* Total 89 ovarian cancer patients with 78 patients shown here having at least 1 postbaseline scan; 8 additional patients ongoing but before 1st postbaseline scan; 3 additional patients discontinued treatment prior to 1st postbaseline scan

** Number of prior lines currently under data cleaning;

BID, twice daily; CDK, cyclin-dependent kinase; i, inhibitor; IHC, immunohistochemistry; intermittent (5 days on, 2 days off); QD, once daily; UNK, unknown

Data on file, Incyte Corporation (as of 26 August 2024)

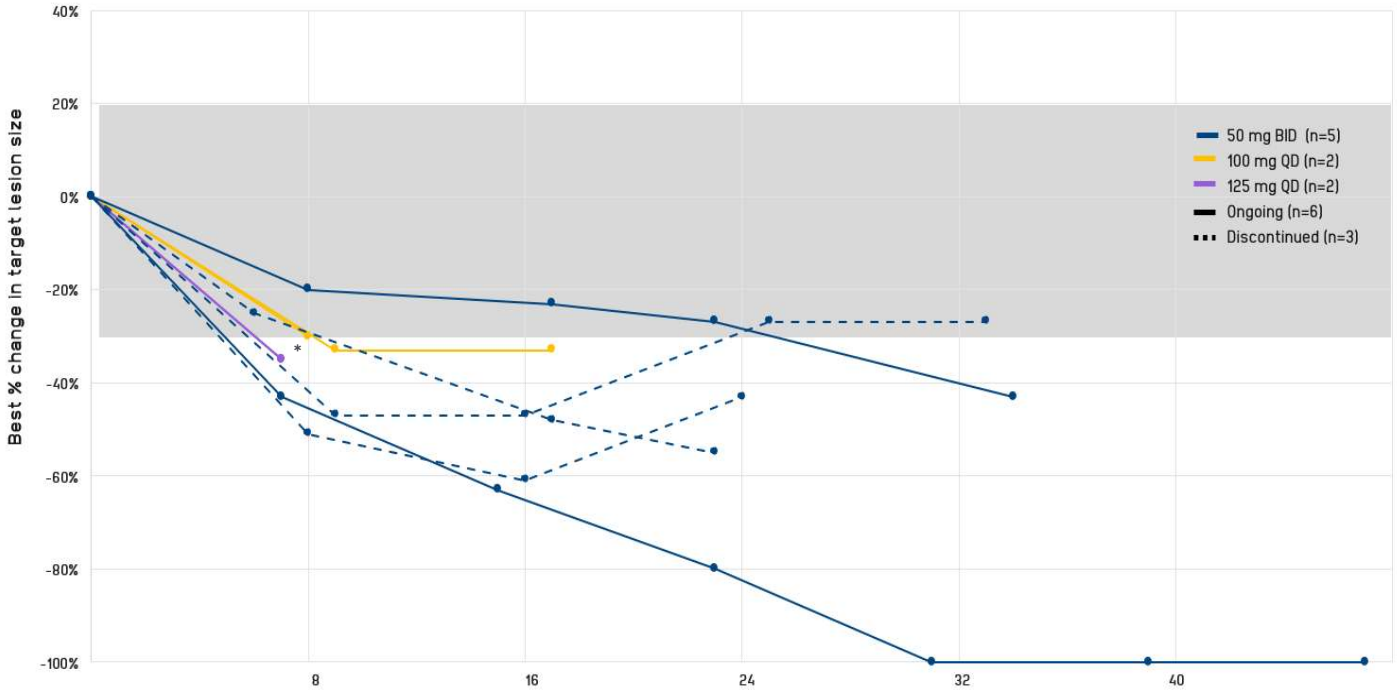
Efficacy in Dose Expansion - Ovarian Cancer Patients

- Three dose levels expanded in Dose Expansion: 50mg BID (n=16), 100mg QD (n=11) and 125mg QD (n=10)
- Sixteen patients are still ongoing, 7 in each QD schedule and 2 patients ongoing in 50 mg BID
- Median of 3 prior lines of therapy (range: 1-4)

Dose Expansion Ovarian Cancer	50 mg BID N=16[a] (%)	100 mg QD N=11[a] (%)	125 mg QD N=10[a] (%)	Total N=37[a] (%)
ORR (CR+PR)	5 (31.3)	2 (18.2)	2 (20.0)	9 (24.3)
CR	2 (12.5)	0	0	2 (5.4)
PR	3 (18.8)	2 (18.2)	2 (20.0)	7 (18.9)
SD	7 (43.8)	7 (63.6)	5 (50.0)	19 (51.3)
Disease control (CR+PR+SD)	12 (75.0)	9 (81.2)	7 (70.0)	28 (75.7)

[a] Includes participants in dose expansion who received at least 1 dose of study treatment (50 mg BID, 100 mg QD or 125 mg QD) completed a baseline scan, and completed at least one postbaseline scan and/or discontinued from study treatment without scan
BID, twice daily, CR, complete response; DCR, disease control rate; ORR, overall response rate, PR, partial response, QD, daily, SD, stable disease

Dose Expansion: Ovarian Cancer Efficacy
Responders (CR+PR) at 50 mg BID, 100 mg QD, 125 mg QD



Majority of ovarian cancer patients in expansion with either CR, PR or SD remain ongoing

2 patients with
Complete Response (CR)
- 1 patient ongoing

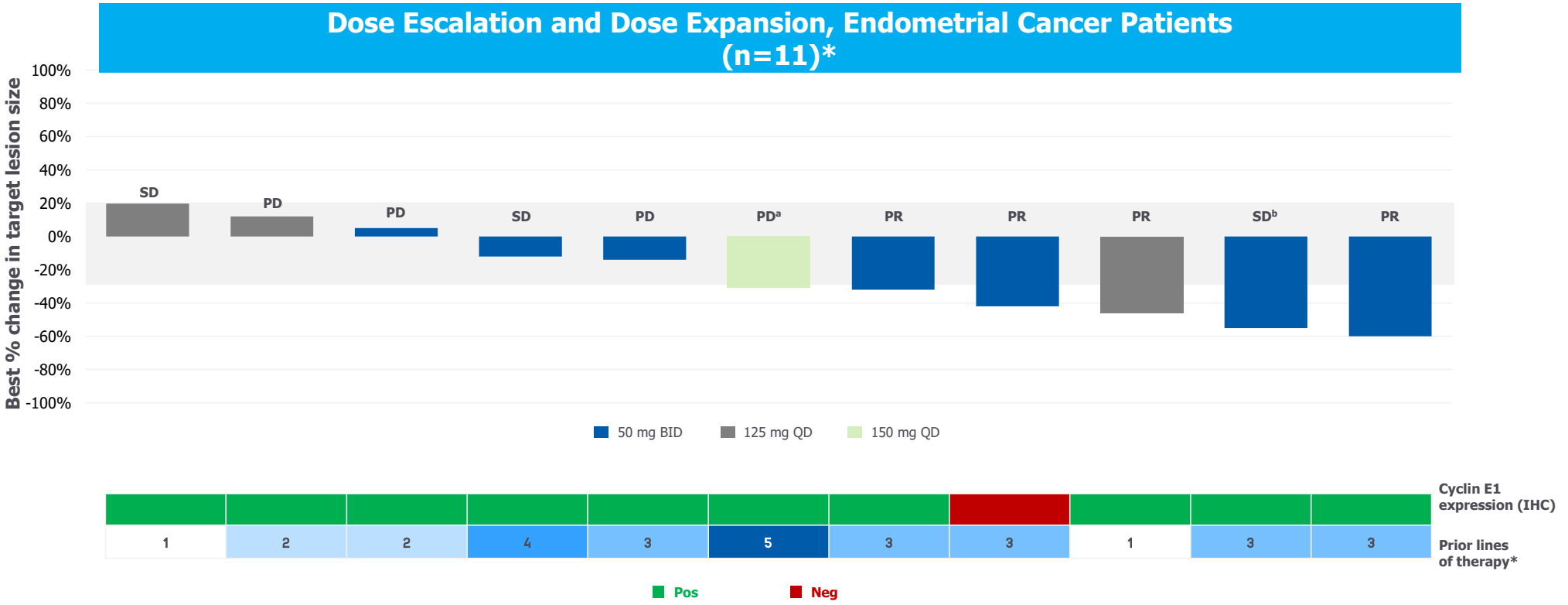
7 patients with
Partial Response (PR)
- 5 patients ongoing

19 patients with
Stable Disease (SD)
- 10 patients ongoing

* Lines for 2 patients overlap (both 125mg QD)

BID, twice daily; CDK, cyclin-dependent kinase; CR, complete response; i, inhibitor; PR, partial response; QD, once daily; SD, stable disease
Data on file, Incyte Corporation (as of 26 August 2024)

Tumor Shrinkage Observed in Endometrial Cancer Patients



* Total of 14 endometrial cancer patients enrolled with 11 patients included with at least 1 on-treatment scan available as of 22-Aug-2024

[a] BOR of PD: 31% decrease in target lesions, but unequivocal PD in non-target lesions at 1st postbaseline scan

[b] BOR of SD: 24% decrease in target lesions at 1st postbaseline scan (SD), followed by 55% decrease in target lesions + unequivocal PD in non-target lesions and appearance of new lesion at 2nd postbaseline scan (PD)

BID, twice daily; IHC, immunohistochemistry; QD, once daily; BOR, best overall response; PD, progressive disease; SD, stable disease

Favorable Safety Profile and Anti-Tumor Activity in Phase 1/2 Trial

1. Incyte's CDK2i is generally well tolerated in patients with advanced/metastatic solid tumors up to a total daily dose of 125 mg – low incidence of discontinuation was observed
2. The most common treatment related AEs are nausea, thrombocytopenia, and anemia with low incidence of grade 3-4 events
3. 50 mg BID, 100mg QD and 125 mg QD doses showed good tolerability and were selected for ongoing expansion
4. Antitumor activity and decreases in ctDNA were observed across a range of doses and regimens, especially in patients with ovarian cancer and endometrial cancer, whose tumors overexpress Cyclin E1
5. Evaluation in combination therapy with selected anticancer therapies is ongoing

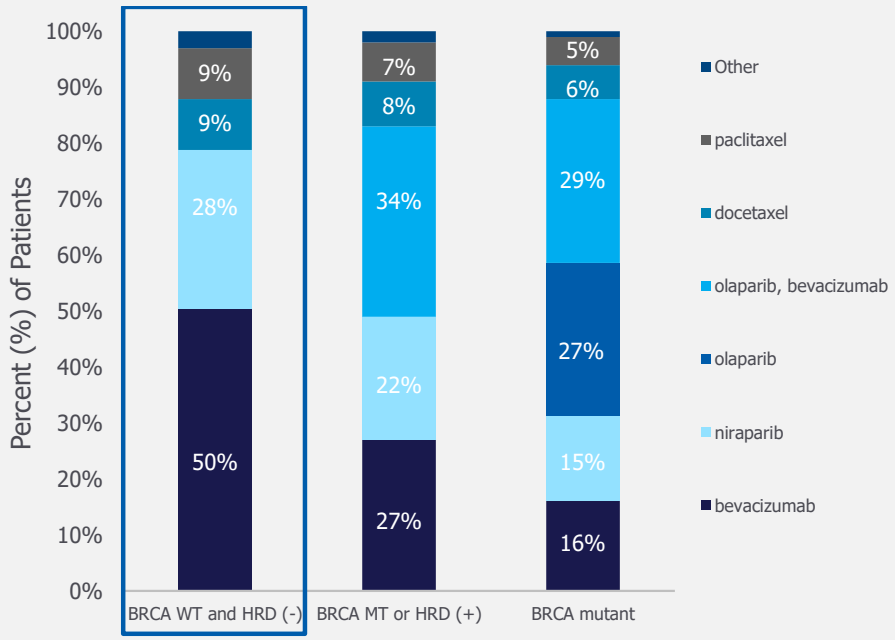
BID, twice daily; CDK2i, cyclin-dependent kinase 2 inhibitor; ctDNA, circulating tumor DNA; QD, once daily; TRAE, treatment-related adverse event.

CDK2i Development Plan

Steven Stein
Chief Medical Officer

PSOC Competitive Landscape: 1L Maintenance for HRD- (BRCA WT) Consists Of Bevacizumab or Niraparib

Utilization of Maintenance Therapy Following Bevacizumab-Based Induction, Stages II-IV, Ovarian Cancer, U.S., 2023 (Table 18)*



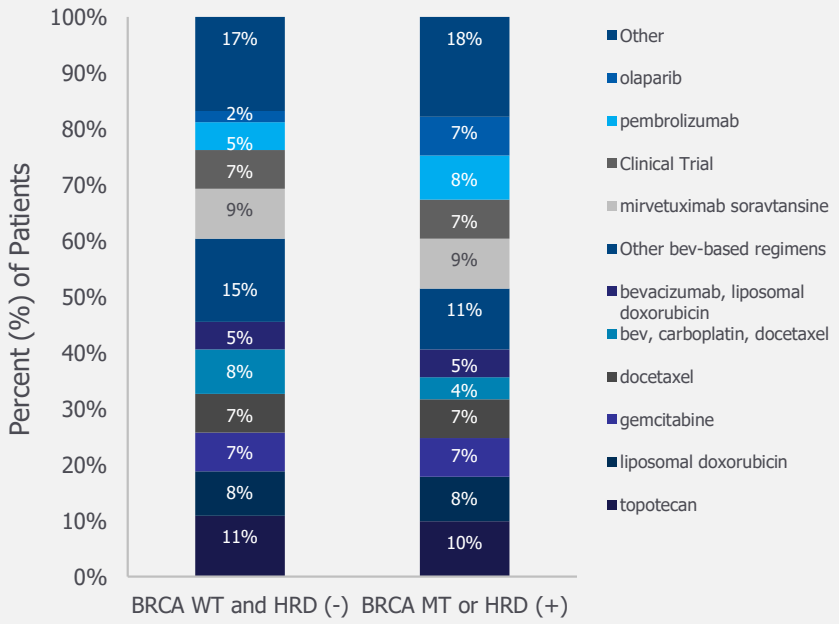
- HRD- represents ~52% of 1L maintenance[1]
  - ~22k patients in US, EU5, and Japan before CCNE1 enrichment
- HRD- is an area of unmet need in 1L maintenance :
  - **HRD- : PFS 10-12 months**
  - HRD+ : PFS ~39 months
  - BRCA mutant: PFS ~56 months
- Cyclin E protein expression is enriched in HRD- :
  - ~60% of HRP patients are Cyclin E high[2]
- In HRD-, niraparib is the only PARPi approved
- The majority of HRD- patients still receive bevacizumab as 1L maintenance

INCB123667 (CDK2i) + bevacizumab could become new SOC in patients with Cyclin E1 overexpression

1. Ray-Coquard, I et al N Engl J Med 2019;381:2416-2428
2. Internal data on file derived from TCGA database

PROC Competitive Landscape: Various Single-agent Chemotherapies and Bevacizumab-Based Regimens Are Commonly Used

Third-Line Systemic Therapy, Stages II-IV Ovarian Cancer, U.S., 2024 (Table 30)[a]



- Unmet need remains high in platinum resistant ovarian cancer with an estimate survival of ~12 months
- Chemotherapy (liposomal doxorubicin, paclitaxel, topotecan) +/- bevacizumab remains the SOC for the majority of patients
- FRα-targeting ADC mirvetuximab approved in March 2024
- Mirvetuximab, similar to other ADCs in development, has a tolerability profile that may be challenging for many patients
- The majority of Cyclin E1 overexpressed patients are not FRα high patients
- WEE-1 inhibitors in development continue to encounter toxicity challenges with azenosertib on partial clinical hold

INCB123667 (CDK2i) could become the new SOC in Cyclin E1 overexpressed PROC patients with a profile that improves outcomes and limits toxicity

CDK2i: Potential Registration Scenarios Ovarian Cancer – Study Designs (Regulatory Feedback Pending)

#	Study Design	Phase	Clinical Setting (Cyclin E1+ by IHC)	Line of Therapy	Treatment arms	Primary Endpoint	Data
1	Expand current study or Single Arm Monotherapy (Accelerated Approval)	2	Platinum Resistant Ovarian Cancer Endometrial Cancer	2-4L	INCB123667	ORR	2H 26
2	Randomized Controlled Trial (incl. IA for ORR)	3	Platinum Resistant Ovarian Cancer**	2-4L	INCB123667 vs. BIC chemotherapy	PFS (IA: ORR)	2H 27
3	Randomized Controlled Trial	3	Maintenance after 1L chemotherapy	1L	INCB123667+Bevacizumab vs. Bevacizumab	PFS	1H 29

For patient selection/stratification, an IHC-based Co-Diagnostic is currently being developed and will be included into the pivotal studies of the clinical development program

1L/2L/4L: first/second/forth line of treatment; BIC: Best Investigator's choice; IA: interim analysis; IHC: immunohistochemistry; LOT: Line of Therapy; ORR: overall response rate; PFS: progression-free survival; PROC: platinum-resistant ovarian cancer; PSOC: platinum-sensitive ovarian cancer

Summary and Outlook

Incyte's CDK2i has shown clinical activity and ctDNA decreases, especially in ovarian cancer

Incyte's CDK2i indicates a favorable safety profile up to 125 mg daily dose

Incyte's CDK2i demonstrates a promising Target Product Profile that warrants further clinical development in gynecological cancers

Based on these encouraging Phase 1 results and pending regulatory feedback, Incyte plans to:

1. Initiate a pivotal study with CDK2i monotherapy in Cyclin $E1^{High}$ PROC
2. Expand CDK2i into other Cyclin $E1^{High}$ cancers, especially endometrial cancer
3. Expand CDK2i in combination regimens into earlier treatment lines in newly diagnosed (combination with bevacizumab) and other gynecological cancers

Closing Remarks

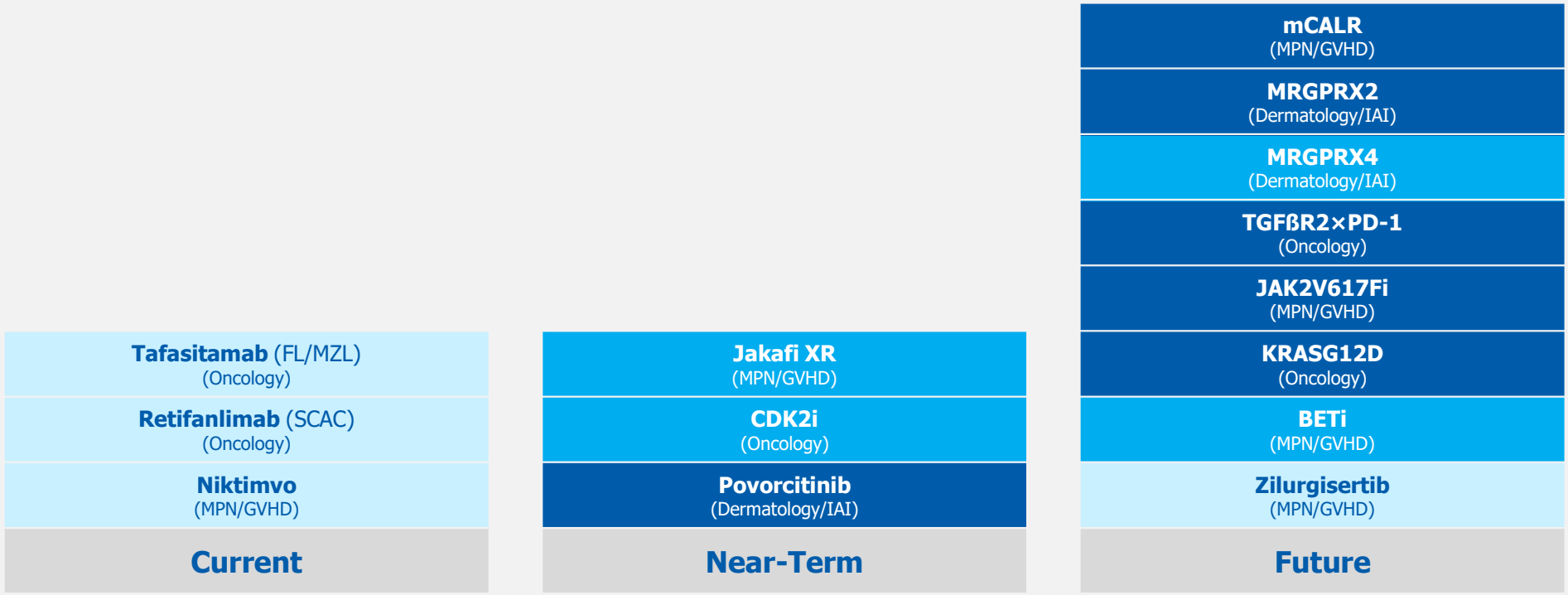
Pablo Cagnoni
President, Head of Research & Development

Meaningful Upcoming Near-Term Catalysts

		2H 2024	1H 2025	2H 2025
MPN / GVHD	Axatilimab	3L+ cGVHD PDUFA		
	BETi	P1 data & pivotal study plans		
	ALK2i	P1 data		
	mCALR		P1 PoC data	
	JAK2V617Fi		P1 MF data	
Oncology	Retifanlimab	P3 data (NSCLC & SCAC)		**SCAC/NSCLC approval**
	Tafasitamab	P3 data (FL/MZL)	P3 data (1L DLBCL)	**FL/MZL approval**
	CDK2i	P1 PoC & pivotal study plans	**Pivotal Study Ovarian Cancer**	
	KRASG12D		P1 PoC data	
	TGFBR2xPD-1		P1 PoC data	
IAI / Derm	Ruxolitinib Cream	Peds AD submission	Peds AD approval	P3 data (PN)
	Povorcitinib		P3 data (HS)	P2 data (asthma/CSU)
	MRGPRX2		P1/2 PoC data (CIndU/CSU/AD)	
	MRGPRX4		P2 PoC data (CP)	
	anti-CD122		P1 data	

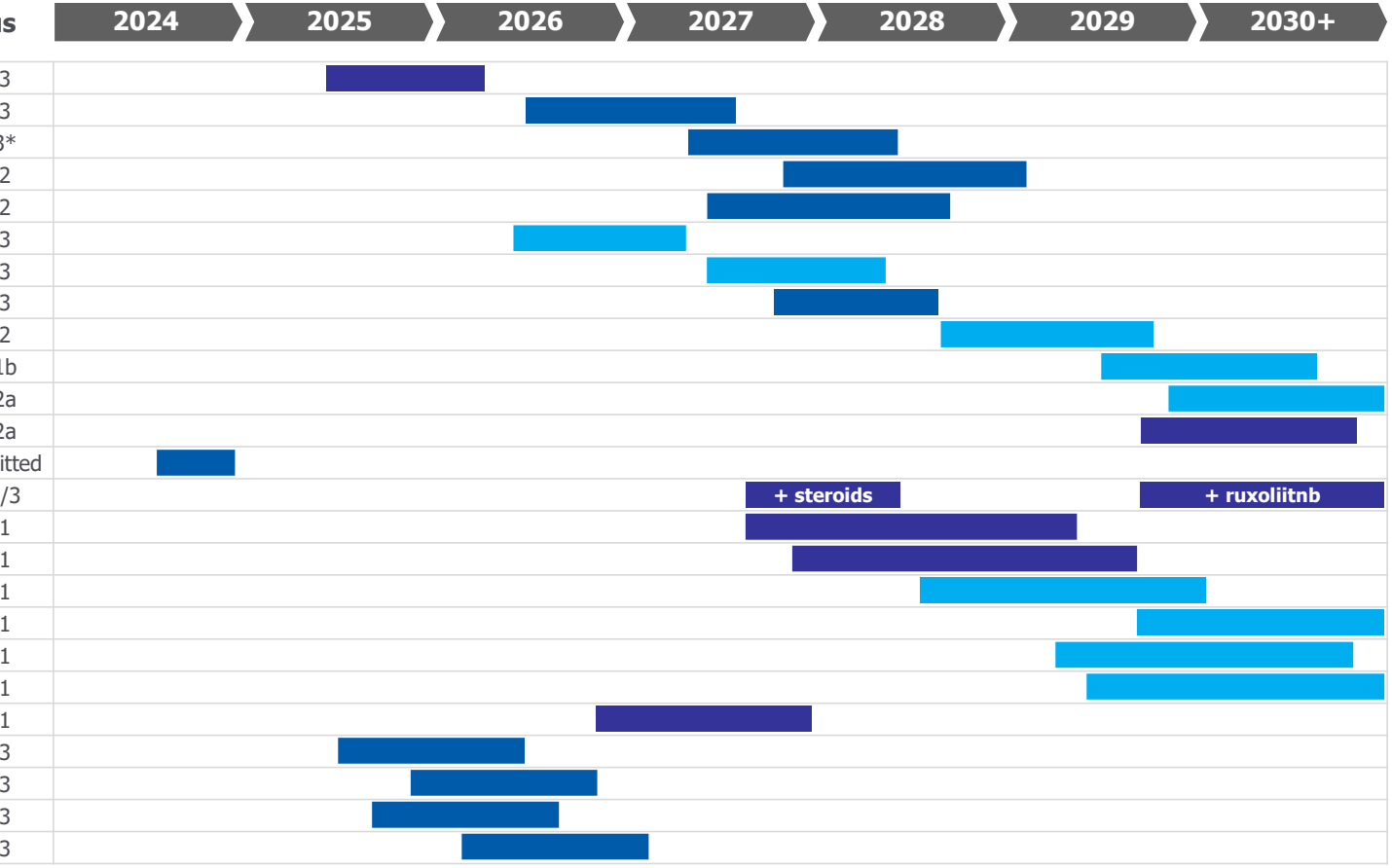
MPN= myeloproliferative neoplasms; GVHD= graft-versus-host disease; IAI= inflammation and autoimmunity; NSCLC= non-small cell lung cancer; SCAC= squamous cell anal carcinoma; FL= follicular lymphoma; MZL= marginal zone lymphoma PoC= proof-of-concept; DLBCL= diffuse large B-cell lymphoma; AD= atopic dermatitis; PN= prurigo nodularis; HS= hidradenitis suppurativa; CIndU= chronic inducible urticaria; CSU= chronic spontaneous urticaria; CP= cholestatic pruritus

New Molecular Entities Driving Portfolio Growth



>10 Potential High Impact Launches by 2030

	Product	Indication	Status
Dermatology/IAI	Ruxolitinib Cream	Pediatric AD	Phase 3
		Prurigo Nodularis	Phase 3
		HS (mild/mod)	Phase 3*
		Lichen Planus	Phase 2
		Lichen Sclerosis	Phase 2
	Povorcitinib	HS (mod/sev)	Phase 3
		Vitiligo	Phase 3
		Prurigo Nodularis	Phase 3
	MRGPRX2	CSU	Phase 2
		CIndU	Phase 1b
		Atopic Dermatitis	Phase 2a
	MRGPRX4	CP	Phase 2a
MPN/GVHD	Axatilimab	3L+ cGVHD	BLA submitted
		1L cGVHD	Phase 2/3
	BETi	MF	Phase 1
	Zilurgisertib	MF	Phase 1
	mCALR	MF & ET	Phase 1
	JAK2V617Fi	MF, PV & ET	Phase 1
Oncology	KRASG12D	Solid Tumors	Phase 1
	TGFßR2×PD-1	Solid Tumors	Phase 1
	CDK2	Solid Tumors	Phase 1
	Retifanlimab	SCAC	Phase 3
		NSCLC	Phase 3
	Tafasitamab	FL/MZL	Phase 3
		1L DLBCL	Phase 3



Incyte

* In planning. Incyte data on file

Potential U.S. approval range and U.S **addressable market size** < $1B $1-3B > $3B

Q&A

Incyte

Solve On.