The BASICS

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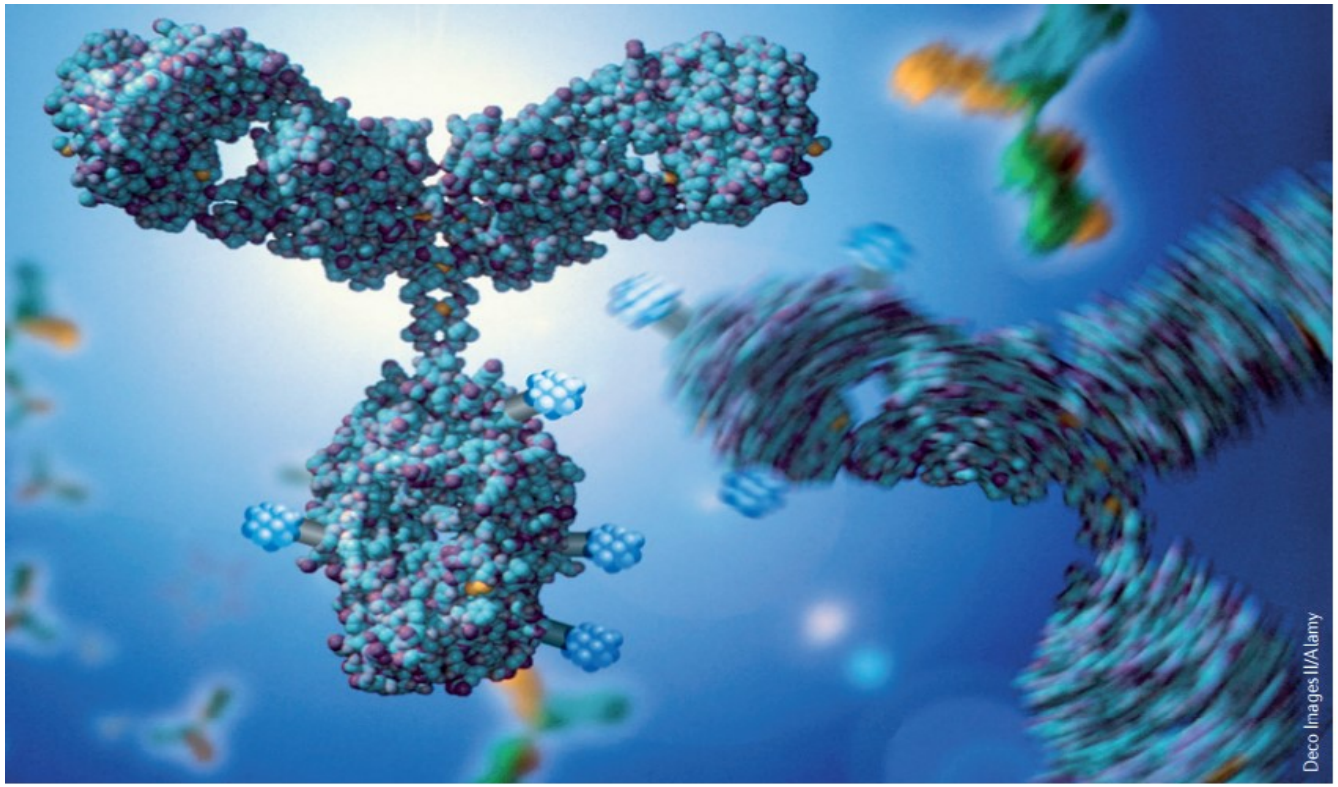
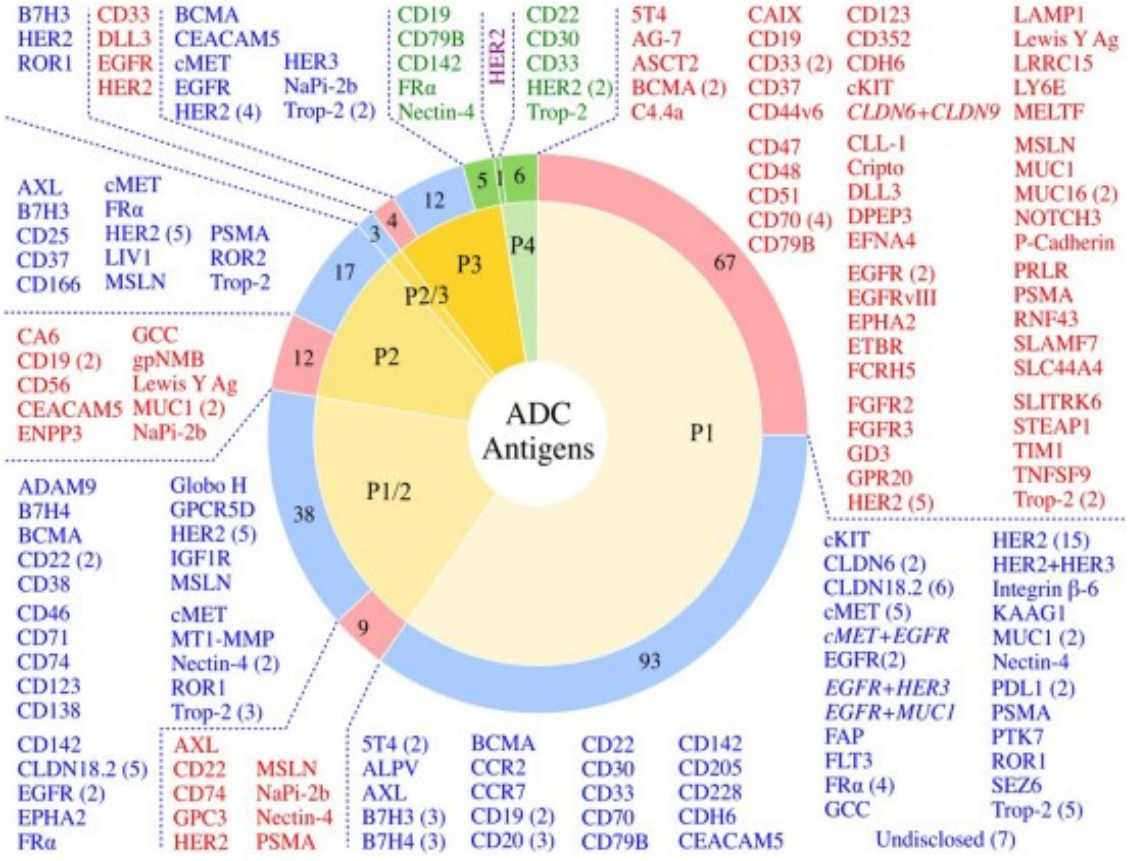
Declaration of interests
Prof. Nicole Concin

Consulting/Advisory:	MSD, ImmunoGen, Seagen, Akesobio, EISAI, GSK, AstraZeneca, Mersana, Seattle Genetics, eTheRNA immunotherapies NV, KARTOS
Travel Expenses:	Roche, Genmab, Amgen
Educational fees:	Kartos, MSD, Medscape Oncology, TouchIME
Functions in societies:	Past-President of ESGO Chair of ENGOT Early Drug Development Network FIGO Committee for women`s cancer

Antibody-Drug Conjugates (ADCs)





260 tested, green FDA approved, Blue activity reported, red stopped

Maecker H et al, MAbs. 2023
Petersen et al. Mol Cancer Ther. 2024
Chau CH, Steeg PS, Figg WD, Lancet 2019
Mullard A, Nat Rev Drug Discov 2013

ADCs UNDER CLINICAL DEVELOPMENT IN GYNAE ONC

Non exhaustive

Target	Drug	DAR	Tumor type
B7-H4	XMT-1660[1]	6	Ovarian, endometrial
	SGN-B7H4V[2–4]	4	Ovarian, endometrial
	AZD8205[5,6]	8	Ovarian, endometrial
CDH6	DS-6000a[7,8]	~8	Ovarian
FRα	Mirvetuximab soravtansine	3.4	Ovarien, endometrial
	IMGN-151	3.5	Ovarian, endometrial
	Luveltamab tazevibulin (STRO-002)[9,10]	4	Ovarian, endometrial
	Farletuzumab ecteribulin (MORAb-202)[11,12]	4	Ovarian, endometrial
HER2	SYD985[13,14]	2.7	Ovarian, endometrial
	T-DXd[15,16]	7–8	Cervical, ovarian, endometrial
	DB-1303/BNT323[17,18]	~8	Endometrial
Mesothelin	BMS-986148[19,20]	3	Ovarian
Tissue factor	XB002[21,22]	4	Cervical, ovarian
TROP2	Sacituzumab govitecan[23, 24]	7.5	Cervical, ovarian, endometrial
	DB-1305[25, 26]	~4	Ovarian, endometrial
	Sacituzumab tirumotecan (MK-2870/SKB264)[27]	7.4	Cervix, endometrial

Maecker H et al, MAbs. 2023

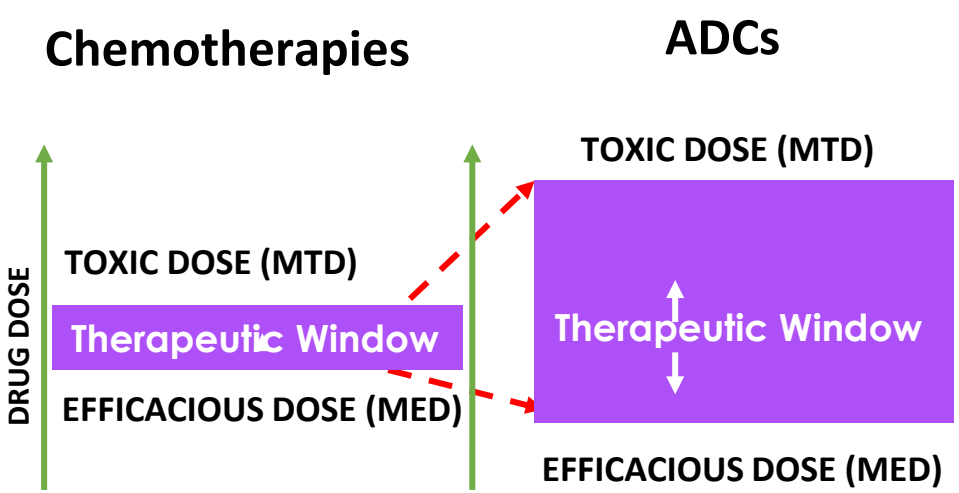
Why ADCs?

Engineered to limit systemic toxicity and improve the therapeutic index of cytotoxic agents

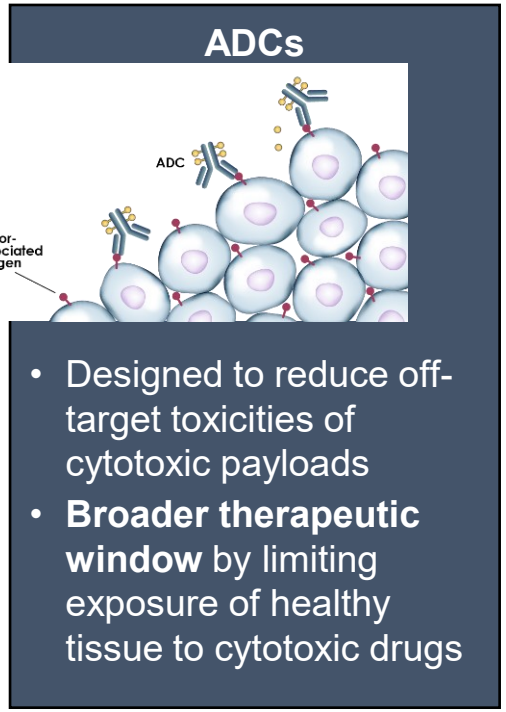
ADCs are a class of targeted therapies that are designed to selectively deliver cytotoxic drugs to cancer cells[1]

Systemic chemotherapies [2]

- Cytotoxic agents that target rapidly dividing cancerous and healthy cells
- Severe side effects limit administrable dose
- **Narrow therapeutic window** resulting from a small therapeutic index



$$\text{THERAPEUTIC INDEX} = \frac{\text{MTD}}{\text{MED}}$$

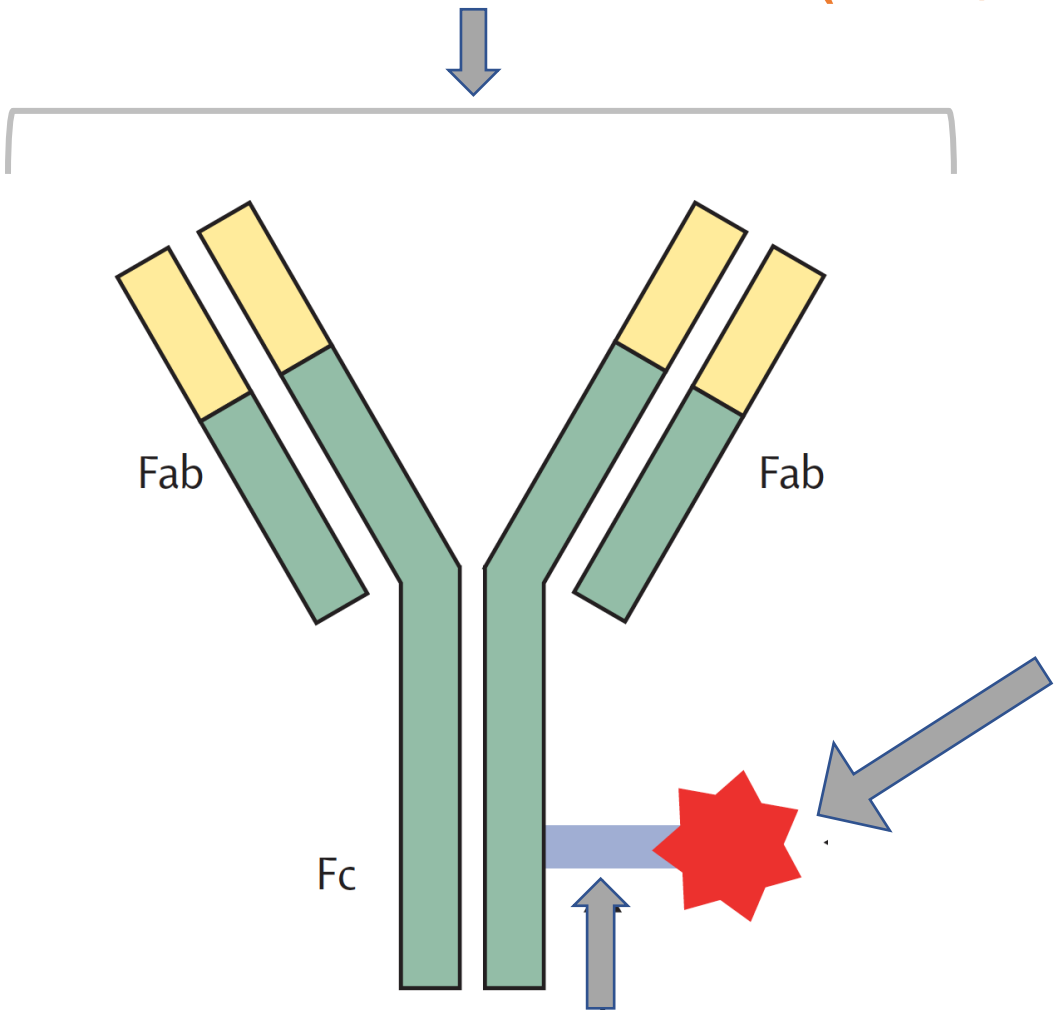


ADC, antibody-drug conjugate; MED, minimum effective dose; MTD, maximum tolerated dose.

1. Criscitiello C et al. *J Hematol Oncol*. 2021;14(1):20.
2. Panowski S et al. *MAbs*. 2014;6(1):34–45.

Structure of Antibody-Drug Conjugates (ADCs)

MONOCLONAL ANTIBODY (mAb)

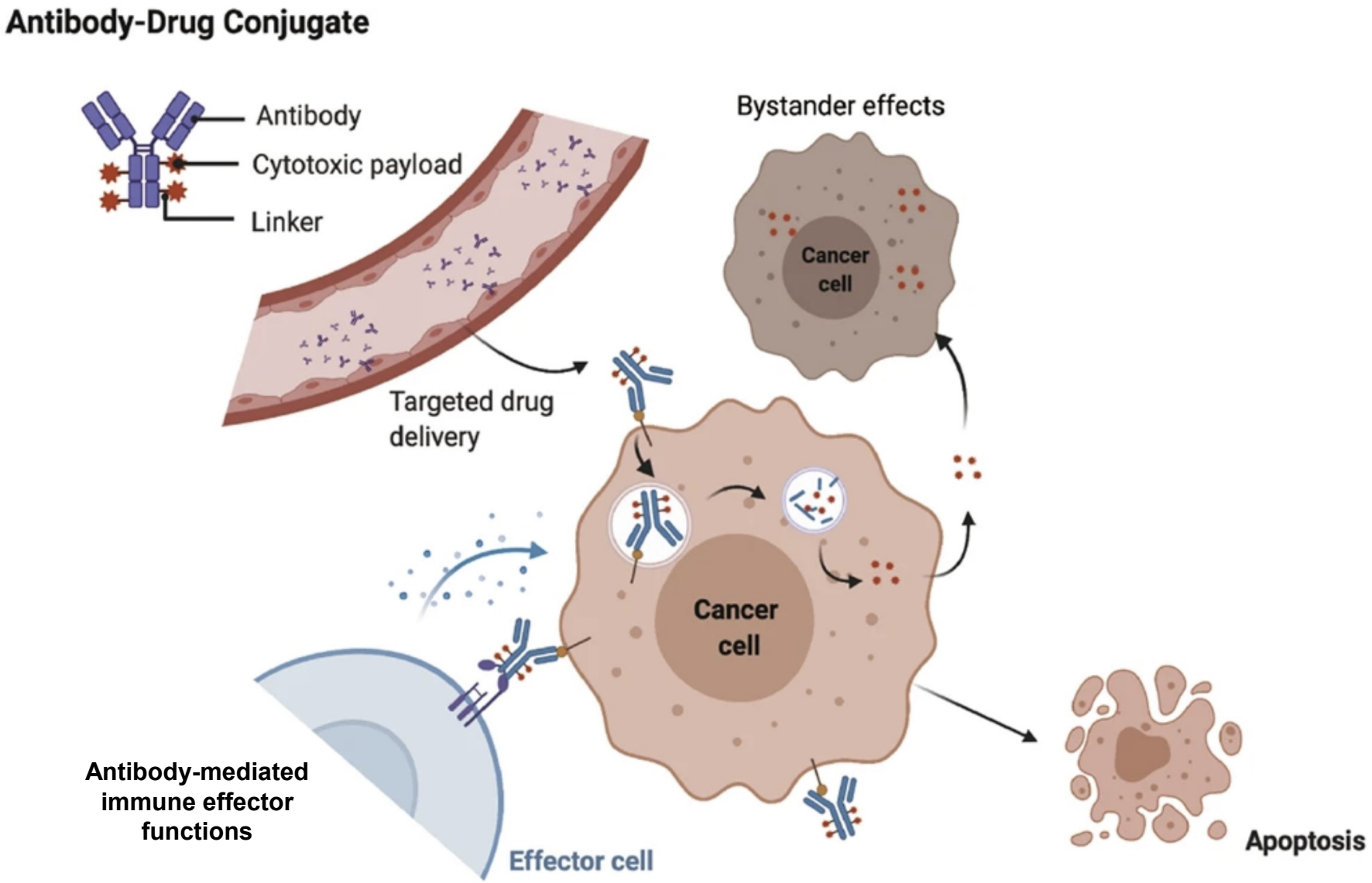


CYTOTOXIC PAYLOAD

LINKER

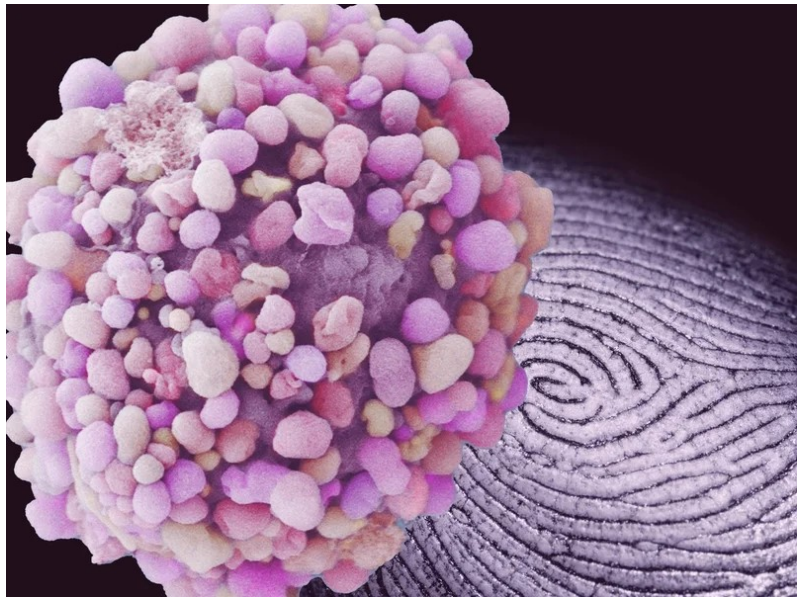
Chau CH, Steeg PS, Figg WD, Lancet 2019

ADCs: Mechanism of action



Fu et al. Sig Transduct Target Ther 2022;**7**:93.

Structure + Function of ADCs: TARGET ANTIGEN

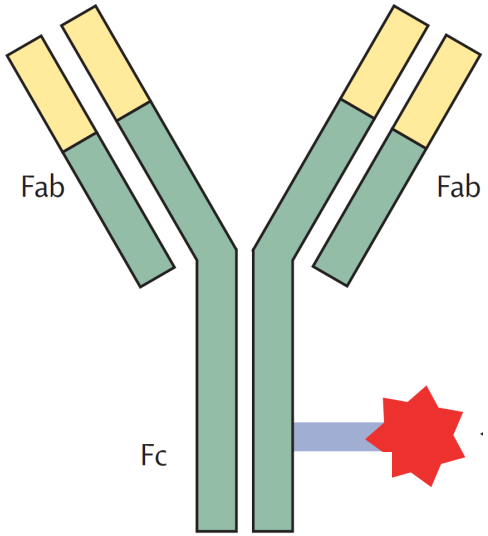


Antigen

- Homogenous expression on surface of tumour cells
- Low/no expression on healthy tissue

to limit on-target, off-tumour toxicity

- High affinity and avidity for antibody recognition

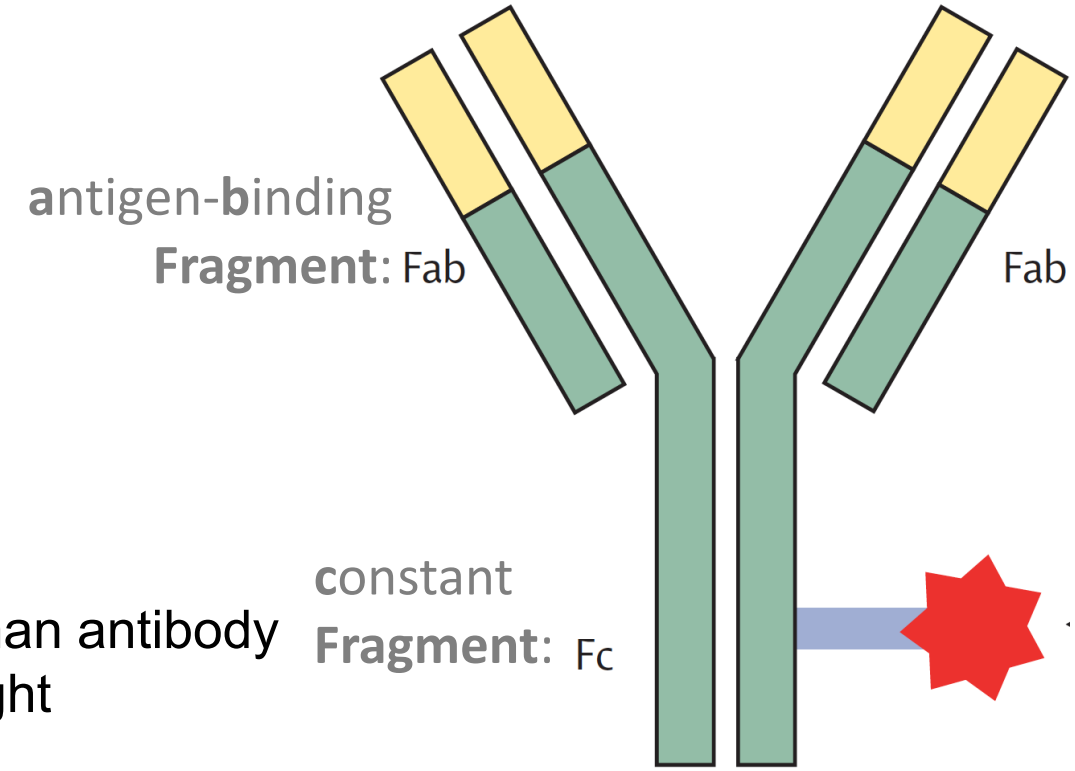


Chau CH, Steeg PS, Figg WD, Lancet 2019

Structure + Function of ADCs: COGNATE ANTIBODY

Antibody
2 fragments (antigen-binding / constant fragment)
4 polypeptides (2 heavy / 2 light chains)

- **High affinity and avidity for tumour antigen**
- **Minimal immunogenicity:** humanised or fully human antibody
- **Long circulating half-life** and high molecular weight

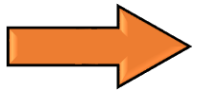


Chau CH, Steeg PS, Figg WD, Lancet 2019

Structure + Function of ADCs: LINKER

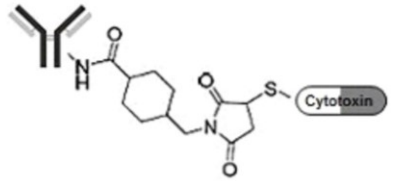
Properties of the linker

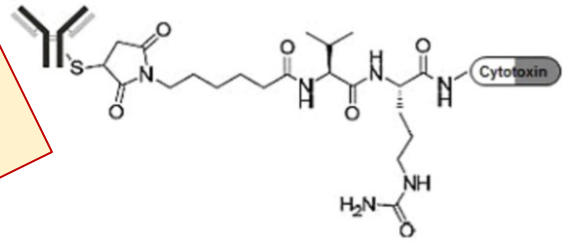
- Stability in systemic circulation
- Efficient release of payload at target site



Reduces the off-targe

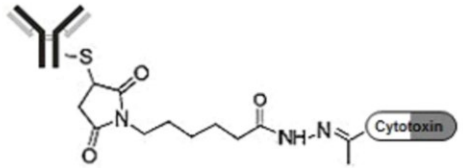
LINKER TECHNOLOGY
= important modulators of overall ADC
pharmacokinetics, pharmacodynamics and toxicity





Two categories of lin

- **CLEAVABLE : *d*** ***ment***

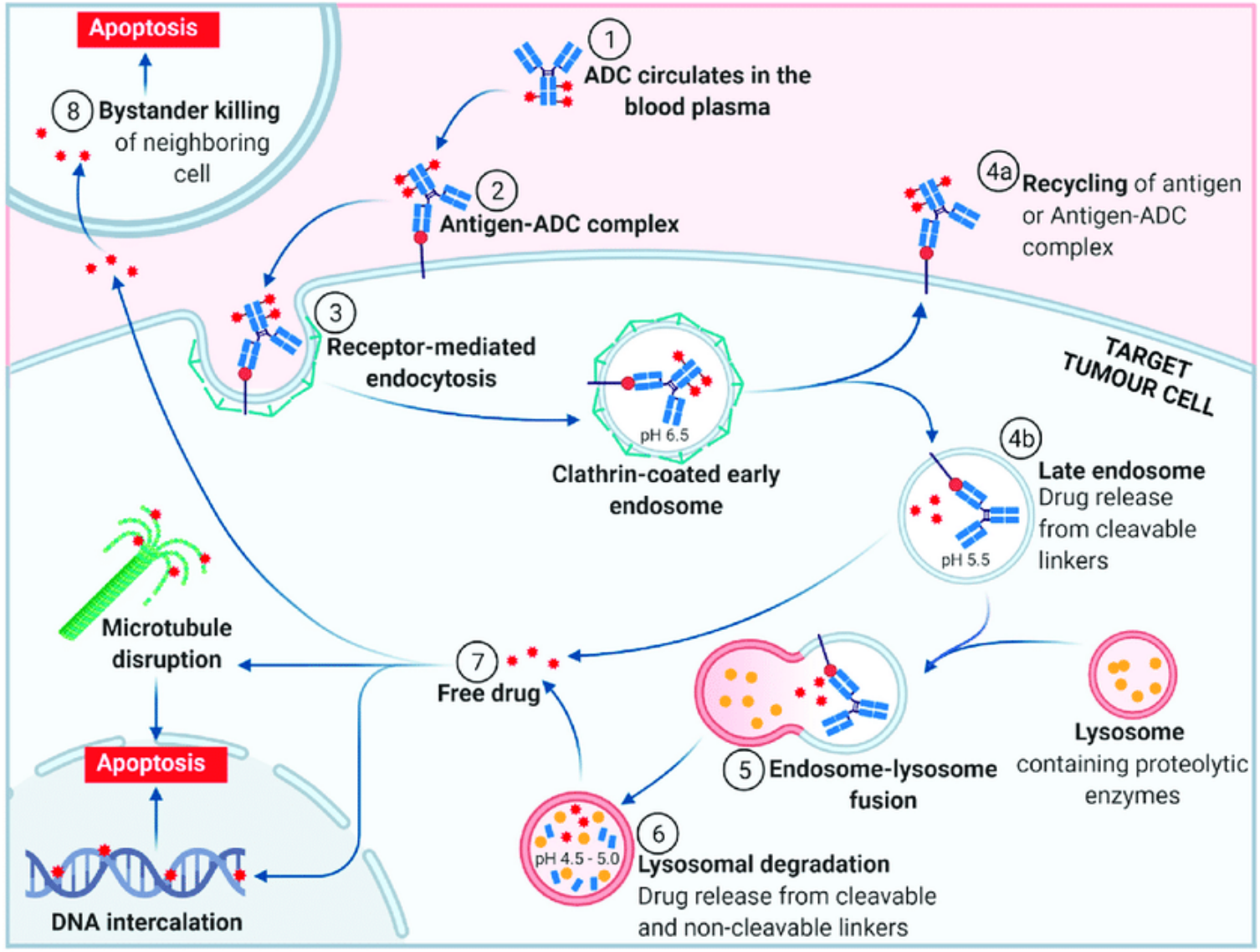


leavable linkers)
glutathione concentrations (disulphide linkers)

- **NON-CLEA** ***epend on lysosomal degradation of the antibody***
  payload release
  form nonreducible bonds with the antibody
  e.g. thioether linker

Drago JZ et al. Nat Rev Clin Oncol 2021
.Lu J et al. Int J Mol Sci. 2016
Sau S et al. Drug Discov Today. 2017
Chau CH, Steeg PS, Figg WD, Lancet 2019
Khongorzul et al, Molecular Cancer Research 2019

Structure + Function of ADCs: LINKER



Cleavable linker

Non-cleavable linker

Tong et al. Molecules 2021,26,5847

Structure + Function of ADCs: CYTOTOXIC PAYLOAD

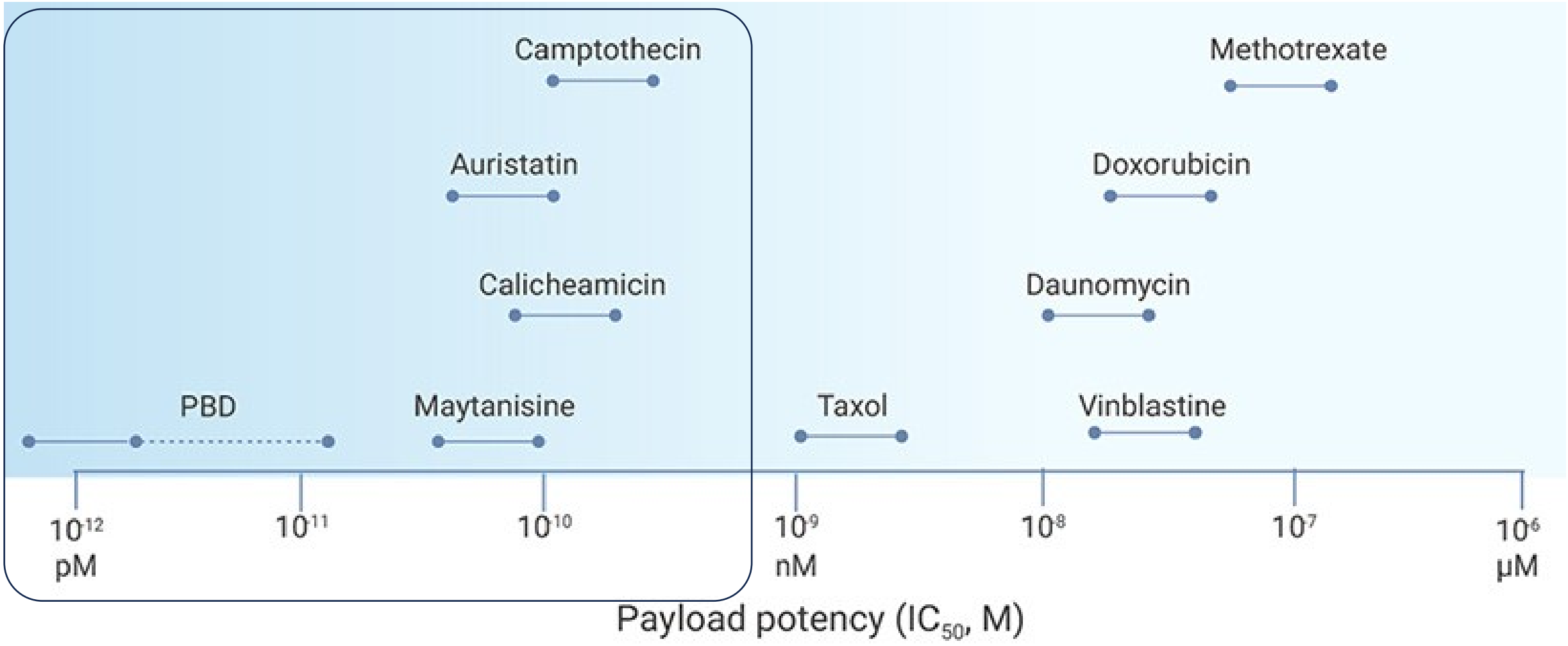
Highly potent agents
- targeting **tubulin**
- targeting **DNA**

Basic criteria
- amenability to conjugation
- solubility
- stability

Class	Mechanism of Action	Example compounds
Auristatins	**Inhibit tubulin assembly**	**MMAE** (vedotin) **MMAF** (mafadotin)
Maytansines	**Inhibit tubulin assembly**	**DM1**: emtansine, mertansine **DM4**: soravtansin, ravtansine
Tubulysins	**Inhibit microtubule polymerization**	AZ13599185
Pyrrolobenzo-diazepines (PBDs)	dimerization of PBD cause **crosslinking** of DNA	
Calicheamicin	induces **double-strand DNA breaks**	N-acetyl-g-calchicheamicin
Duocarmycins	**alkylating agent**	Seco-DUBA
Indolinobenzo-diazepines	**alkylate** only one strand of target DNA	
Camptothecin analogues	Inhibit DNA topoisomerase 1	Govitecan Deruxtecan

Lee EK, Liu JFI, Gynecologic Oncology 2019
Stewart D, Cristea M, curr Opin Obstet Gynecol 2019
Fu Z et al. Signal Transduct Target Ther. 2022
Donaghy H et al. MAbs. 2016
Tang H et al. Front Pharmacol. 2019
Cheng X et al. Mol Cancer Ther. 2018
Chen H et al. Molecules. 2017
Chau CH, Steeg PS, Figg WD, Lancet 2019

Payloads potency

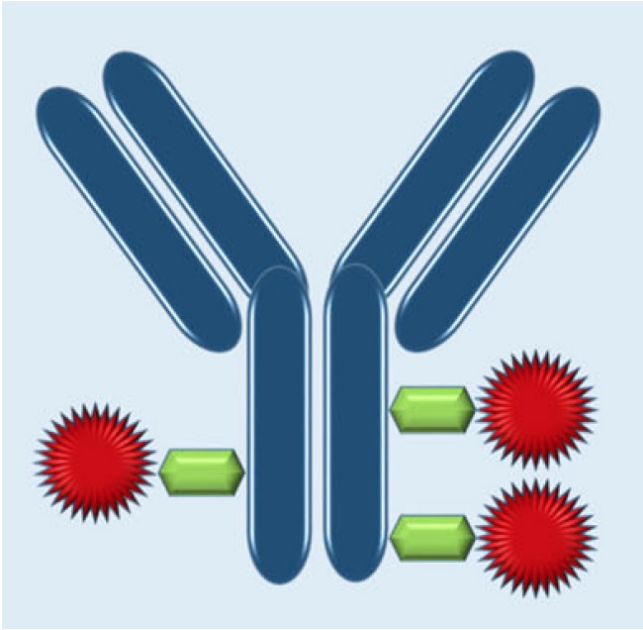


Pander et al. Drug Discovery Today 2022

Structure + Function of ADCs: DRUG TO ANTIBODY RATIO (DAR)

drug to antibody ratio (DAR) =
number of drug molecules
attached to the antibody

-> ADC potency and toxicity



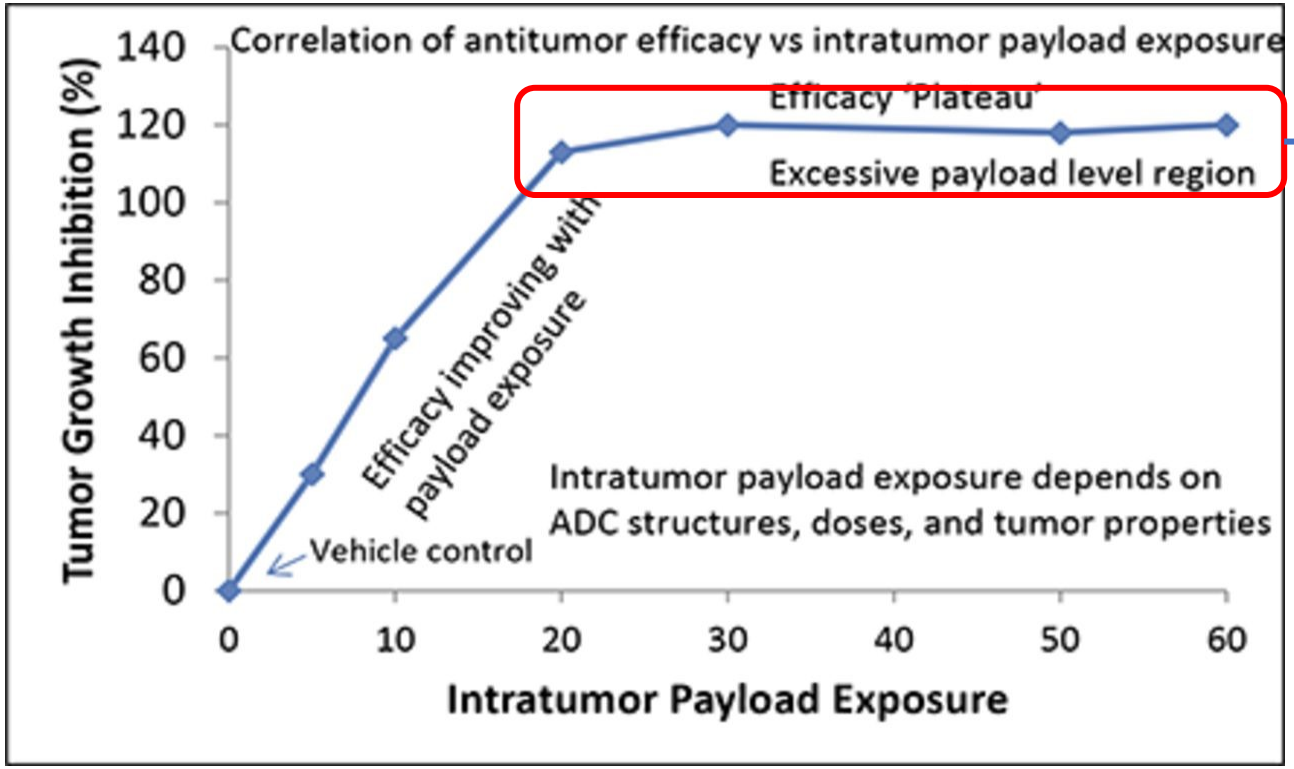
Chau CH, Steeg PS, Figg WD, Lancet 2019
Stewart D, Cristea M, curr Opin Obstet Gynecol 2019
Lee EK, Liu JFI, Gynecologic Oncology 2019

	Ag	Payload	DAR
Mirvetuximab-Soravtansine	FRα	DM4	3-4
Anetumab-Ravtansine	Mesothelin	DM4	3.2
Tisotumab-Vedotin	TF	MMAE	NR
Lifastuzumab-Vedotin	NaPi2b	MMAE	3-4
Luveltamab-Tazevibulin (STRO-002)	FRα	3-aminophenyl hemiasterlin	4
Farletuzumab-Ecteribulin (MORAb-202)	FRα	Eribulin	4
Upifitamab-Rilsodotin (UpRi)	NaPi2b	MMAF	10-12
DMOT4039A	Mesothelin	MMAE	3.5
BMS-986148	Mesothelin	Tubulysin	3
DMUC4064A	MUC16	MMAE	2

Adapted from O'Malley et al. Current Oncology Reports 2021

Dose / Payloads

More is not always better



Only increase in AEs

Zhang et al. Drug Metab Dispos 2019

UPLIFT / ENGOT-OV67 / GOG-3048

Design: Single arm Phase II (continued out of Phase I trial)

Key inclusion criteria:

- Platinum-resistant[a] HGSOC[b]
- 1–4 prior lines of therapy
- Prior bevacizumab required if patient received only 1–2 prior lines of therapy
- ECOG PS 0–1
- Available archived or fresh tissue for retrospective NaPi2b evaluation
- Grade ≤ 2 peripheral neuropathy
- Measurable disease per RECIST v1.1

Key exclusion criteria:

- 1–2 prior lines AND bevacizumab-naive
- Primary platinum-refractory disease

UpRi 36 mg/m² up to max 80 mg; IV q4w

36 mg/m² dose selected based on favorable safety profile and similar efficacy as dose Group 43 seen in the Phase 1b study

Statistical Assumptions

- α=0.025 (one-sided)
- power = 90%
- ORR 24% (vs 12% based on single agent chemo)

Primary endpoint

- Investigator-assessed **confirmed ORR in NaPi2b-positive population**

Secondary endpoints

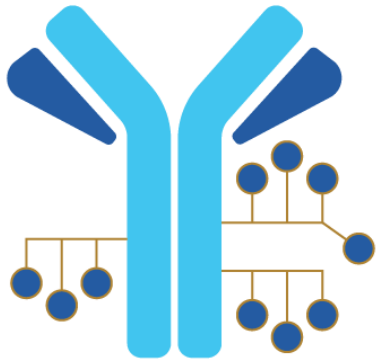
- Investigator-assessed confirmed ORR in overall population
- DOR
- Safety

UPLIFT

ENGOT European Network of Gynaecological Oncological Trial groups

GOG FOUNDATION Transforming the standard of care

UPIFITAMAB RILSODOTIN (UPRI; XMT-1536)



Dolaflexin ADC designed to minimize the common toxicities associated with ADCs (peripheral neuropathy, neutropenia, ocular toxicity)

Antibody: Humanized monoclonal anti-SLC34A2 (NaPi2b)
Linker: Polymer scaffold; Stochastic cysteine conjugation
Payload: AF-HPA - controlled bystander effect; highly potent anti-tubulin inhibitor selectively toxic to rapidly dividing cells
Drug-to-Antibody Ratio: Heterogeneous; ~10

NCT03319628

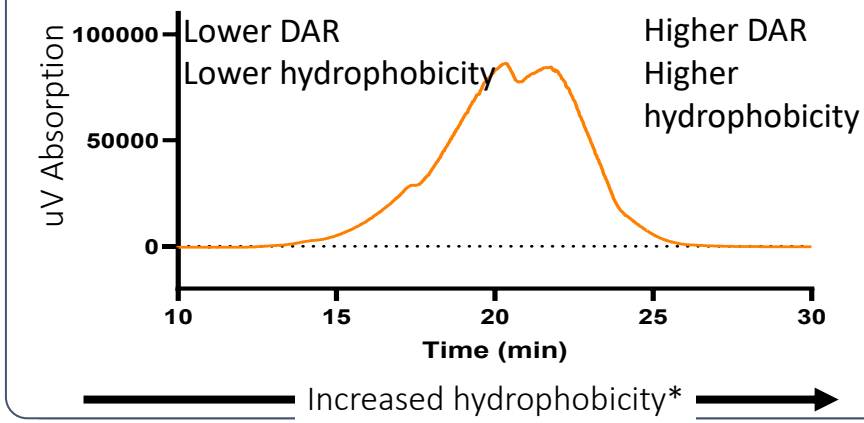
[a] Platinum-resistant is defined as disease that has progressed within 6 months of the last dose of platinum. HGSOC, including fallopian tube and primary peritoneal cancer. DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ENGOT, European Network of Gynaecological Oncological Trial Groups; GOG, Gynecologic Oncology Group; HGSOC, high-grade serous ovarian cancer; IV, intravenous; NaPi2b, sodium-dependent phosphate transport protein 2B; ORR, overall response rate; q4w, every 4 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; UpRi, upifitamab rilsodotin.

Richardson et al. IGCS 2022
Concinet al ESGO, 2024

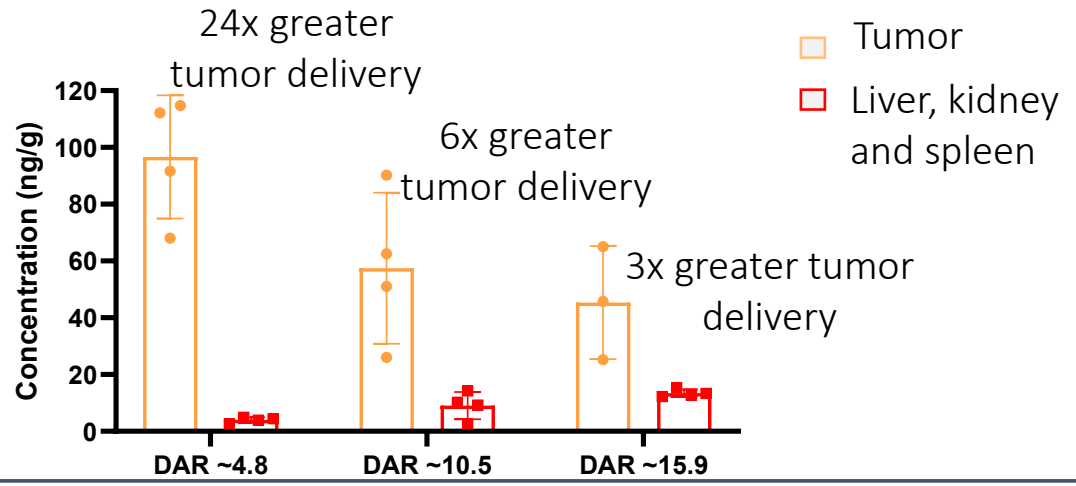
UPLIFT / ENGOT-ov67 / GOG-3048 Upifitamab-Rilsodotin (UpRi)

High-DAR Sub-Populations are believed to have contributed to Off-Target Toxicities

Dolaflexin Heterogeneous ADC population – an ADC sub-population mixture



Dolaflexin High-DAR Sub-Populations Show Reduced Tumor-Specific Delivery

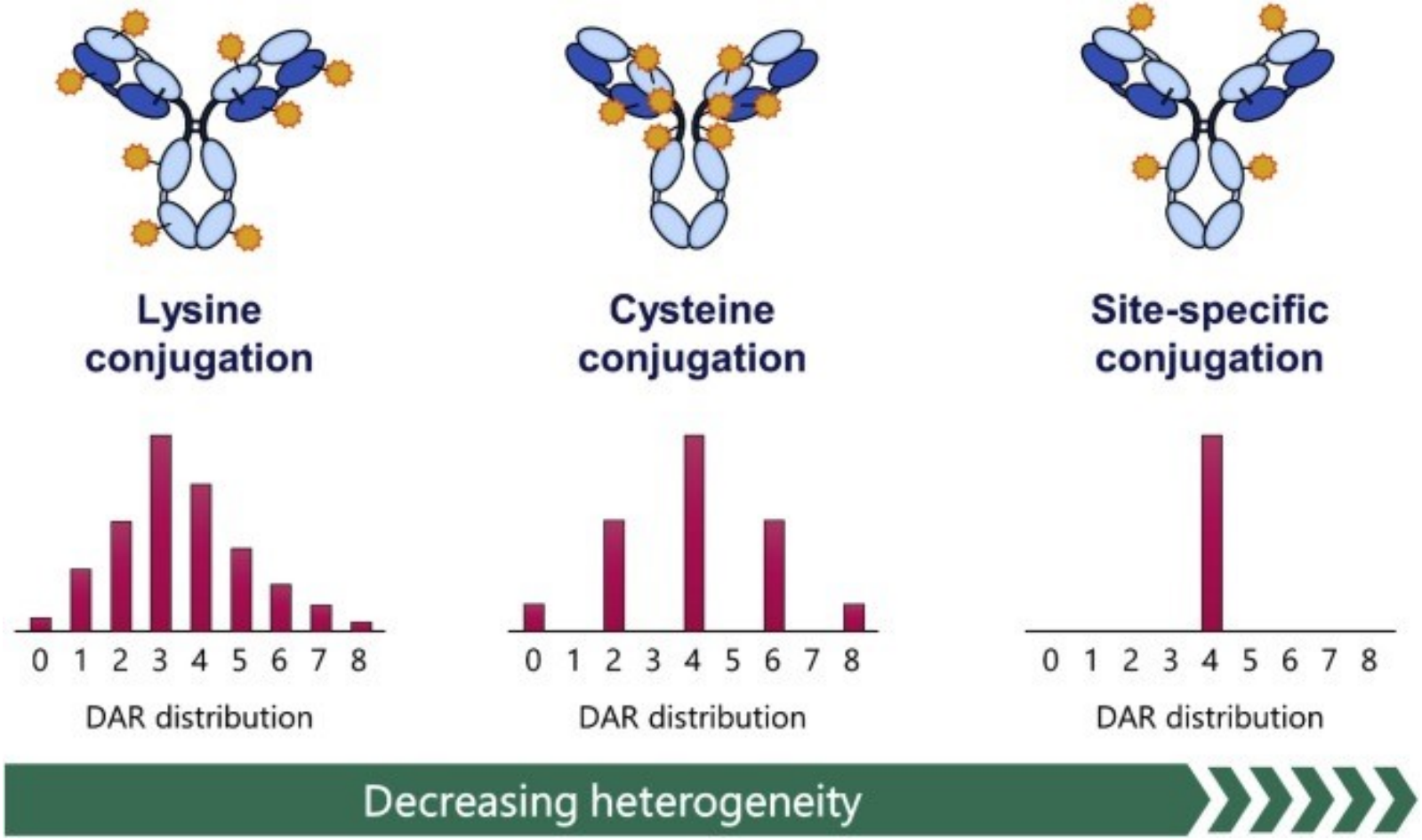


Hypothesized that the high-DAR subpopulation may have reduced UpRi's efficacy while also increasing toxicity, including potentially thrombocytopenia and bleeding

* As measured by hydrophobic interaction chromatography, 280 nanometers

Concin et al, ESGO 2024 Barcelona

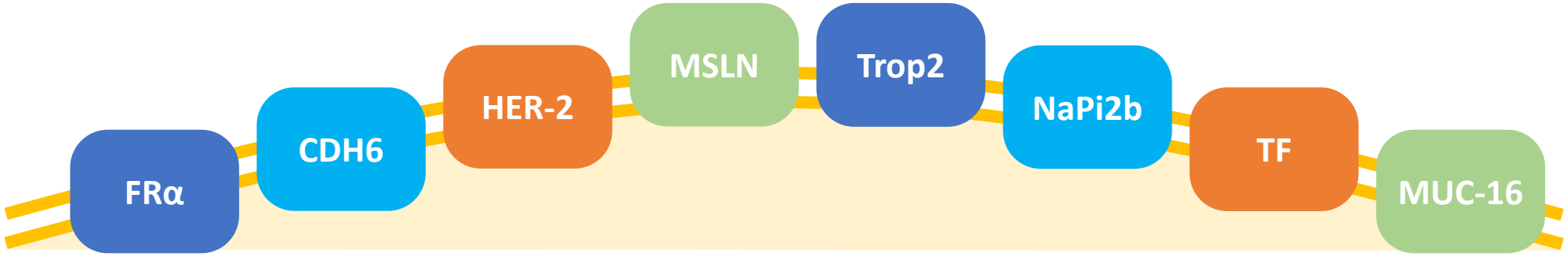
Position payload, DAR (drug-antibody ratio), and linker technology ARE important



Ideal ADC:

- DAR predictable
- Low heterogeneity
- Hydrophilic

Examples of antigens exploited for ADC development in OC[1]



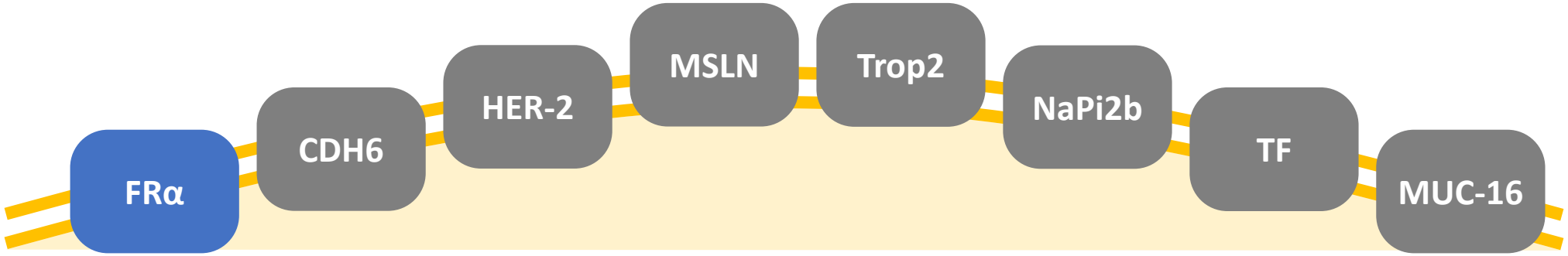
Reported expression in OC	60–100%	70%	5–60%	55–100%	80–90%	95%	25–100%	70–90%

Note: Some ADCs may only demonstrate efficacy in higher expression levels of the target antigen.[2,3]

1. Chelariu-Raicu A, et al. Int J Gynecol Cancer. 2023
2. Moore KN, et al. ESMO Annual Meeting. 2019; Presentation 992O
3. Meric-Bernstam F, et al. J Clin Oncol. 2024

FRα

Examples of antigens exploited for ADC development in OC[1]



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Note: Some ADCs may only demonstrate efficacy in higher expression levels of the target antigen.[2,3]

FRα has emerged as a very attractive candidate for molecularly targeted approaches in ADC development for OC due to its **almost ubiquitous expression on the surface of HGSOC** and its **ability to internalize large molecules containing a cytotoxic payload**

1. Chelariu-Raicu A, et al. Int J Gynecol Cancer. 2023
2. Moore KN, et al. ESMO Annual Meeting. 2019; Presentation 992O
3. Meric-Bernstam F, et al. J Clin Oncol. 2024

FRα is a transmembrane glycoprotein that facilitates the unidirectional transport of folate into cells via receptor-mediated endocytosis

- Folate binding to FRα creates a receptor-ligand complex[1]
- Invagination and budding off into caveolae-type vesicles gives rise to early endosomes[1]
- The endosomes undergo acidification and subsequent fusion with lysosomes, ultimately resulting in folate release[1]
- **Folate is required for the synthesis of DNA and RNA[1]**
  - Anti-folates, such has methotrexate, have long been used in the treatment of cancer[2]

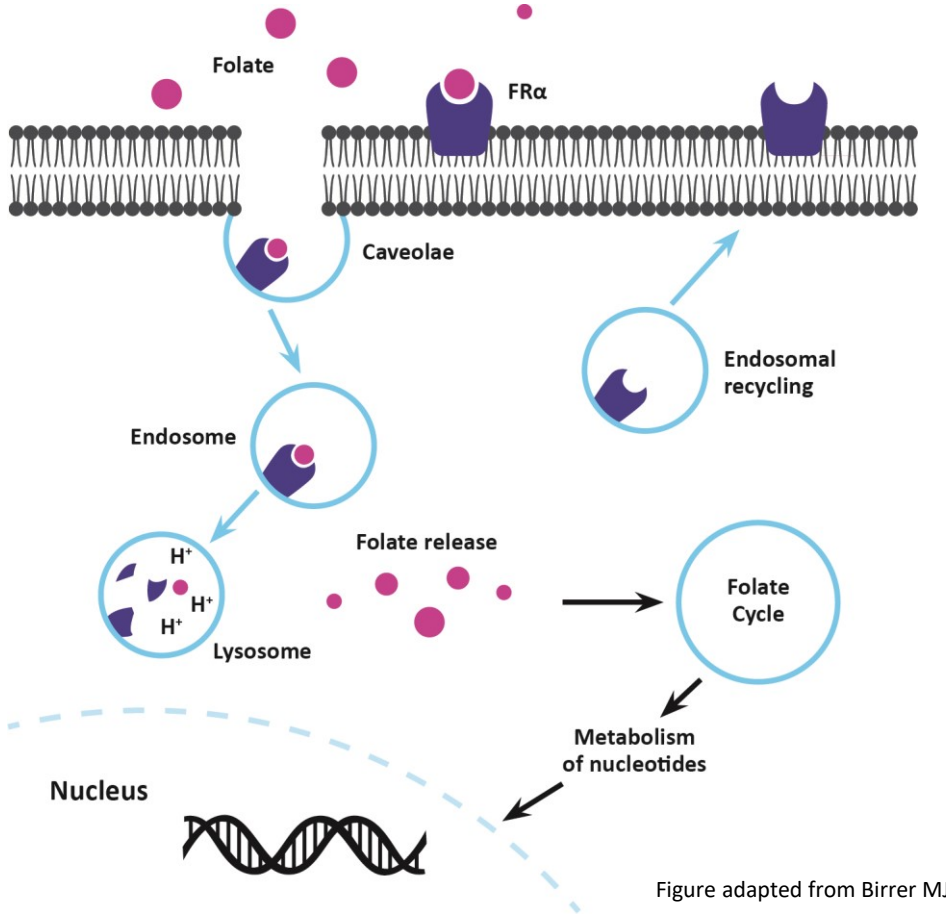


Figure adapted from Birrer MJ, et al.[1]

FR, folate receptor.

1. Birrer MJ, et al. Oncologist. 2019;24(4):425-429.
2. Newman AC, et al. Br J Cancer. 2017;116(12):1499-1504.

Rationale for targeting FRα in ovarian cancer

FRα in ovarian tumours

- Expression **varies by sub-type**, e.g., a consortium-based analysis of data from 12 studies showed FRα expression in:[2]
  - **76%** of high-grade serous
  - **50%** of low-grade serous
  - **32%** of clear cell carcinomas
- Expression is **retained in recurrent and metastatic** tumours and is **not significantly altered in response to chemotherapy**[3-5]

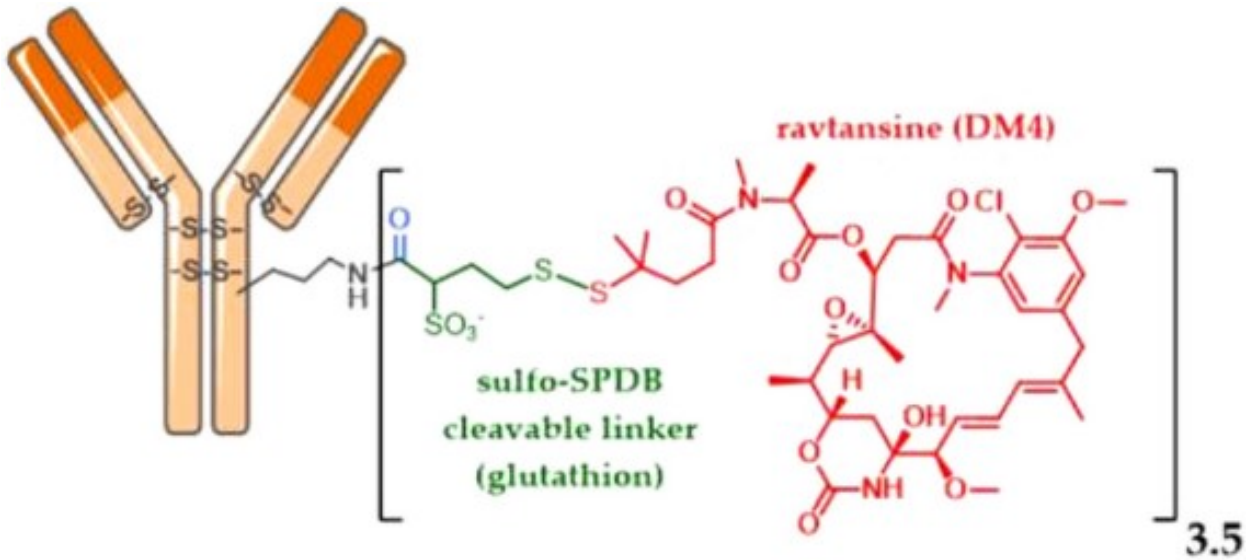
FRα in non-malignant ovarian tissues

- FRα is **scarcely expressed** in non-malignant ovarian tissues[6]
- Limited to polarized epithelia, such as in the choroid plexus, kidney, lung, and placenta[3,7]
- FRα has a **minimal physiological role in non-malignant tissues** after embryogenesis[6]

FR, folate receptor; HGSOC, high-grade serous ovarian cancer; OC, ovarian cancer.

1. Chelariu-Raicu A, et al. Int J Gynecol Cancer. 2023;33(3):420-429. 2. Köbel M, et al. Br J Cancer. 2014;111(12):2297-307. 3. Birrer MJ, et al. Oncologist. 2019;24(4):425-429. 4. Despierre E, et al. Gynecol Oncol. 2013;130(1):192-9. 5. Rubinsak LA, et al. Appl Immunohistochem Mol Morphol. 2018;26(8):567-572. 6. Scaranti M, et al. Nat Rev Clin Oncol. 2020;17(6):349-359. 7. Elnakat H, et al. Adv Drug Deliv Rev. 2004;56(8):1067-84.

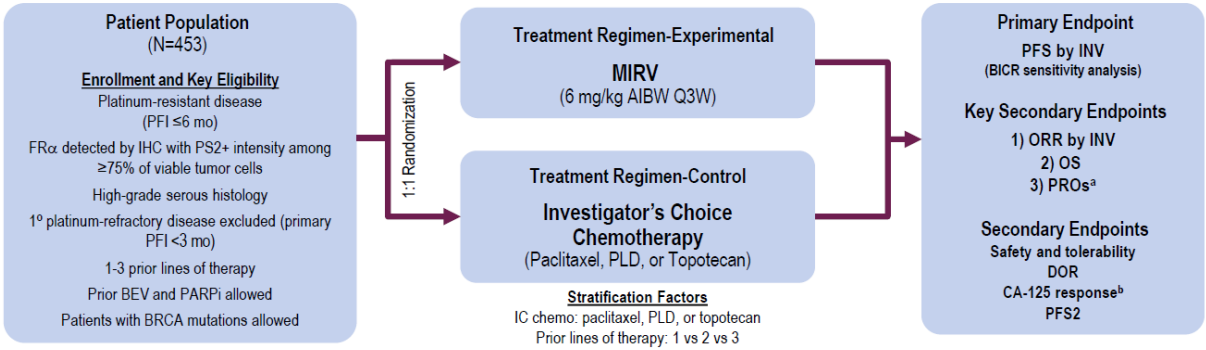
Mirvetuximab Soravtansin



anti-Folate R1 mirvetuximab soravtansine

MIRASOL STUDY

an open label, phase 3 randomized trial of MIRV vs investigators´s choice chemotherapy
in patients with FRα-high platinum-resistant ovarian cancer

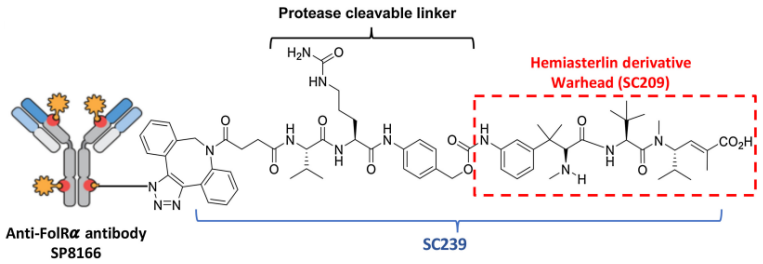


Moore KN et al. *Ann Oncol.* 2021

Luveltamab Tazevibulin (STRO-002) *FRα-targeted ADC*

in recurrent, epithelial ovarian cancer

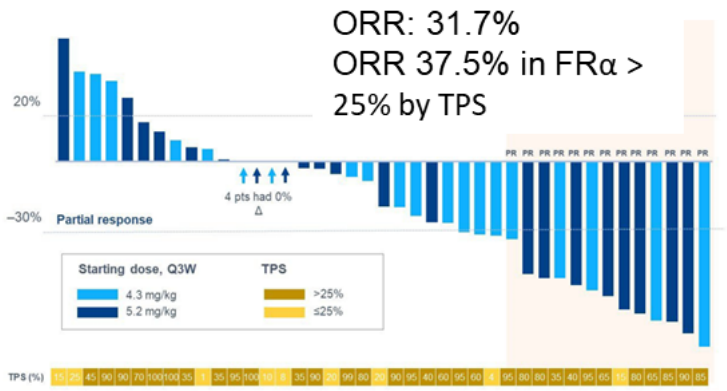
Luveltamab tazevibulin

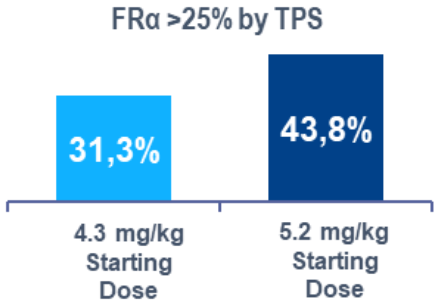


Luvelta (STRO-002) is a homogenous ADC targeting FRα
Cathepsin B linker, which is a stable protease-cleavable linker
Hemiasterlin-derivative[a] cytotoxic payload
DAR=4

Efficacy

Phase 1 dose-expansion study (NCT03748186)





Currently moving to late phase trial

Safety

Phase 1 dose-expansion study

TRAEs leading to dose reduction in 61.4%

- Neutropenia[a] in 17 patients (39%)
  - Primarily G3/4 uncomplicated (abnormal lab value only)
  - Febrile neutropenia in 2 patients (4.5%)
  - Resolved without growth factor support in most patients
  - Median duration of G3+ AEs, 8 days
- Arthralgia in 8 patients (18%)
- Peripheral neuropathy in 3 patients (6.8%)
  - Most G1/2

TEAEs leading to dose discontinuation in 3 patients (6.8%)

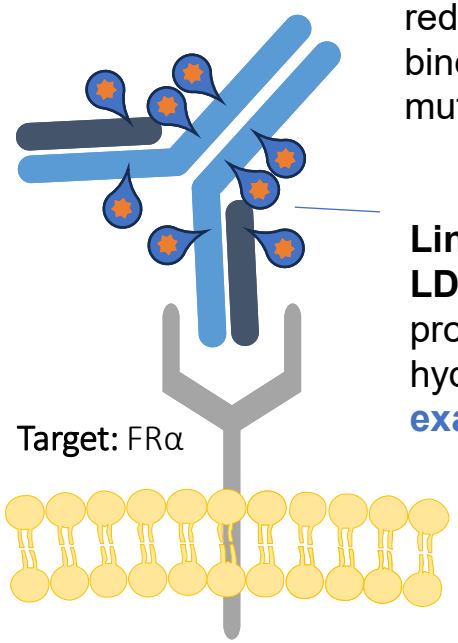
- G3 fatigue
- G2 neuropathy
- G5 Sepsis

1. Oaknin et al. Poster presented at ASCO 2023; Abstract 5508. 2. Sutro Biopharma. Accessed March 2, 2023. https://www.sutrobio.com/wp-content/uploads/2023/01/Sutro-STRO-002-Luvelta-update-Jan-9-2023-FINAL.pdf

Rinatabart sesutecan (Rina-S; PRO1184) *FRα-targeted ADC*

in recurrent, epithelial ovarian cancer

Rinatabart sesutecan (Rina-S; PRO1184)1,2



mAb: F131, proprietary human IgG1, rapidly internalizing, reduced FcγR binding (LALA mutation)

Linker-payload: LD038 sesutecan; proprietary hydrophilic linker, **exatecan** payload

DAR 8

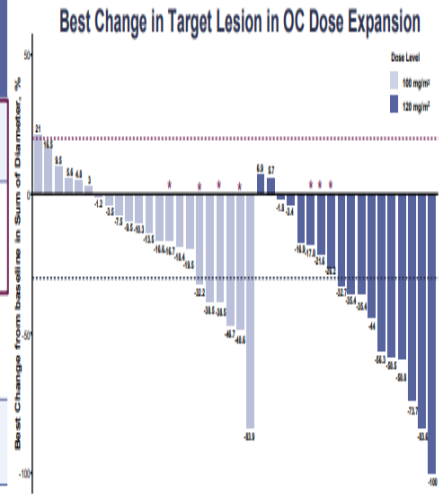
Efficacy1

Antitumor Activity | OC – Dose Expansion

Rina-S showed encouraging antitumor activity at 120 mg/m² Q3W, including a complete response, in patients with heavily pretreated OC

OC Dose Expansion	Rina-S 100 mg/m² n = 22[b]	Rina-S 120 mg/m² n = 18[b]
Confirmed ORR,[a,b] % (95% CI)	18.2 (5.2-40.3)	50.0 (26.0-74.0)
Best overall response,[b] n (%)		
CR	0	1 (5.6)
PR	4 (18.2)	8 (44.4)
SD	15 (68.2)	7 (38.9)
PD	3 (13.6)	1 (5.6)
Not evaluable	0	1 (5.6)
DCR, % (95% CI)	86.4 (65.1-97.1)	88.9 (65.3-98.6)
Median DOR (95% CI)	NR (NR-NR)	

Treatment duration, range: 3.0-42.0+ weeks
Median on-study follow-up: 24 weeks



Median no. of cycles: 6.5 (100 mg/m²) and 7.0+ (120 mg/m²)

Safety1

Phase 1 dose-expansion study

Summary of Drug-Related TEAEs occurring in at least 10% of overall population – Part B

	100 mg/m² (n=9*) n(%)			120 mg/m² (n=9) n(%)		
	Any	G3	G4	Any	G3	G4
Nausea	4 (44.4)	-	-	4 (44.4)	-	-
Neutropenia	2 (22.2)	1 (11.1)	-	5 (55.6)	1 (11.1)	2 (22.2)
Anemia	2 (22.2)	1 (11.1)	-	4 (44.4)	2 (22.2)	-
Leukopenia	2 (22.2)	-	-	4 (44.4)	1 (11.1)	-
Fatigue	3 (33.3)	1 (11.1)	-	2 (22.2)	-	-
Diarrhoea	2 (22.2)	-	-	2 (22.2)	-	-
Thrombocytopenia	-	-	-	4 (44.4)	1 (11.1)	1 (11.1)
Malaise	-	-	-	3 (33.3)	1 (11.1)	-
Vomiting	1 (11.1)	-	-	2 (22.2)	-	-

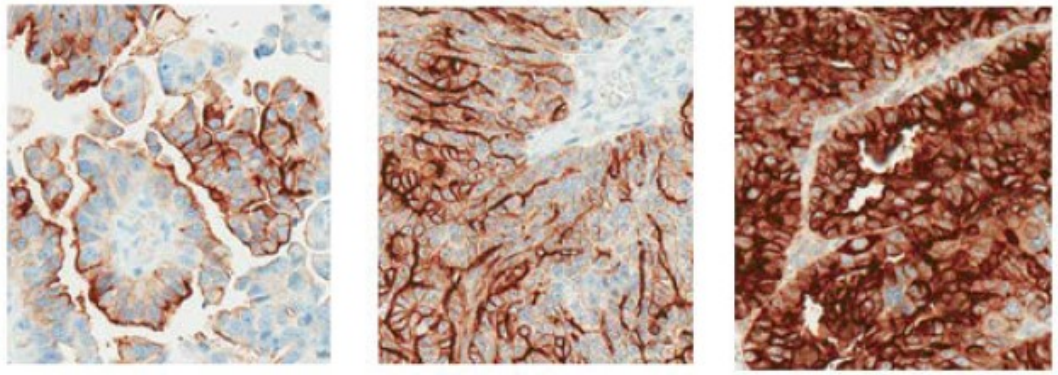
[a]CI calculations: ORR, DRC–Clopper-Pearson's exact method; PFS, OS–Kaplan-Meier estimate and Greenwood formula.

ADC, antibody-drug conjugate; CI, confidence interval; CR, complete response; DAR, drug-to-antibody ratio; DCR, disease control rate; FRα, folate receptor alpha; Gr, grade; HGS, high-grade serous; ILD, interstitial lung disease; mOS, median overall survival; mPFS, median progression-free survival; NE, not estimable; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PR, partial response; SD, stable disease; TEAE, treatment-emergent adverse event.

1. E.K. Lee[1], O. Yeku[2], I. Winer[3], E.P. Hamilton[4], D.L. Richardson[5], J. Zhang[6], G.E. Konecny[7], I.C. Anderson[8], X. Wu[9], D. Orr[10], S. Patel[11], A. Jewell[12], J. Wang[13], A.I. Spira[14], A. Melnyk[15], L. Seamon[16], E. Kavalerchik[17], Z. Chen[18], E. Song[17], J.A. Call[19] ESMO 2024

Patient selection for the FRα-targeting therapy with MIRV: characterization of folate receptor alpha (FRα) expression

Representative low, medium, and high staining patterns for FRα from archival tumour specimens[1]



Low
25–49% of cells with ≥2+ intensity

Medium
50–74% of cells with ≥2+ intensity

High
≥75% of cells with ≥2+ intensity

Figure adapted from Martin LP, et al.[1]

Prevalence of PS2+ FRα expression in 2,869 pooled samples from patients with HGSOC[2]

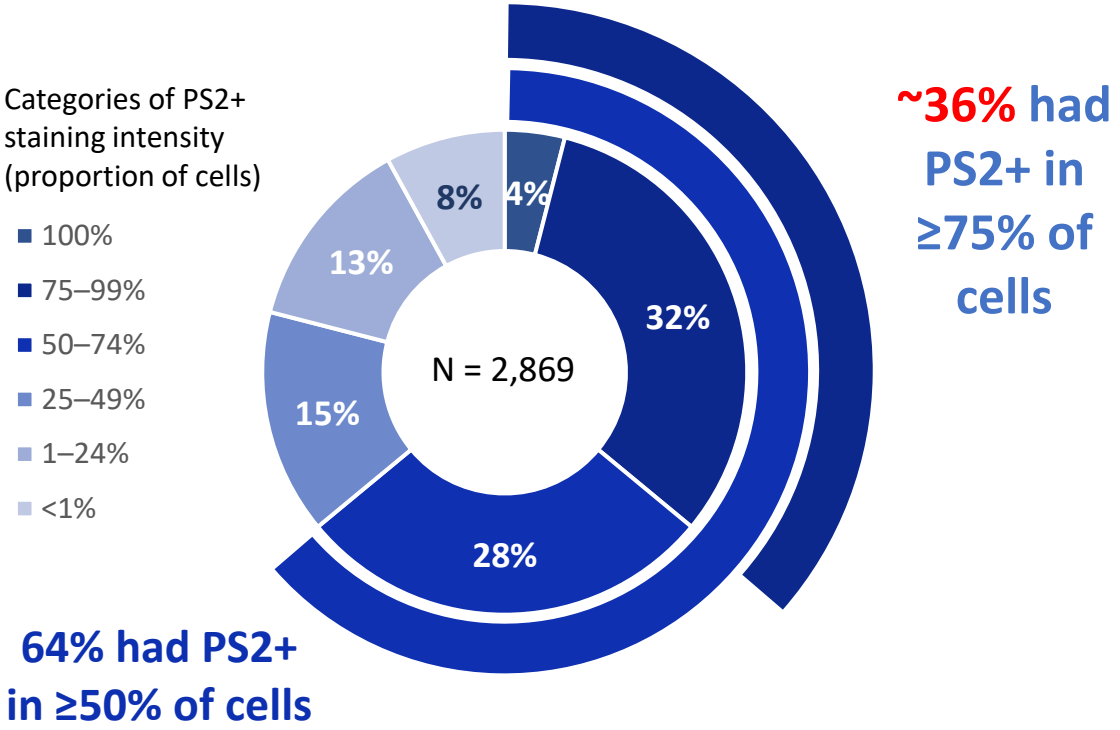


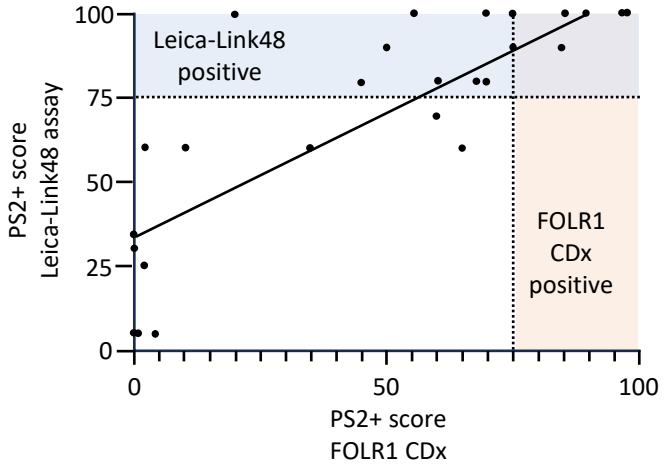
Figure adapted from Deutschman E, et al.[2] with a modified layout.

FRα, folate receptor alpha; HGSOC, high-grade serous ovarian cancer; MIRV, mirvetuximab soravtansine; PS2+, positive staining intensity ≥2.

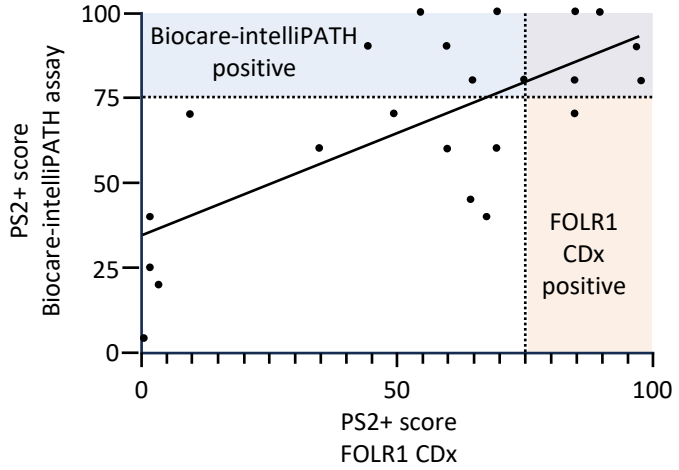
1. Martin LP, et al. Gynecol Oncol. 2017;147(2):402-407. 2. Deutschman E, et al. 36th European Congress of Pathology (ECP). 2024; Abs 2093 and poster.

Comparison of the Ventana FOLR1 (FOLR1-2.1) CDx assay vs other IHC research assays for FRα detection in FFPE samples

Correlation plot between the FOLR1 CDx and Leica-Link48 assays



Correlation plot between the FOLR1 CDx and Biocare-intelliPATH assays



Percentage agreement with the FOL1 CDx assay

	Positive	Negative	Overall
Leica-Link48 assay	100	60	71
Biocare-intelliPATH assay	86	74	77

Figures adapted from Deutschman E, et al.[1]

Authors' conclusions:

- These data highlight the **need for caution in antibody selection** when developing IHC-based assays, as some antibodies failed to identify FRα cleanly and specifically
- **The Ventana FOLR1 (FOLR1-2.1) CDx assay should be used during patient selection for the FRα-targeting therapy MIRV**

CDx, companion diagnostic; FFPE, formalin-fixed paraffin-embedded; FOLR1 or FRα, folate receptor alpha; IHC, immunohistochemical; MIRV, mirvetuximab soravtansine; PS2+, positive staining 2+.

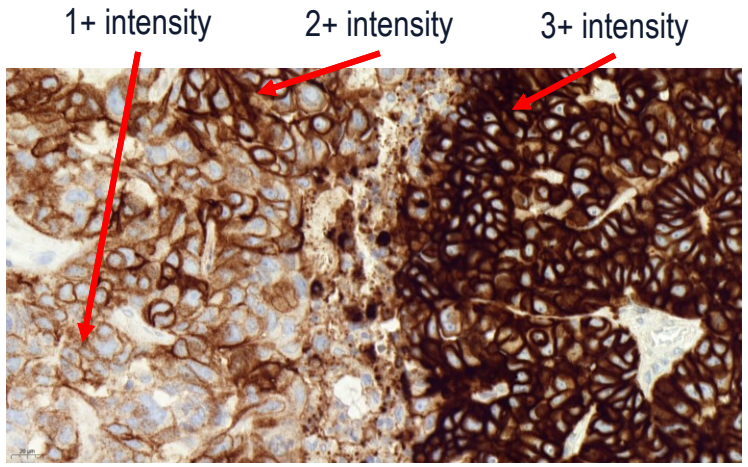
1. Deutschman E, et al. 36th European Congress of Pathology (ECP). 2024; Abs 1566 and poster.

FORWARD I

PS2+ Scoring

- In all prior studies, PS2+ scoring was used to assess FRa expression
- Eligibility determined by staining intensity and percentage of tumor cells staining at 0, 1+, 2+, or 3+

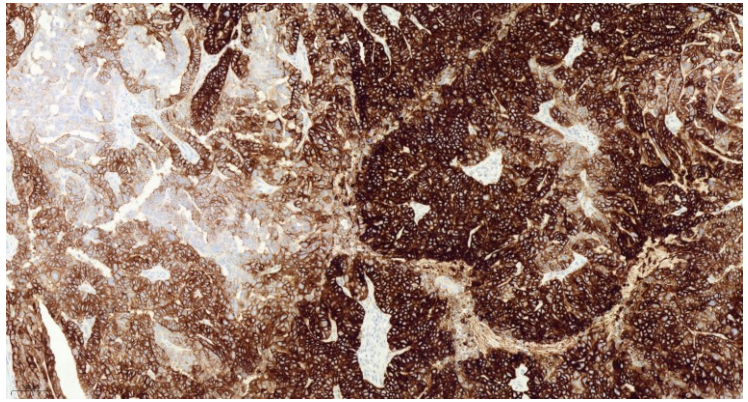
PS2+ Scoring
Positive: ≥ 50% of tumor cells with FRa membrane staining with ≥ 2+ intensity



10X Scoring

- In FORWARD I, a simplified scoring method to assess FRa expression was implemented
- Eligibility was determined by scoring just the percentage of cells with membrane staining by ≤10X magnification, without regard to intensity

10X Scoring
Positive: ≥ 50% of tumor cells with FRα membrane staining visible at 10X microscope objective



Bridging study indicated that 10X scoring was sufficient for patient selection

Exploratory analyses suggest that the change in scoring method from PS2+ to 10X introduced a population of patients into FORWARD I with lower levels of FRα expression than intended

Key takeaways

ADCs an exciting new class of drugs, which are COMPLEX

many ADCs in clincila development with different antibodies, targets, linkers and payloads

All great opportunites come with challenges/questions

- Which ADC to choose?
- How much target/biomarker is needed?
- What is the best cut-off (if any)?
- Intra- and intertumoral heterogeneity
- What is the best assay?
- How to sequence?
- Apply in which setting (treatment line or maintenance)?
- Adverse event profile?
- Possible combinations with other drugs?

We are learning through experience

some ADCs will succeed, some will fail

First approval of ADC in Gynae Onc in Europe:

Mirvetuximab Soravtansine in platinum-resistant ovarian cancer

Scientific Programme Chair
Isabelle Ray-Coquard

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20-23 February 2025

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