23 de octubre de 2024

Aurkines: novel chemical entities with marked polyelectrophilic properties, specifically designed to induce double-strand DNA breaks

Fernando Cossío

MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES
AGENCIA ESTATAL DE INVESTIGACIÓN
MEDICAMENTOS INNOVADORES Plataforma Tecnológica Española
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IkerChem (2006-2016)
Was a UPV/EHU spin-off focused on the design and development of new oncology drugs in the field of epigenetics. The company had a solid portfolio of products under development in the main areas of action of DNA methyltransferase (DNMT) inhibitors with a new mode of action, potent new-generation histone deacetylase 6 (HDAC6) inhibitors and the GASC1 target within the JMJ histone demethylase family.

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QUIMATRIX

New drugs
against epigenetic targets

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WO2011039353 - New Histone Deacetylase Inhibitors Based Simultaneously On Trisubstituted 1*h*-pyrroles And Aromatic And Heteroaromatic Spacers

WO2012136722 - Hydroxyphenyl Pyrrole Compounds Containing An Hydroxamic Acid As HDAC Inhibitors And Medicinal Applications Thereof

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New drugs
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    49 (as PI: **4.07M €**)
    18 (as AI: **1.97M €**)
9 Contracts with Pharmaceutical Industry (**1.15M €**)
5 Industry – Sponsored Clinical Trials
3 Academically led Clinical Trials

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- Ursodeoxycholic Acid Derivatives For The Treatment Of Polycystic Diseases — atlas
- Methods Of Treating Cancer — Intercept (ALFASIGMAGROUP)
- Use Of Metalloprotease Inhibitors For The Treatment Of Polycystic Liver Diseases — spherium biomed
- Use Of 5' -Methylthioadenosine For The Inhibition Of The Epithelial-mesenchymal Transition — DIGNA BIOTECH

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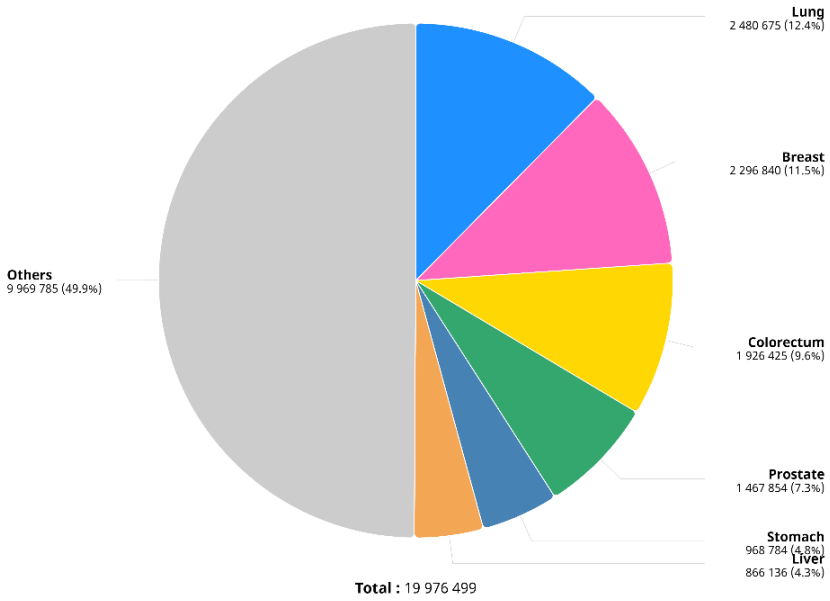
ESTAHEP-2010 (NCT01418729) – Phase II

CURSOR, PLD11-01 (NCT02021110) – Phase II

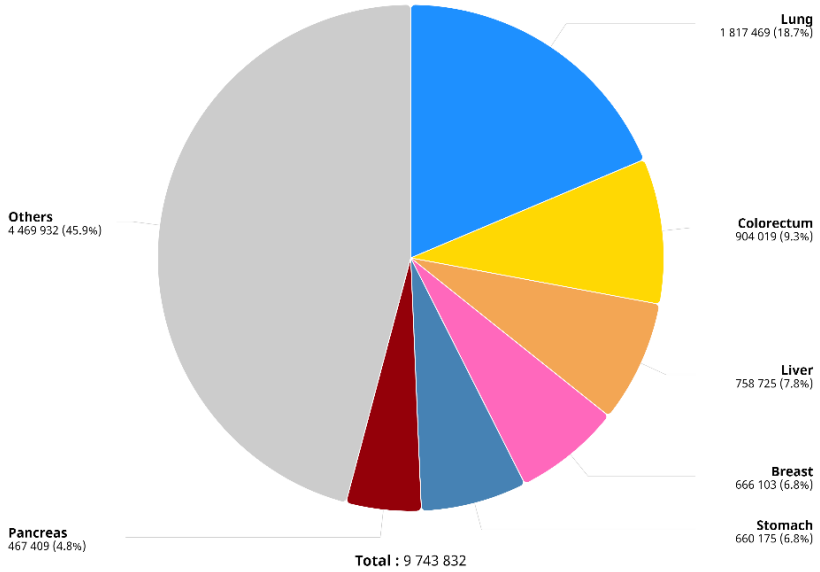
URSOPOL (nº EUCT 2024-513644-28-00)

Target Indications

Number of cases in 2022
(both sexes, all ages)



Number of deaths in 2022
(both sexes, all ages)



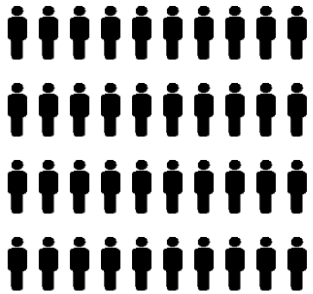
International Agency for Research on Cancer
World Health Organization

GLOBAL CANCER OBSERVATORY

Target Indications

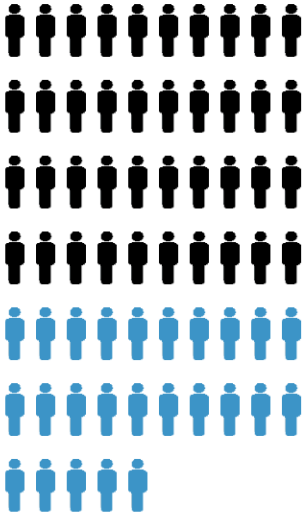
Number of new cases 2022-2050
(both sexes, all ages)

2022

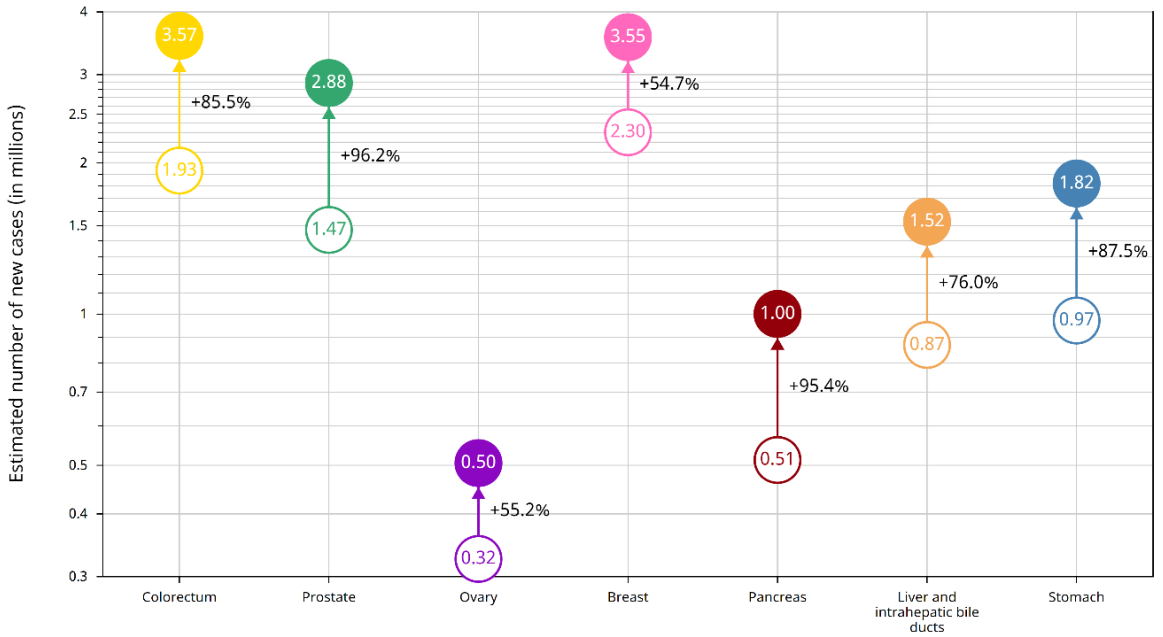


20.0 M

2050



32.6 M



International Agency for Research on Cancer
World Health Organization

GLOBAL CANCER OBSERVATORY

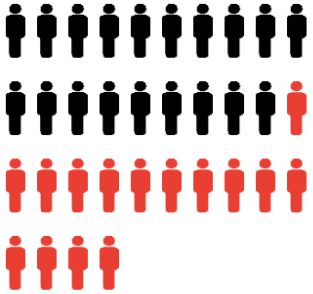
Target Indications

Number of deaths 2022-2050
(both sexes, all ages)

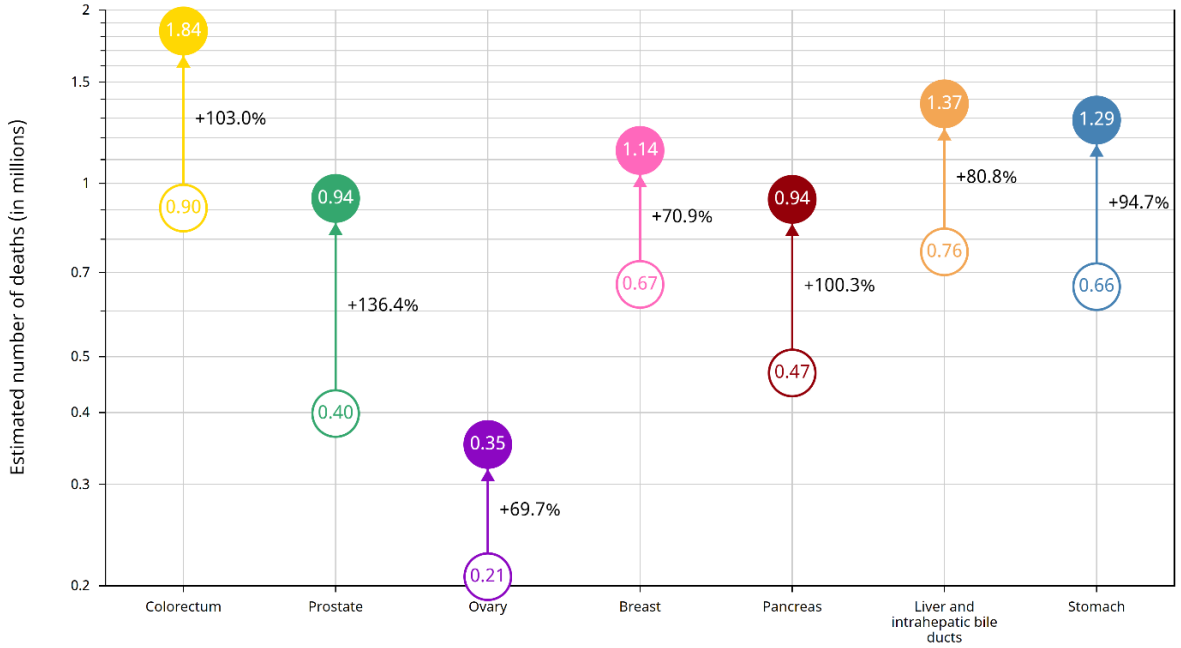
2022

9.74 M

2050



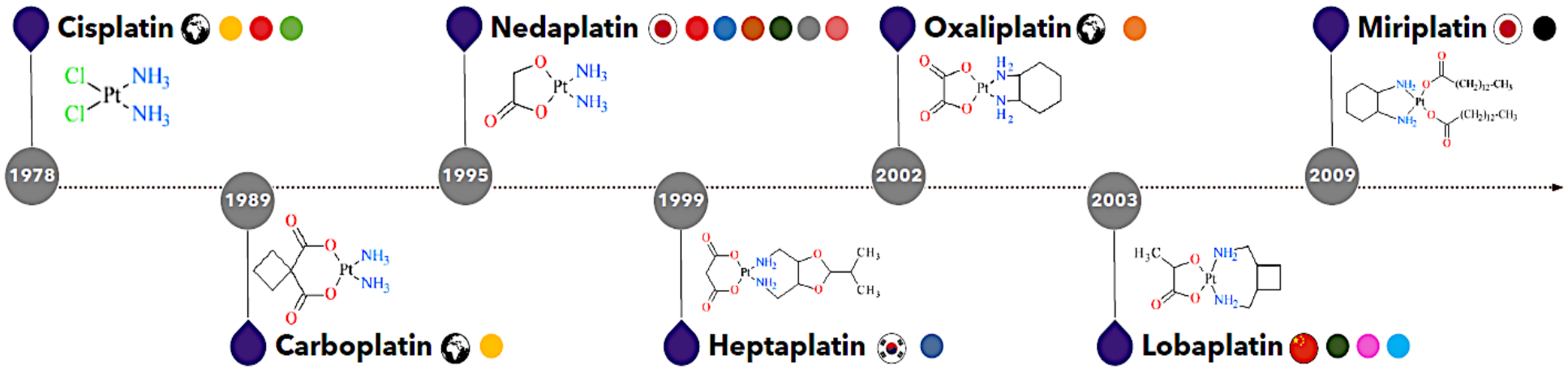
16.9 M



International Agency for Research on Cancer
World Health Organization

GLOBAL CANCER OBSERVATORY

Evolution of approved platinum-based drugs over time



Approved indications (no off-label included)

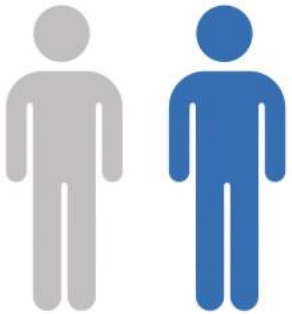
- Ovarian cancer
- Testicular cancer
- Bladder cancer
- Head & Neck cancer
- Oesophagus cancer
- Lung cancer
- Cervical cancer
- Prostate cancer
- Gastric cancer
- Colorectal cancer
- Breast cancer
- Leukaemia
- Liver cancer

Cisplatin, Carboplatin & Oxiplatin (worldwide approval)

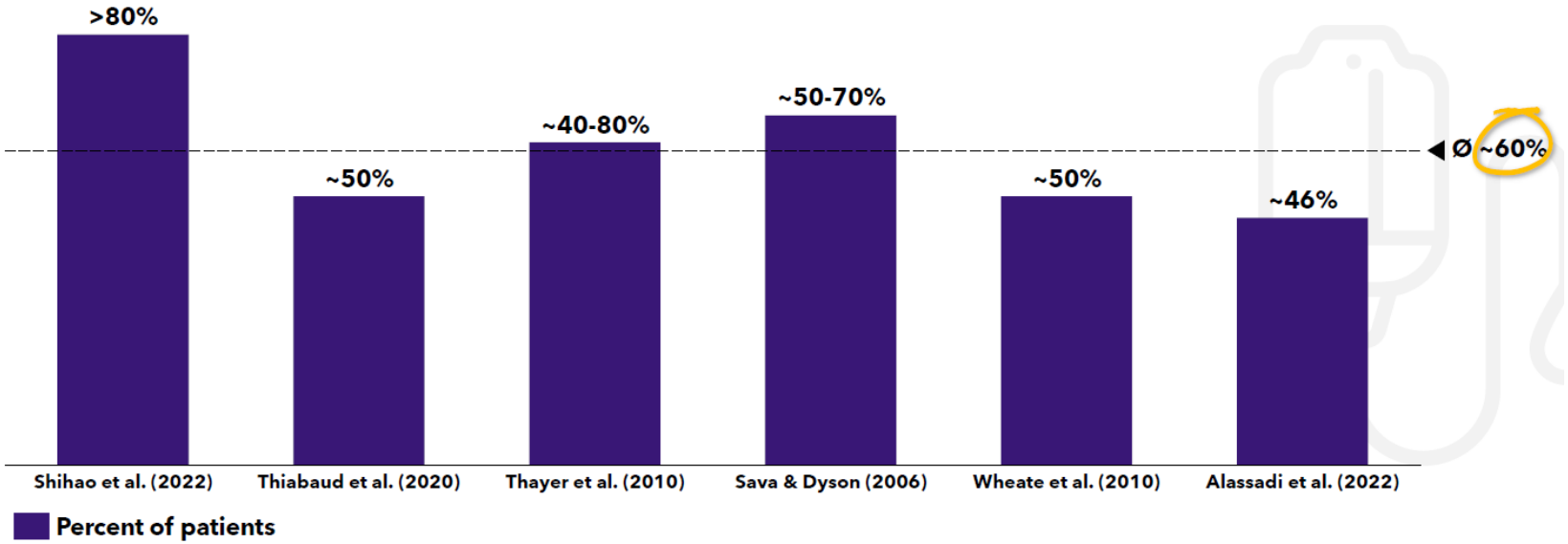
Nedaplatin (Japan), Lobaplatin (China), Heptaplatin (Korea, iriplatin (Japan)

Kopacz-Bednarska A, Król T. *J Oncol.* 2022; 72: 96–105

Use of platinum-based drugs in cancer treatment

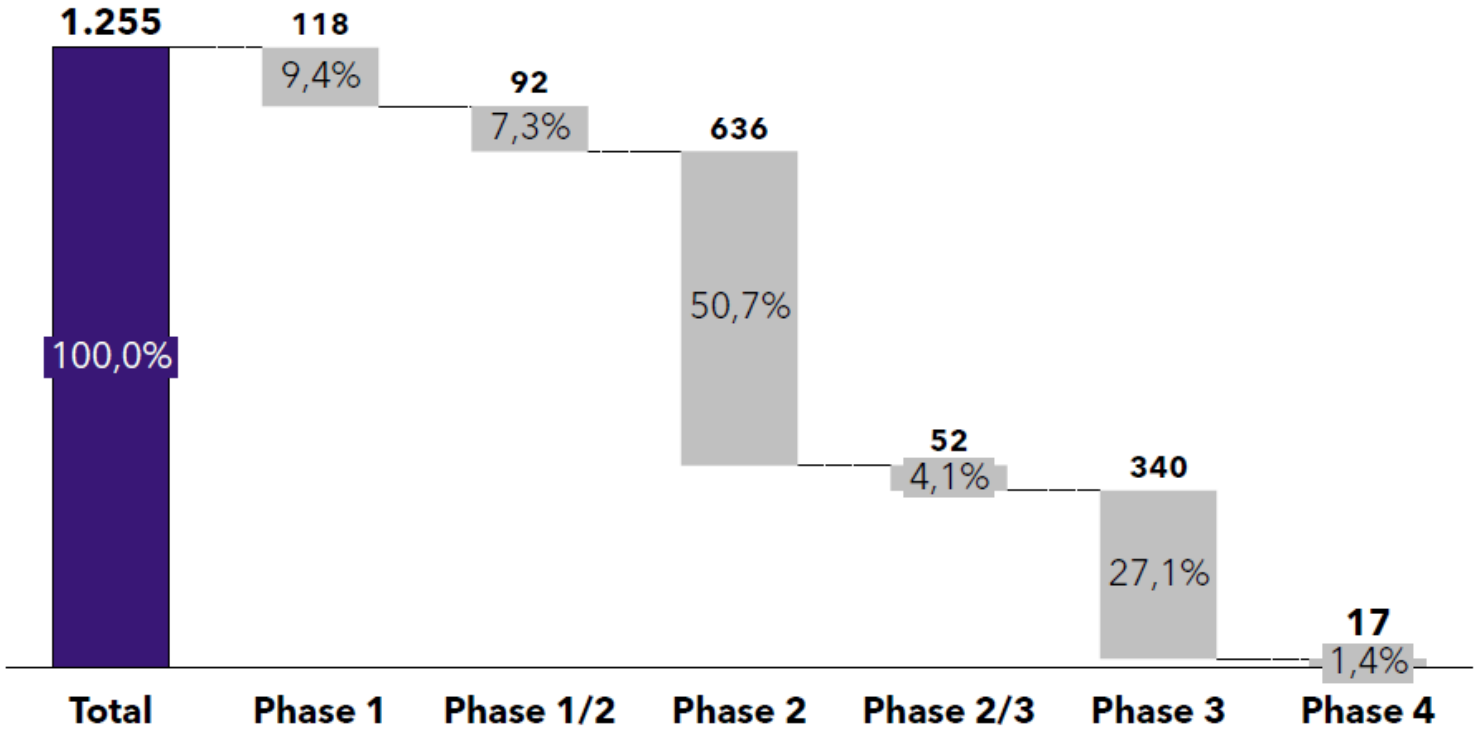


1 in every 2 patients with **cancer** is currently being treated with platinum derivatives



Cisplatin: *clinical trials (in 2024)*

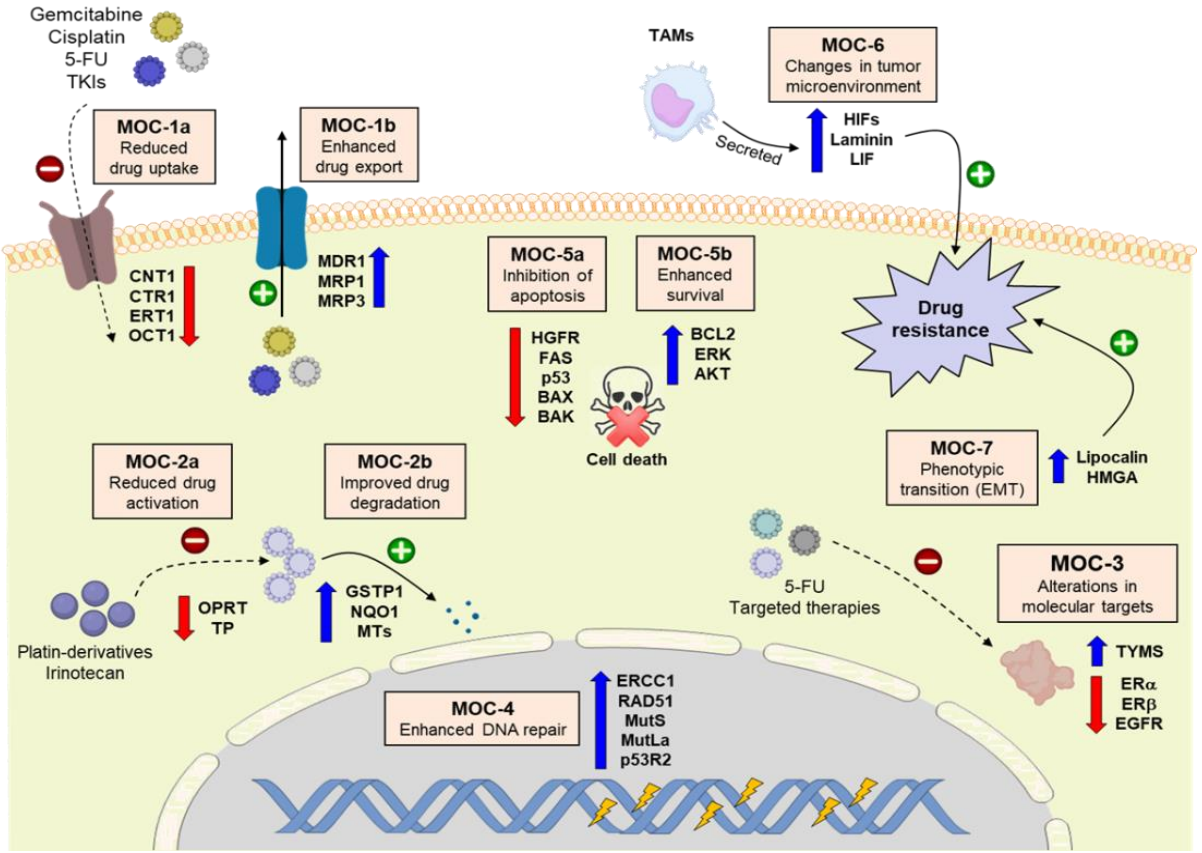
- Cisplatin is being used in clinical trials: **1.255** (mostly Phase 2)



Clinicaltrials.gov

Cisplatin: *resistance*

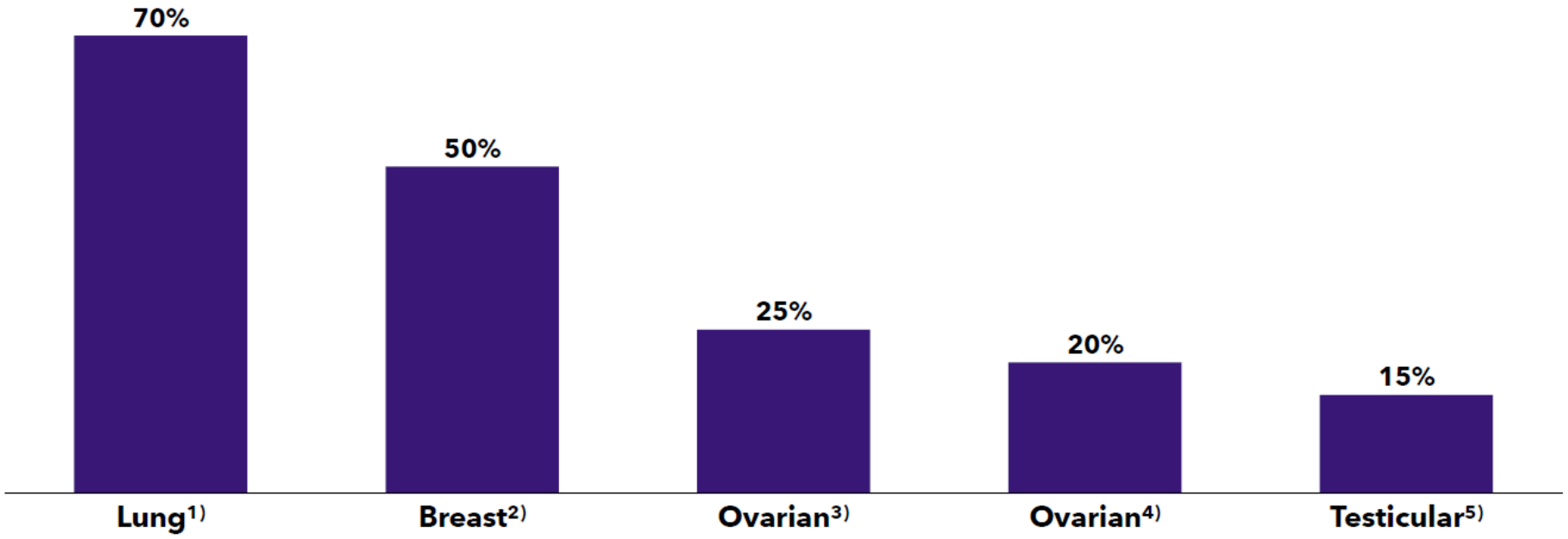
- Intrinsic or Adquired molecular **mechanims of chemoresistance** (**MOCs**)



Rodrigues PM,…,Banales JM. *Annu Rev Pathol.* 2021; 16:433-463

Cisplatin: *resistance*

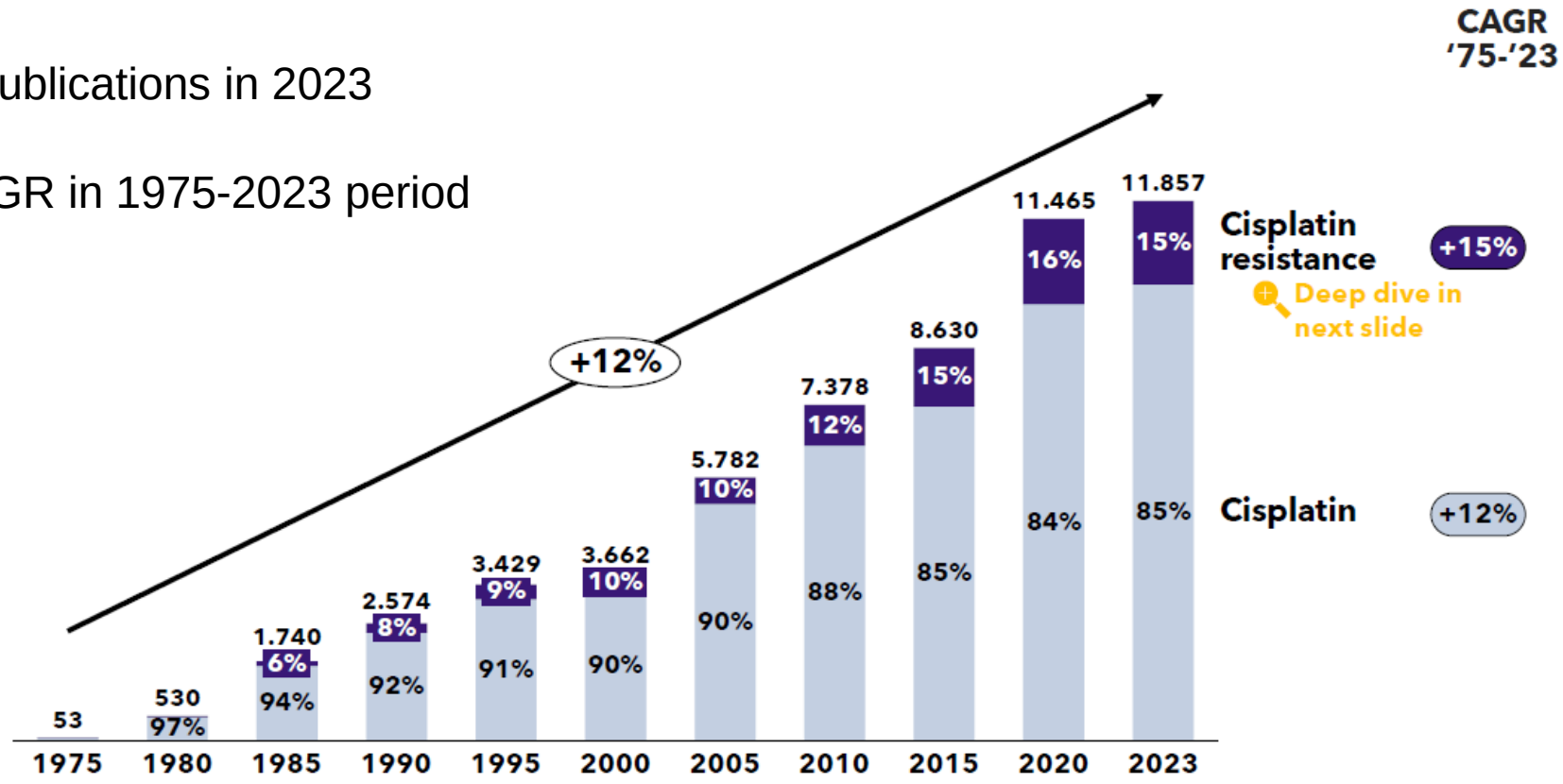
- Major limitation in cancer treatment



1. Gonzalez Rajal A, et al. *Elife.* 2021; 2.Pogribny PI, et al. Cancer Cell Biology. 2010; 3. Atallah GA, et al. *Int. J. Mol. Sci.* 2023; 4. Pothuri B. *Clin. Adv. Hematol. Oncol.* 2023; 5. González-Barrios R, et al. *Cancers.* 2022.

Cisplatin: *research*

- Increasing scientific and pharmaceutical interest
- 12.000 publications in 2023
- 12% CAGR in 1975-2023 period



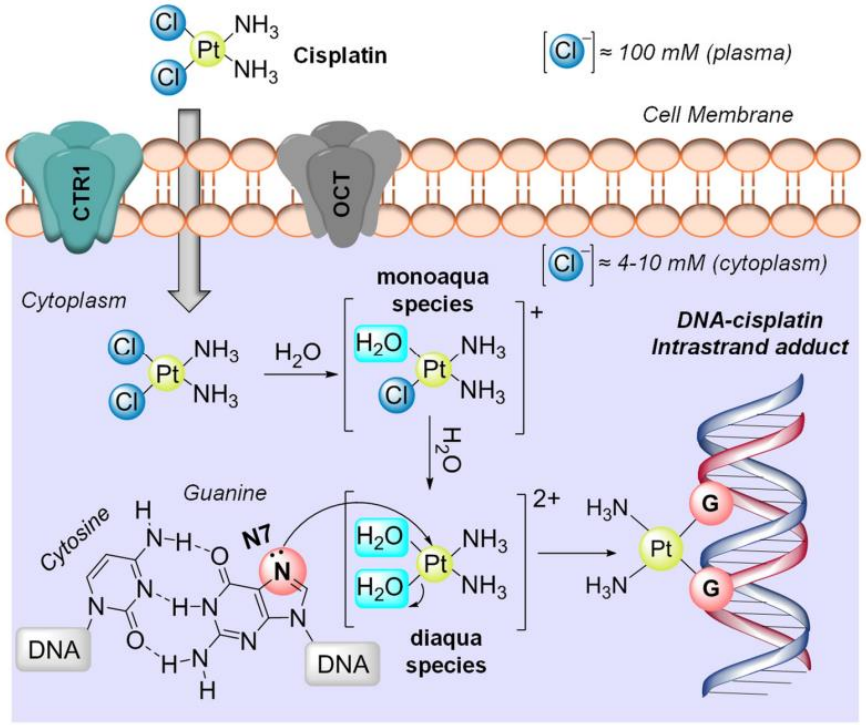
SOURCE: SCOPUS
CAGR: compounded annual growth rate

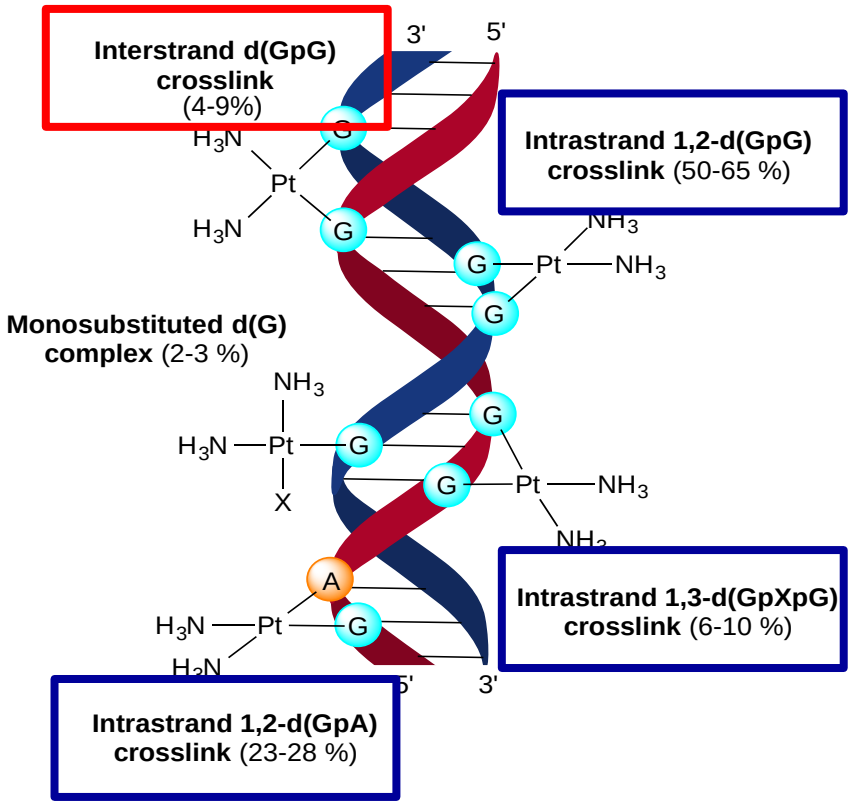
Target Indications

URGENT NEED TO DEVELOP NEW CHEMOTHERAPEUTIC AGENTS TO OVERCOME CISPLATIN RESISTANCE

Cisplatin: *mechanism of action*

- Platinum (Pt) derived compound
- Single-strand DNA breaks
- Cancer cell death

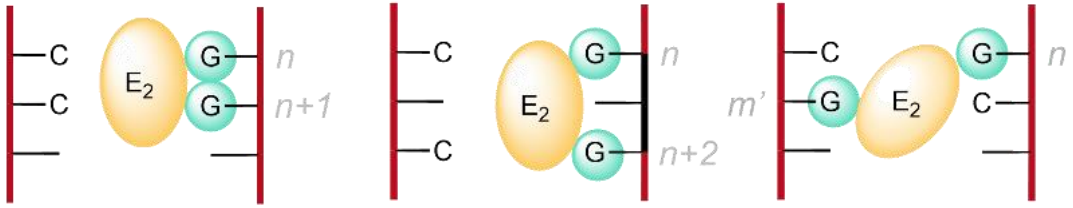




New chemotherapeutic agents: *Aurkines*

95% **5%**

Cisplatin **Cisplatin** **Cisplatin**

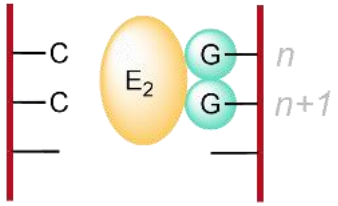


1,2-intrastrand *1,3-intrastrand* *1,2'-interstrand*

New chemotherapeutic agents: *Aurkines*

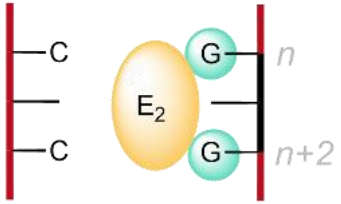
95% **5%**

Cisplatin



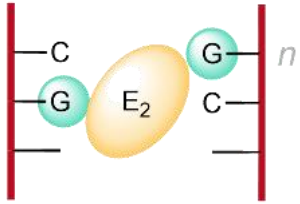
1,2-intrastrand

Cisplatin



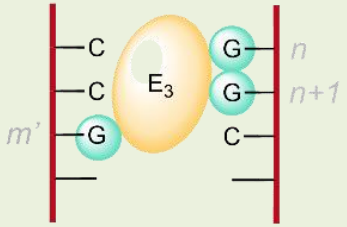
1,3-intrastrand

Cisplatin



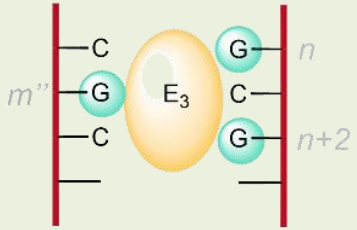
1,2'-interstrand

Aurkine

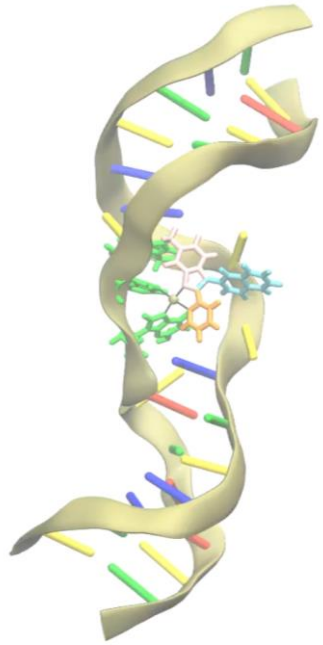


3'-inter+1,2-intrastrand

Aurkine

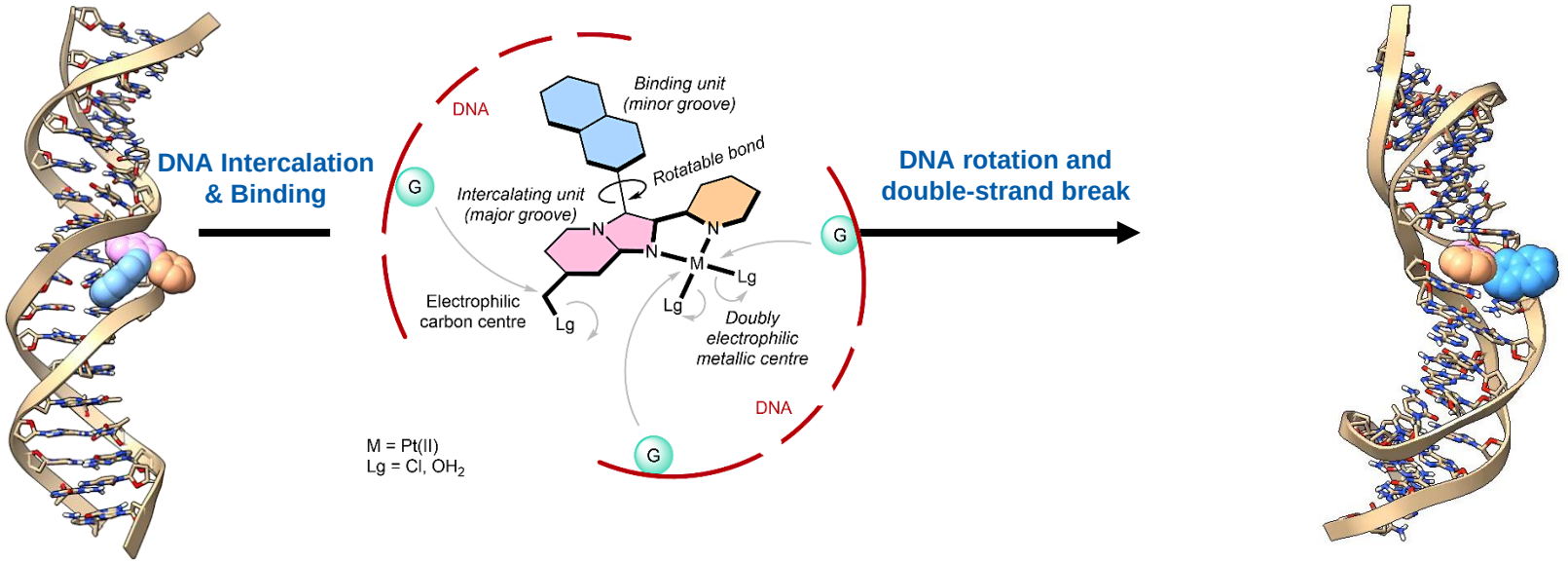


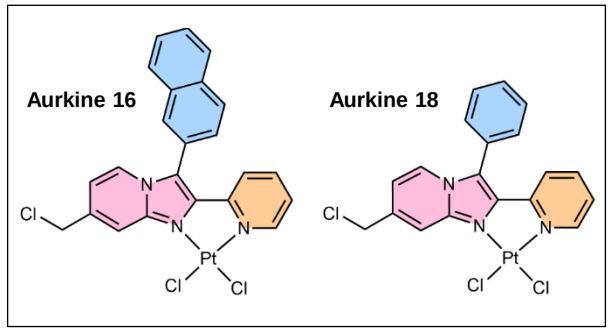
2'-inter+1,3-intrastrand



Innovative mechanism of action

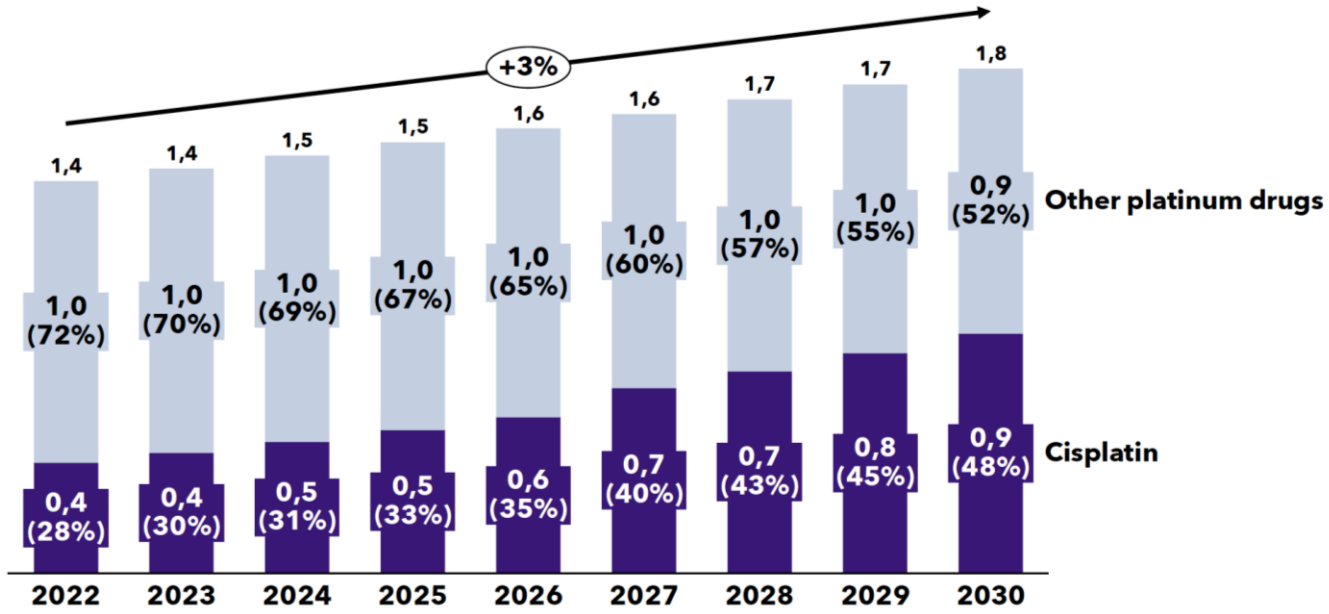
New chemotherapeutic agents: *Aurkines*





Differential features facing the market

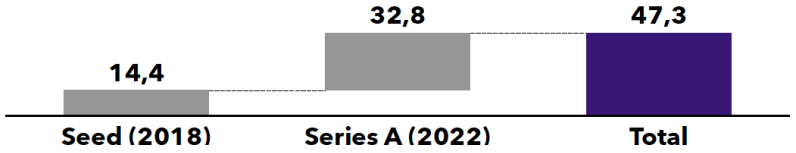
Platinum-based drugs market size, 2022-2030



promontory THERAPEUTICS

- Founded in 2010, **Promontory Therapeutics (formerly Phosplatin Therapeutics)** is a private, clinical-stage drug development company focusing on oncology therapeutics, running multiple clinical trials in the US and Europe.
- **PT-112** is a novel platinum-pyrophosphate conjugate under clinical development for cancer therapy. PT-112 mediates cytostatic and cytotoxic effects against a variety of human and mouse cancer cell lines in vitro
  - PT-112 has demonstrated evidence of clinical benefit and pre-clinical proof of immunogenic cell death (ICD).
  - In 2014, Promontory launched its First-in-Human Phase I Clinical Trial of PT-112 in Solid Tumors.
  - In 2017, PT-112 received FDA **Orphan Drug Designation** for use in relapsed or refractory **multiple myeloma**
  - In 2018, PT-112 received FDA **Orphan Drug Designation** for use in **thymoma** and **thymic carcinoma.**
- The company is currently in **Phase 2 clinical development** with two ongoing studies in solid tumors and has completed a Phase 1 study in hematological oncology.

Financing activity [EUR m]



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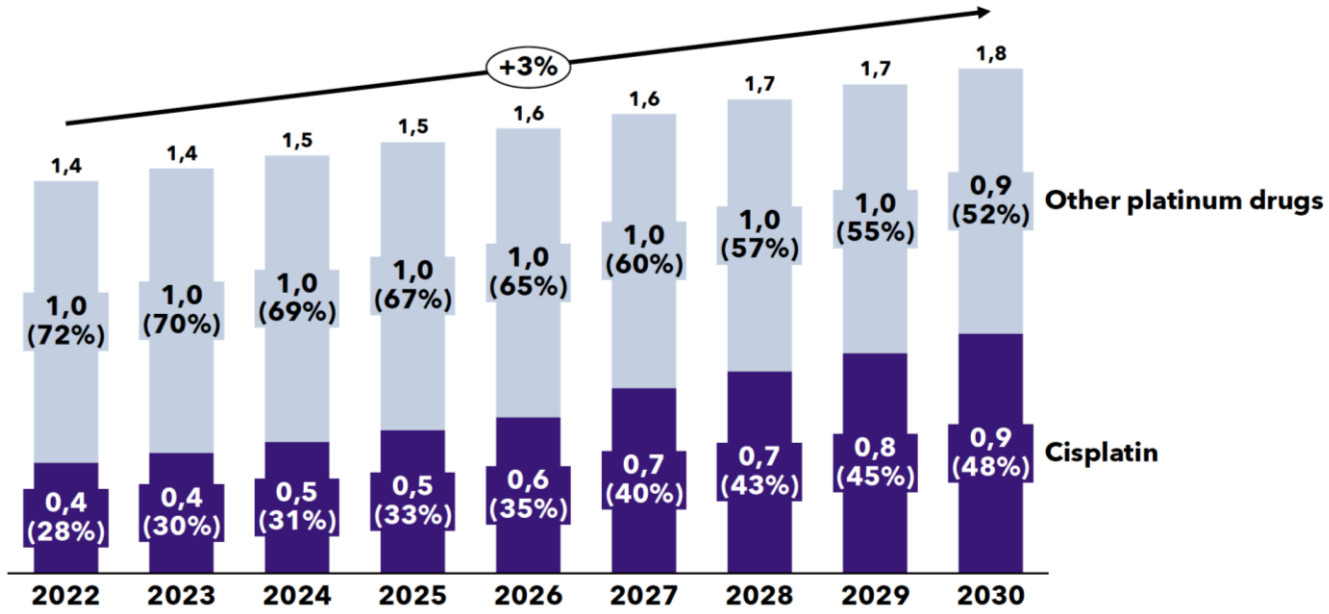
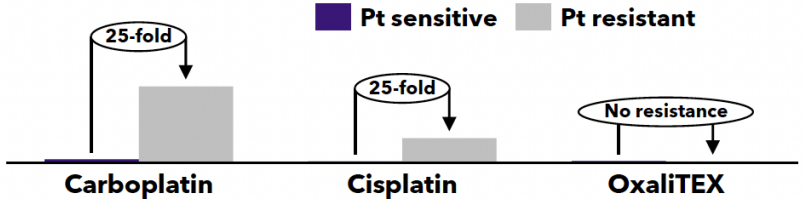


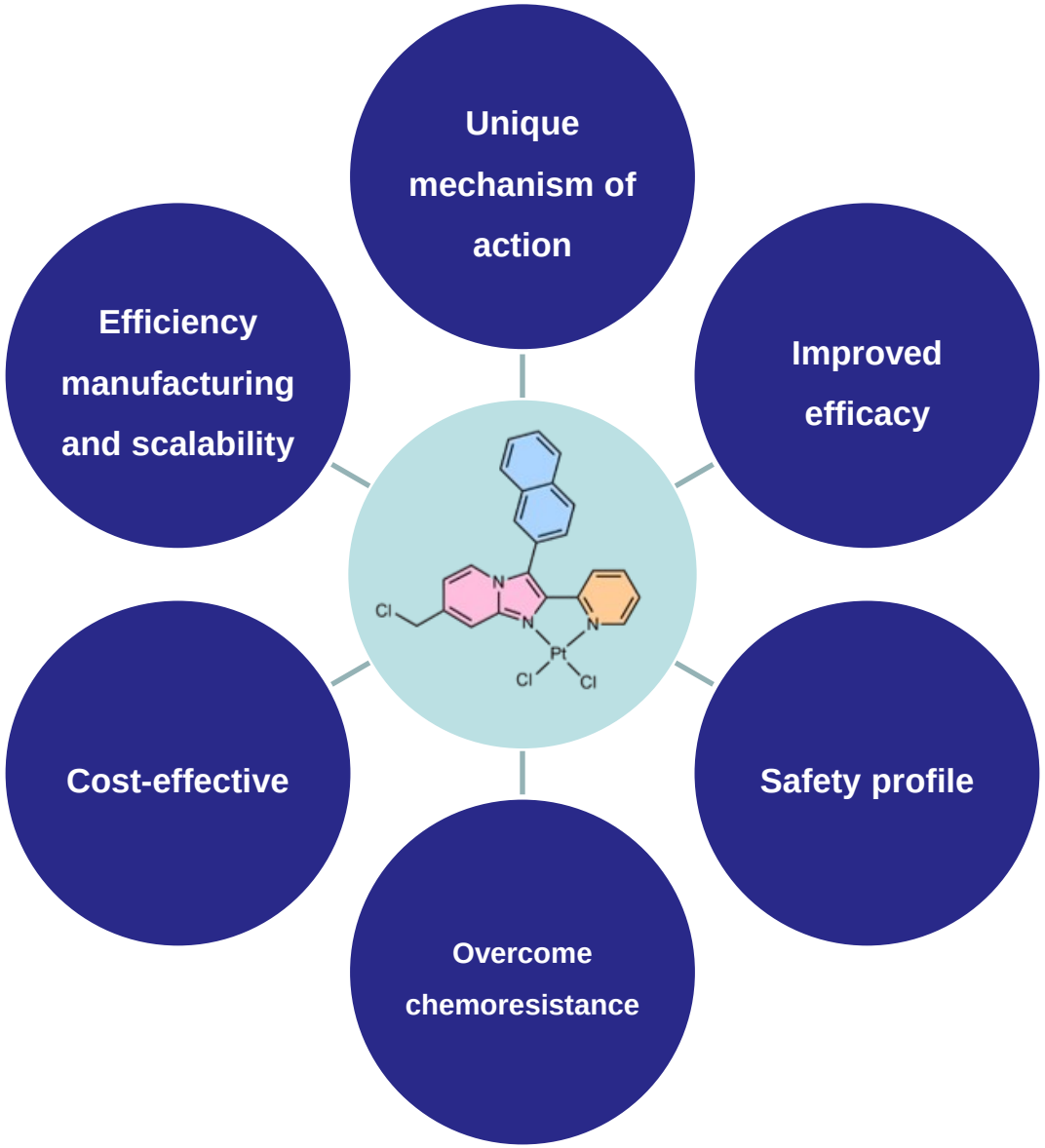
InnovoTEX Inc.

- Founded in 2022, **InnovoTEX Inc**. is a mid-stage pharmaceutical company developing the TEX Core portfolio of novel therapeutics capable of targeting multiple solid tumor
- OxaliTEX-Pt(IV) is the first product candidate being developed from the TEX CORE platform. Initial indication is **platinum-resistant ovarian cancer**
- The drug candidate, called **OxaliTEX**, is made of two parts: a star-shaped molecule called texaphyrin that acts like a kind of delivery truck, and a **modified version of a platinum drug** that acts like a toxic package for cancer cells.
- A **patent** on the drug candidate OxaliTEX is held jointly by UT Austin and MD Anderson. The drug is licensed to the iQ Group Global and planned for further development by its subsidiary, OncoTEX. Sessler serves as a nonexecutive board member and scientific adviser for OncoTEX.

OxaliTEX overcomes resistance in ovarian cancer cells (in vitro)



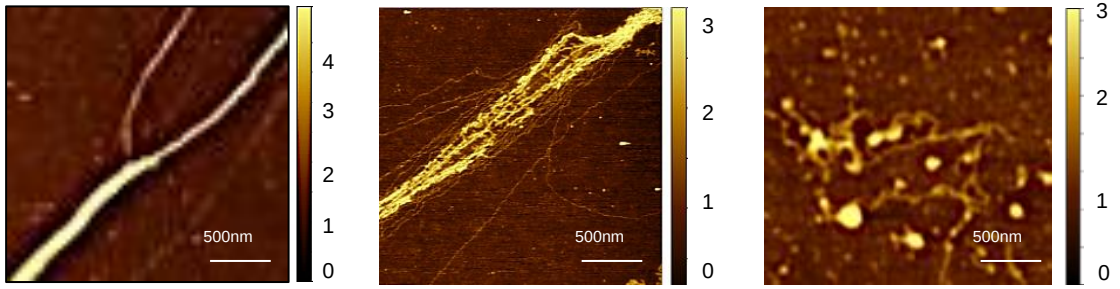
Differential features facing the market



Aurkines completely disrupt isolated DNA structure

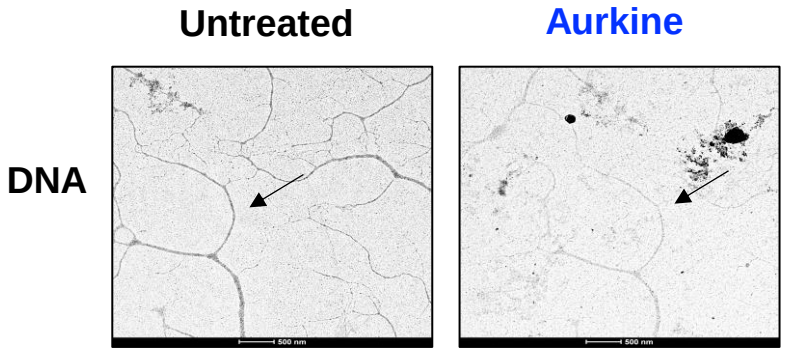
- Isolated DNA from *Escherichia Coli*

AFM studies
(**A**tomic **F**orce **M**icroscopy)



DNA bending ↑↑ DNA destruction

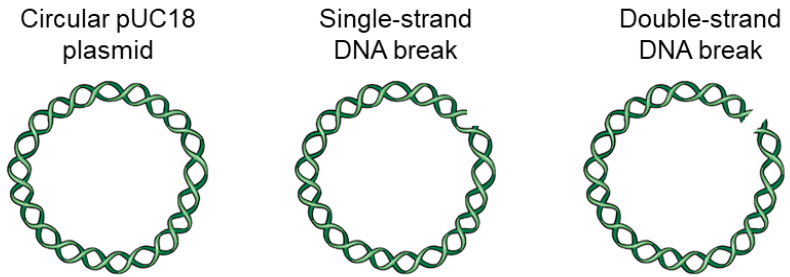
TEM studies
(**T**ransmission **E**lectron **M**icroscopy)

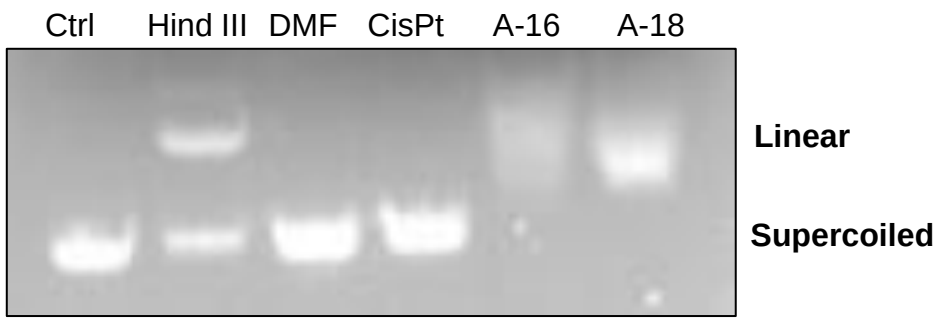


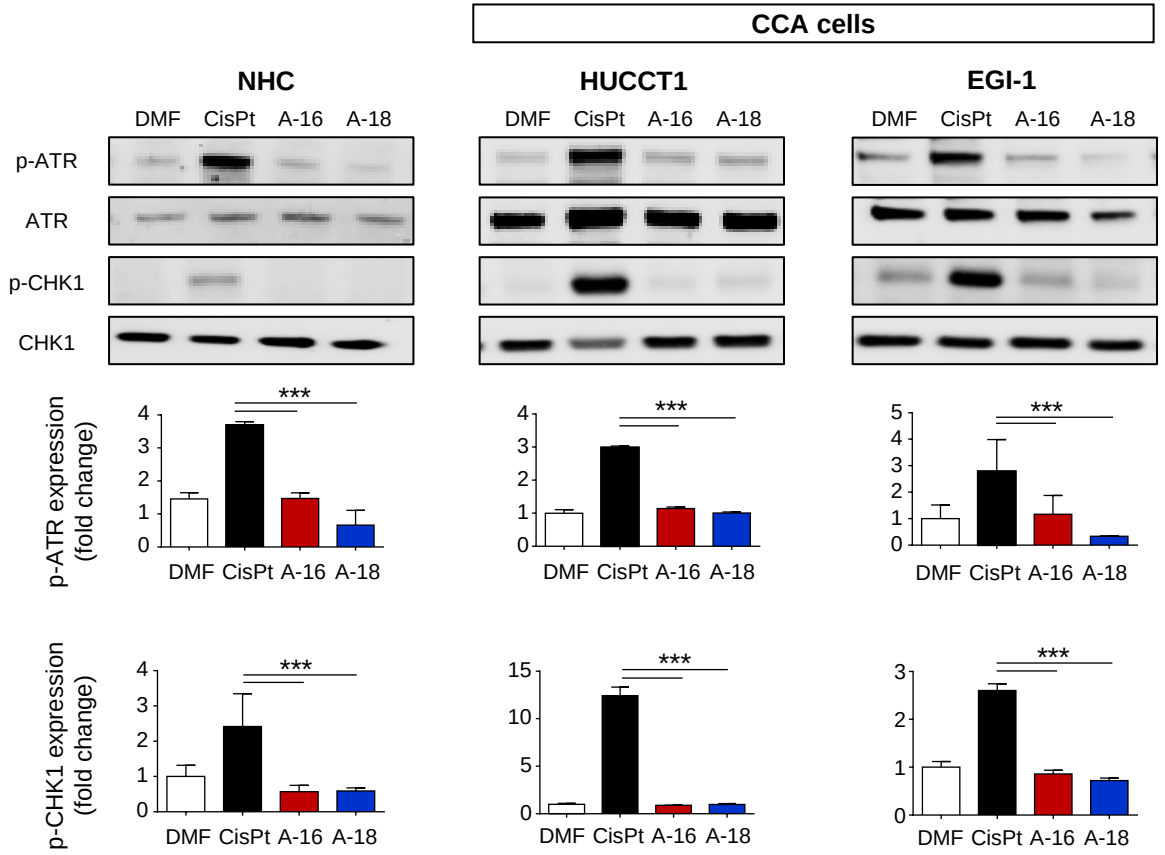
↓↓ DNA density

Aurkines induce double-strand DNA breaks, contrary to CisPt

Electrophoretic mobility: pUC18 plasmid



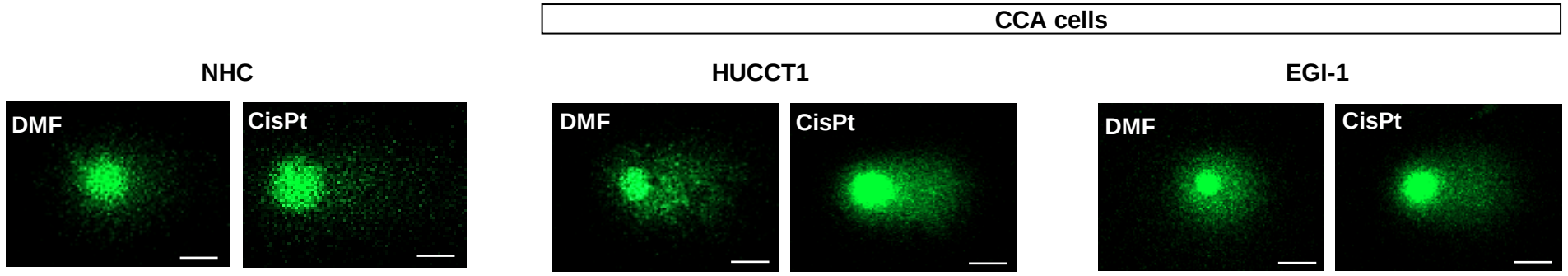


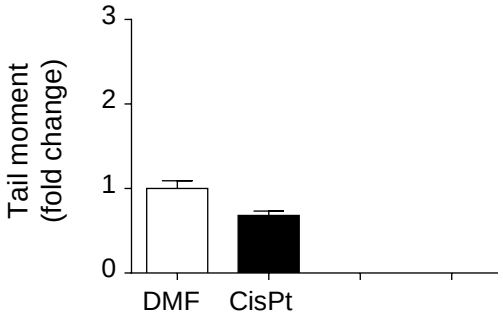


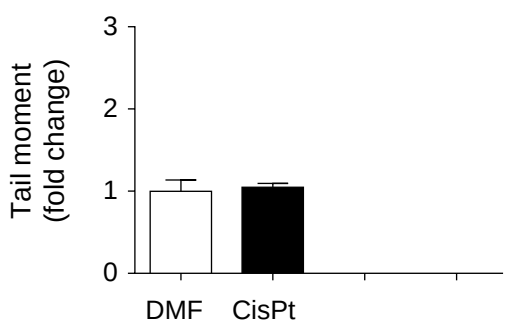
CCA, cholangiocarcinoma; NHC, normal human cholangiocytes

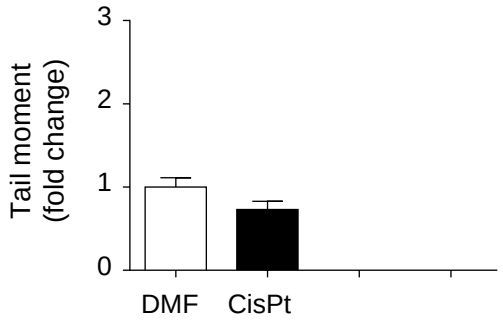
Aurkines promote DNA damage specifically in CCA cells

Genotoxity: *Comet assay (DNA damage in cells)*



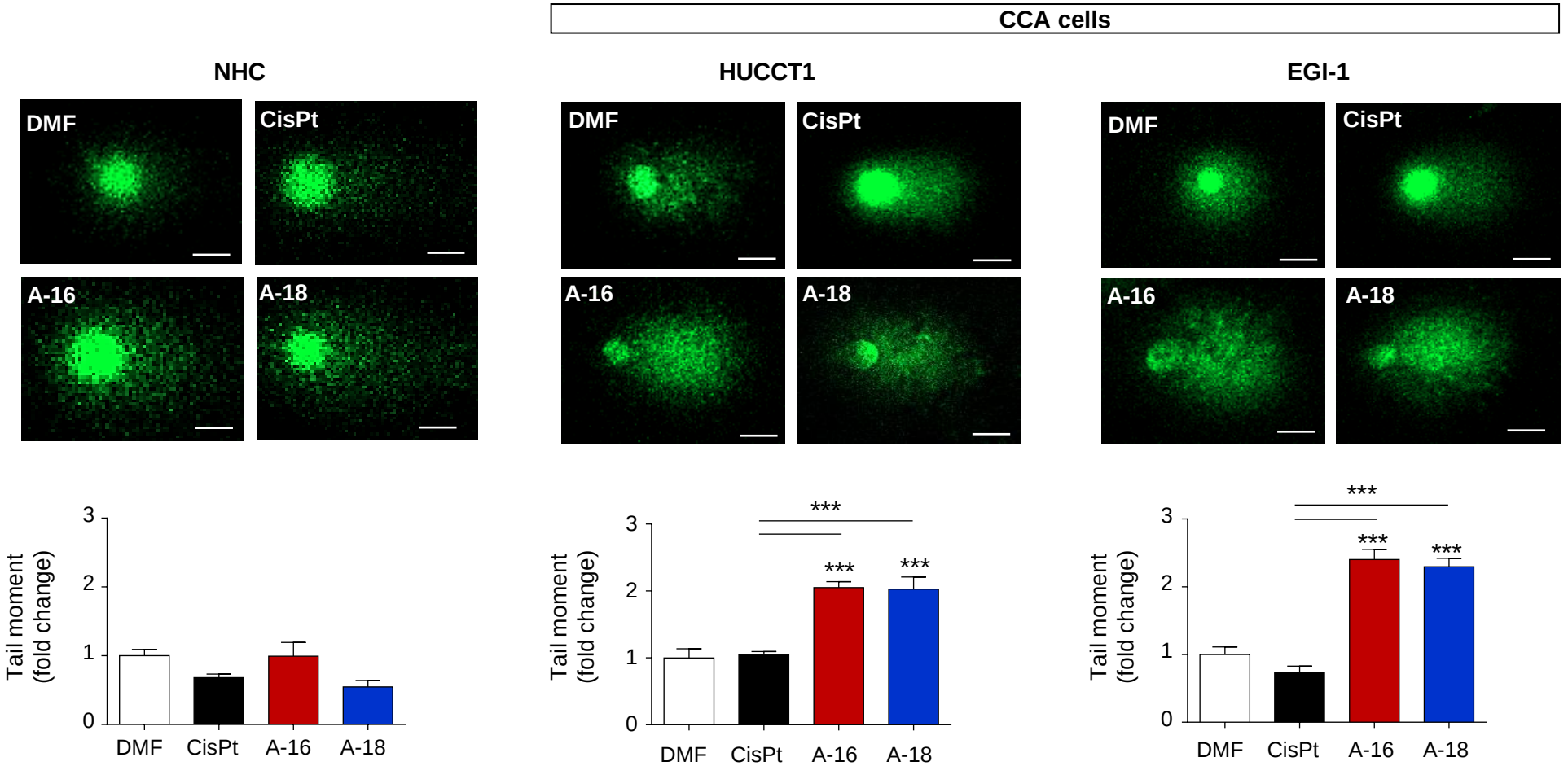






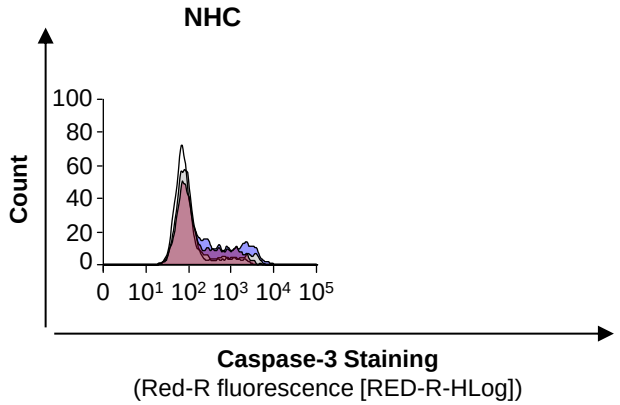
Aurkines promote DNA damage specifically in CCA cells

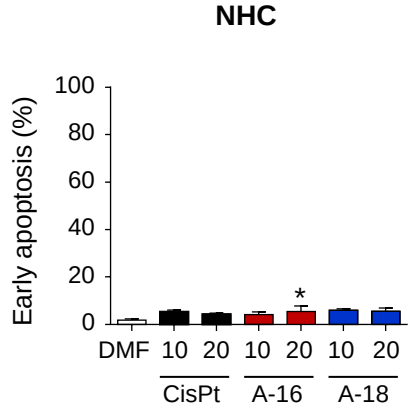
Genotoxity: *Comet assay (DNA damage in cells)*



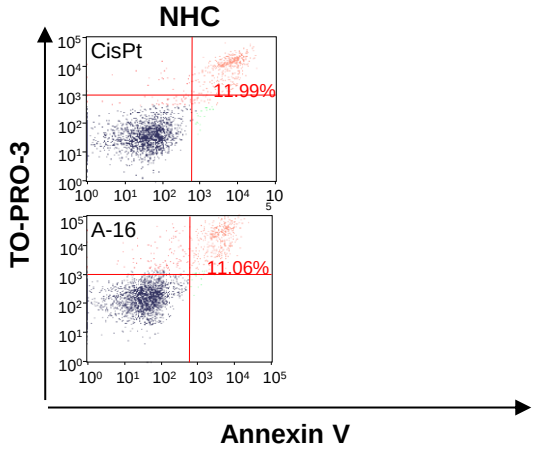
Aurkines promote apoptosis specifically in CCA cells

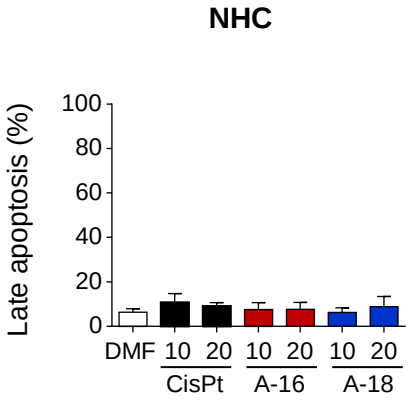
Early cell death (caspase-3)





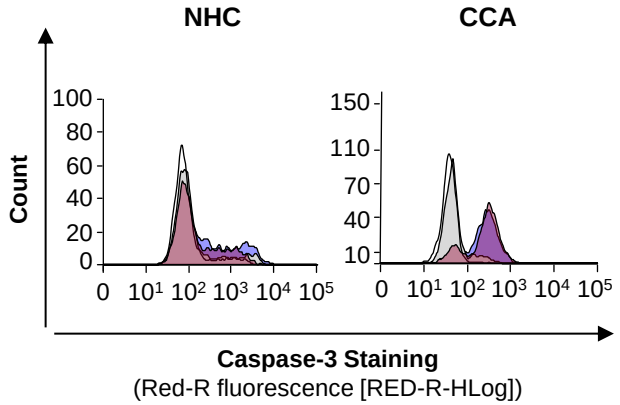
Late cell death (annexin-V – TO-PRO-3)

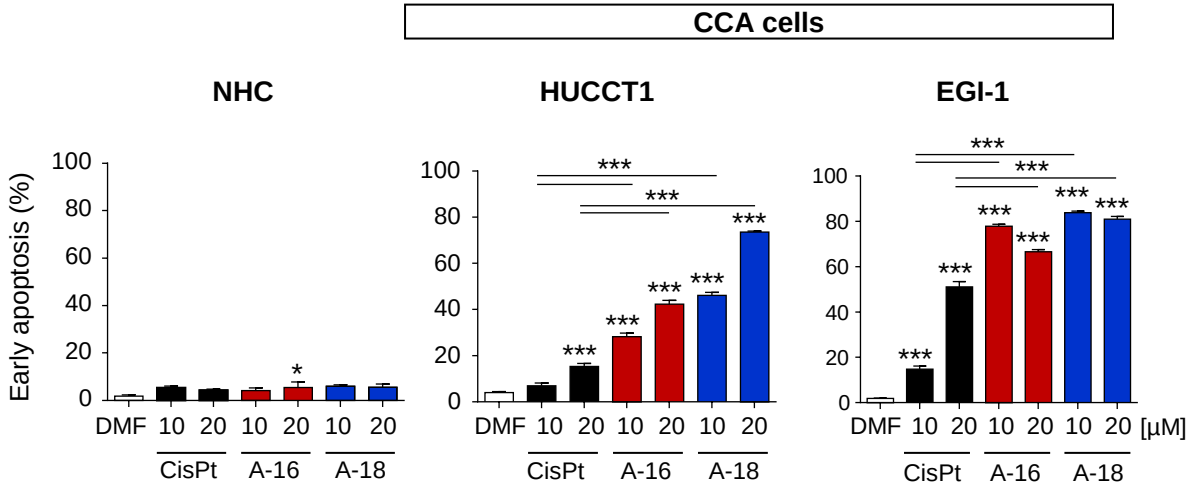




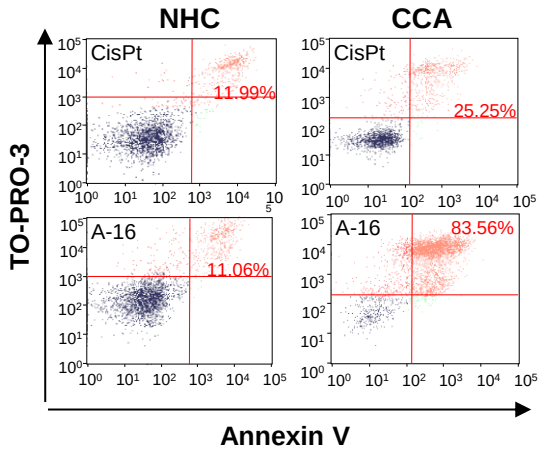
Aurkines promote apoptosis specifically in CCA cells

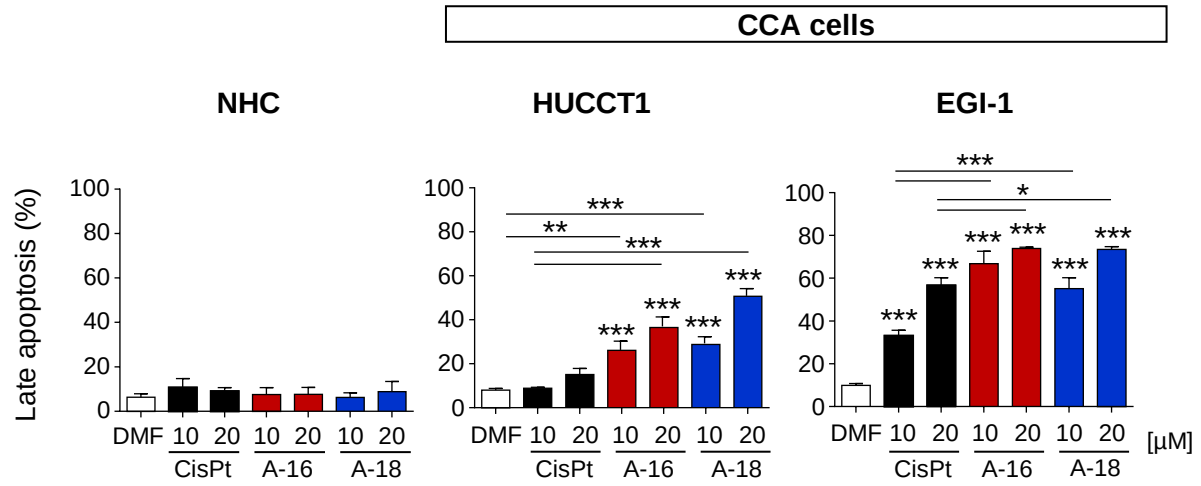
Early cell death (caspase-3)



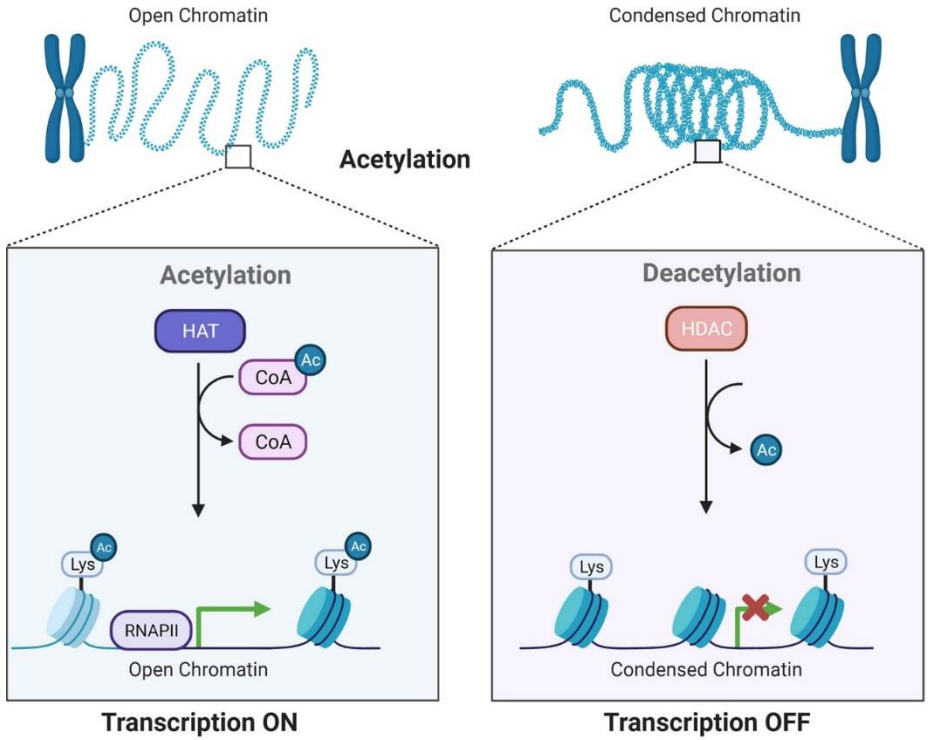


Late cell death (annexin-V – TO-PRO-3)

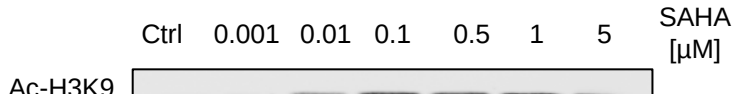


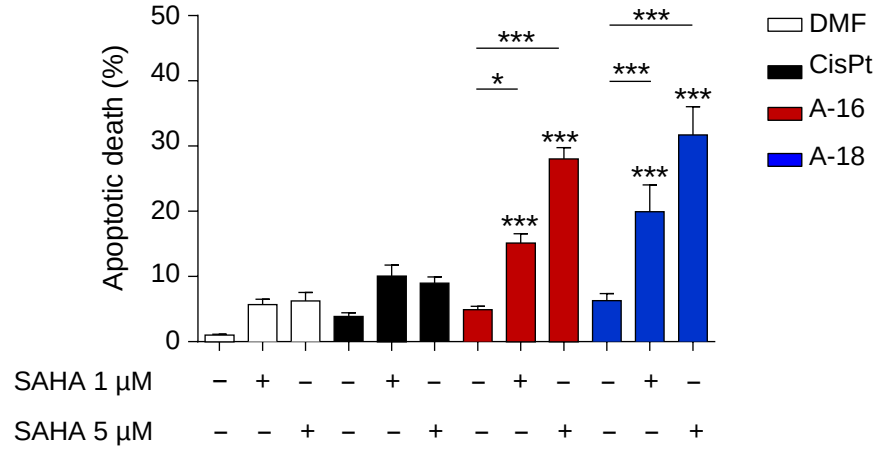


Unpacking NHC chromatin structure enables Aurkine cytotoxic effect



NHC: Normal human cholangiocytes

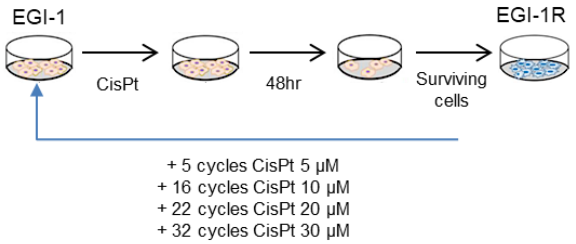


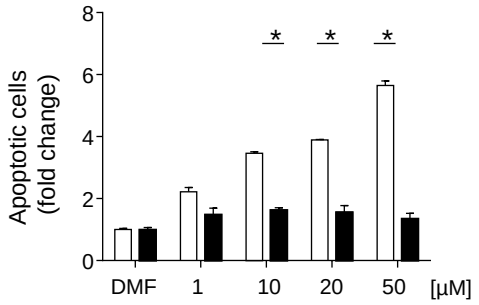


Hai R, et al. *Front. Oncol*. 2021; 11:700947

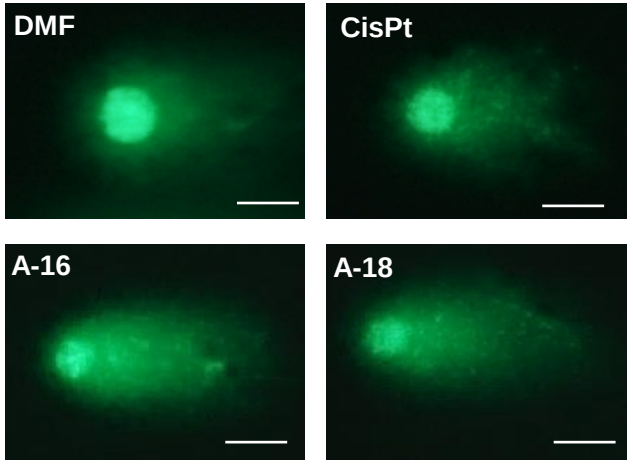
SAHA, suberanilohydroxamic acid

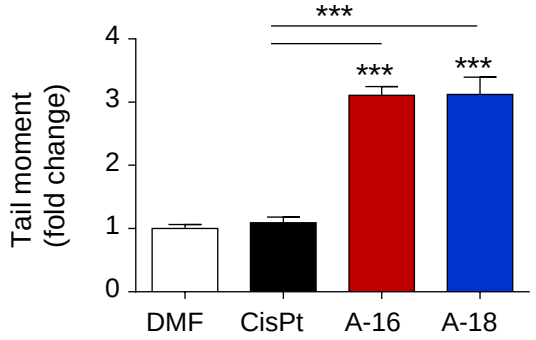
Aurkines promote DNA damage and induce apoptosis in CisPt-resistant CCA cells



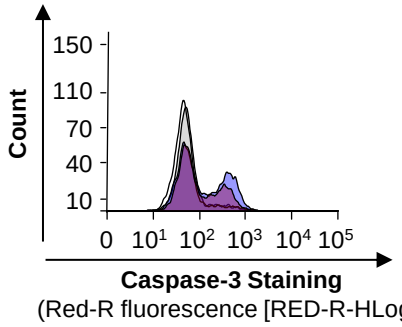


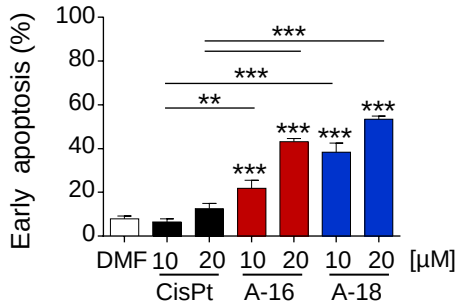
Comet assay



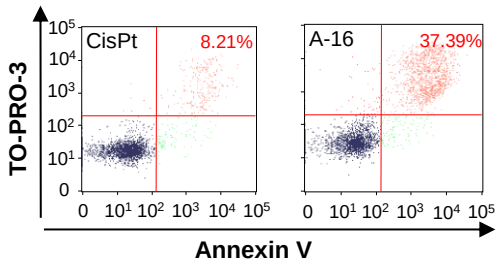


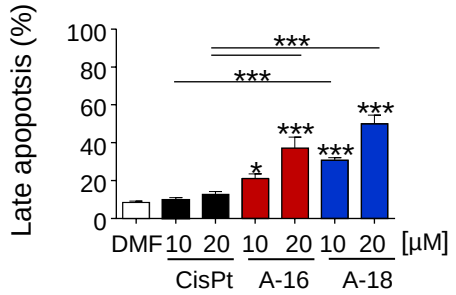
Early cell death (caspase-3)





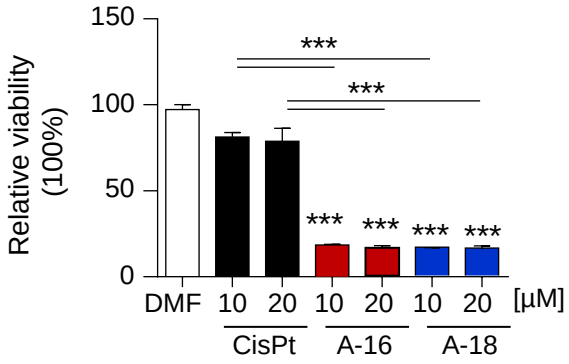
Late cell death (annexin-V – TO-PRO-3)



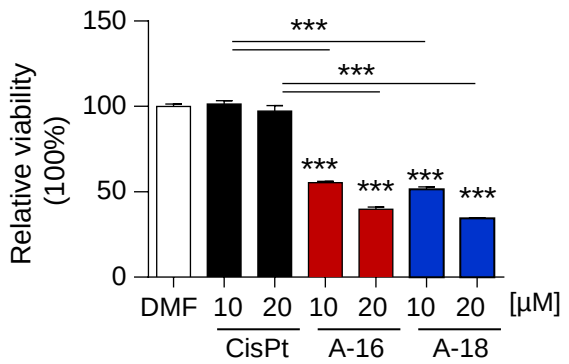


Aurkines reduce cell viability in other CisPt-resistant human cancer cell lines

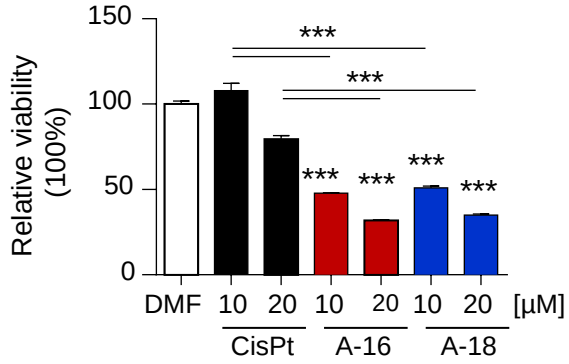
A2780Cis: Ovarian cancer



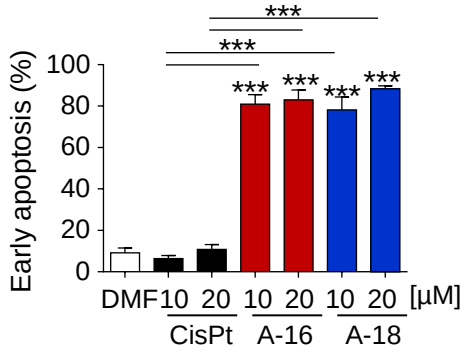
MDA-453: Breast cancer

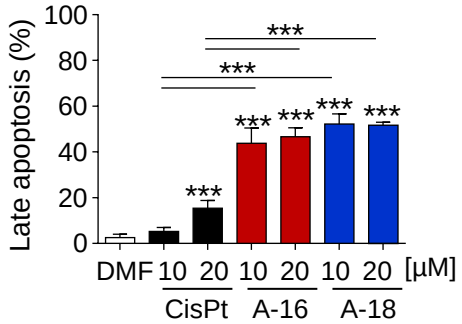


MDA-231: Breast cancer



A2780Cis: Ovarian cancer



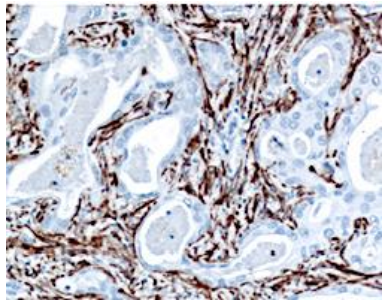


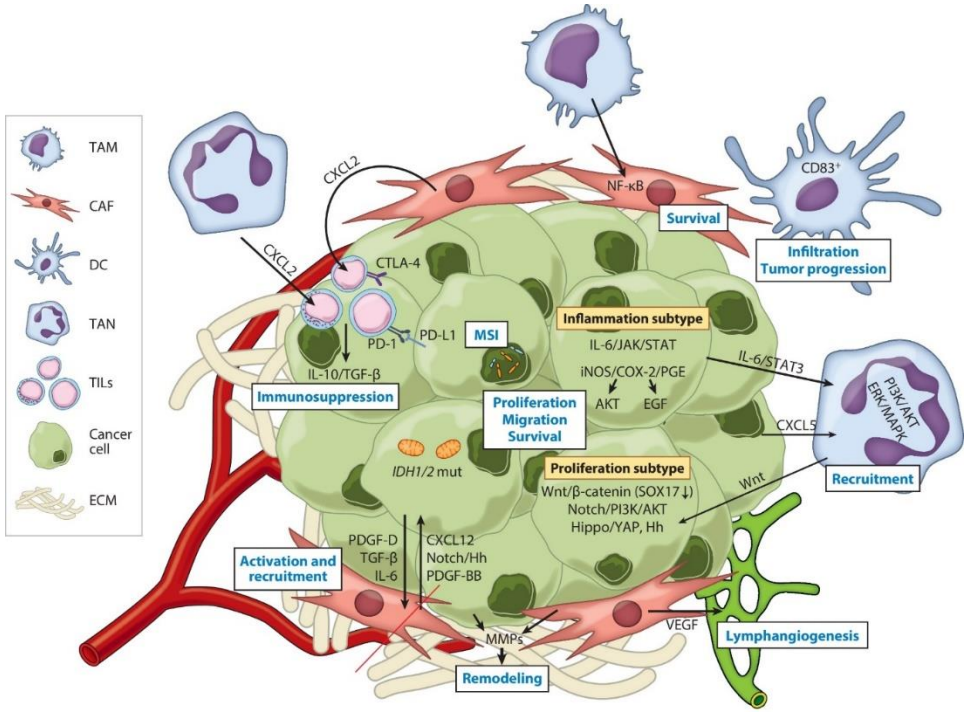
Tumour microenvironment of CCA

Desmoplastic tumours

⇩

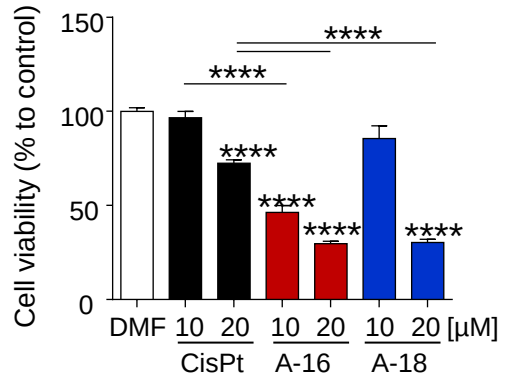
Growth
Dissemination
Chemoresistance



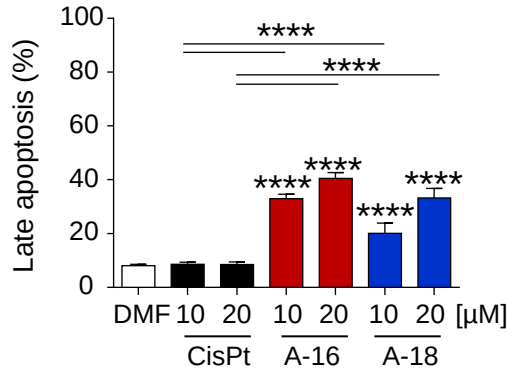


CAFs: cancer-associated fibroblasts

Cell viability (WST-1)



Cell death (Annexin-V/TO-PRO-3)

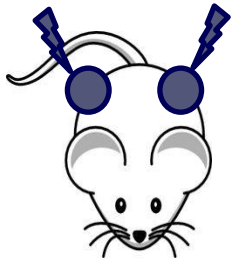


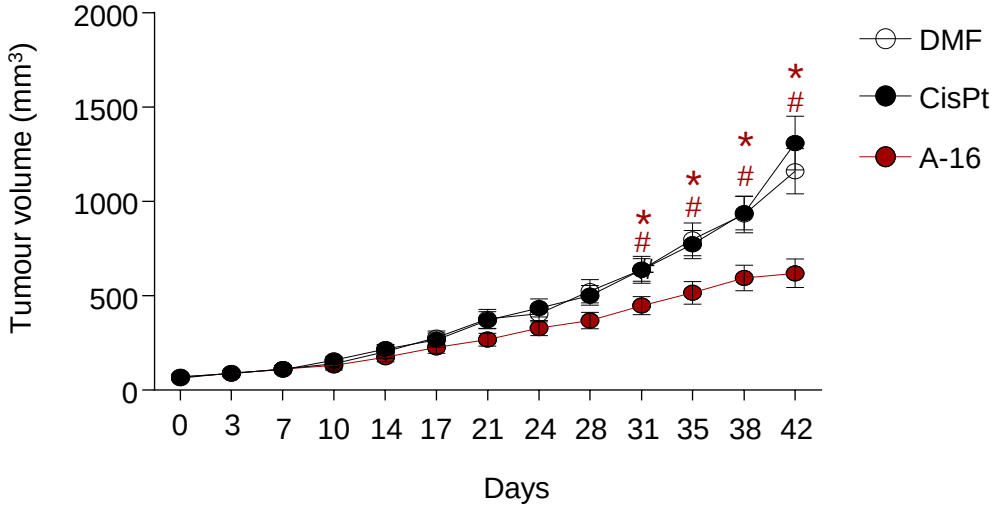
Rodrigues PM,…,Banales JM. *Annu Rev Pathol.* 2021; 16:433-463

Aurkine 16 halts tumour growth in a subcutaneous mouse model of human CCA

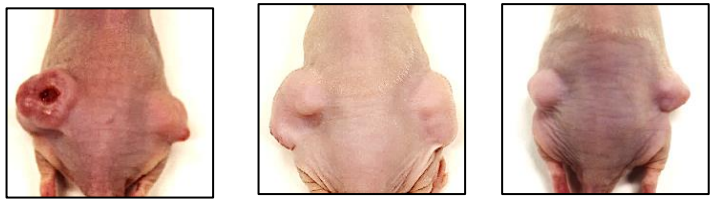
Dose: 0.5 mg/kg

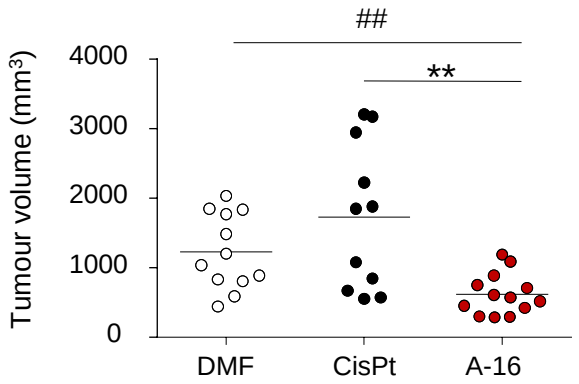
EGI-1
1x10^6





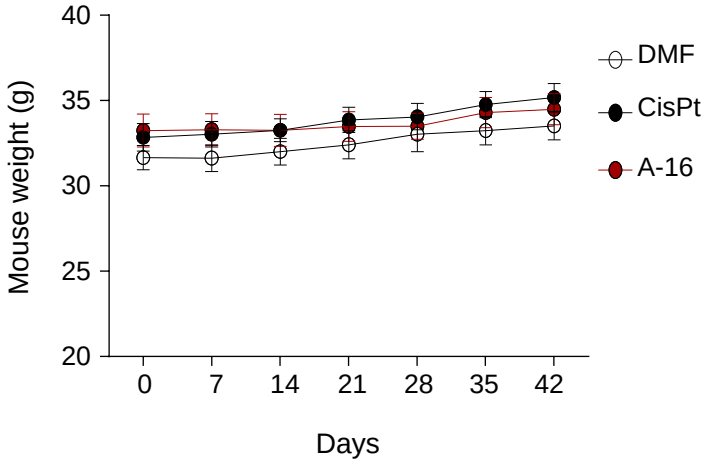
DMF CisPt A-16

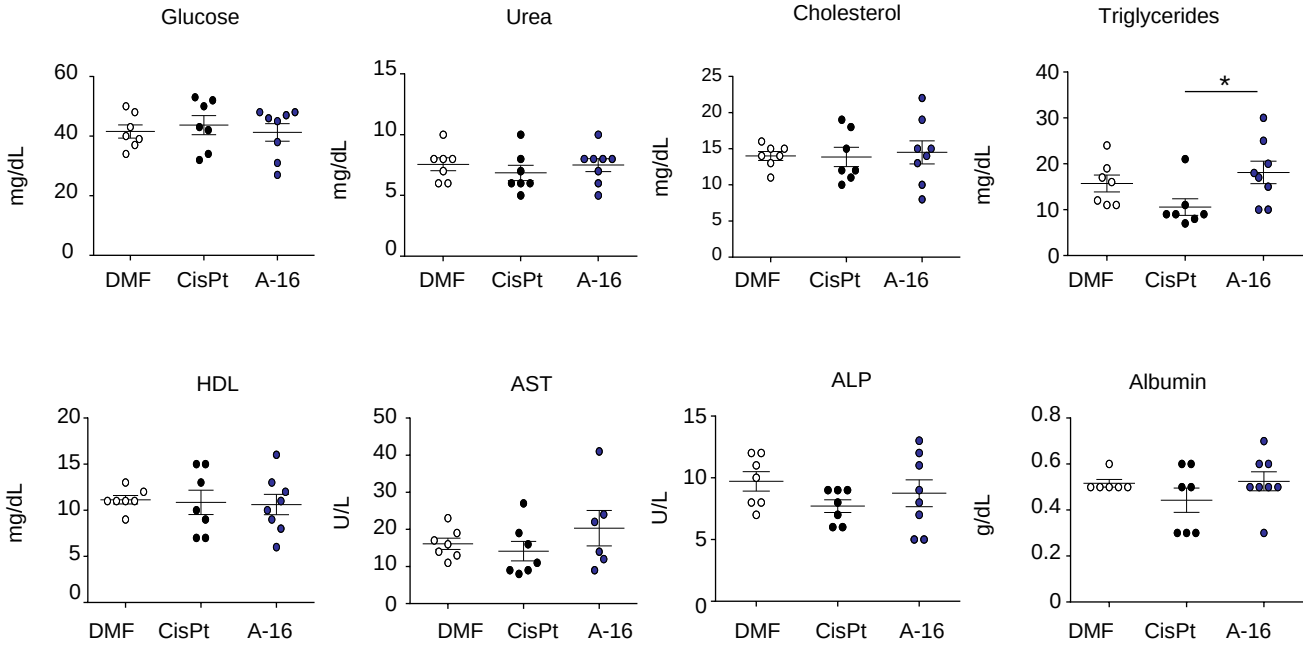




Current status of development

No evidence of toxicity

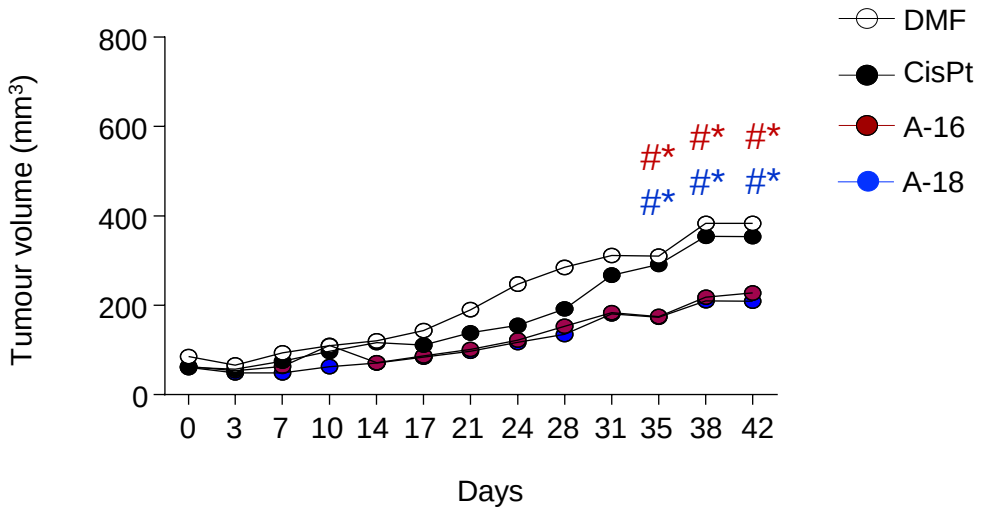




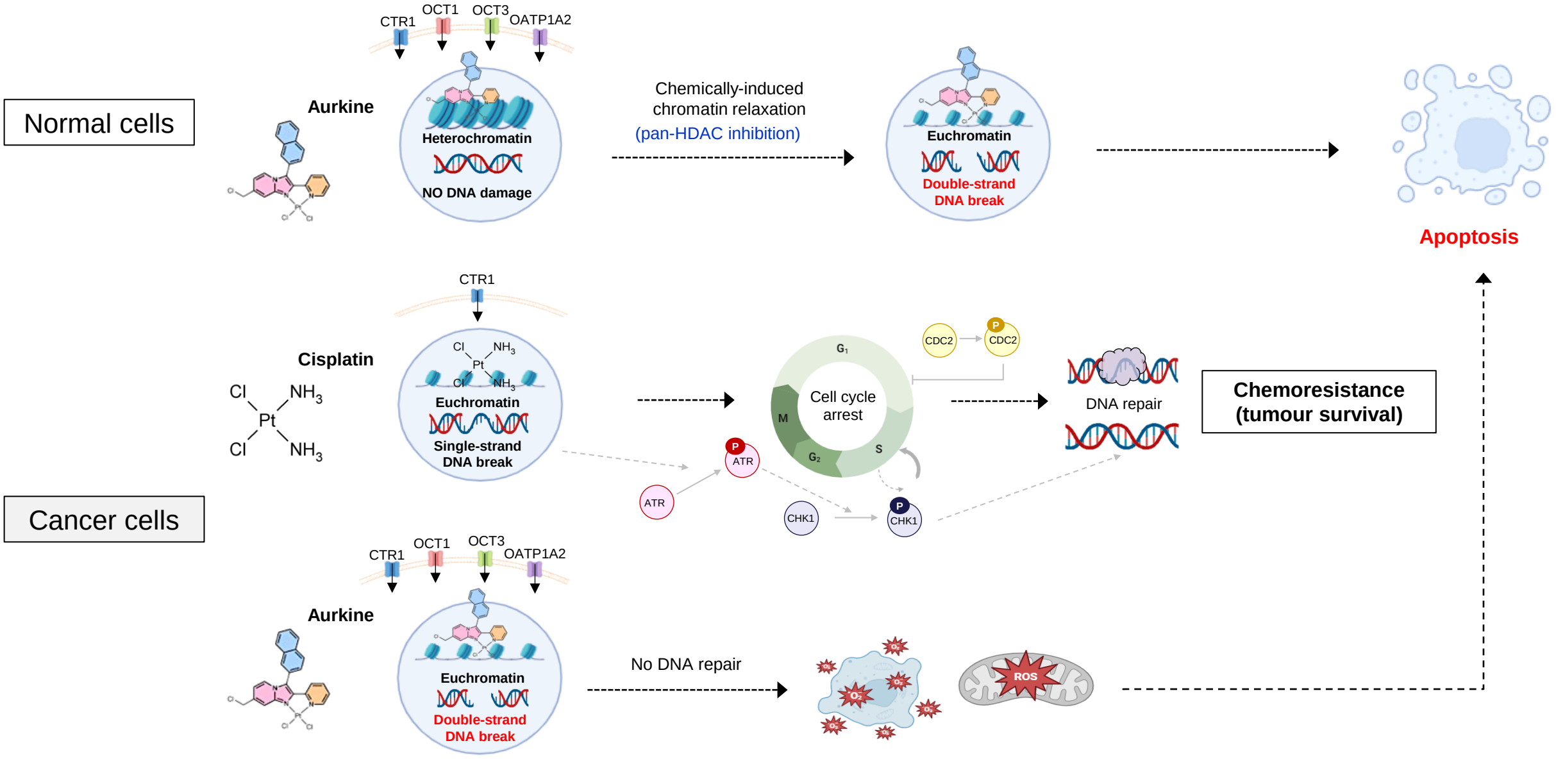
Aurkines halt tumour growth in a subcutaneous mouse model of human CisPt-resistant CCA

Dose: 2 mg/kg

EGI-1R
$5x10^6$



Current status of development

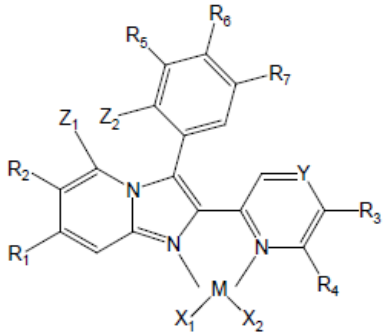


Current status of development

- **Unique mechanim of action**
- ↑↑ efficacy
- ↓ ↓ toxicity
- ↑↑ selectivity for cancer cells
- **Aurkines** represent a promising therapeutic tool for **naïve or CisPt-resistant cancers**
- **Value in 1st or 2nd line**

IPR protection

PATENT PROTECTED



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INVESTIGACIÓN VASCA EN SALUD
BASQUE HEALTH RESEARCH

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Pitfalls & Risks to be considered

Platinum:

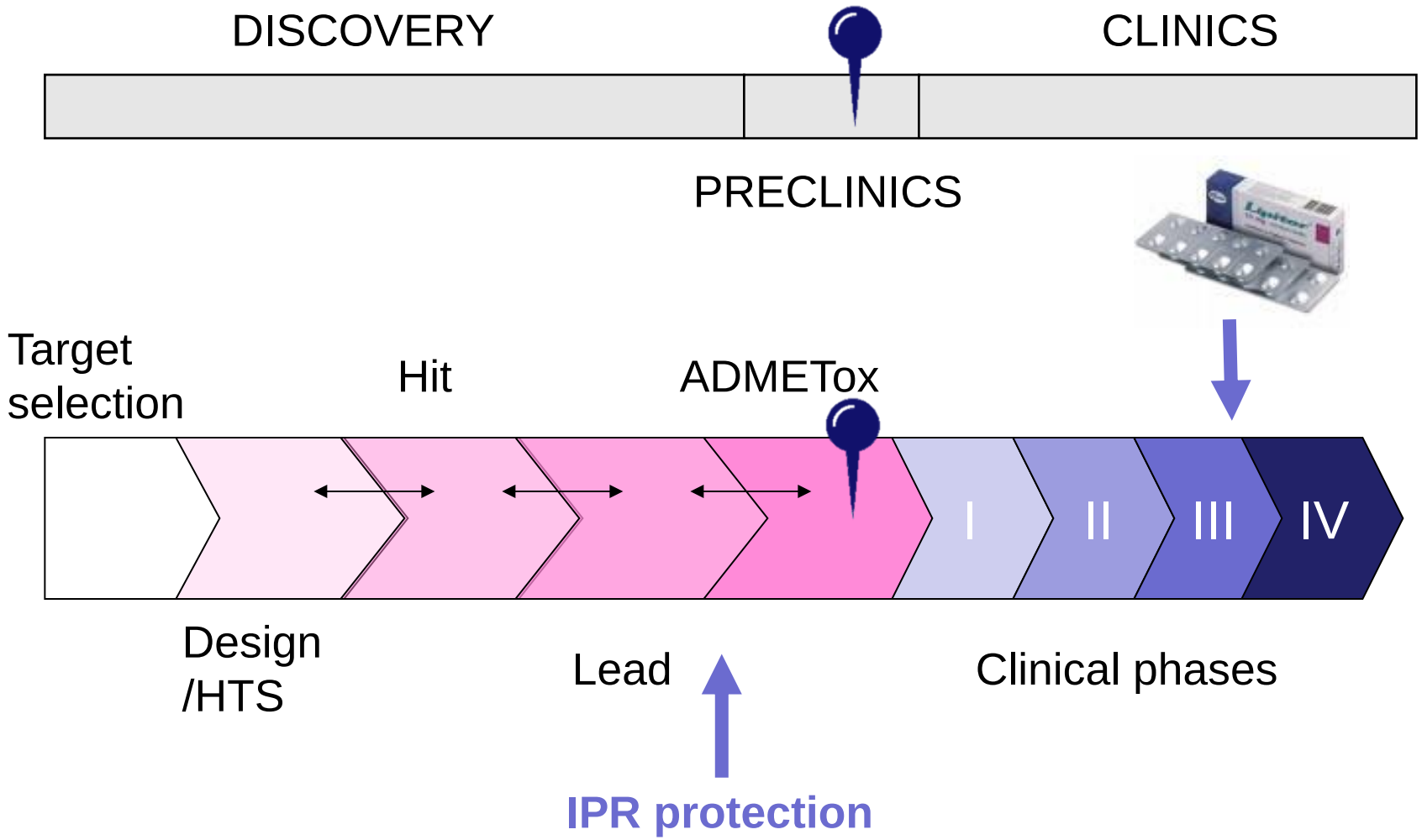
- High toxicity, off-target
- Side effects

Response:

- Triple electrophilicity combining metallic and carbon G-attractors
- Low toxicity
- High selectivity for cancer cells
- Efficacy against CisPt-resistant cells (1^{st} + 2^{nd} line)

Aurkine is **more than** another platinum drug

Partnering opportunities



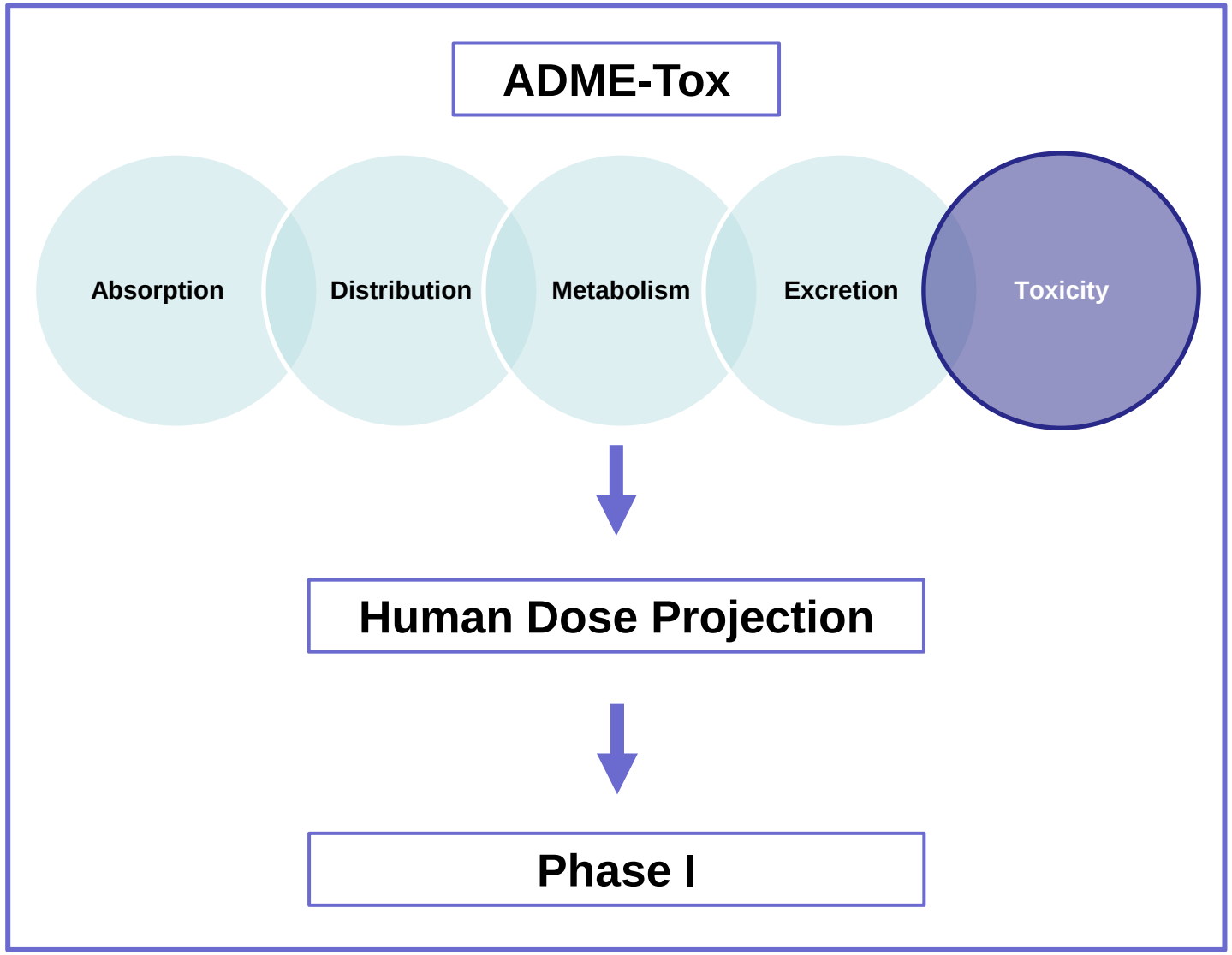
Partnering opportunities

Next milestones

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

May 2010
EMA/CHMP/ICH/646107/2008

ICH guideline S9 on nonclinical evaluation for anticancer pharmaceuticals
Step 5



Partnering opportunities

Partnering and strategic alliance

Licensing

Acknowledgements

Acknowledgements









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Aurkines: novel chemical entities with marked polyelectrophilic properties, specifically designed to induce double-strand DNA breaks

Fernando Cossío

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