# Oscotec R&D Day

June 24, 2025

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CEO

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# Highlights

- Cevidoplenib
  - P2 (IIT, 1st line ITP) IND filed (MFDS)
  - BD activity update
- Denfivontinib
  - Deprioritized in solid tumor; AML to be revisited
- ADEL-Y01
  - P1 progressing smoothly; Part B (MAD) initiated
- OCT-598
  - IND cleared by FDA; FIH dosing to start in Q4
  - AACR presentation
- Cancer Therapy Resistance
  - The first target disclosed in AACR (NUAK1/2)

[BD = Business Development; IIT = Investigator-Initiated Trial; ITP = Immune Thrombocytopenia; AML = Acute myeloid leukemia; MAD = Multiple Ascending Dose; FIH = First-in-human]

# Cevidoplenib

- Highly potent and selective SYK inhibitor
- Quick entry to market; immune thrombocytopenia (ITP)
  - Orphan drug designated
  - Proven efficacy and safety in P2 (2nd line); **P3-ready**
  - Potential expansion to the 1st line (IIT to start in 2025)
- 'Pipeline in a product' – indication expansion
  - Rheumatoid arthritis (precision immunology for 'early RA')
  - wAIHA, cGVHD, AbMR, AAV, etc
- Partnering activities
  - Commercialization in ITP (global/regional)
  - PoC in RA subpopulation (precision immunology)

IIT = Investigator-initiated trial; wAIHA = warm Autoimmune Hemolytic Anemia; cGVHD = chronic Graft-versus-Host Disease; AbMR = Antibody-mediated (organ transplantation) Rejection; AAV = ANCA-Associated Vasculitis; PoC = Proof of Concept

# ADEL-Y01

- Anti-tau antibody targeting a pathological form of tau protein (AcK280) to treat tauopathies including Alzheimer Disease
- First-in-human study underway (US)
  - First in Human, Phase Ia/b study for safety, tolerability, pharmacokinetics, and clinical activity evaluation of ADEL-Y01 in healthy participants and in participants with Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's disease
  - P1a (SAD) dosing completed (2.5 ~ 100 mg/kg)
    - No safety concern reported to date
    - PK exposure exceeding prediction; q4w possible
  - P1b (MAD) study initiated; enrolling MCI/AD patients
- Partnership discussion ongoing

SAD = Single Ascending Dose; MAD = Multiple Ascending Dose; PK = Pharmacokinetics; q4w = dosing every 4 weeks

# OCT-598

- EP2/4 dual antagonist for cancer therapy resistance
  - Will OCT-598 combination delay the development of resistance and prolong the responses to standard-of-care anti-tumor therapies?
- IND cleared by US FDA
  - A Phase 1 Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of OCT-598 as a Single Agent and in Combination With Standard-of-Care Treatment in Patients With Advanced Solid Tumors
  - IND to be filed in MFDS, FIH dosing to start in Q4
  - To begin with docetaxel combination in multiple tumor types (lung, breast, prostate, gastric, and head and neck cancer); potentially expand to other combinations

FIH = First-in-human

Abstract #3069

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# Inhibition of PGE2 Signaling by An EP2/4 Dual Antagonist OCT-598 Prevents Acquisition of Therapy-resistance And Tumor Relapse


**Youngrae Lee**[1], Hain Choi[1], Jong-Won Lim[1], Sung Eun Lee[2], Yeeun Kim[2], Changhoon Choi[2], Taeyoung Yoon[1]

[1]Oscotec Inc., Seongnam, Korea, Republic of,
[2]Samsung Medical Center, Seoul, Korea, Republic of


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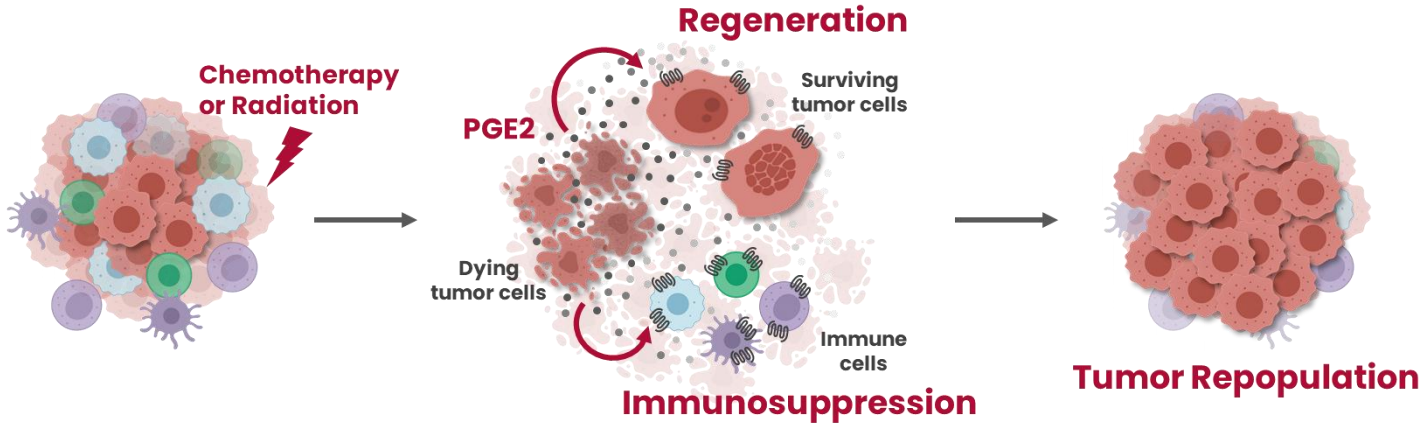
# Introduction

❖ **Prostaglandin E2 (PGE2)**: Regenerative Signal Driving Resistance

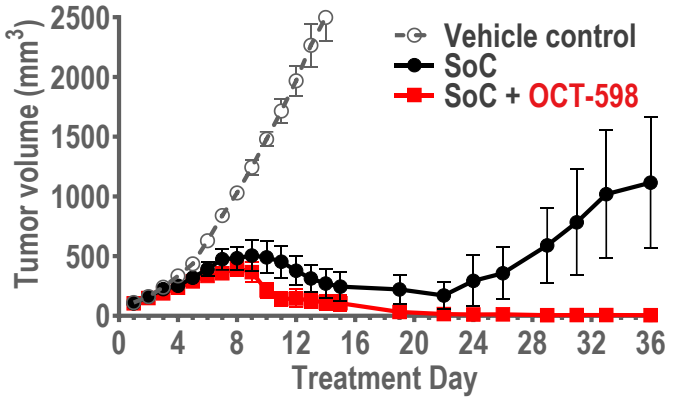
- Therapy-induced cancer cell death activates the “Phoenix Rising” pathway, producing PGE2
- PGE2 promotes regenerative and immunosuppressive niche formation, via EP2 and EP4, in TME

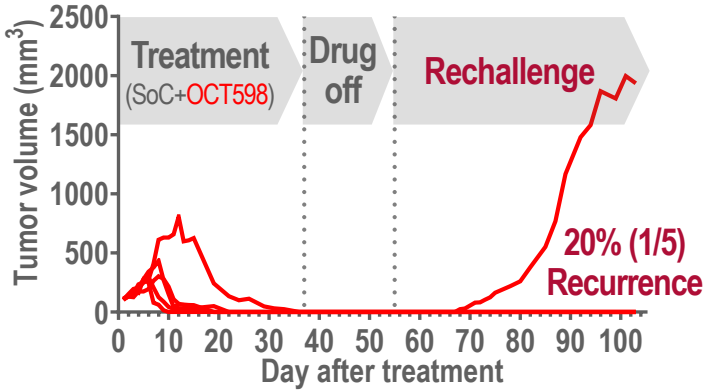



❖ **OCT-598, EP2/4 dual antagonist**

- **OCT-598** induced **complete regression** and **durable responses** in a mouse syngeneic TC-1 tumor model when **combined with standard of care (SoC) chemo-immunotherapy** (Abstract #3234, AACR 2023).

*SoC = Cisplatin + Pemetrexed + Anti-PD-1 Ab

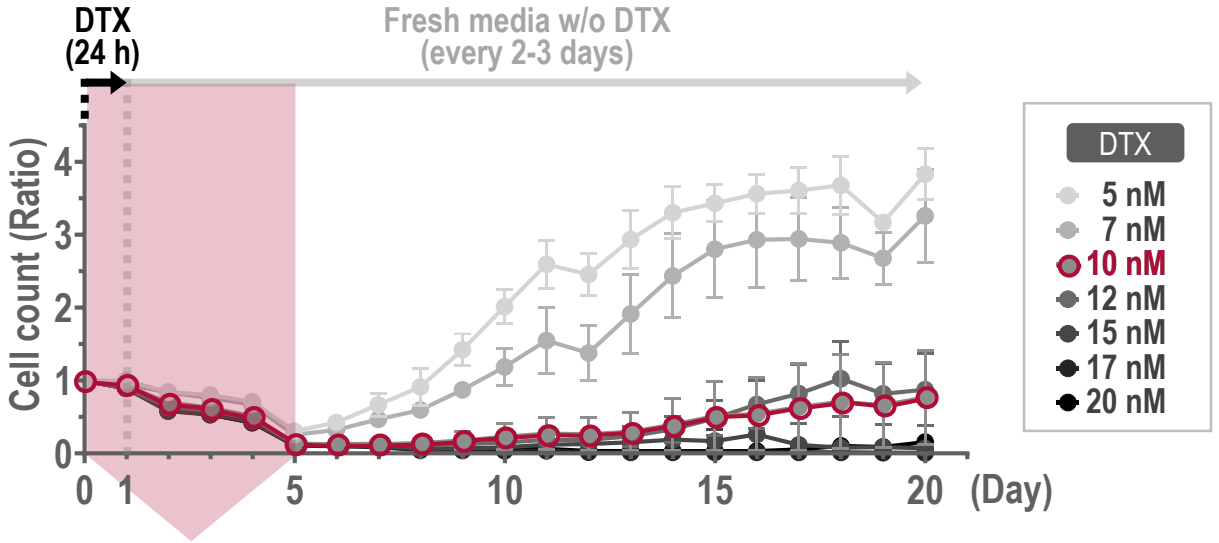


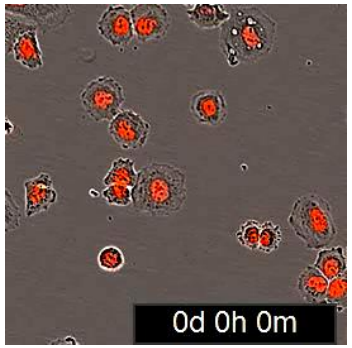
# Tumor Repopulation after Docetaxel Treatment

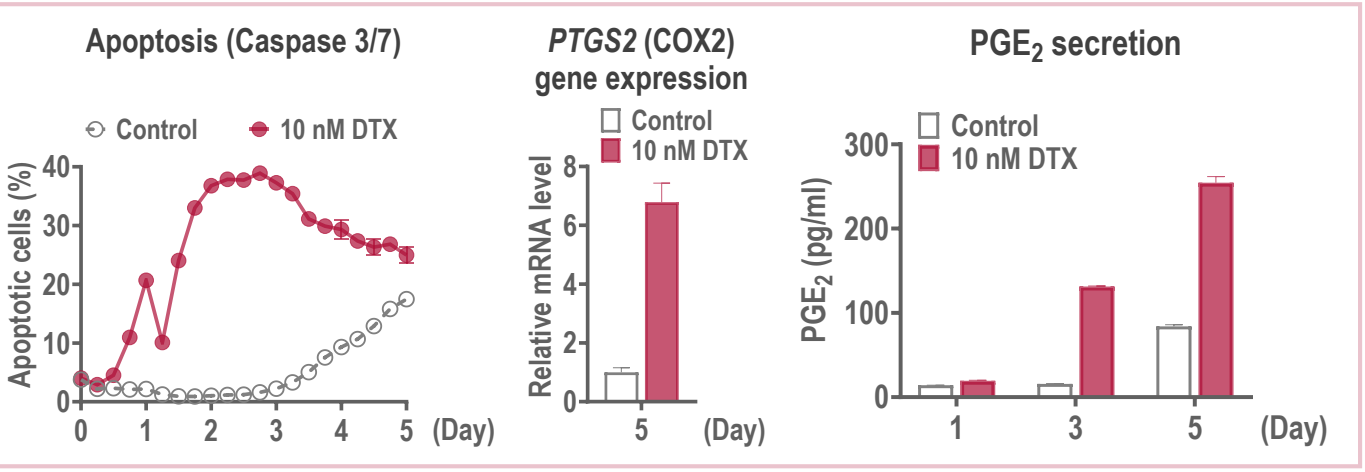


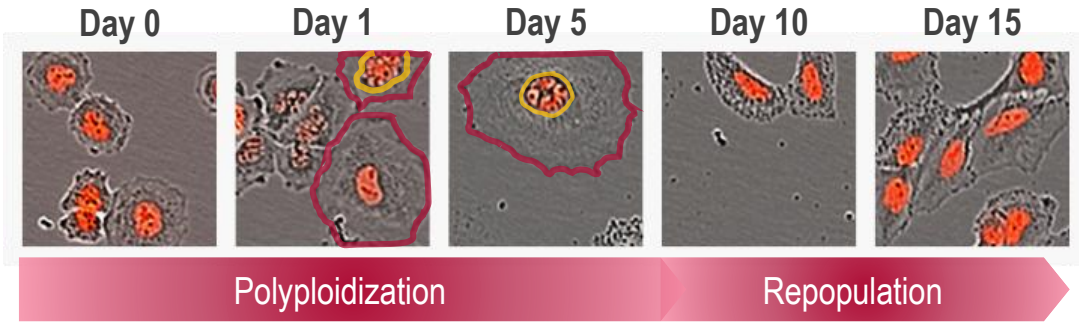
H460 lung cancer cell line with red fluorescently labeled nuclei




10 nM DTX (24 h)



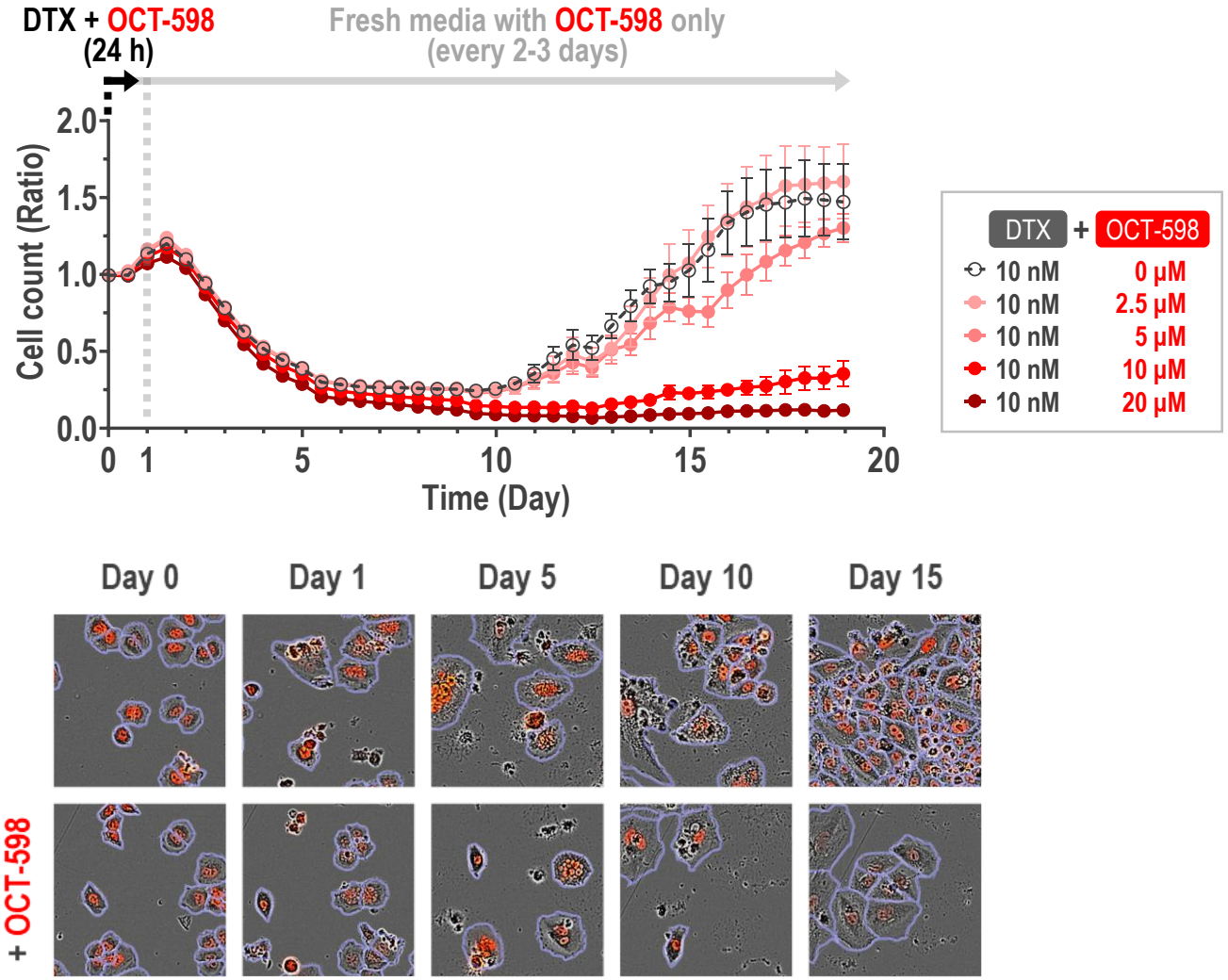



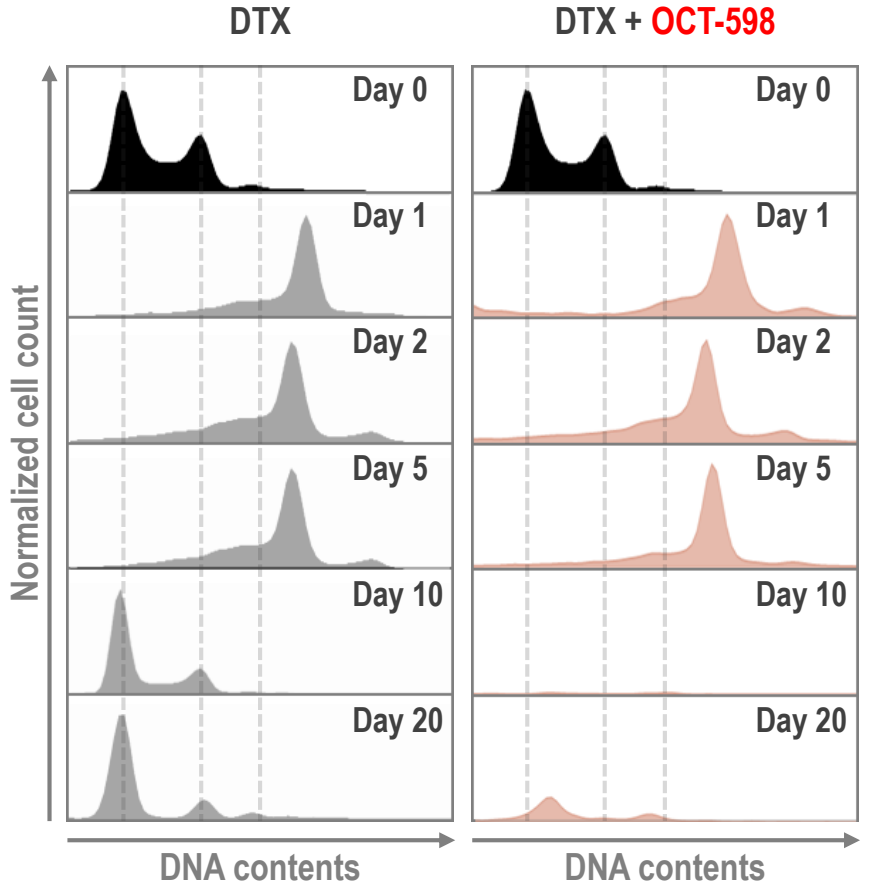
# OCT-598, Inhibition of Tumor Repopulation *In Vitro*



## H460 lung cancer cell line with red fluorescently labeled nuclei




## DNA Content (Flow cytometer)



# Inhibition of Post-Therapy Tumor Relapse — In Vivo PoC Study

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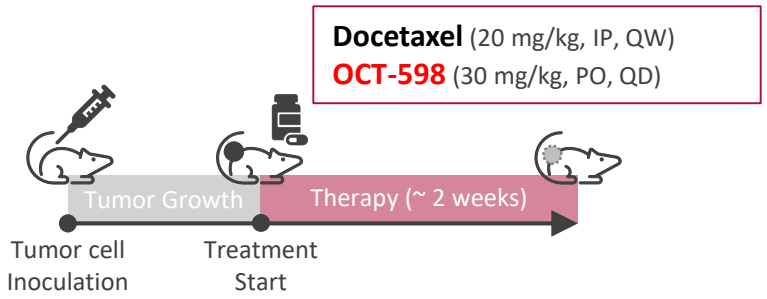
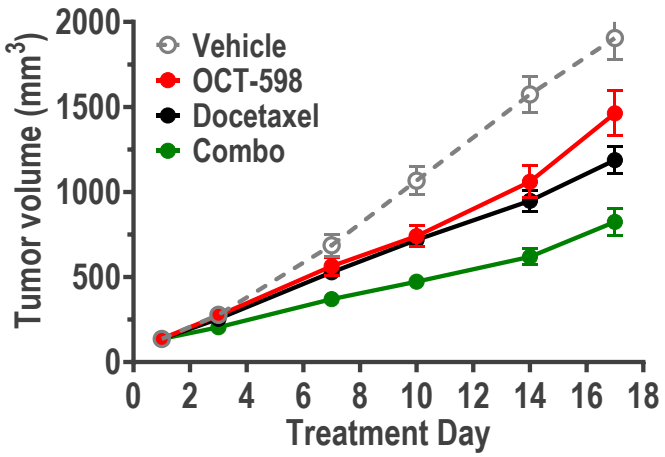
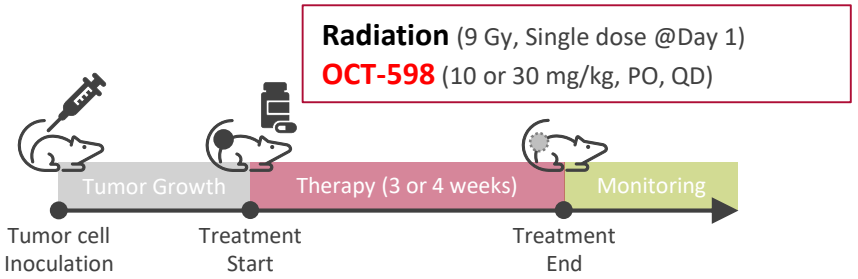
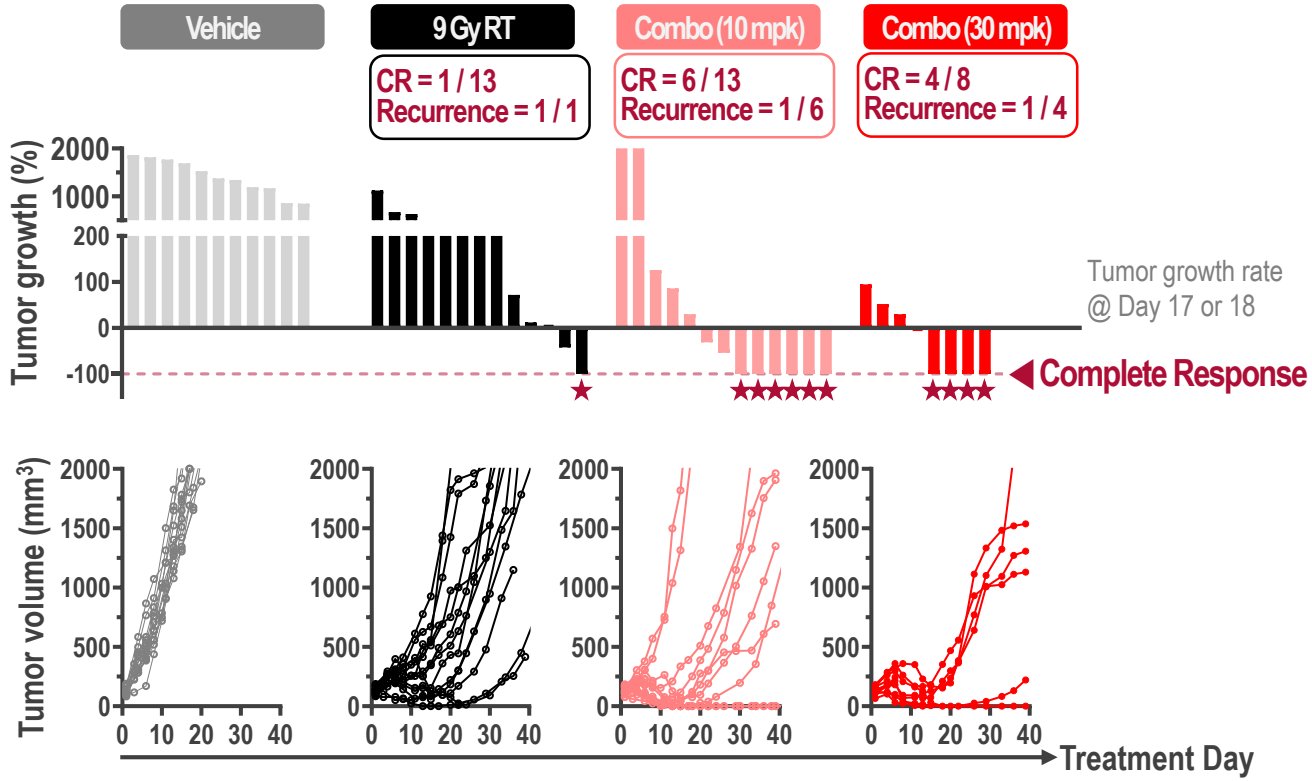
## ❖ NCI-H460 Lung Tumor Xenograft Mouse Model



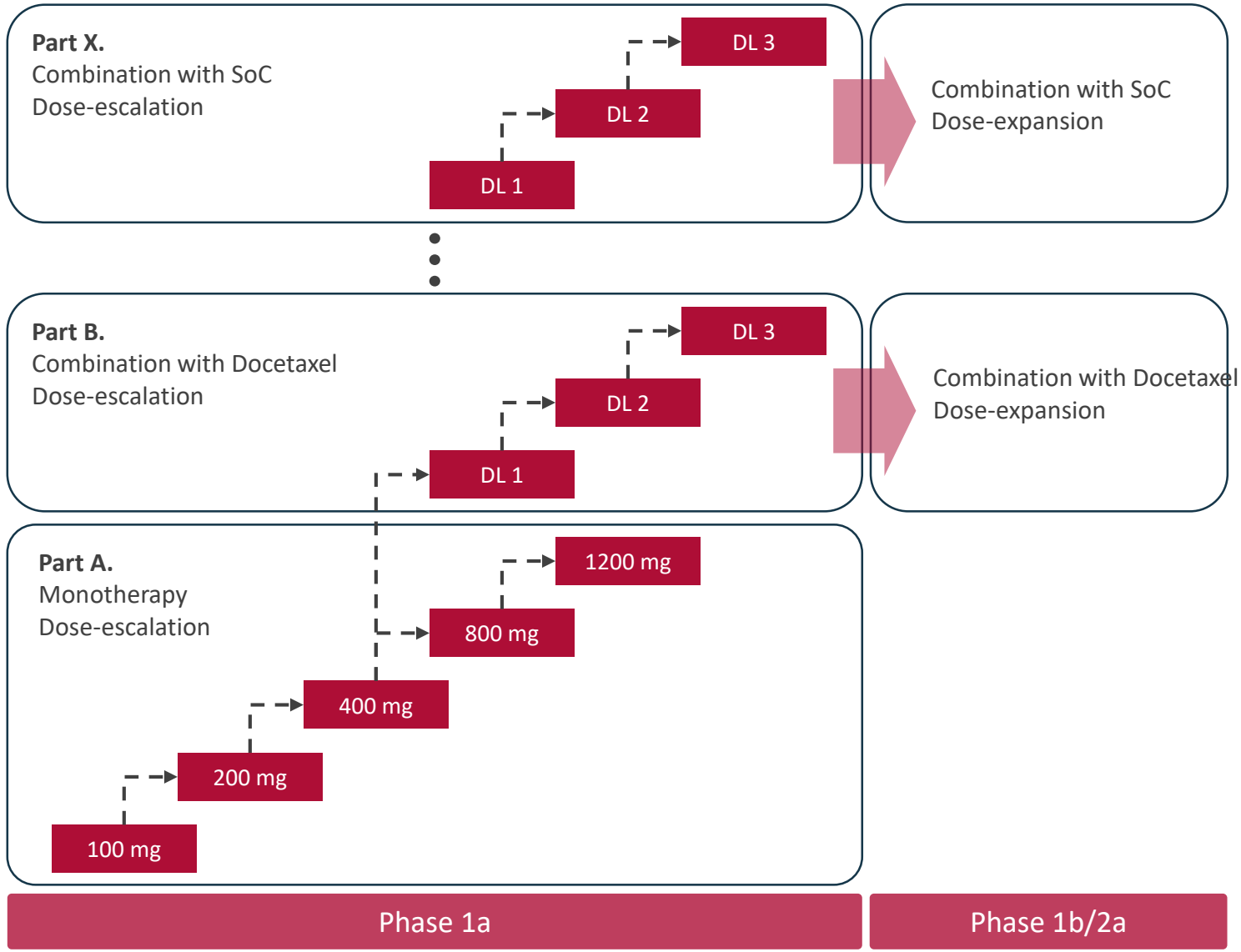

## ❖ CT26 Colon Tumor Syngeneic Mouse Model



# OCT-598, Clinical Development Plan

- We aim to develop **OCT-598** as **an 'anti-resistance' agent** to prevent tumor cells from acquiring resistance to SoC therapies.
- Strategic Plan
  - Rapid initiation of combination dose-finding studies with SoC therapies.
  - Initial combination will be with docetaxel.
  - Additional combination regimens will be explored in future stages.



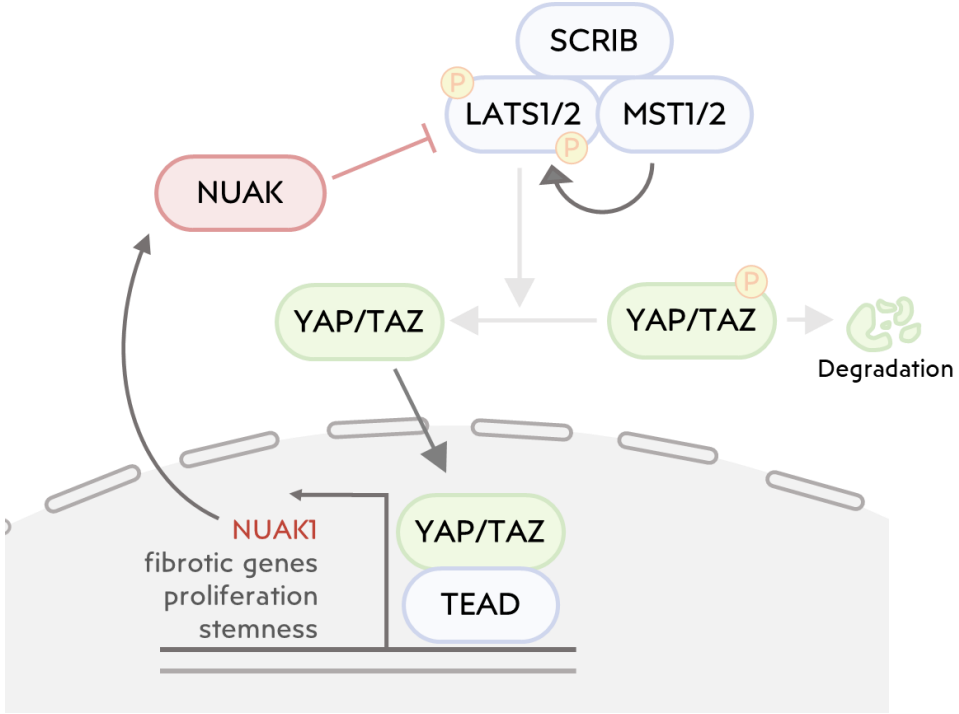
# Pharmacological inhibition of NUAK1/2 synergizes with chemotherapy in pancreatic cancer models by abrogating drug resistance and suppressing fibrosis

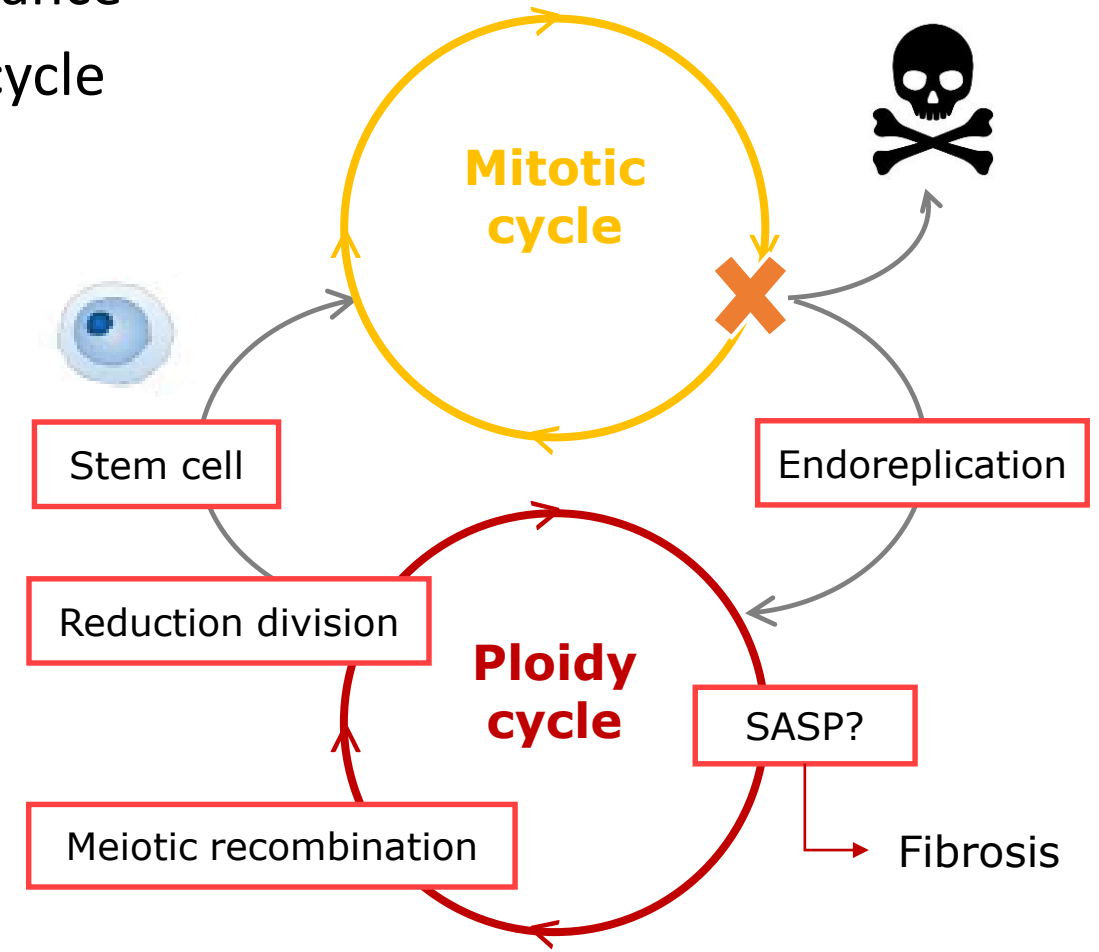
**Minji Seo, Jihye Yoon, Song-Eun Park, Jong-Won Lim, Sungho Park, Yuntae Kim, Taeyoung Yoon**

*OSCOTEC Inc.,Seongnam, Korea.*

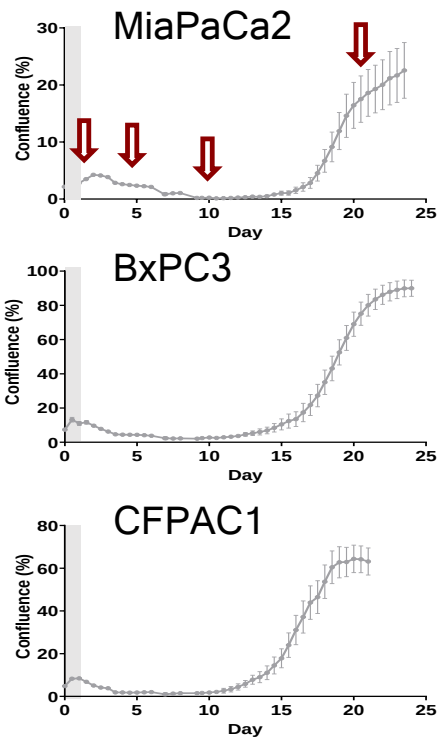
# Background and Hypothesis

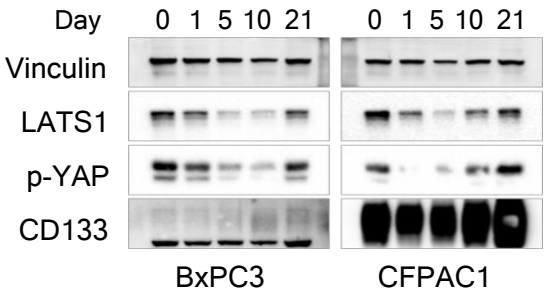
- Ploidy cycle mediates cancer therapy resistance
- YAP activation unlocks the entry to ploidy cycle
- NUAK1/2 feed forward YAP activation



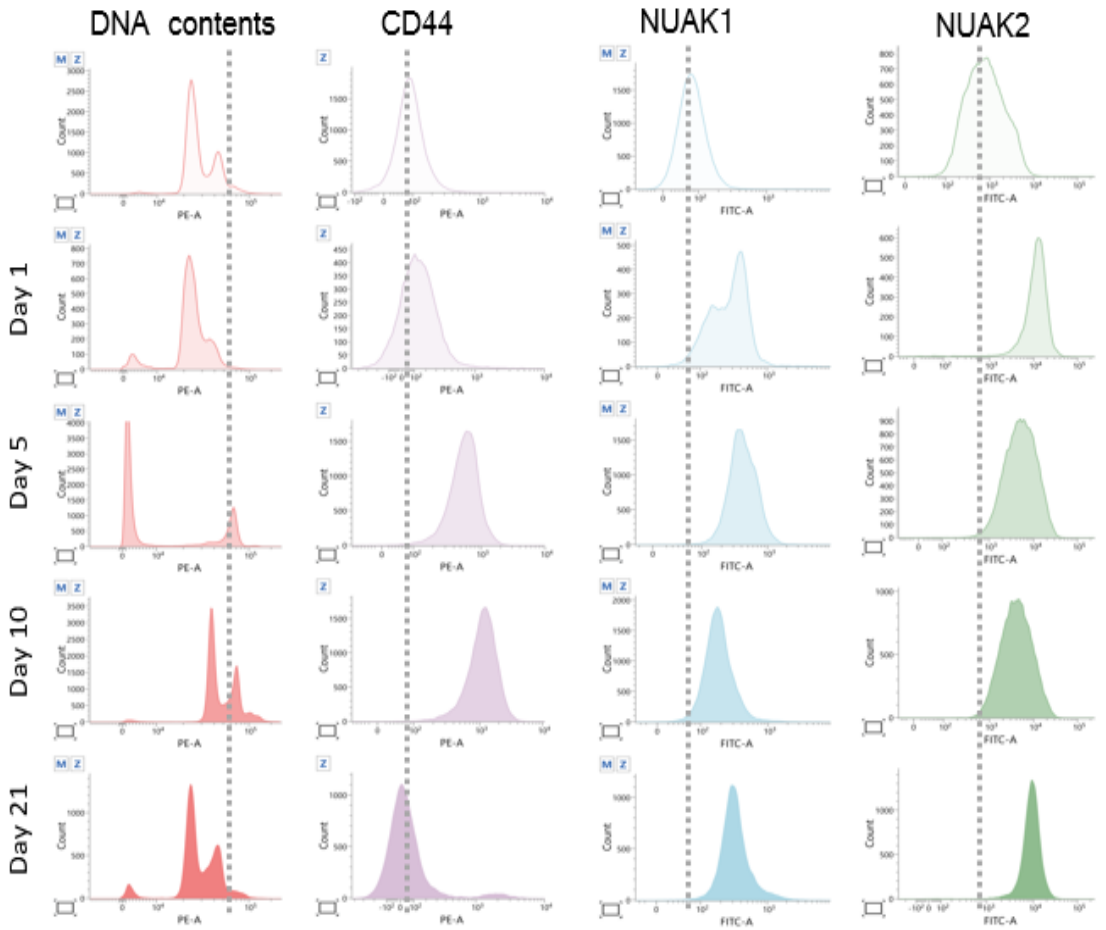



# Ploidy-mediated Repopulation of PDAC Cells after Gemcitabine

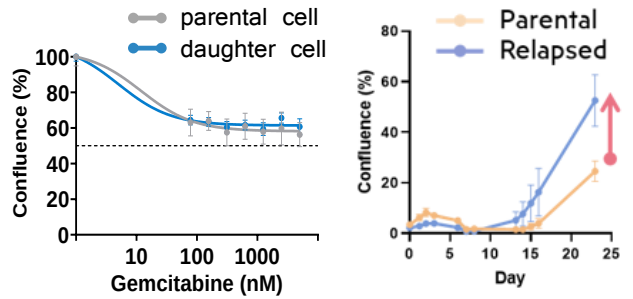


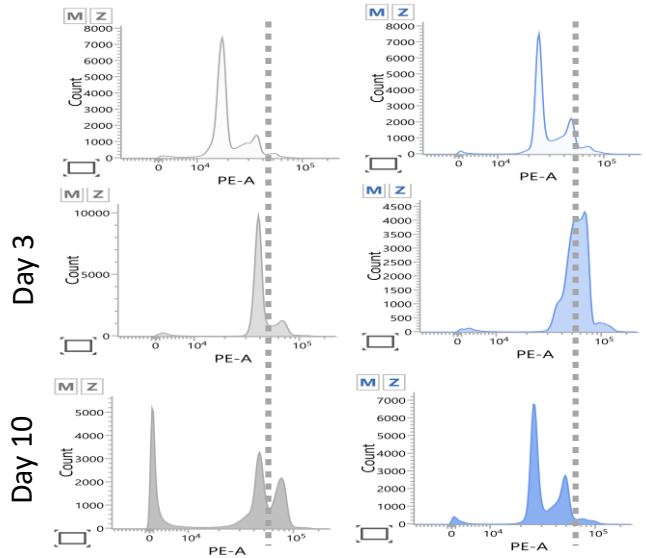




- Upon gemcitabine treatment, surviving PDAC cells become hyperploid before giving birth to para-diploid daughter cells




- The daughter cells remain sensitive to gemcitabine, but enter the next ploidy cycle much more readily

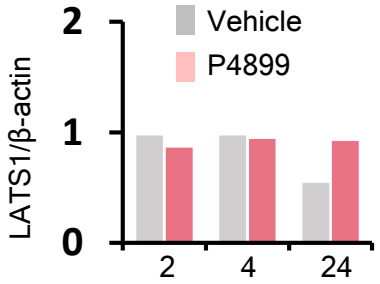


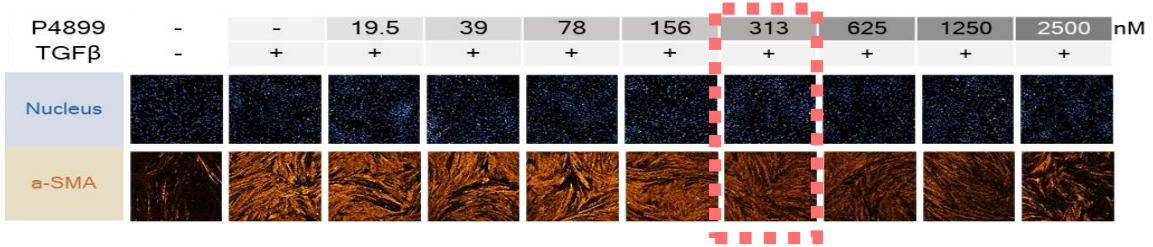
# NUAK1/2 Inhibitor P4899 Abrogates Repopulation In Vitro

- In vitro activities of P4899

| P4899 | $IC_{50}$ |
|---|---|
| NUAK1 | 0.9 nM |
| NUAK2 | 51.4 nM |

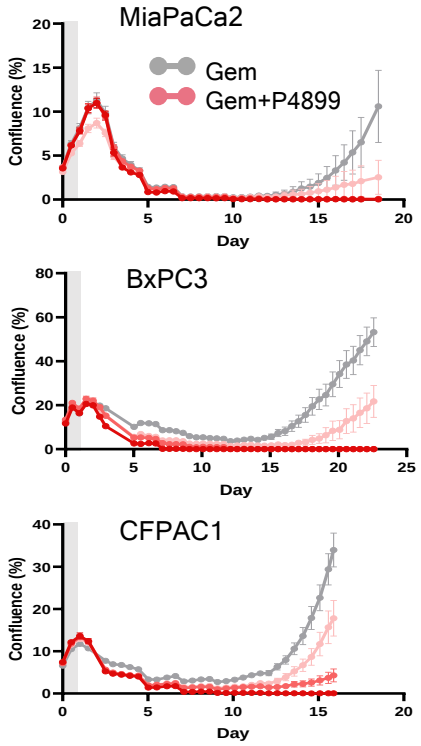



- P4899 inhibits TGFβ-mediated fibroblast activation

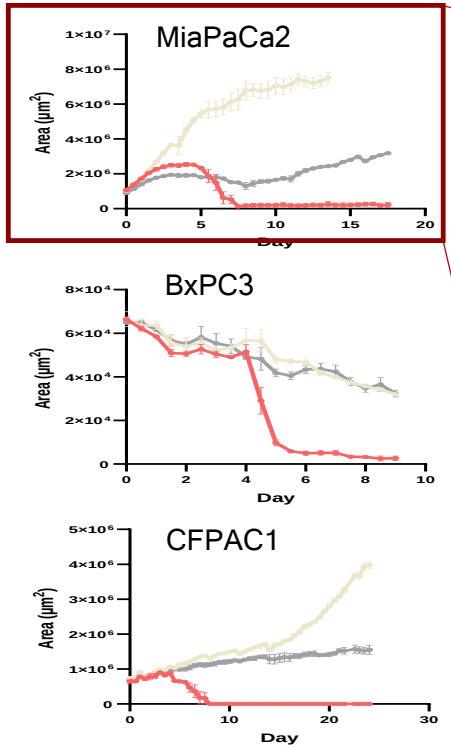


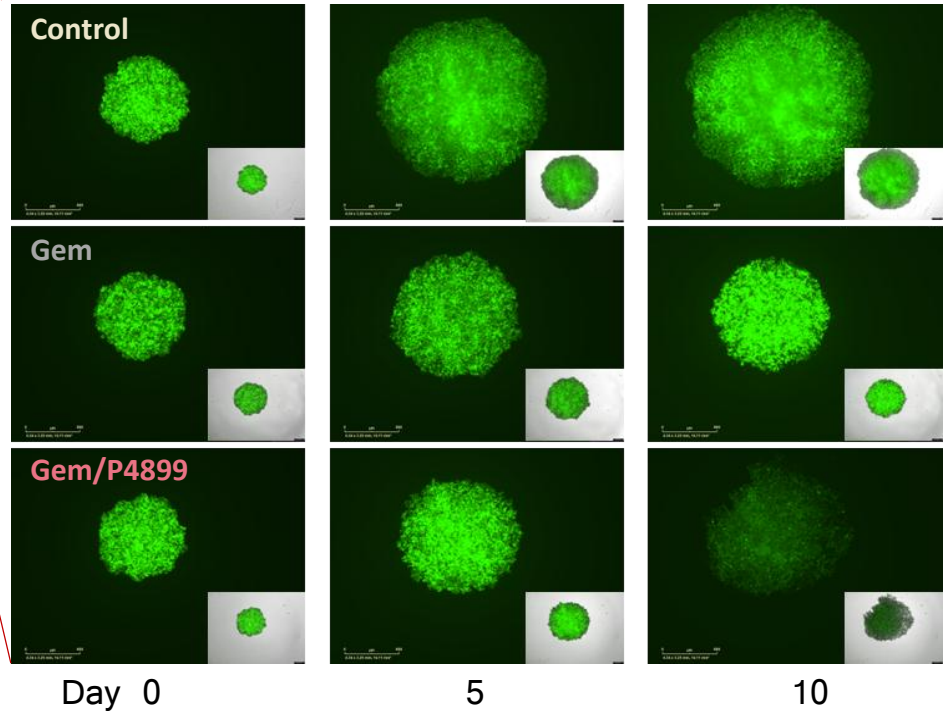

$EC_{50}$: 322.4 nM

Dose-dependent inhibition of repopulation after gemcitabine



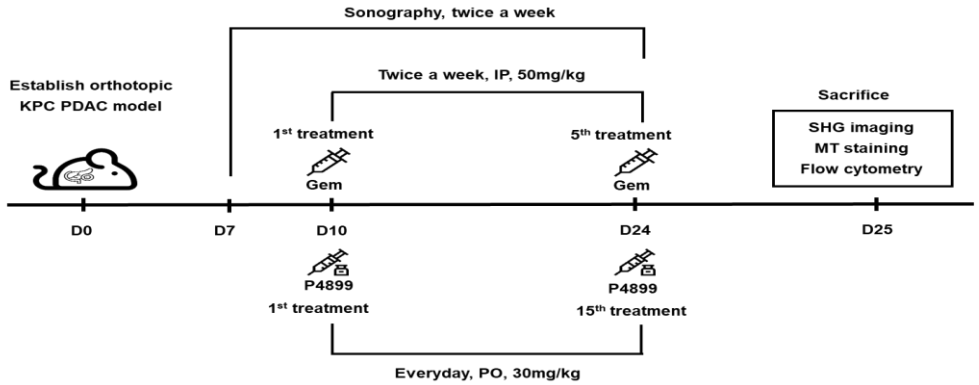

Inhibition of tumorsphere growth



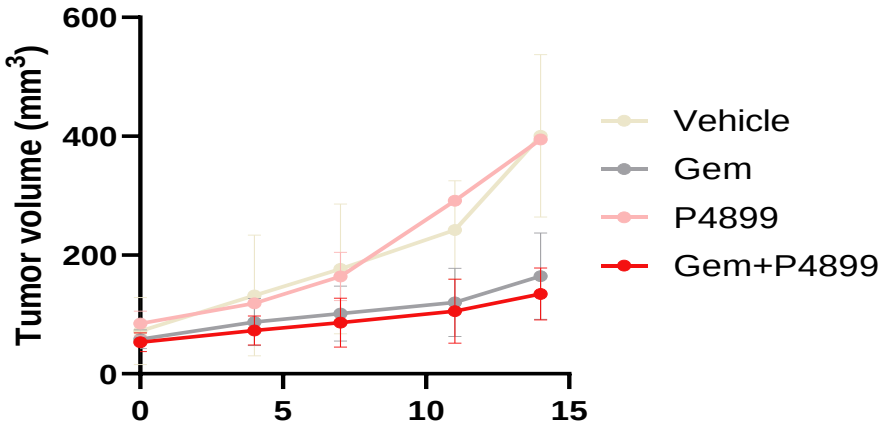



# NUAK1/2 Inhibitor P4899 Alleviates Fibrosis In Vivo

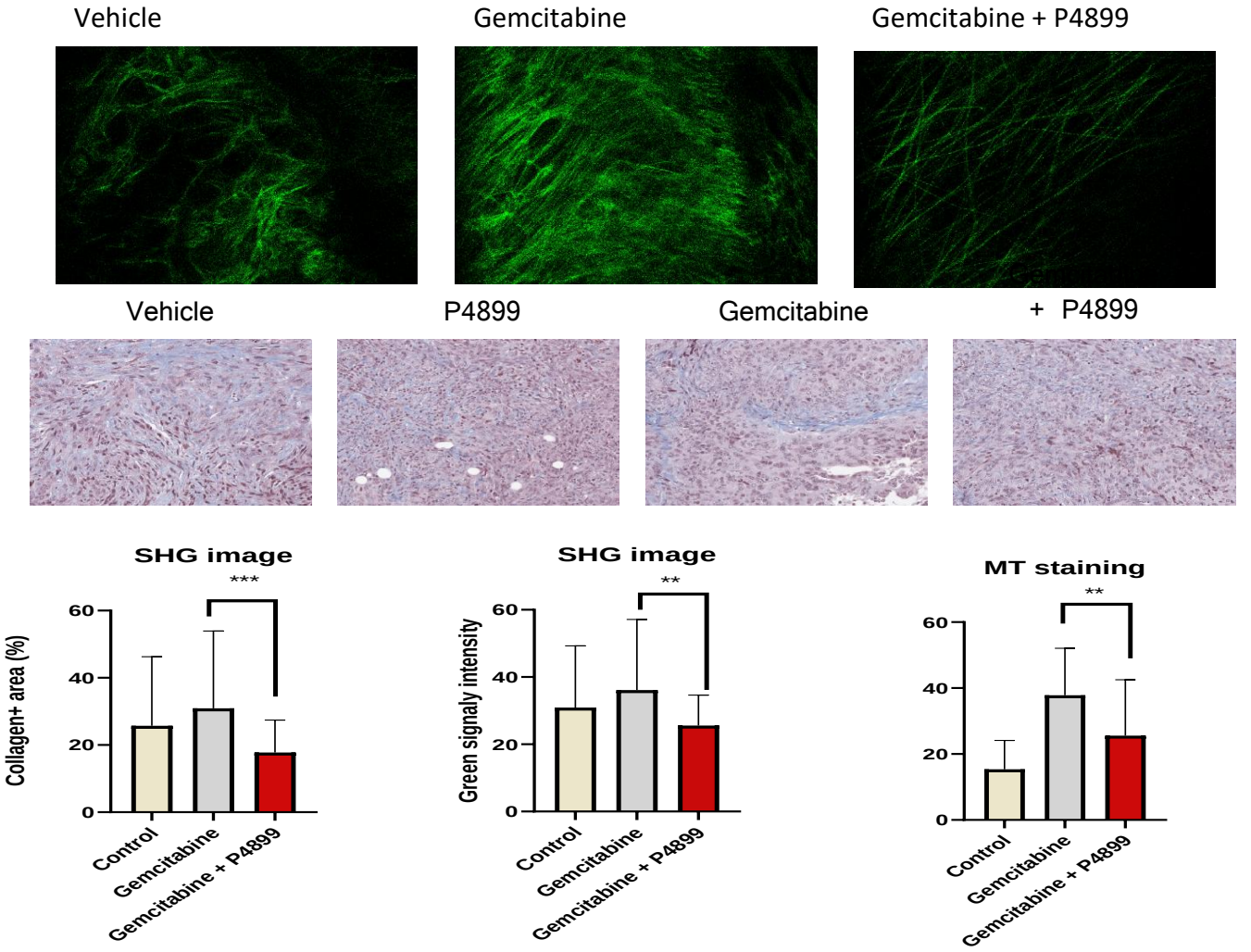
- Mouse KPC orthotopic tumor model




- Tumor growth inhibition




- P4899 significantly reduced gemcitabine-induced fibrosis



# Q & A