Oscotec R&D Day

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CEO

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Agenda

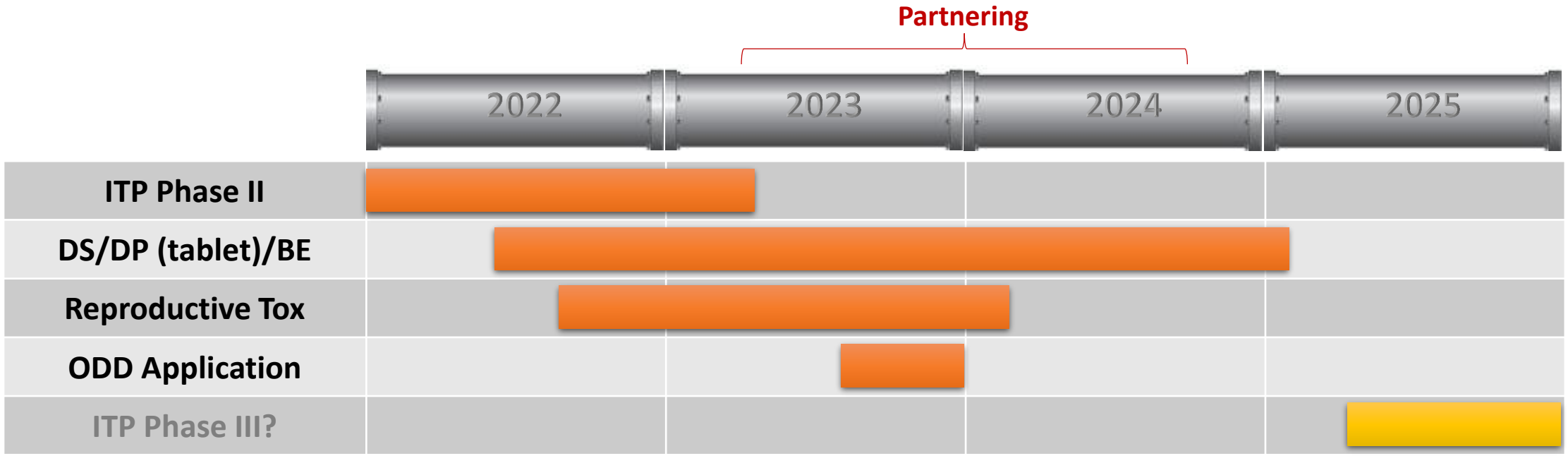
- 2023 Milestones
  - Lazertinib on the cusp of global approval
  - Cevidoplenib (SKI-O-703) completes Phase 2 study in ITP
  - Denfivontinib (SKI-G-801) wrapping up Phase 1a in solid tumors
  - ADEL-Y01 files IND to FDA
- Oscotec oncology strategy
  - Addressing therapy resistance, tumor relapse, and metastasis
  - Denfivontinib (SKI-G-801) cohort expansion plan
  - OCT-598 to enter the clinic in 2024
- Upcoming catalysts
- Q&A

2023 Milestones

Milestone 1; Lazertinib Coming Through

- Lazertinib Clinical Trials
  - CHRYSALIS1/2; exploratory trials for amivantamab that includes lazertinib combination in EGFR-mut NSCLC patients who exhausted SoC options
  - Laser301; lazertinib monotherapy vs 1st generation EGFR-TKIs
  - MARIPOSA; 1st line lazertinib/amivantamab combination head-to-head vs osimertinib
- Approved as 1st line treatment by MFDS in June 2023
  - Passed Drug Reimbursement Evaluation Committee in October 2023
- Janssen presents MARIPOSA1/2 results at ESMO 2023
  - MARIPOSA-1, the first pivotal study to show a clinically meaningful benefit in a chemotherapy-free regimen vs osimertinib
  - MARIPOSA-2, the first P3 study to show statistically significant and clinically meaningful improvement in PFS in the post-osimertinib setting

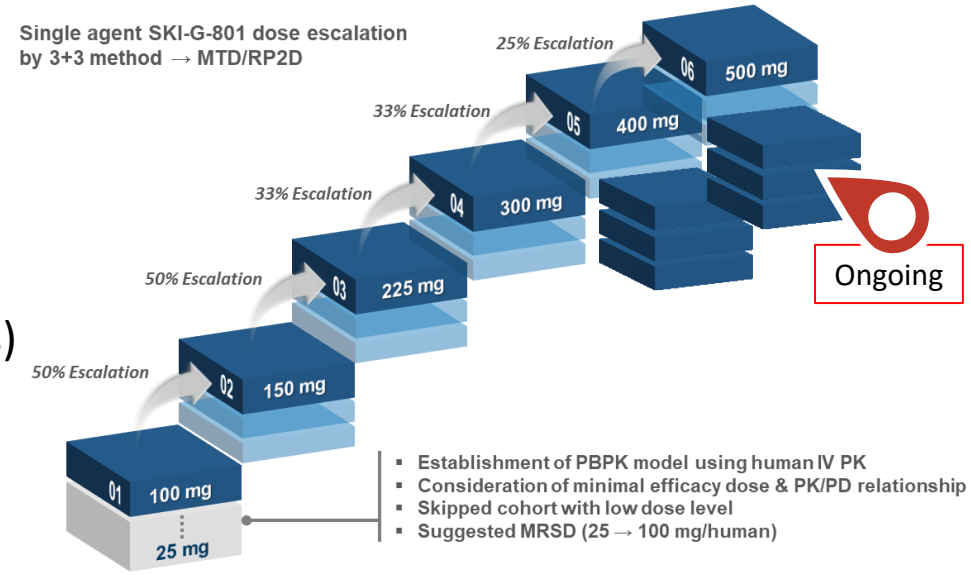
Milestone 2; Cevidoplenib Completes Phase 2 in ITP



- Successful completion of Phase 2 study in patients with chronic ITP
  - Fast-onset, durable efficacy in many patients who are refractory to current therapies
  - Proven safety with, especially, superior GI tolerability
- Development ongoing for 'Phase 3 readiness' (CMC, reproductive toxicology, etc)
- Partnering discussions ongoing
- Indication expansion on hold until partnering

Milestone 3; Denfivontinib (SKI-G-801) Ready for Primetime

- Denfivontinib (SKI-G-801) is a FLT3/AXL dual inhibitor
- Phase 1 monotherapy dose escalation study in patients with solid tumors
  - As expected, negligible monotherapy efficacy so far; 3/18 stable disease
  - Very well tolerated up to 400 mg; 1 DLT (cholangiohepatitis) at 300 mg and 1 SAE (diarrhea) at 400 mg
  - Pharmacokinetics; long half-life, dose-dependent (yet not dose-proportional) increase of exposure



- Phase 1b/2a 'proof-of-concept' cohort expansion plan
  - 'Concept'; AXL inhibition will cut off an adaptive response of tumors to stress and thereby prevent the development of therapy-resistance
  - Denfivontinib to be tested as an add-on to the platinum-based standard-of-care chemotherapy in non-small cell lung cancer patients
  - Phase 1b combination dose-ranging study followed by randomized, placebo-controlled P2a study vs standard-of-care chemotherapy
  - <u>Discussion ongoing with MFDS on the trial design</u>

Milestone 4; ADEL-Y01 Enters the Clinical Phase

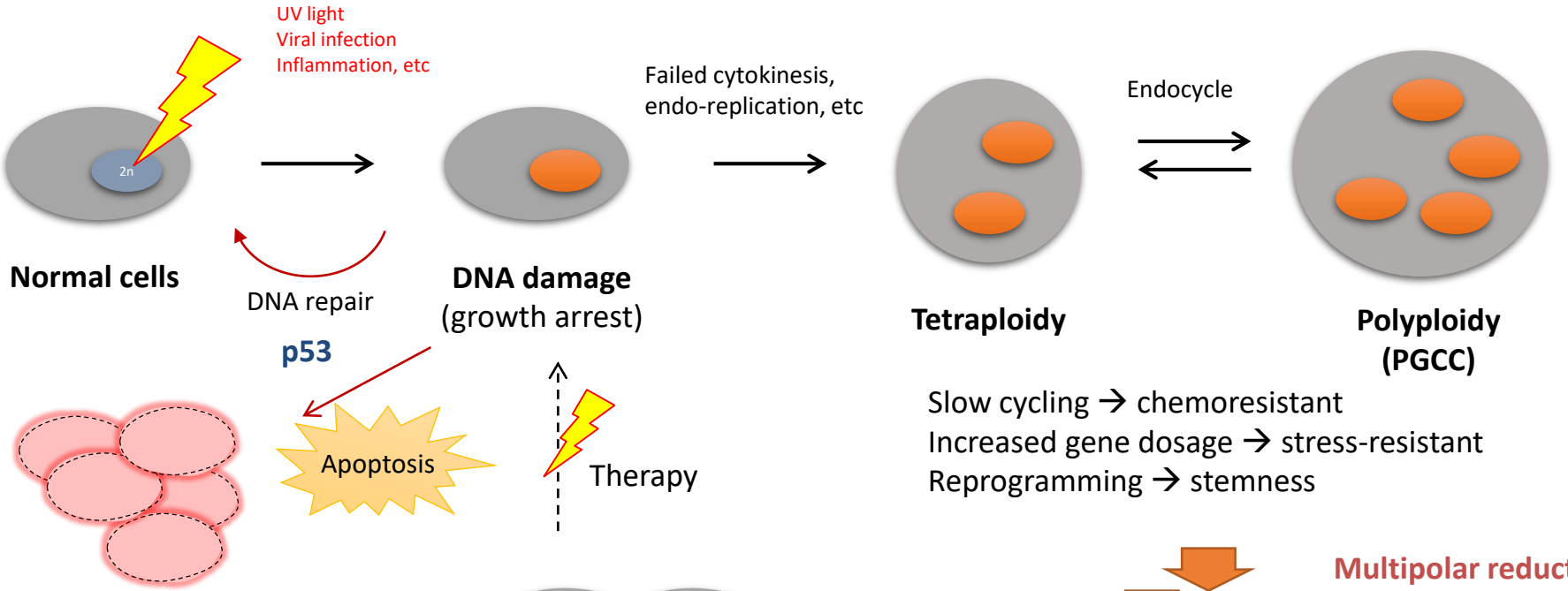
- ADEL-Y01 is a monoclonal antibody targeting a pathological form of tau protein (AcK280) to treat tauopathies including Alzheimer Disease
  - Highly effective in various preclinical in vitro/in vivo models (Journal of Clinical Investigation 2023)
  - Superior efficacies vs competitors' 2nd Generation anti-tau mAbs
- After (pending) approvals of anti-Aβ antibodies with limited efficacy, all eyes on anti-tau therapy
  - First generation anti-tau antibodies targeting N-terminal region predictably failed in P2s
  - Second generation antibodies targeting mid region in development; P2 data expected in 2025
  - High expectations on anti-Aβ/anti-tau combination therapy
- IND approved by FDA; first-in-human dosing to start in early 2024
  - P1a single ascending dose study in healthy volunteers
  - P1b multiple ascending dose study in AD patients

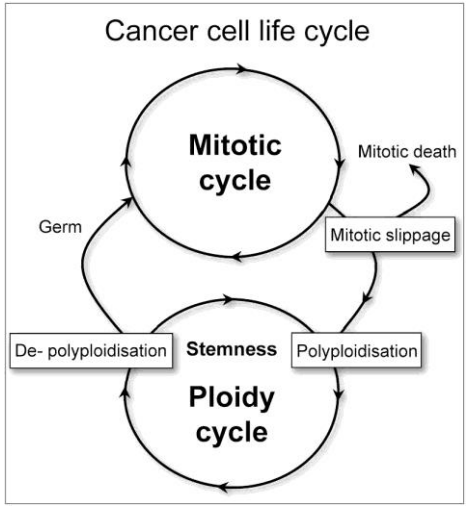
Oscotec Oncology Strategy

Cancer Therapy Failures; Resistance, Relapse, and Metastasis

- **Most cancers come back after therapy, stronger than before**
  - Line after line after lines of therapies
  - Drug treatment may even accelerate malignancy progression and death
- Current treatment paradigm is based on maximal tumor cell killing
  - Focus on selective killing of cancer cells vs normal cells
  - Tumor size is the primary measure of efficacy (ORR or PFS)
  - Yet, overall survival (OS) is frequently NOT correlated with PFS
- Mechanisms of therapy resistance
  - Intratumor heterogeneity
  - Cancer stem cells, drug-tolerant persisters, dormancy
  - Accelerated evolvability of tumors via whole genome doubling (WGD) and chromosome instability (CIN); **therapy spurs its own resistance**

Cancer Reproductive Life Cycle and Evolution

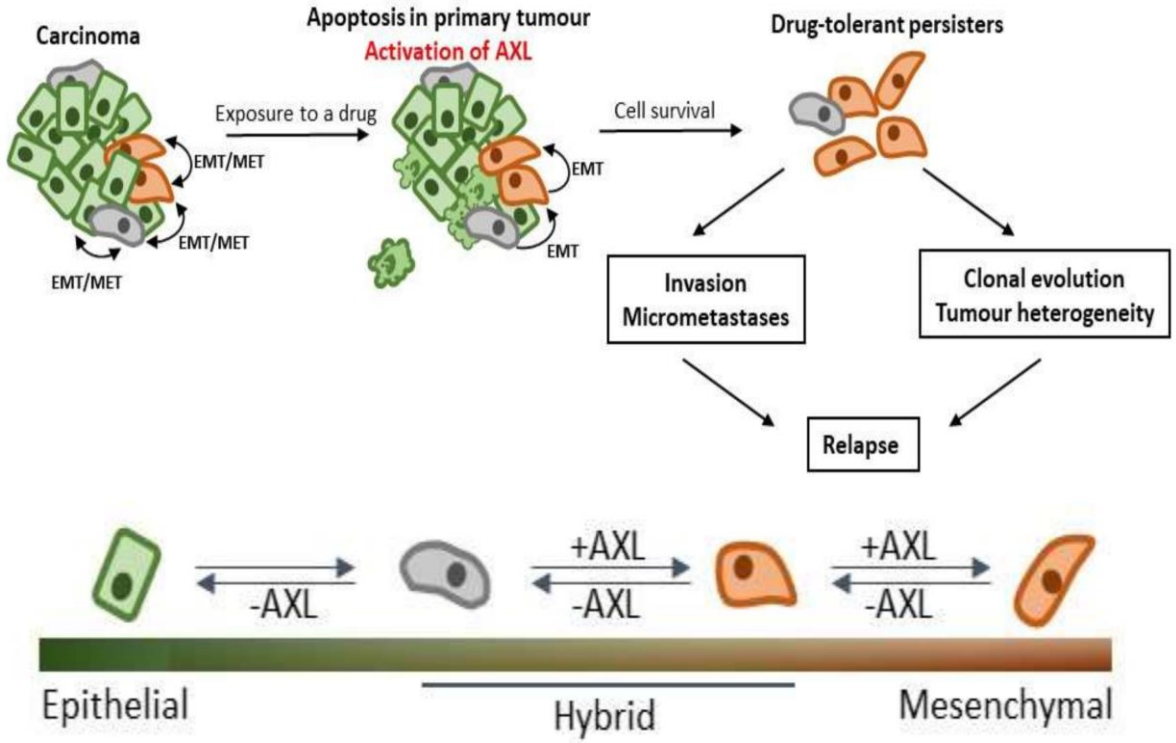




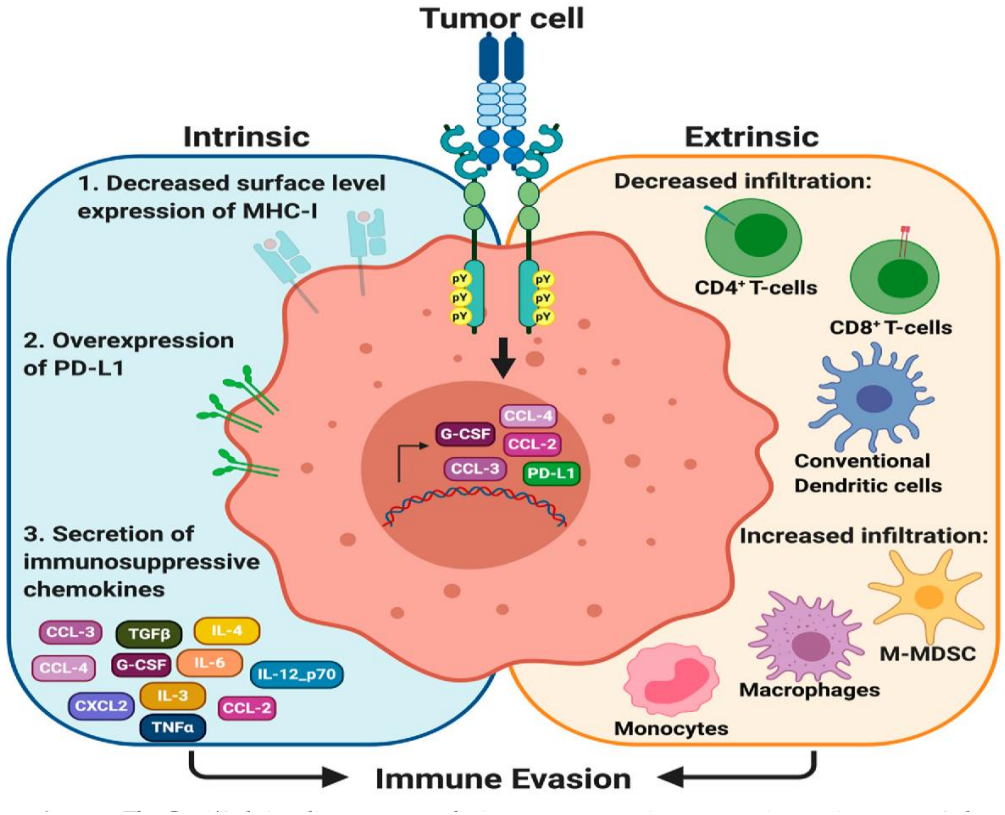
Erenpreisa et al., Seminars in Cancer Biology 2022

AXL Mediates Drug-Tolerance and Immune Evasion

- AXL senses the stressful conditions by recognizing apoptotic cell deaths
- Activation of AXL promotes cancer cell survival by inducing stress-resistance (EMT, DDR, etc) and immune evasion (IL-10, TGFβ, etc)



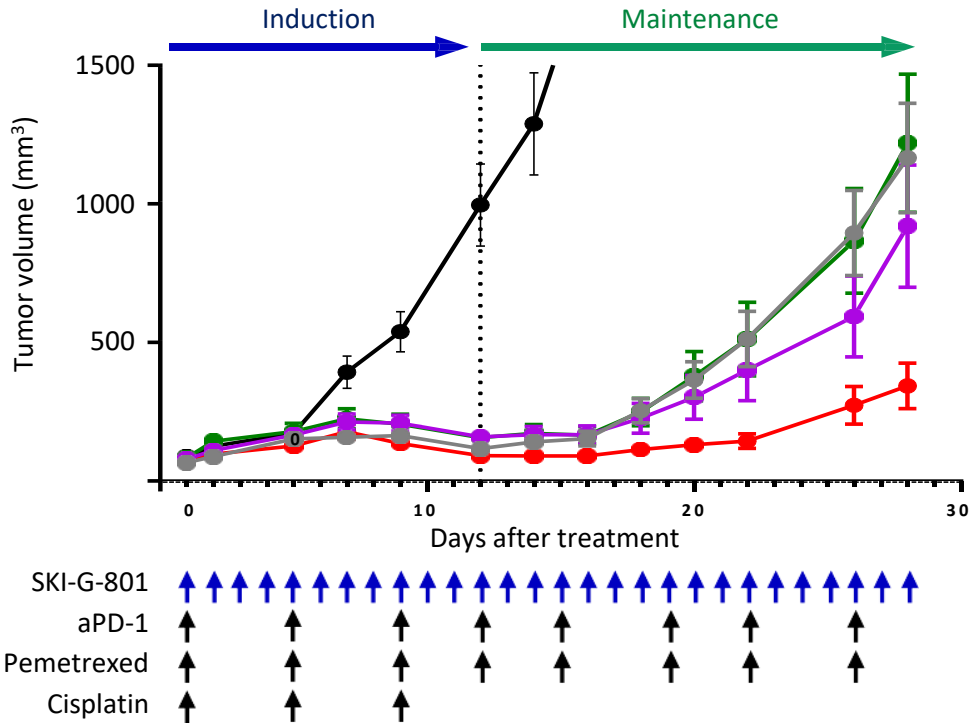
Auyez et al., Cancers 2021



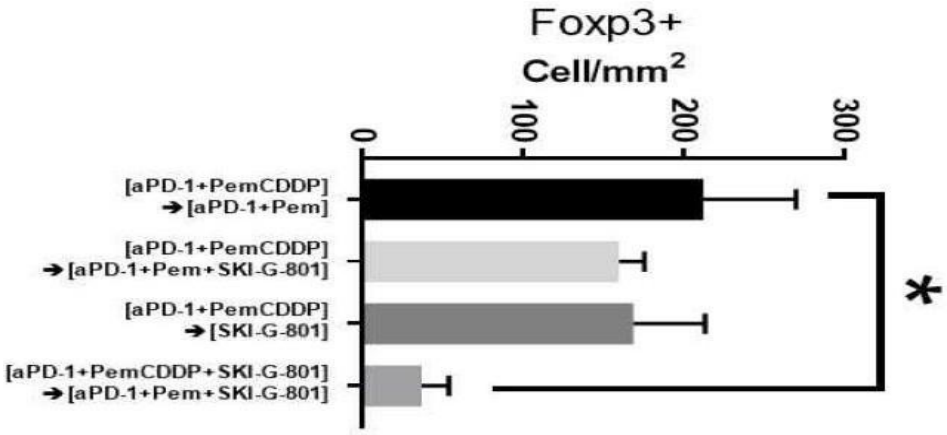
Tanaka and Siemann, Cancers 2020

Denfivontinib (SKI-G-801) Significantly Delays Tumor Regrowth

TC-1 syngeneic mouse adenocarcinoma model

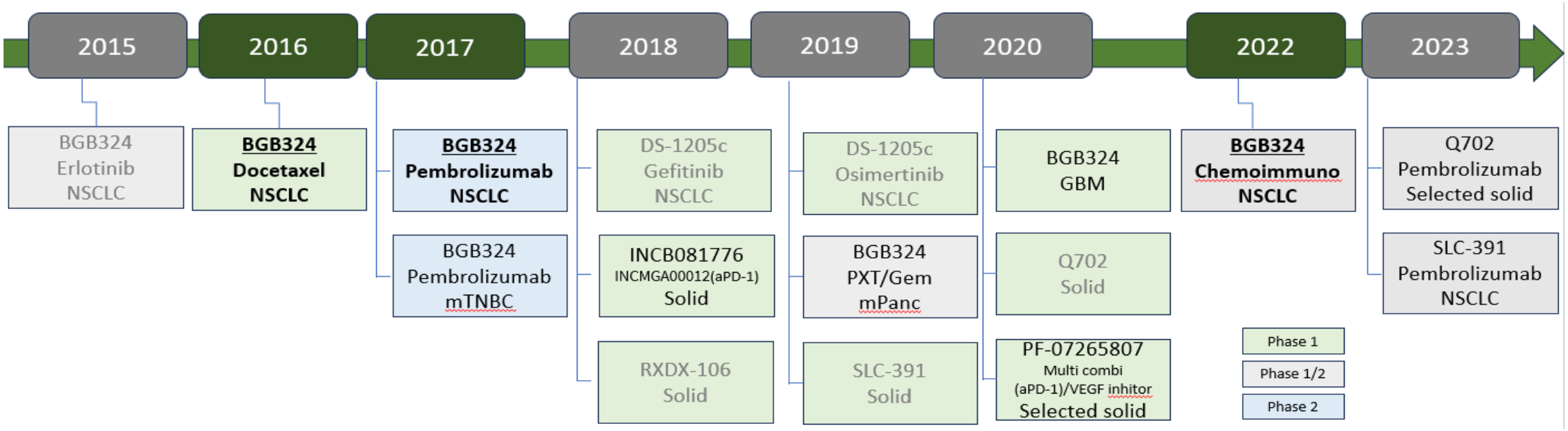


- Vehicle control
- [aPD-1 + PemCDDP] → [aPD-1 + Pem]
- [aPD-1 + PemCDDP] → [SKI-G-801]
- [aPD-1 + PemCDDP] → [aPD-1 + Pem + SKI-G-801]
- [aPD-1 + PemCDDP + **SKI-G-801**] → [aPD-1 + Pem + SKI-G-801]



- AXL inhibition by denfivontinib during the <u>chemotherapy induction phase</u>, when the tumor cell apoptosis is at the highest, significantly delays tumor regrowth
- FoxP3+ regulatory T cells are dramatically reduced

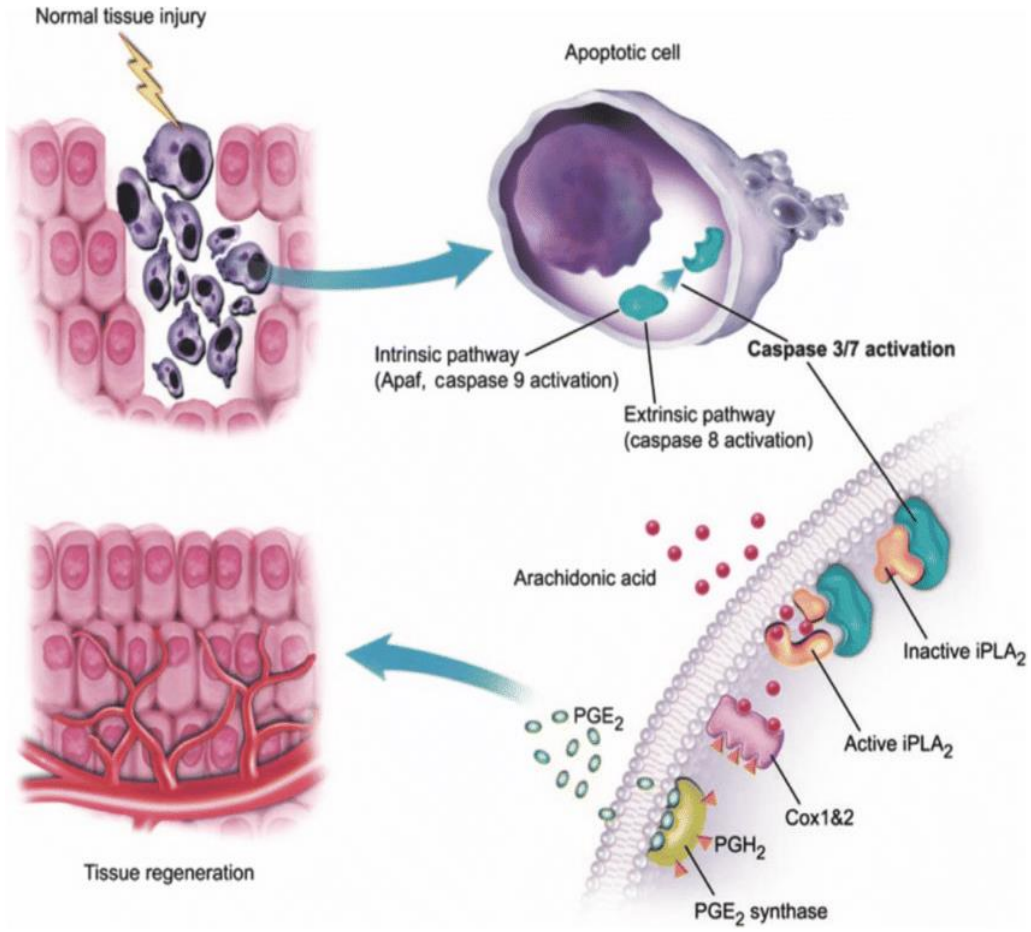
AXL Inhibitors in the Clinical Trials



- No meaningful efficacies observed as a single agent
- Combination with an EGFRi in patients who progressed after targeted therapy
- Combination with an ICB in patients who progressed after ICB monotherapy
- Ongoing Phase 2a, first-line treatment with bemcentinib (BGB324) combination with pembrolizumab/carboplatin/pemetrexed in NSCLC patients with STK11 mutation

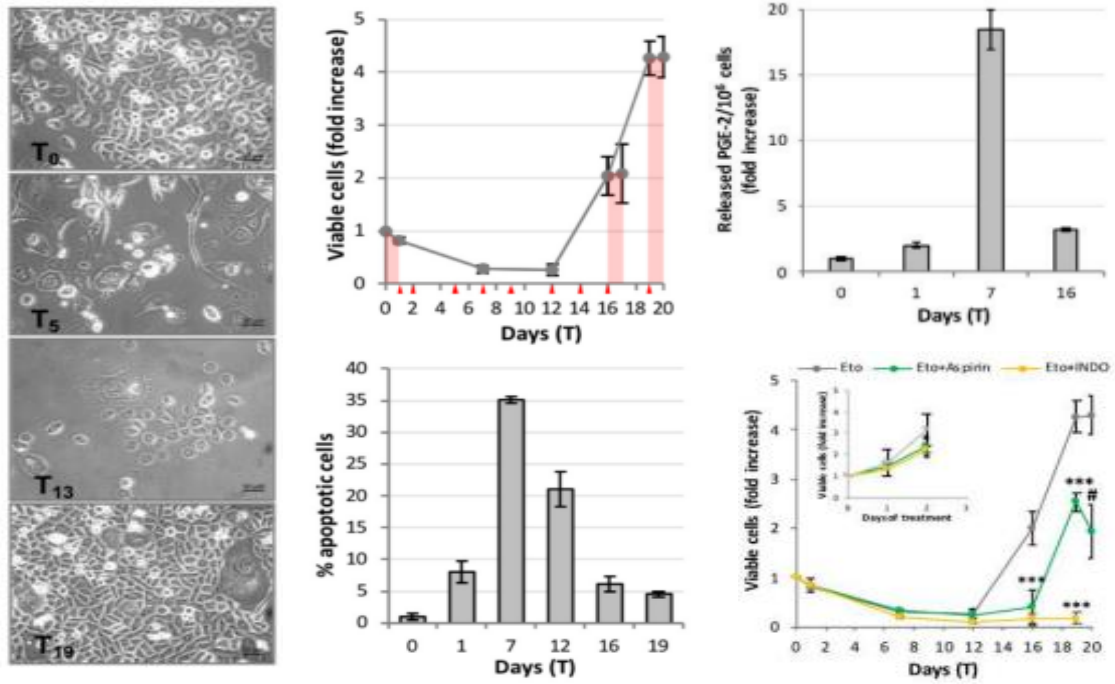
Cancer Repopulation via Phoenix-Rising (PGE2)

- Phoenix-rising pathway (Casp3-iPLA2-COX2) in wound healing



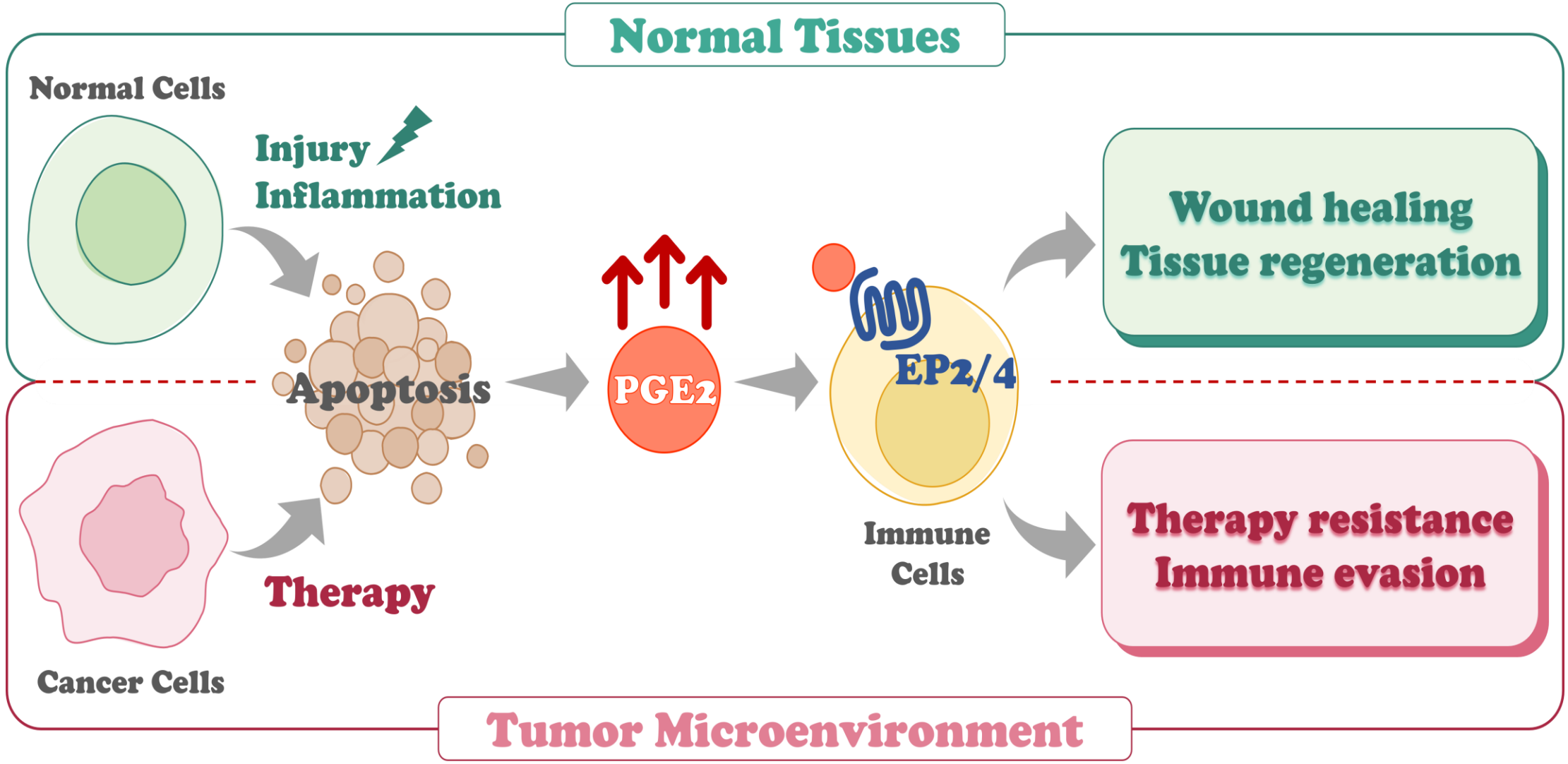
Li et al., Sci Signal 2010

- Emergence of chemo-resistance in cancer
  - Prostate cancer cells (PC3) treated with etoposide for 24h followed by recovery
  - Apoptosis > quiescence > repopulation
  - PGE2 level highest at the peak of apoptosis
  - COX2 inhibitor abolishes repopulation



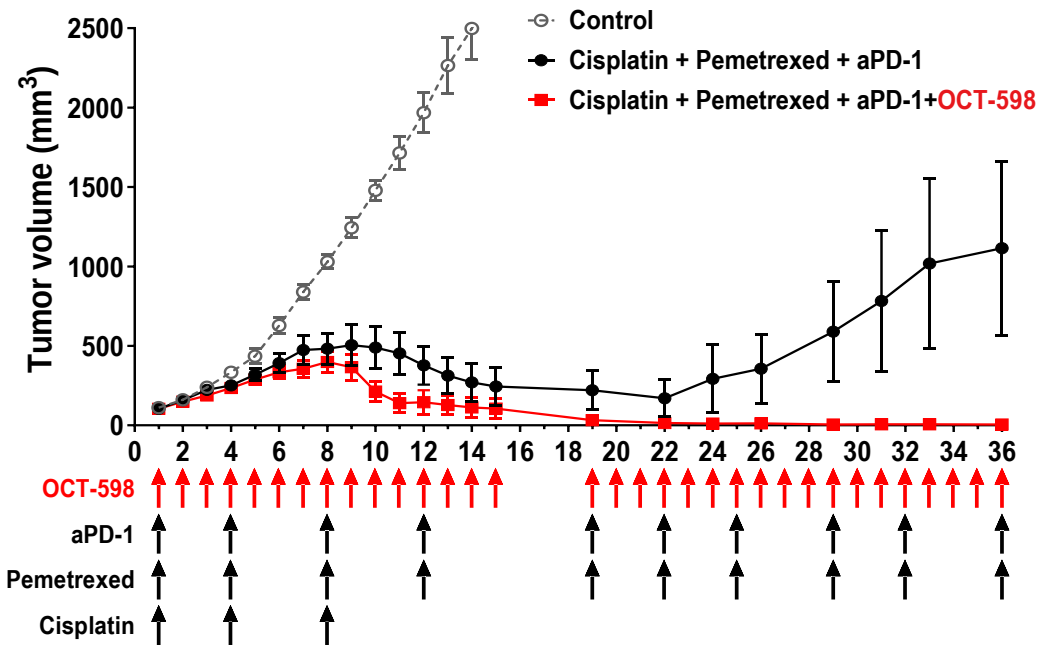
Corsi et al., Int J Mol Sci 2022

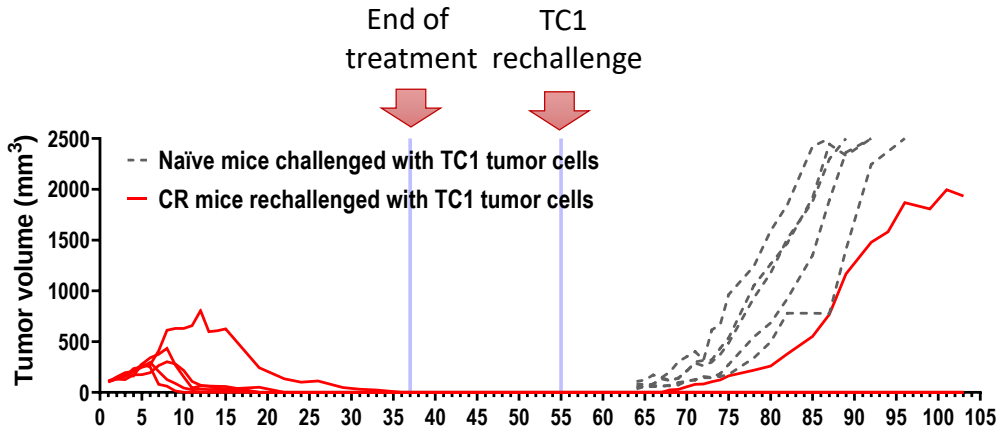
PGE2-EP2/4 Axis at the Center of Tumor Resurrection



OCT-598 Abrogates Tumor Regrowth After SoC Therapy

- OCT-598 is a potent and selective EP2/EP4 dual antagonist
- TC-1 mouse syngeneic lung adenocarcinoma model
  - OCT-598 add-on to standard-of-care regimen (cisplatin/pemetrexed/αPD-1) gave rise to 100% tumor regression
  - Upon TC1 rechallenge in the CR mice, 4 out of 5 mice remained tumor-free
  - Presented in AACR 2023
- Other translational studies ongoing (SoC combination and radio-combination in GC, mCRPC, etc)
- IND to be submitted in 3Q2024





Oscotec R&D Pipeline

	MoA	Indication	Discovery	Lead Opt	Preclinical	Phase I	Phase II	Partner
Cevidoplenib (SKI-O-703)	SYK Inhibitor	RA						
		ITP						
Denfivontinib SKI-G-801	FLT3/AXL Dual Inhibitor	AML						
		Solid tumors						
ADEL-Y01	Anti-TAU mAb	Alzheimer						ADEL
OCT-598	EP2/4	Cancer						KANAPH
ONC1	(Undisclosed)	Cancer/Fibrosis						
ONC2	(Undisclosed)	Cancer						
ONC3	(Undisclosed)	Cancer						biorevert
ONC4	(Undisclosed)	Cancer						biorevert

Upcoming Catalysts

Program	4Q23	1Q24	2Q24	3Q24	4Q24
Lazertinib	ESMO	NDA (?)			Approval (?)
Cevidoplenib	Potential partnering deal				
	ODD				
Denfivontinib		P1b start			
ADEL-Y01		FIH dosing			
OCT-598				IND	
				Meeting Presentation	
Discovery				Meeting Presentation	

Q & A