

Oscotec R&D Day

March 6, 2023

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CEO

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Agenda

- 2022 Review
- Pipeline update
 - Cevidoplenib
 - SKI-G-801
 - ADEL-Y01
 - OCT-598
- Looking ahead; 2023 and beyond
- Q&A

2022 Review

➤ 개발 단계 과제별 주요 성과

■ Cevidoplenib

- ITP 임상2상 환자모집 완료 및 마무리
- 루푸스 및 류마티스관절염 비임상실험 결과 학술지 게재 (Clinical & Experimental Immunology 2022)

■ SKI-G-801

- 고형암 국내 임상1상 개시
- 항암면역 효능 비임상실험 결과 학술지 게재 (Clin Transl Immunology 2021, Front Oncol. 2022)

■ ADEL-Y01

- 생산 완료에 따른 IND 준비 돌입

➤ 지속적인 오픈이노베이션 통한 후보물질 확충

- 카나프로부터 EP2/4 이중저해 항암제 도입 (OCT-598), 전임상 개발 착수
- 바이오리버트 공동연구 협약

➤ 펀딩 통한 재무구조 안정화

- CPS 발행 및 유상증자 통해 4분기 결산 기준 1000억원 현금성 자산 보유 → 충분한 현금유동성 확보

Oscotec R&D Pipeline

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

Cevidoplenib (SKI-O-703)

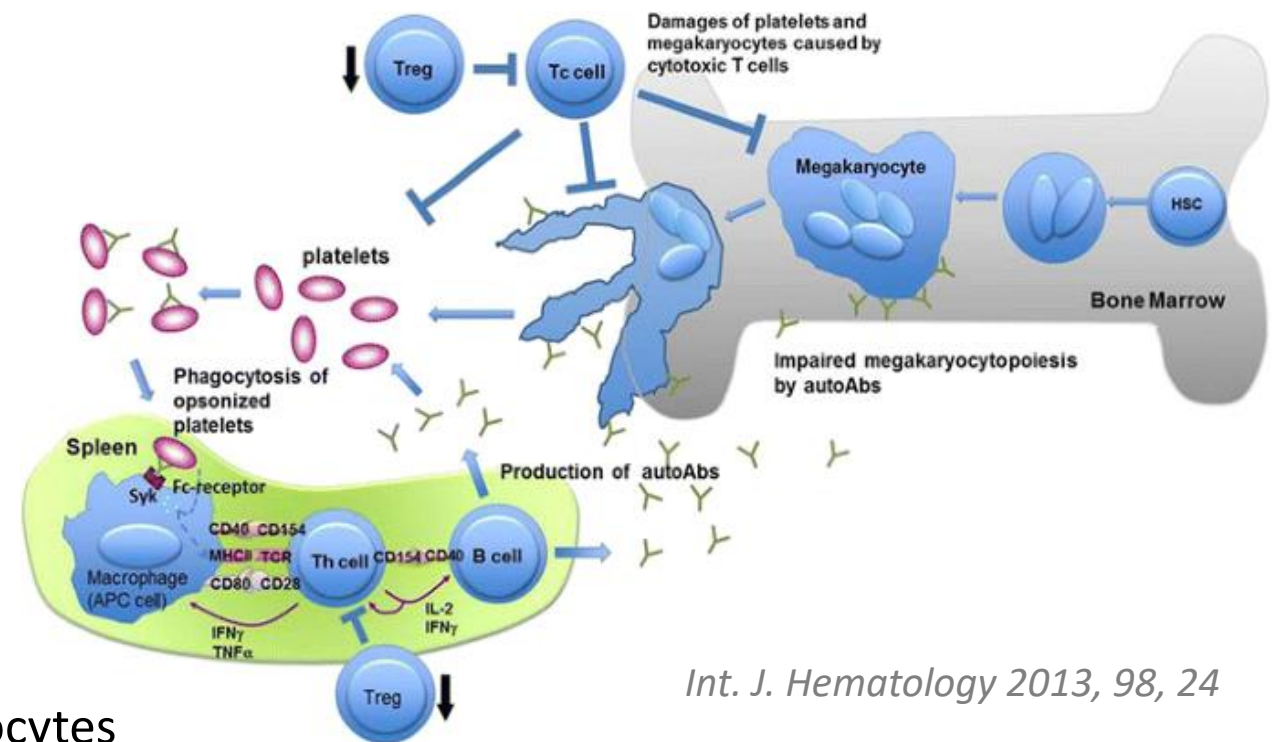
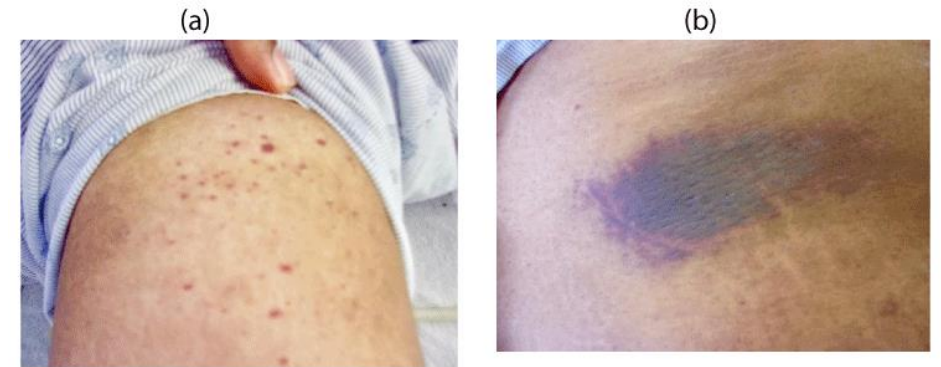
**Highly Selective SYK Inhibitor for
Autoantibody-driven Immune Disorders**

Chronic Immune Thrombocytopenia

- A blood disorder characterized by decreased number of platelets in the blood
 - Platelet count < 100,000/uL for >12 months
 - Overall prevalence of ~10/100,000 individuals
 - Many are asymptomatic
 - Easy or excessive bruising and bleeding
 - Increased risk of thromboembolism

- Pathophysiology

- Anti-platelet autoantibodies
- Platelet destruction by macrophages
- Autoreactive B cells and plasma cells
- Autoantibody-mediated suppression of megakaryocytes
- Impaired Tregs and Tc-mediated destruction of platelets and megakaryocytes



Int. J. Hematology 2013, 98, 24

IMMUNE THROMBOCYTOPENIA (ITP) MARKET

Global Immune Thrombocytopenia Market Size, 2018-2026 (USD Billion)



Global Immune Thrombocytopenia Market Share, By Treatment, 2018



North America Immune Thrombocytopenia Market Size, 2018



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Current Standard-of-Care and Emerging Therapies

Pharmaceuticals 2022, 15, 779

➤ Standard of care

- 1st line; corticosteroid, IVIg
- 2nd line; **TPO receptor agonists**
- Rituximab, fostamatinib, MMF, etc
- Splenectomy

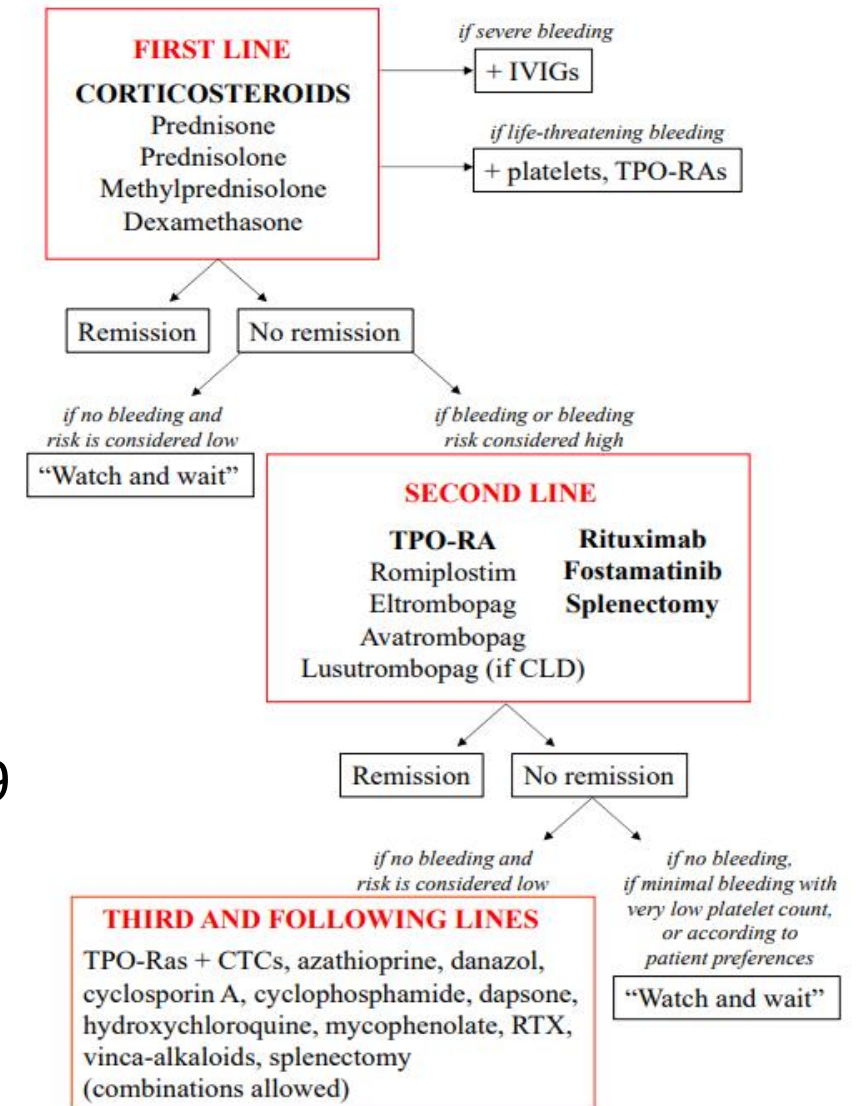
➤ TPO-RAs

- Approved in 2008
 - Promacta® (eltrombopag, Novartis; \$2B in 2021)
 - Nplate® (romiplostim, Amgen; \$1B in 2021)
- ‘Durable’ response rate (PLT# > 50,000/uL) of 40~60%
- Lack of response in ~1/3 of patients

➤ Fostamatinib (Rigel, SYK inhibitor) approved in 2019

➤ Emerging therapies

- Rilzabrutinib (Sanofi, BTK inhibitor) in P3
- Efgartigimod (Argenx, FcRn blocker) in P3



Cevidoplenib in Phase II Study for ITP

A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Dose Study to Evaluate the Efficacy and Safety of Oral SKI-O-703, SYK Inhibitor, in Patients with Persistent and Chronic Immune Thrombocytopenia (ITP): NCT04056195

Subjects (N=60)

- Diagnosis of primary ITP (persistent or chronic)
- **Failed to respond or relapsed after at least 1 prior therapy**
- Platelet count of $<30,000/\mu\text{L}$ on 2 occasions at least 7 days apart with confirmatory count being taken during screening

Randomized 1:2:2

Arm 1
(N=12)

Placebo

Arm 2
(N=26)

Cevidoplenib 200mg

Arm 3
(N=22)

Cevidoplenib 400mg

← BID, 12 weeks →

Primary Endpoint

- Patient platelet response is defined as platelet count $\geq 30,000/\mu\text{L}$ and doubling the baseline (average of 2 previous counts) at any visit during the treatment period and without use of rescue medication

Secondary and Exploratory Endpoints

- Multiple measures designed to assess the durability and stability of response, safety etc.

Participant Baseline Characteristics

	Placebo (N=12)	200 mg BID (N=26)	400 mg BID (N=22)	Total (N=60)	Rilzabrutinib (N = 60)
Median age (range) -yr	69.5 (25-86)	59.5 (24-81)	57.0 (23-80)	60.0 (23-86)	50 (19-74)
Sex – no. (%)					
Female	5 (41.7)	13 (50.0)	16 (72.7)	34 (56.7)	26 (43)
Male	7 (58.3)	13 (50.0)	6 (27.3)	26 (43.3)	34 (57)
Median baseline platelet count (range) – 10 ⁹ /L	8.0 (2-20)	8.5 (2-25)	10.5 (2-27)	8.5 (2-27)	15 (2-33)
Number of previous lines of therapy – no. (%)					Median 4 (1-17)
0-2	4 (33.3)	9 (34.6)	6 (27.3)	19 (31.7)	
≥3	8 (66.7)	17 (65.4)	16 (72.7)	41 (68.3)	
Response to previous treatment – no. (%)					
Non-responder	9 (75.0)	12 (46.2)	17 (77.3)	38 (63.3)	
Relapsed	10 (83.3)	21 (80.8)	18 (81.8)	49 (81.7)	
Previous splenectomy – no. (%)	0 (0.0)	6 (23.1)	5 (22.7)	11 (18.3)	15 (25)
TPO-receptor agonist use – no. (%)	7 (58.3)	13 (50.0)	15 (68.2)	35 (58.3)	
Baseline platelet count <15,000/mL – no. (%)	8 (66.7)	19 (73.1)	14 (63.6)	41 (68.3)	

Comparison of Efficacy Data vs Competitors

Endpoint	Description	Cevido Placebo	Cevido 200 mg		Cevido 400 mg		Fosta P3	Rilza P1/2	Efgar P3
		%	%	p-value	%	p-value	%	%	%
Primary	AVG_PLT \geq 30,000 and AVG_PLT \geq 2x baseline	33.3	46.2	0.504	63.6	0.151			
Ad hoc	PLT \geq 30,000 and AVG_PLT \geq 2x baseline	25.0	50.0	0.178	72.7	0.012			
Secondary	\geq 2 consecutive PLT \geq 30,000	8.3	38.5	0.049	50.0	0.015			
	\geq 2 consecutive PLT \geq 50,000	8.3	19.2	0.371	40.9	0.055		40*	
	\geq 2 consecutive PLT \geq 100,000	0	11.5	-	13.6	-			
	PLT \geq 50,000 in \geq 3 of the last 4 visits	8.3	19.2	-	22.7	-			
'Eye-test'	PLT \geq 50,000 in \geq 4 of the last 6 visits	0	19.2	-	27.3	-	18*		22*
	PLT \geq 50,000 in \geq 4 of the last 8 visits	0	23.1	-	36.4	-		28	
	PLT \geq 50,000 at least once	33.3	42.3	-	50.0	-	43		

* Primary endpoint

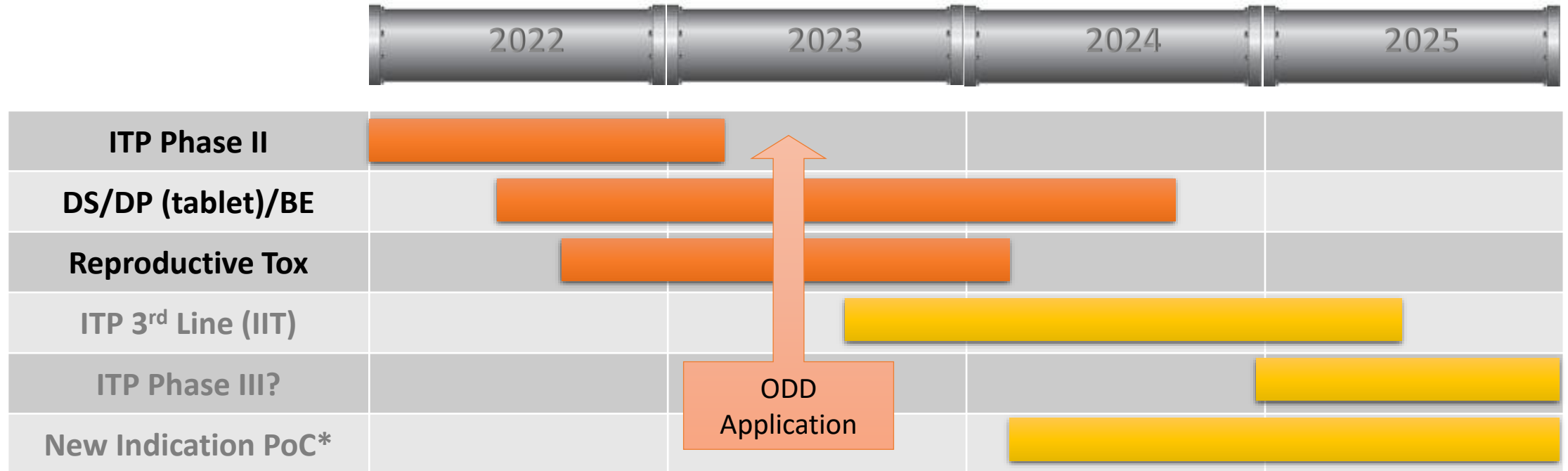
Safety

Overall Summary of Adverse Events
Safety Set

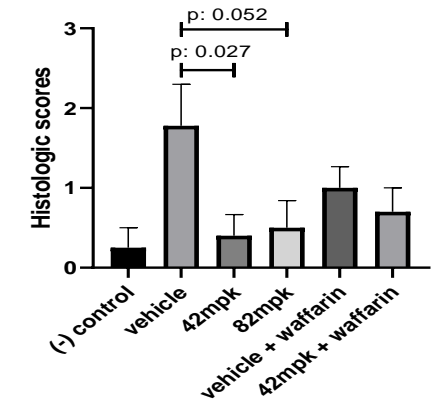
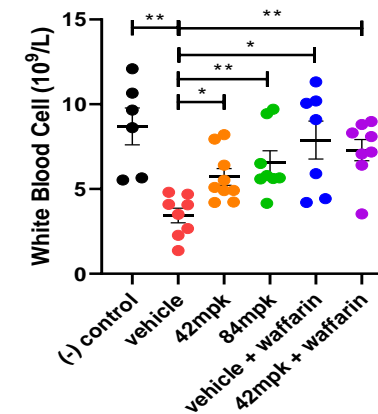
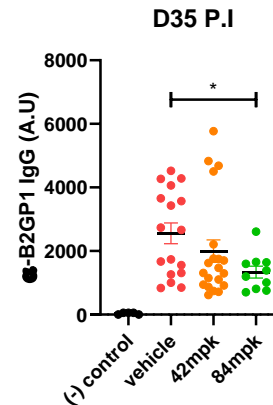
Event Category	Placebo (N=12)	200 mg BID (N=26)	400 mg BID (N=22)	Combined Active (N=48)
	n (%) [e]	n (%) [e]	n (%) [e]	n (%) [e]
Any TEAE	8 (66.7) [38]	15 (57.7) [41]	17 (77.3) [47]	32 (66.7) [88]
Any Treatment-related TEAE	1 (8.3) [1]	7 (26.9) [10]	10 (45.5) [14]	17 (35.4) [24]
Any Serious Adverse Event (SAE)	3 (25.0) [4]	0	2 (9.1) [3]	2 (4.2) [3]
Any Treatment-related SAE	0	0	1 (4.5) [1]	1 (2.1) [1]
Any Grade 3 or 4 TEAE	2 (16.7) [5]	2 (7.7) [5]	5 (22.7) [6]	7 (14.6) [11]
Any Grade 3 or 4 Treatment-related TEAE	0	0	3 (13.6) [3]	3 (6.3) [3]
Any TEAE Leading to Dose Reduced or Drug Interrupted	2 (16.7) [2]	2 (7.7) [2]	4 (18.2) [5]	6 (12.5) [7]
Any TEAE Leading to Drug Withdrawn	1 (8.3) [1]	2 (7.7) [2]	0	2 (4.2) [2]
Any TEAE Leading to Death	0	0	0	0

What's Next?

Partnering



* Antiphospholipid syndrome (APS)
Antibody-mediated Rejection (AbMR)
RA in combination, etc

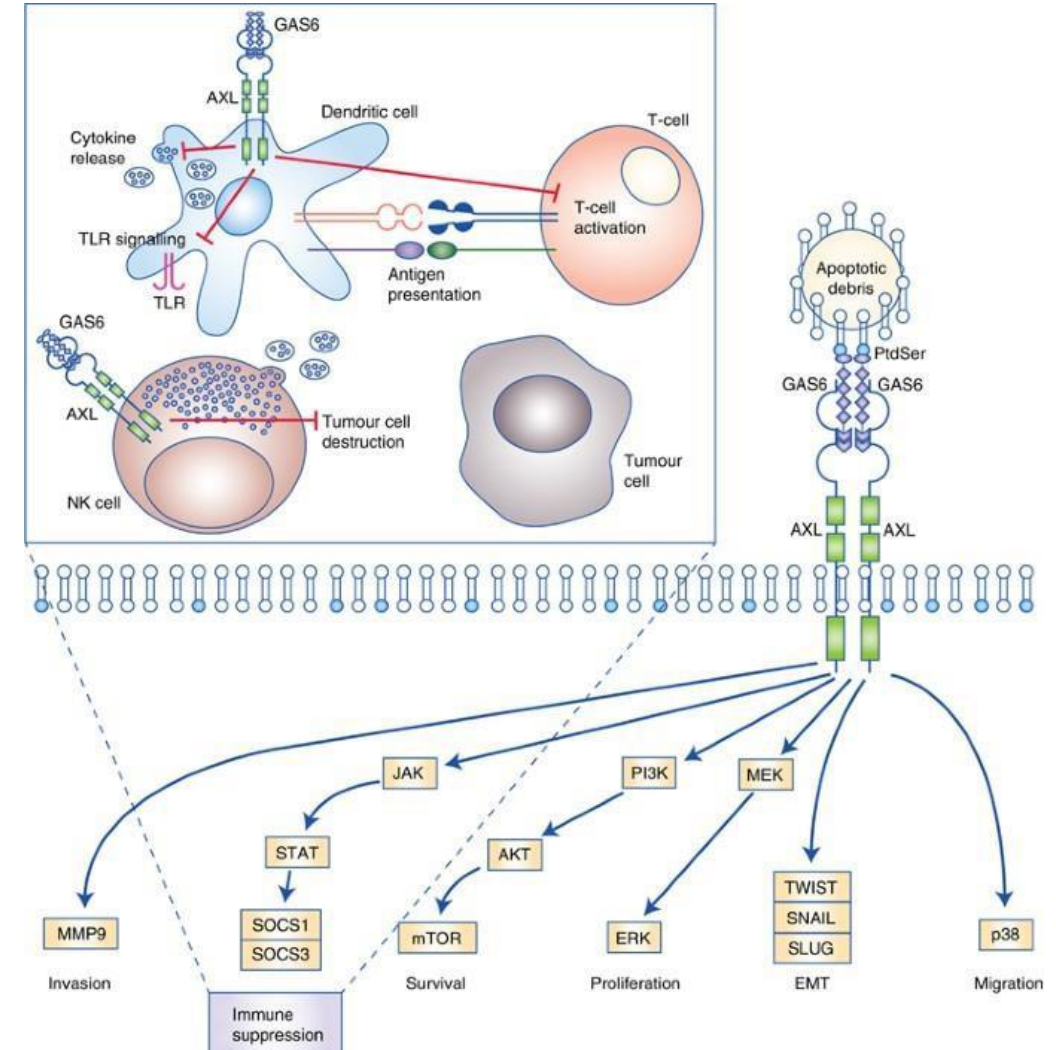


SKI-G-801

The Best-in-class FLT3/AXL Dual Inhibitor

SKI-G-801 for Solid Tumors; Therapeutic Rationale

- AXL overexpression is correlated with **malignant tumor progression**
 - Associated with poor prognosis in multitudes of cancers
 - Promotes epithelial-mesenchymal transition (EMT) and metastasis
 - Drives therapy-resistance; esp. **TKI-resistant EGFR-mutant NSCLC**
- **Innate immune checkpoint**
 - AXL in macrophages and DCs reinforces apoptotic cell-mediated immune suppression in the tumor microenvironment
 - AXL is upregulated in **checkpoint inhibitor-resistant tumors**

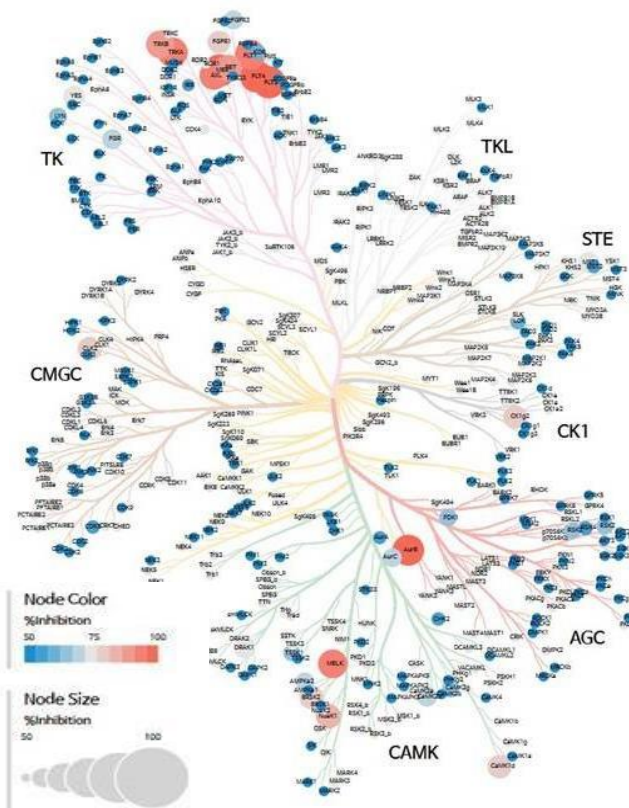


Gay et al., British J Cancer 2017

AXL Inhibitors; Competitive Landscape

Asset	Company	AXL IC50	Others	Indication	Phase	Remark
Bemcentinib (R428, BGB-324)	BerGenBio	14nM		AML, MDS	II	Completed
				COVID-19	II	Completed
				NSCLC, Keytruda combination	II	
ONO-7475	Ono Pharma	0.7 nM	Mer (1.0 nM), FLT3 (147 nM)	R/R AML/MDS Alone and in combi with venetoclax	I/II	
				Advanced or Metastatic Solid Tumors Alone and in combi with ONO-4538 (nivolumab)	I	
AB-329 DS-1205	Daiichi Sankyo	1.3 nM		EGFR-mut NSCLC in combi with gefitinib (n = 21)	I	Completed
				EGFR-mut NSCLC in combi with Osimertinib (n = 13)	I	Completed ORR = 0%
Dubermatinib (TP-0903)	Sumitomo Dainippon	27 nM		Advanced solid tumors (n = 177)	I	
				CLL, alone and combi with ibrutinib	I/II	Terminated
				FLT3-mut AML (n = 80)	Ib/II	
HH30134	Haihe Biopharma	AXL	FLT3, NTRK	Advanced Solid Tumor (n =50)	I	
Q702	Qurient	0.7nM	Mer (0.8 nM) CSF1R (8.7nM)	Advanced Solid Tumor (n = 78)	I	

SKI-G-801; a Potential Best-in-Class AXL inhibitor



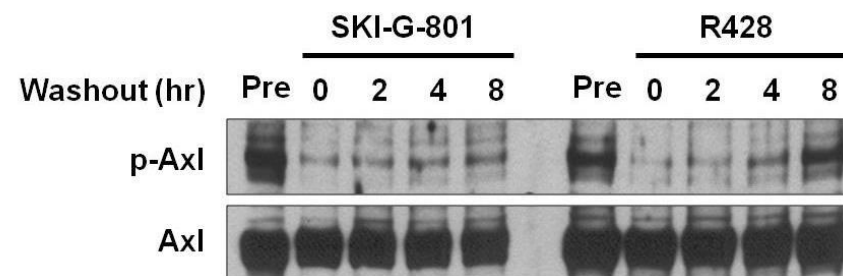
Kinase	IC50 (nM)
FLT3	1
Mer	1
Aurora B	6
Ret	9
FLT1	18
Fms	19
Axl	20
Aurora C	24
FGFR1	25
FGFR3	30
KDR	39
c-Kit	142
IGF-1R	300
PDGFRa	300
PDGFRb	300
EGFR	300

Enzyme inhibition (Eurofins, UK)

Kinase	IC ₅₀ (nM)	
	SKI-G-801	R428
Axl(h)	18	6
Mer(h)	2	9
Tyro(h)	>1,000	612

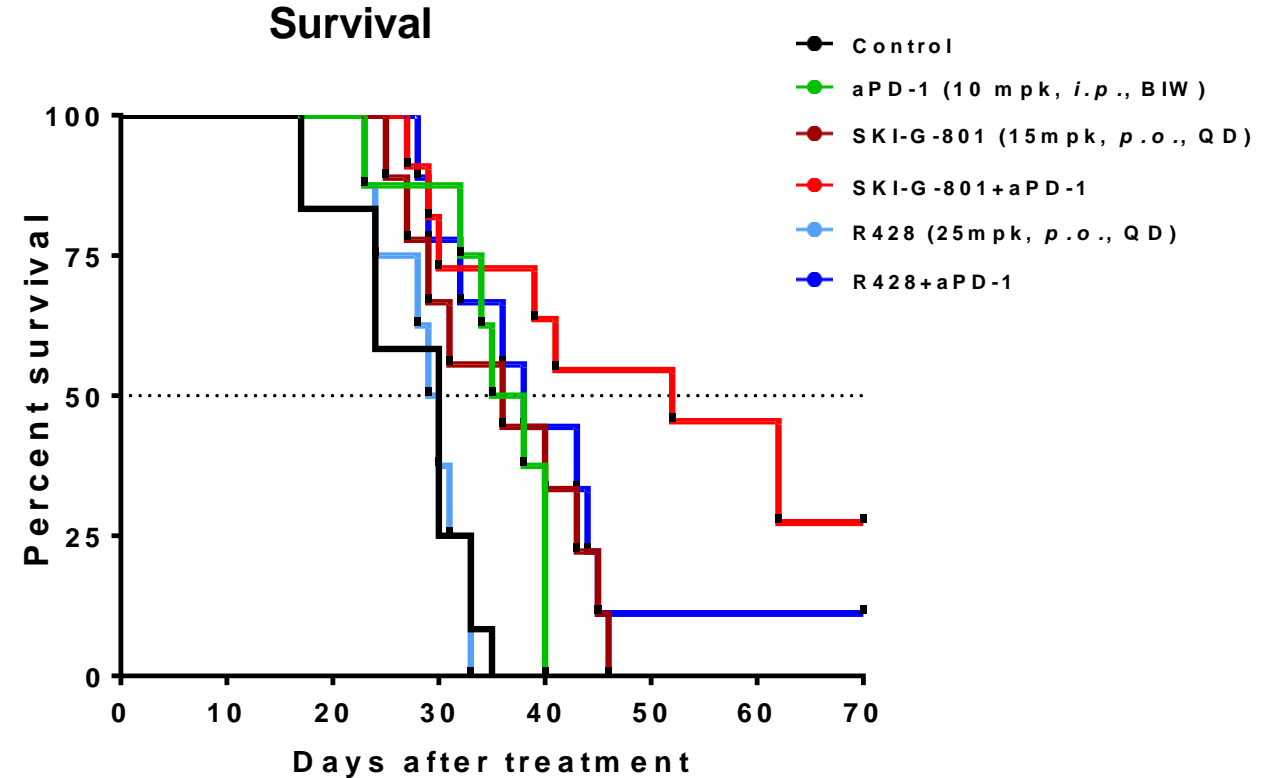
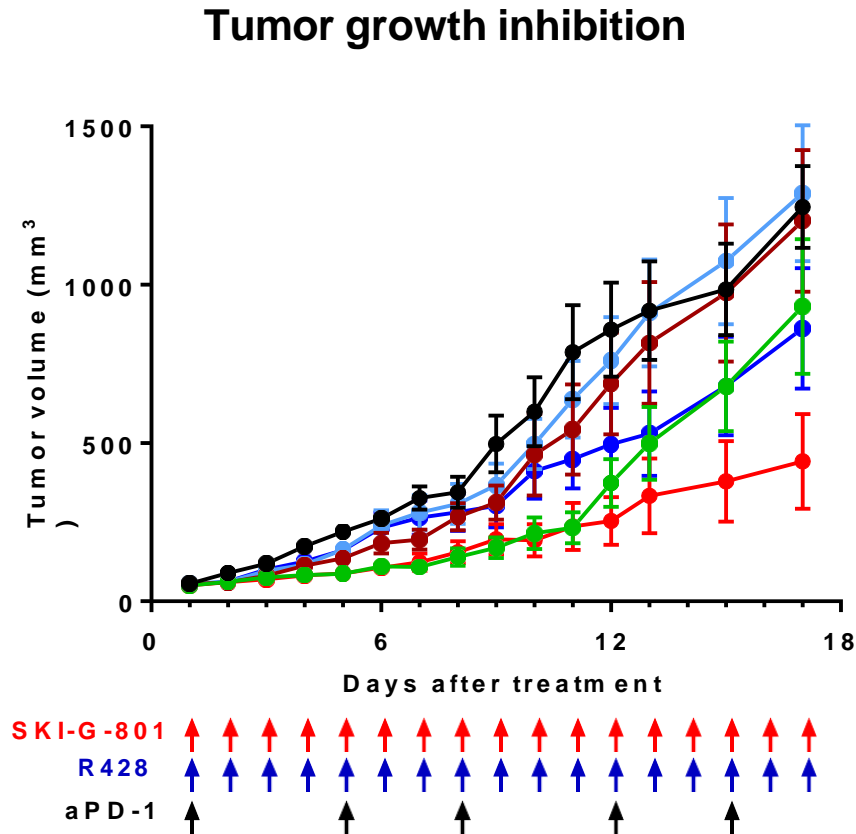
ATP dependency (in-house)

Compound	AXL (IC ₅₀ , nM)		
	ATP Km	1 mM ATP	Fold
SKI-G-801	12.5	113.9	9.1
R428	6.3	240.8	38.2



- Narrow spectrum kinome selectivity
- Superior inhibition at high ATP concentrations
- Persistent inhibition of p-AXL in cells after washout

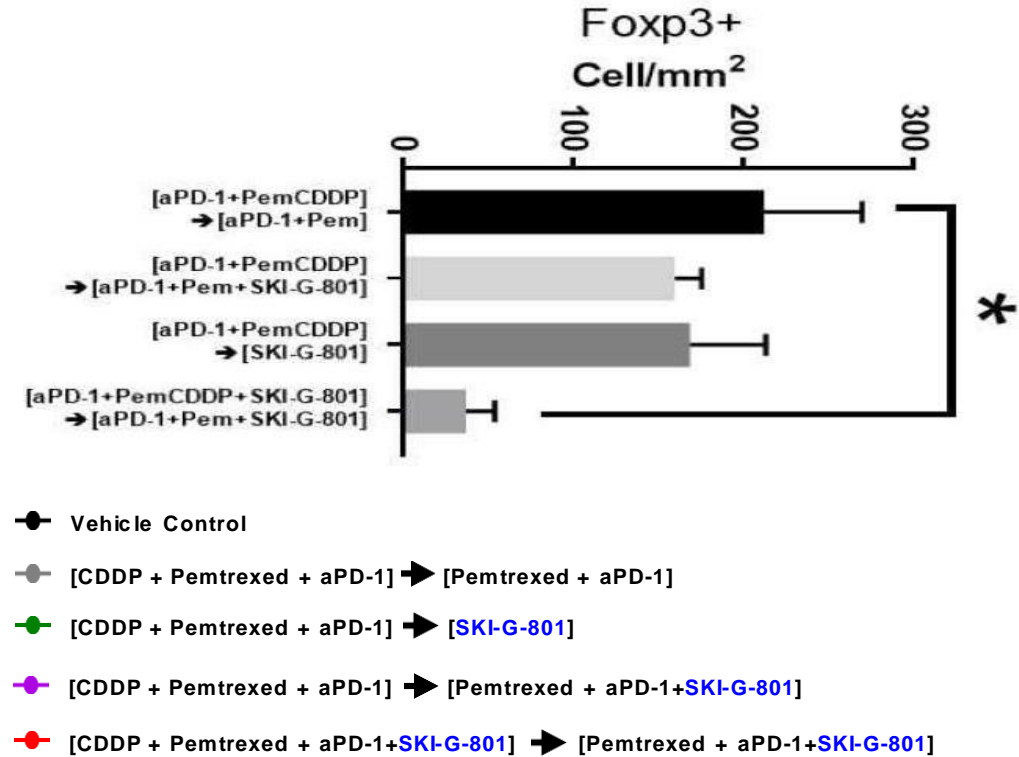
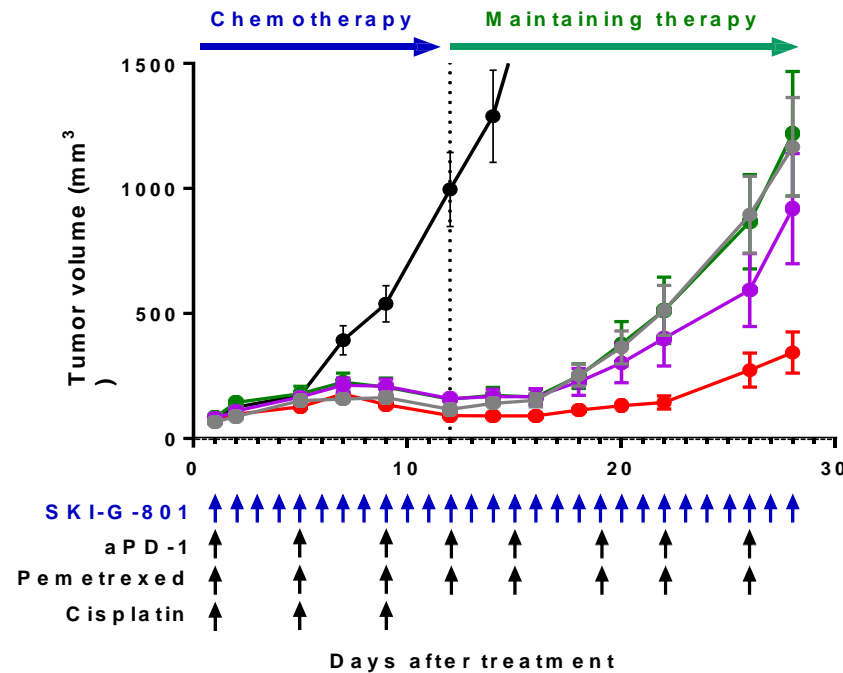
SKI-G-801; Preclinical Efficacy Highlight 1



Efficacy superior to bemcentinib at a lower dose as monotherapy as well as in combination with anti-PD-1 antibody in CT26 mouse syngeneic tumor model

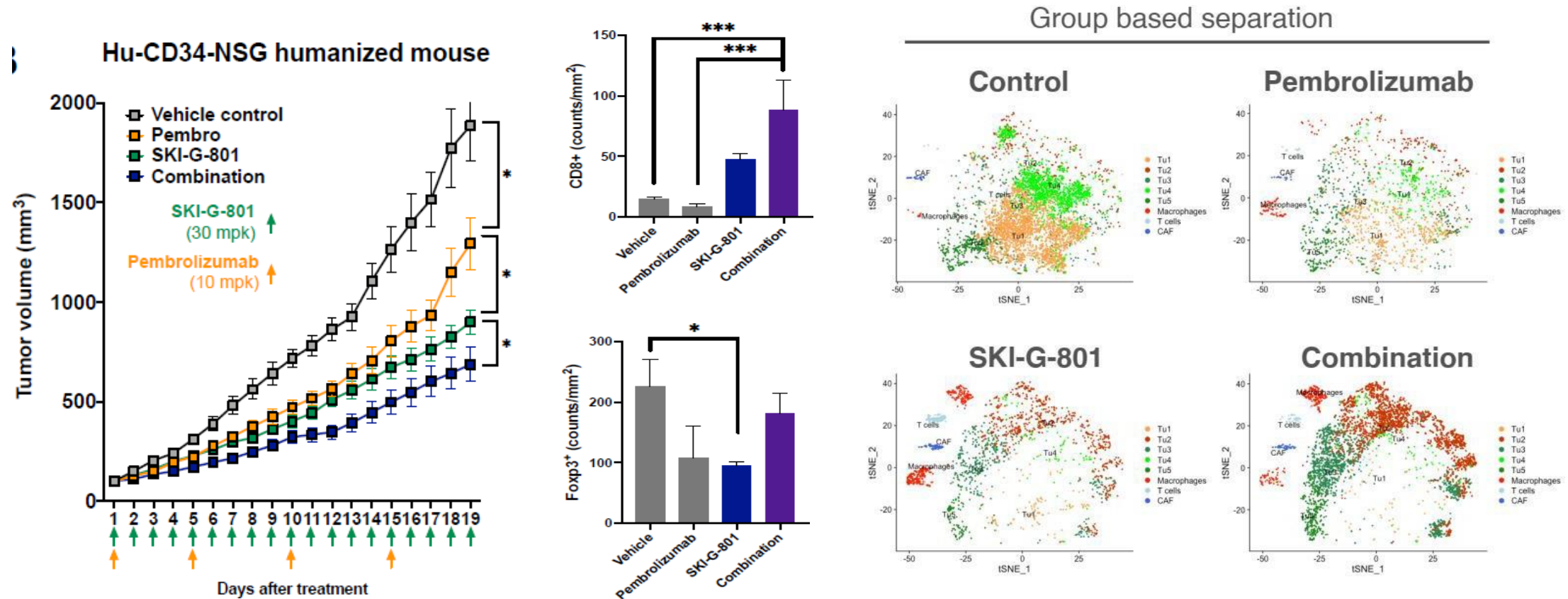
SKI-G-801; Preclinical Efficacy Highlight 2

TC1 Lung adenocarcinoma model



SKI-G-801, when present in the **induction phase** of lung adenocarcinoma standard-of-care regimen, greatly reduced the number of FoxP3+ Treg cells in the TME, significantly delayed tumor regrowth and increased survival

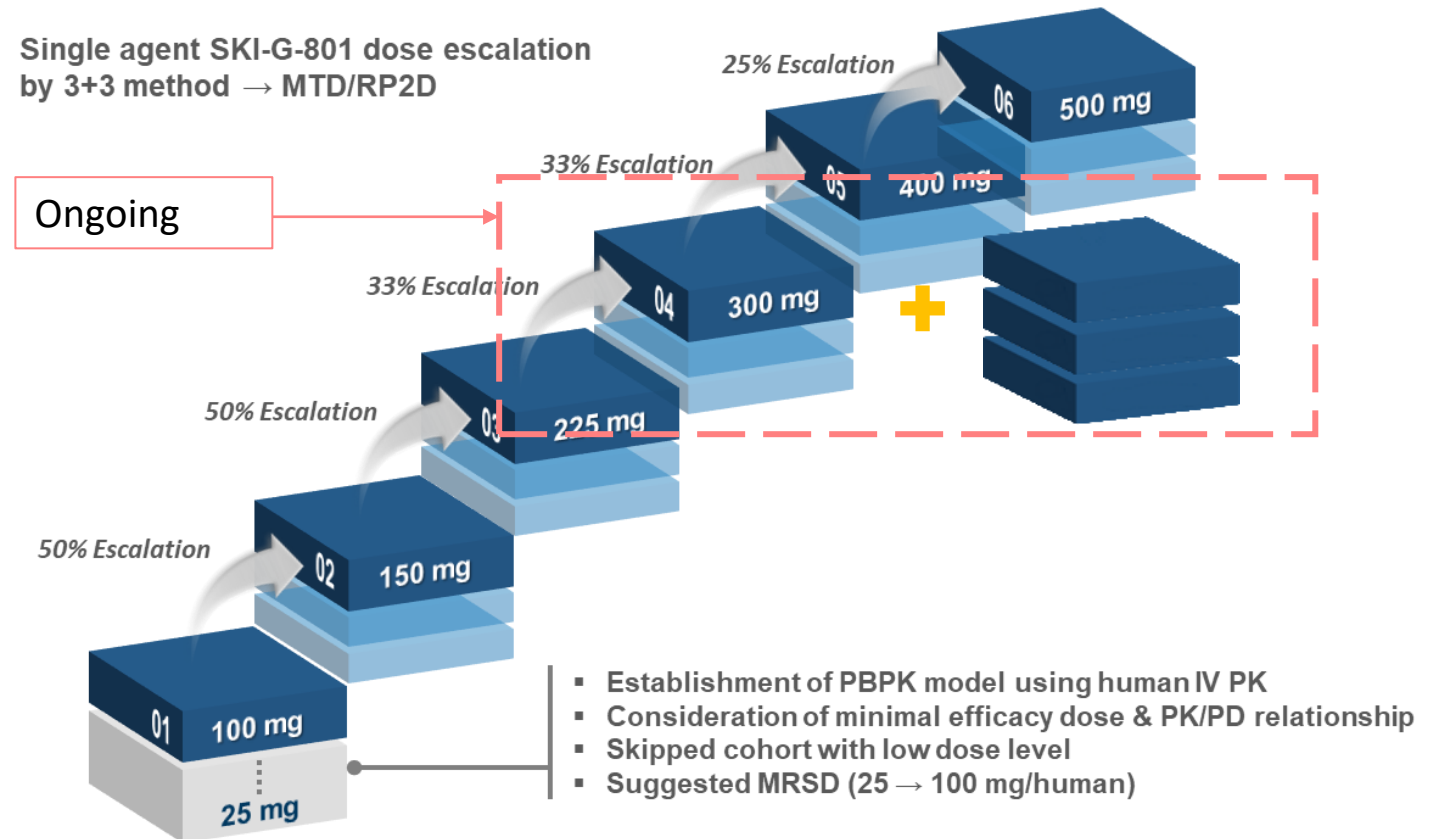
SKI-G-801; Preclinical Efficacy Highlight 3



Pronounced tumor growth inhibition in SCLC PDX model on humanized NSG mice; dramatically increased CD8 T cells and reduced Tregs; further enhanced by pembrolizumab as supported by single cell RNA sequencing

SKI-G-801 for Solid Tumors; Clinical Development

- Open-label, multi-center dose-finding study as monotherapy in patients with solid tumors to assess safety, tolerability, and PKs
- Dose escalation ongoing, 3 dose level completed (100, 150, 225 mg)
- Dose Level 4 (300 mg): 1 DLT occurred, 3 additional patients enrolled
- Cohort expansion plan under development



SKI-G-801; Clinical Development Timeline

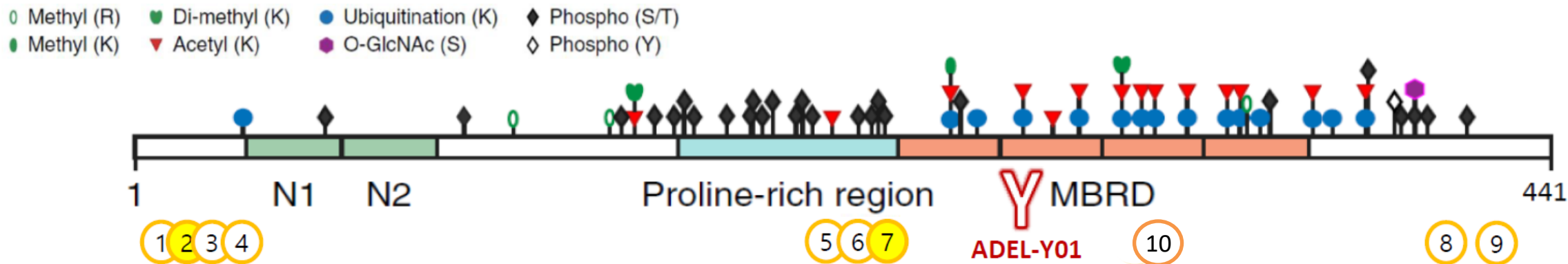
	2023				2024				2025			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Dose escalation												
IND amendment												
Combination Dose finding												
Cohort expansion PoC												

- Phase Ib/II cohort expansion study
- Combination with Keytruda for NSCLC patients who failed previous immunotherapy (ICB)

ADEL-Y01

**Anti-tau AcK280 Antibody for Tauopathies
including Alzheimer Disease**

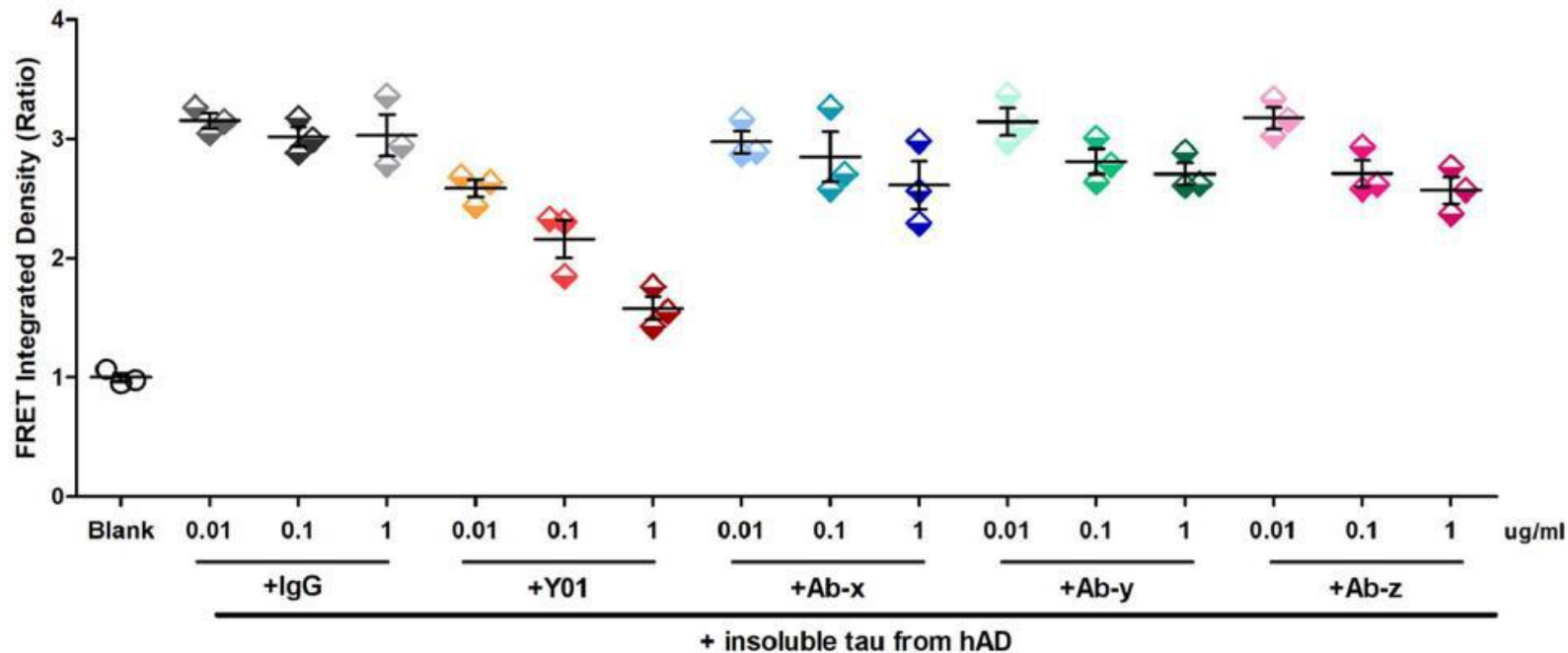
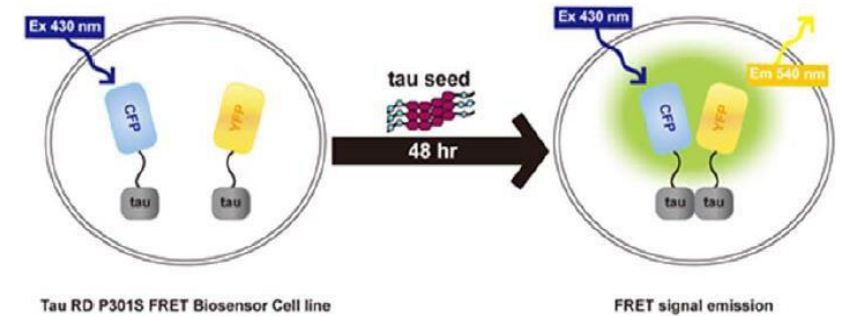
ADEL-Y01; Competitive Landscape



	Drug	Synonyms	Companies	Epitope	Clinical Trial Status
1	Zagotenemab	LY3303560, MC1	Eli Lilly	Tau aggregate (7-9:313-322)	Failed in P2
2	Gosuranemab	BIIB092, BMS-986168, IPN007	Biogen, BMS, iPerian	Secreted N-term fragment (15-24)	Terminated at P2
3	C2N-8E12	HJ8.5 (m)	Abbvie, C2N	Extracellular tau (25-30)	Failed in P2
4	Semorinemab	RO7105705, RG6100	Roche, AC Immune	Tau N-term	Failed in P2; another ongoing
5	JNJ-63733657		Janssen	Phospho tau PRR (pT217)	P2 ongoing until 2025
6	PNT001		Pinteon	Phospho tau PRR (cis-pT231)	Stopped at P2 in TBI; AD pending
7	Bepranemab		UCB, Roche	Tau PRR (235-246)	P2 ongoing until 2025
8	Lu AF87908		Lundbeck	Phospho tau C-term (pS396)	P1 ongoing
9	RG7345	RO6926496	Roche	Phospho tau C-term (pS422)	Stopped at P1
10	E2814		Eisai	Mid domains (R2 and R4)	P1 onglong

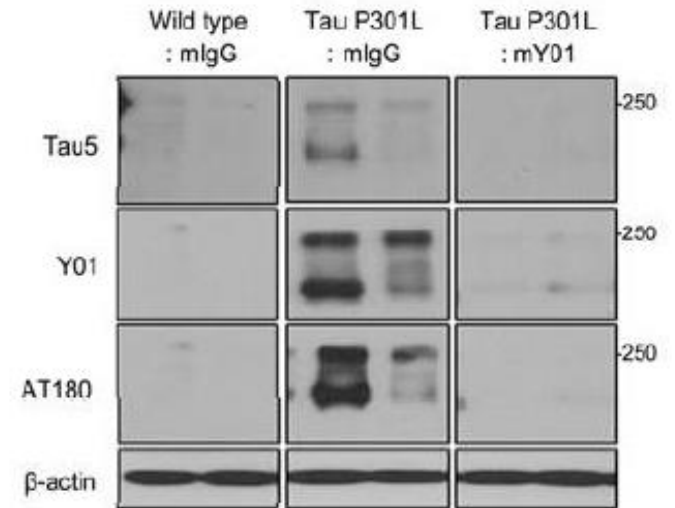
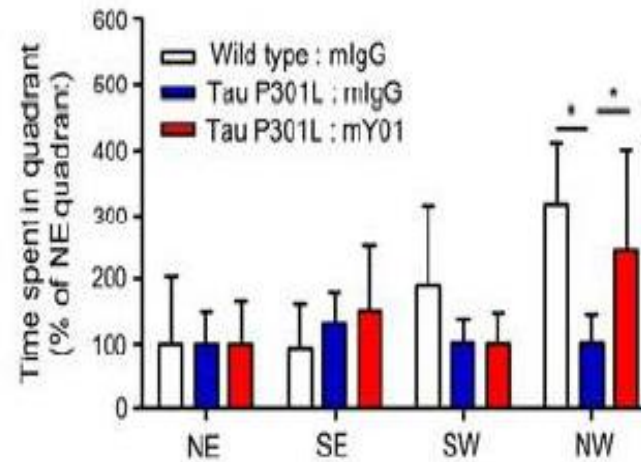
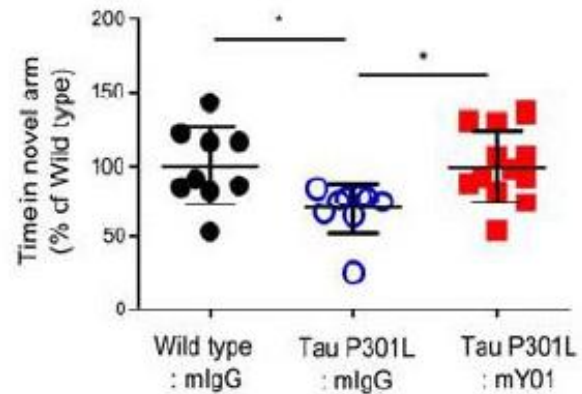
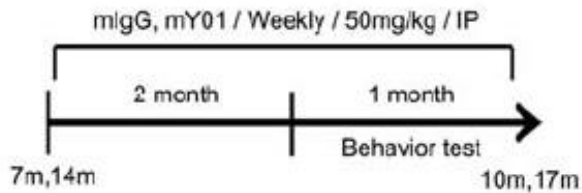
ADEL-Y01; Inhibition of Tau Propagation

- Biosensor assay to measure Tau spreading and seeding
- ADEL-Y01 displays superior activity to competitor antibodies
- Ex vivo screening using AD patients' CSF (cerebrospinal fluid) ongoing



x = gosuranemab
y = bepranemab
z = E2814

ADEL-Y01; In Vivo Efficacy (P301L Mouse)



In P301L tauopathy mouse model, treatment with Y01 prevented accumulation of tau aggregates in the brain and significantly improves cognition (Y-maze and water maze test) compared to control

ADEL-Y01; Development Timeline

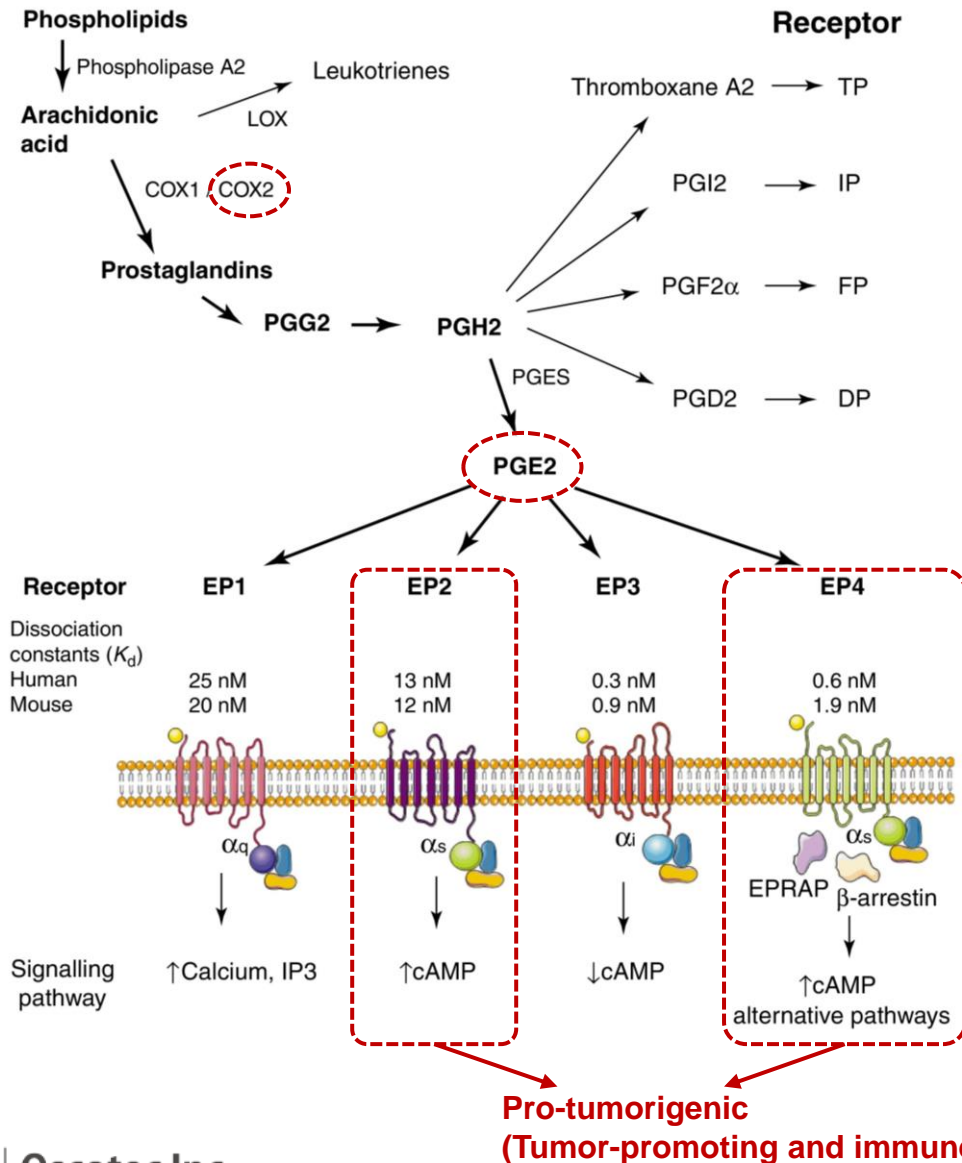
	2022				2023				2024			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
cGMP batch												
GLP tox (4w)												
GLP tox (26w)												
IND (FDA)												
Phase 1a SAD												
Phase 1b MAD												

- GMP manufacturing completed
- GLP tox studies (26 weeks) completed; no adverse effect up to maximum dose (500 mg/kg)
- **IND (US FDA) filing targeted in 2023Q2, P1 to start in 2023Q4**
- Extensive pre/clinical biomarker studies ongoing/planned

OCT-598

EP2/4 Dual Antagonist

Target Rationale



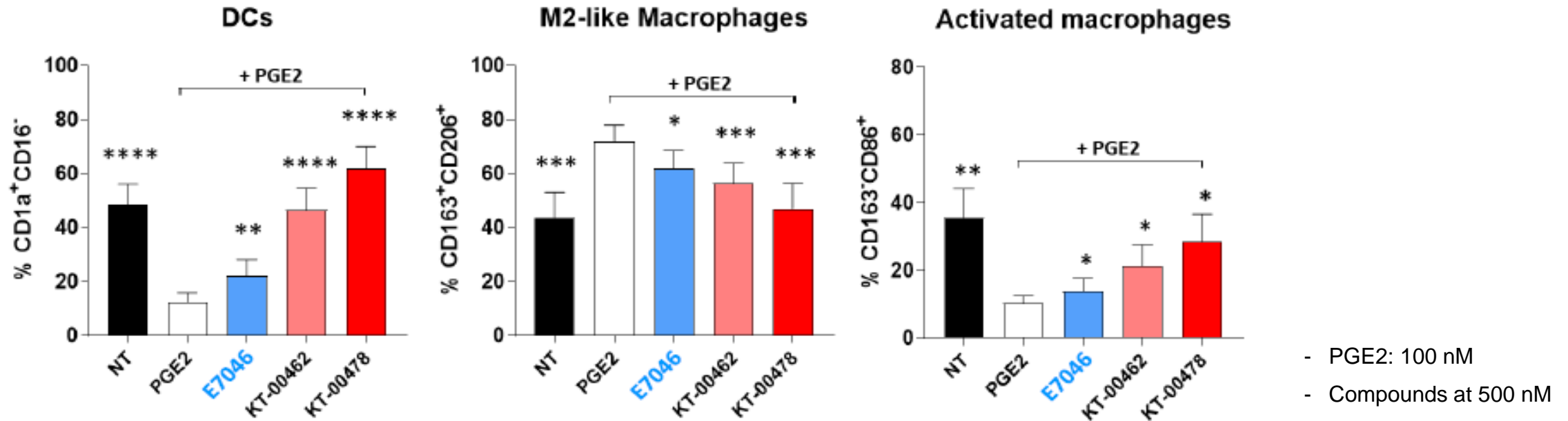
- The expression levels of **COX2**, a key enzyme for PGE2 synthesis, are **high in many tumor tissues**, including colon, lung, breast, bladder, skin, and ovarian cancers, and contributes to tumor initiation, proliferation, and metastasis
- Inhibition of PGE2 by **COX2 inhibitors** suppress tumor growth in animal tumor models, while **cardiovascular and gastrointestinal safety concerns** prevent further development of the drugs in human
- PGE2 promotes tumorigenesis via **EP2 and EP4 receptors** that increase intracellular cAMP levels upon activation
- **Genetic and pharmacological inhibition** of EP2 and EP4 suppresses tumor growth in animal models

Kalinski P (2011) *J.Immunology*; Nakanish M et al (2013) *Semin Immunopathol*; Markovic T et al (2017) *Drug Discovery Today*; Nagahisa A (2020) *Frontiers in Immunology*

Competitive Landscape

	EP2/EP4 dual antagonist	EP4 antagonist			
	TPST-1495	AN0025 (E7046)	ONO-4578 (BMS-986310)	IK-007 (Grapiprant)	INV-1120
Structure	Not known	Known	Not known	Known	Known
Company	Tempest	Adlai Nortye	BMS/Ono	Ikena Oncology	Shenzhen Ionova Life Sciences
Target Indication	Solid Tumors, MSS CRC, Lung, Head and Neck, Bladder, TNBC, Gastric	Neoadjuvant Therapy in Rectal Cancer, Solid tumors, Colorectal cancer	Solid tumors	NSCLC, colorectal cancer	Solid tumors
Development Status	<ul style="list-style-type: none"> NCT04344795 P1a/P2b (mono and with anti-PD-1) 	<ul style="list-style-type: none"> NCT03152370 P1 NCT04432857 P1 (combo with anti-PD-1) 	<ul style="list-style-type: none"> NCT03155061 P1 (mono and combo with anti-PD-1) NCT03661632 P1 (mono), P2 (combo with anti-PD-1) 	<ul style="list-style-type: none"> NCT03696212 P1/2 (combo with anti-PD-1) NCT03658772 P1 (combo with anti-PD-1) 	<ul style="list-style-type: none"> NCT04443088 P1 (mono)
Dose	BID	QD		300mg BID, 450mg q12h, 600mg q12h	QD

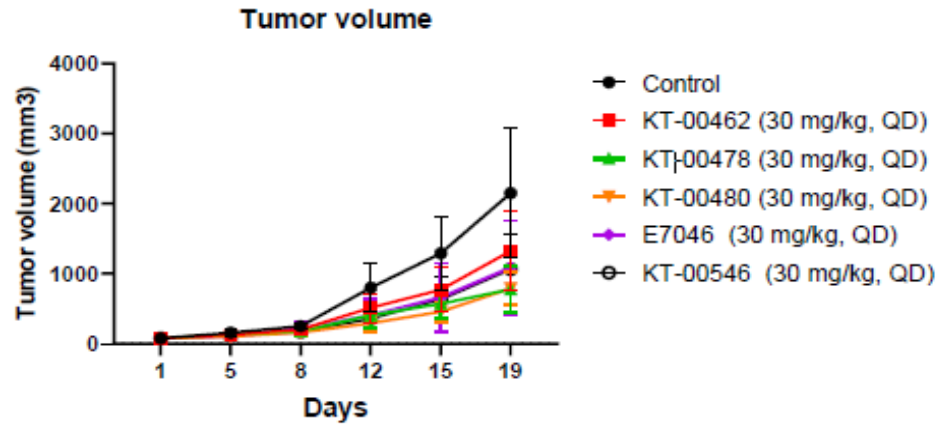
In Vitro (Ex Vivo) Activity of OCT-598 (KT-00478)



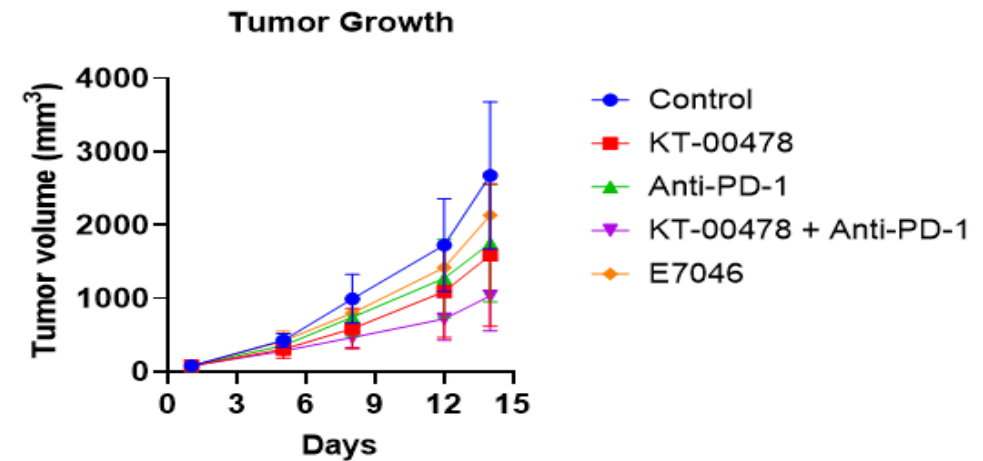
- OCT-598 potently reversed PGE2-induced polarization of human monocyte differentiation; increased DCs and M1 macrophages and decreased M2-like macrophages
- Superior to E7046, an EP4-specific antagonist

In Vivo Efficacies in Syngeneic Mouse Tumor Models

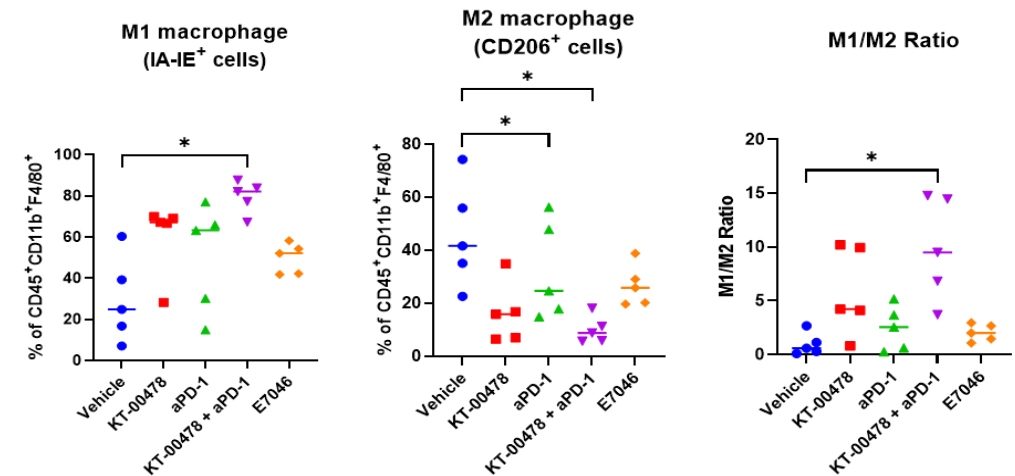
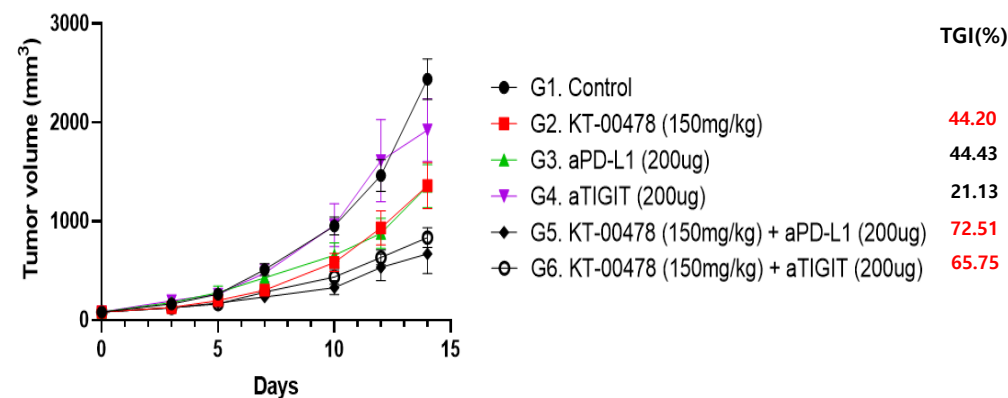
➤ Single agent efficacy in MC38 model



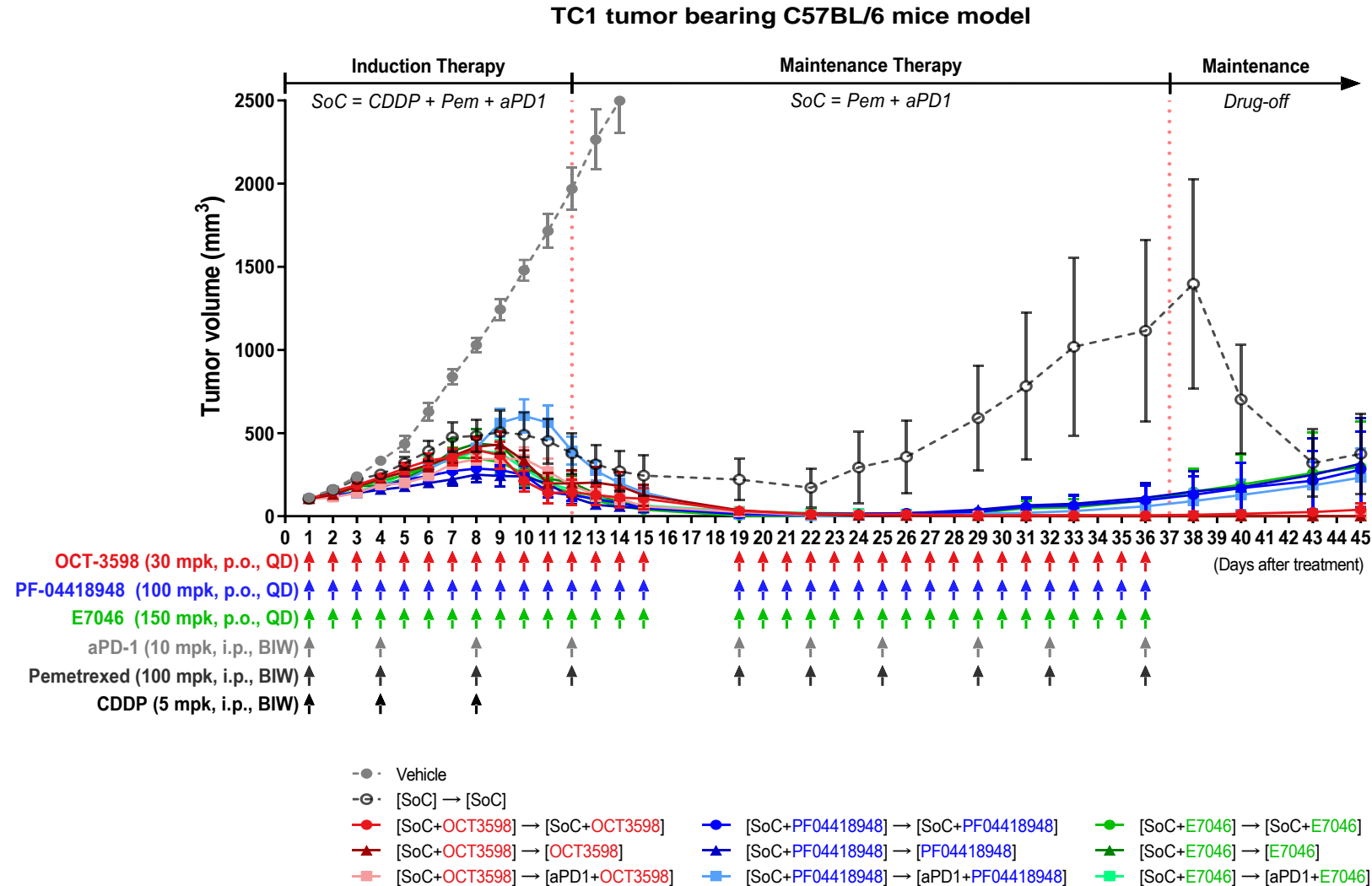
➤ Anti-PD-1 combination efficacy in CT26 model



➤ Anti-TIGIT combination efficacy in MC38 model



Complete Regression in Lung Cancer SoC Combination



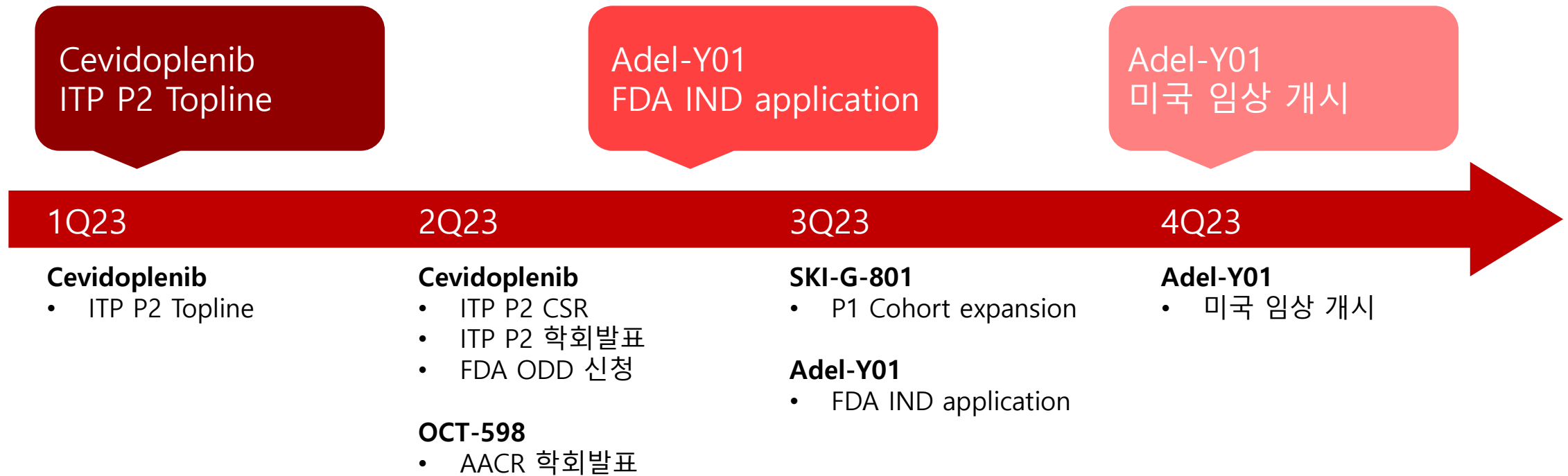
Development Timeline

		2022			2023				2024			
		Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacology	Translational models											
	Biomarker study											
Toxicology	2-week DRF study											
	GLP tox											
CMC	DS production											
	DP production											
IND												

- Translational/biomarker studies ongoing; presentation at AACR (Apr 2023)
- Process development, pilot production, and polymorph studies initiated
- DRF completed; IND-enabling studies (incl. GLP tox) to start in Q3
- IND filing targeted in 2024Q2

Looking Ahead

Major Milestones in 2023



Partnering activities in 2023

- **글로벌 기술이전 (L/O)** : Cevidoplenib P2 결과 기반 글로벌 L/O을 위한 파트너링 박차
OCT-598 전임상 진입에 따른 본격적인 글로벌 파트너링 개시
- **플랫폼기술 협업 강화**

1Q23

BioEU (March)

- **Cevidoplenib** 신규 및 f/u 미팅
- G801
- ADEL-Y01

2Q23

AACR

- OCT-598

BioUSA

- Cevidoplenib
- G801
- ADEL-Y01
- OCT-598

3Q23

- **F/U BioEU and BioUSA**

The Best is Yet to Come

A large iceberg floats in a blue ocean under a clear sky. The visible tip of the iceberg is jagged and white, while the much larger, submerged portion is visible below the water line, illustrating the concept of 'The Best is Yet to Come'.

➤ Clinical Pipeline

- Cevidoplenib for ITP and others
- SKI-G-801 for solid tumors

➤ Preclinical Pipeline

- ADEL-Y01 for Alzheimer disease (IND in 2023)
- OCT-598 for solid tumors (IND in 2024)

➤ Discovery Pipeline

- Multiple internal programs in cancer/fibrosis
- The most advanced program could enter development phase in 2024
- Novel targets from BioRevert collaboration

➤ Platform Technologies

- Undruggable targets
- Transformative screening technology

Q & A