Oscotec Inc.

March 2023

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Overview

“OUR VISION is to be the LEADING INNOVATION ENGINE that translates the science of LIFE into first-in-class medicine for unmet clinical needs”

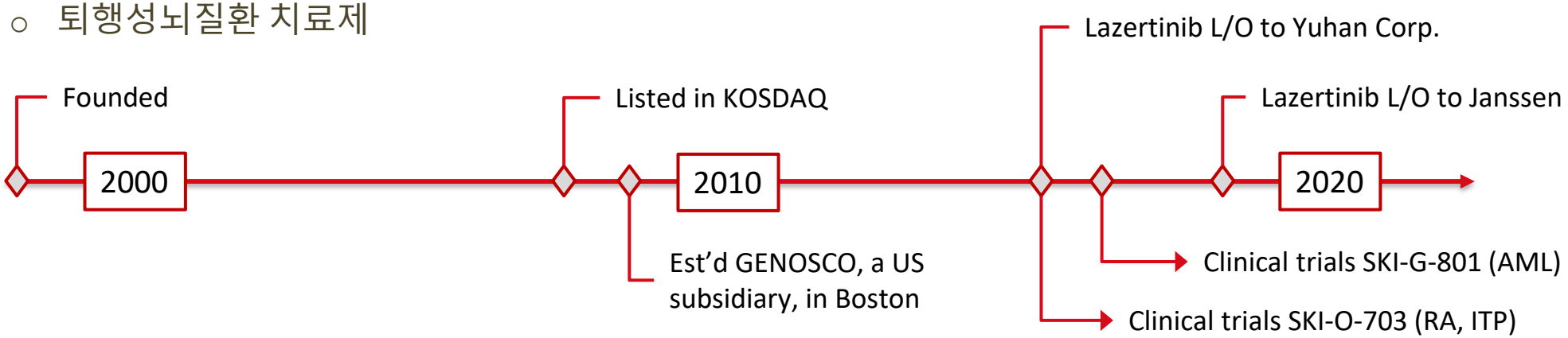
Profile

- 1998년 설립, 판교 코리아바이오파크 내 위치
- 2007년 코스닥 상장
- 자본금 : 189억원 (발행주식의 총수 : 보통주식 36,742,911주)
- 직원수 : 48 (연구개발: 29)
- 자회사 : Genosco (Boston), Ectodor (Boston)

Area

- 항암제/면역항암제
- 자가면역질환 치료제
- 퇴행성뇌질환 치료제

History



Leadership

Oscotec Inc.

James Kim Ph.D., D.D.S CEO

- Ph.D. in biochemistry, Seoul National University
- Professor, Dankook Univ.
- Visiting Professor, Harvard Medical School

Taeyoung Yoon Ph.D. CEO

- Ph.D. in Organic Chemistry, Yale Univ.
- Postdoc, California Inst. of Technology
- Sr. Research Investigator, Novartis
- SVP and Head of Research, Dong-A ST

Yuntae Kim Ph.D. CTO

- Ph.D. in organic chemistry, Univ. of Pittsburgh
- Postdoc, California Inst. of Technology
- Sr. Research Fellow, Merck
- Director of Medicinal Chemistry, CKD

Scott Lee MBA CFO

- Director/Management
- MBA in Business Administration, Dankook Univ.

GENOSCO

John Koh Ph.D. CEO

- Ph.D. in Bio-organic Chemistry, California Institute of Technology
- President, KABIC
- R&D Head, LG Life Science

Steve Kim Ph.D., D.D.S CTO

- Ph.D. in Pharmacology, Seoul Nat. Univ.
- Professor, Dankook Univ.
- Visiting Professor, Harvard Medical School

Kevin Yang B.Sc CFO

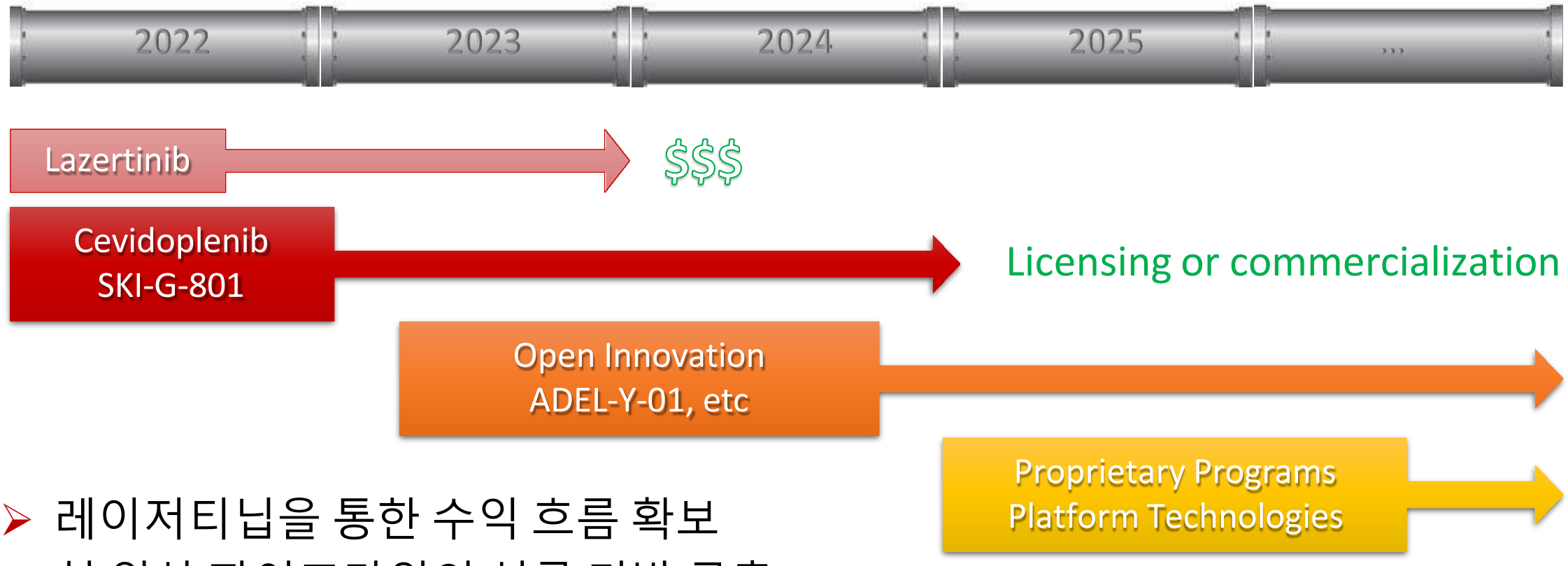
- Director/Management
- B. Sc in Communication from Seoul National Univ.

ectodor therapeutics

Katie Lee Ph.D. CEO

- Ph.D. in Organic Chemistry, Wesleyan University
- Postdoc, Yale Univ.
- Research Associate, Harvard Medical School and Broad Institute

Oscotec Growth Strategy



- 레이저티닙을 통한 수익 흐름 확보
- 현 임상 파이프라인의 성공 기반 구축
- 오픈 이노베이션을 통한 파이프라인 강화
- 자체 개발 과제와 플랫폼 기술 구축을 통한 지속적인 성장

Oscotec R&D Pipeline

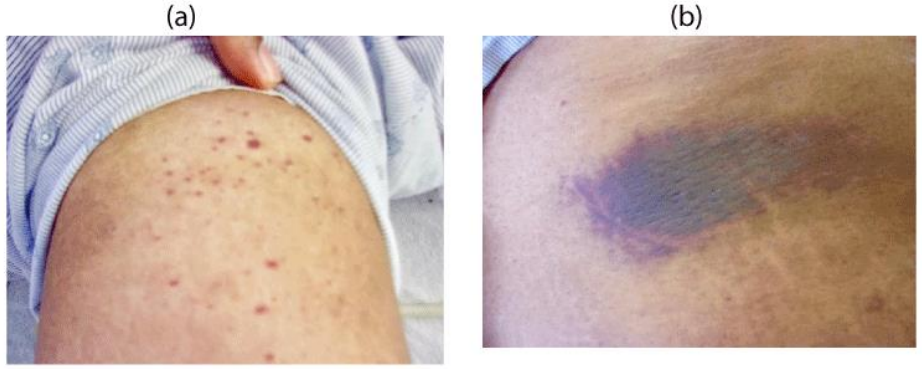
	MoA	Indication	Discovery	Lead Opt	Preclinical	Phase I	Phase II
Cevidoplenib (SKI-O-703)	SYK Inhibitor	류마티스관절염 (RA)					
		면역혈소판감소증 (ITP)					
SKI-G-801	FLT3/AXL Dual Inhibitor	급성골수성백혈병 (AML)					
		고형암					
ADEL-Y01	Anti-TAU mAb	알츠하이머성 치매					
OCT-598	EP2/4	면역항암					
ONC1	(Undisclosed)	고형암/섬유증					
ONC2	(Undisclosed)	고형암					
ONC3	(Undisclosed)	고형암					
...							

Cevidoplenib (SKI-O-703)

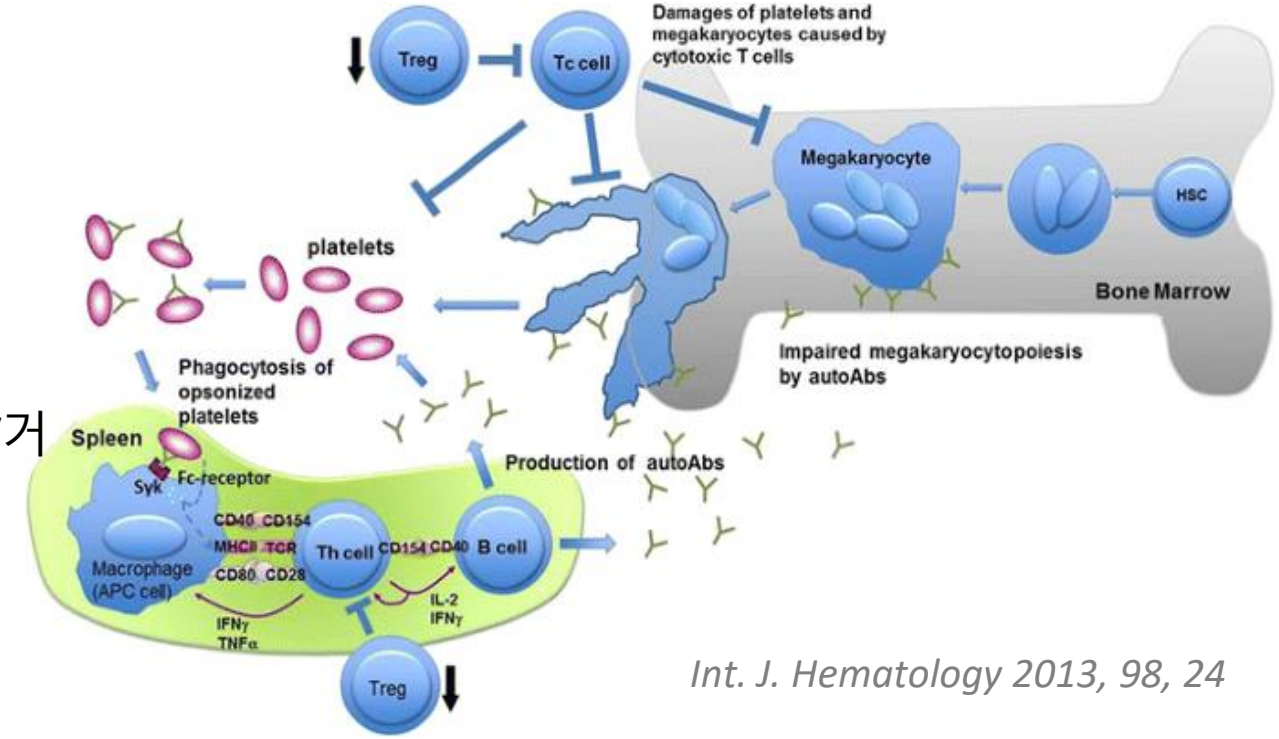
Highly Selective SYK Inhibitor for Autoantibody-driven Immune Disorders

만성 면역혈소판감소증 (Chronic Immune Thrombocytopenia)

- 혈소판 감소로 인한 혈액질환
  - 12개월 이상 혈소판 수치 100,000/uL 이하
  - 100,000명당 10명 이하 발생하는 희귀질환
  - 쉽게 멍이 들거나 출혈이 일어날 수 있음
  - 혈전증 발생할 가능성 높아짐



- 면역혈소판감소증 병태생리 기전
  - 자가항체에 의한 혈소판 공격
  - 대식세포가 혈소판을 파괴
  - Autoreactive B 세포와 형질세포
  - 자가항체에 의한 거대핵세포 (megakaryocytes) 억제
  - 조절T세포 손상 및 T세포에 의한 혈소판/거대핵세포 파괴



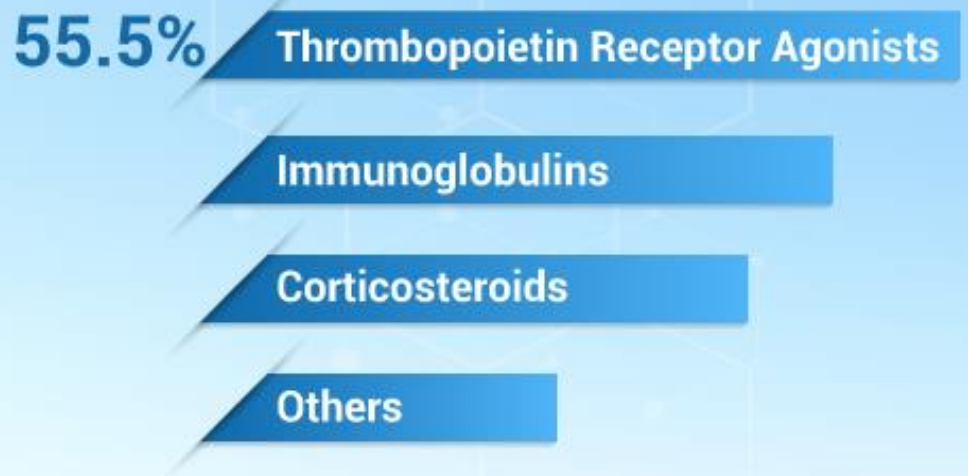
Int. J. Hematology 2013, 98, 24

IMMUNE THROMBOCYTOPENIA (ITP) MARKET

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

In 2018 **$2.99 Billion** & **$3.33 Billion** by 2026

Global Immune Thrombocytopenia Market Share, By Treatment, 2018

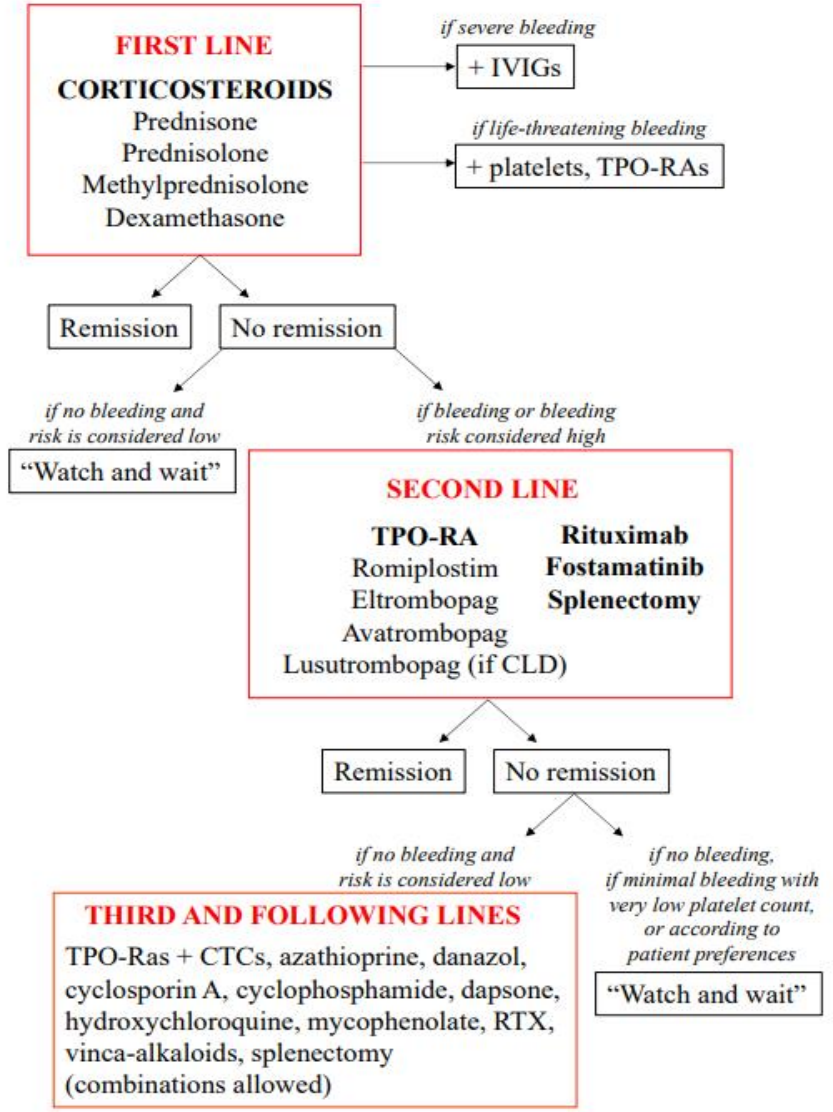


North America Immune Thrombocytopenia Market Size, 2018

표준요법 및 개발중인 치료제

- 표준요법
  - 1차치료제; corticosteroid, IVIg
  - 2차치료제; **TPO receptor agonists**
  - Rituximab, fostamatinib, MMF, etc
  - 비장절제술 (Splenectomy)
- TPO-RAs (혈소판 수용체 작용제)
  - 2008년 승인
    - Promacta® (eltrombopag, Novartis; $2B in 2021)
    - Nplate® (romiplostim, Amgen; $1B in 2021)
  - 40~60% (PLT# > 50,000/uL)의 반응률
  - 1/3 정도의 환자는 반응이 없어
- 2018년 Fostamatinib (Rigel, SYK inhibitor) 승인
- 개발중인 치료제
  - Rilzabrutinib (Sanofi, BTK inhibitor) in P3
  - Efgartigimod (Argenx, FcRn blocker) in P3

Pharmaceuticals 2022, 15, 779



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)

- 면역혈소판감소증 환자
- **1회 이상 치료 받았으나 반응이 없거나 재발한 환자**
- 스크리닝 기간 중 최소 7일 이상 간격으로 2회 이상 혈소판수치 30,000/μL 미만인 경우

1:2:2 무작위배정

BID, 12주

Arm 1 (N=12)	**위약군**
Arm 2 (N=26)	**Cevidoplenib 200mg**
Arm 3 (N=22)	**Cevidoplenib 400mg**

일차평가지표

- 구제요법 사용 없이 혈소판수치 30,000/μL 이상 및 기저 대비 두배 이상 (직전2회 평균) 개선

이차평가지표

- 효능 및 안전성 등을 평가하기 위한 다양한 디자인의 평가지표

Participant Baseline Characteristics

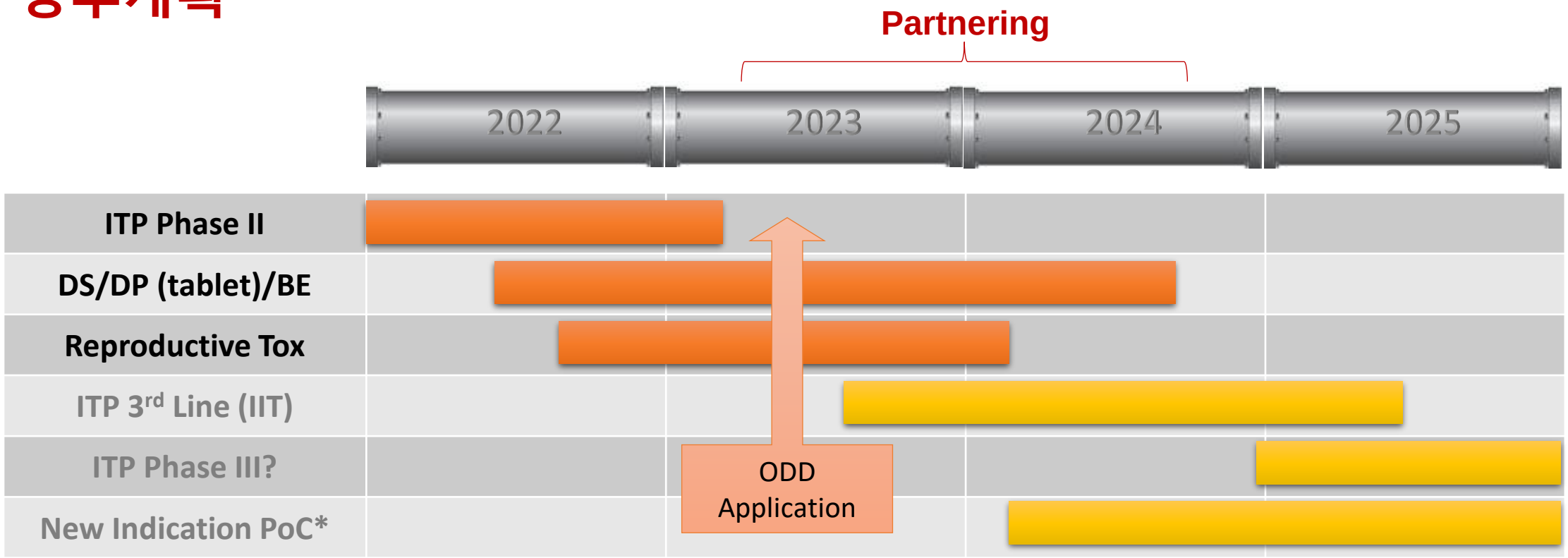
	Placebo (N=12)	200 mg BID (N=26)	400 mg BID (N=22)	Total (N=60)	Rilzabrutinib (N = 60)
Median age (range) -yr	69.5 (25-86)	59.5 (24-81)	57.0 (23-80)	60.0 (23-86)	50 (19-74)
Sex – no. (%)					
Female	5 (41.7)	13 (50.0)	16 (72.7)	34 (56.7)	26 (43)
Male	7 (58.3)	13 (50.0)	6 (27.3)	26 (43.3)	34 (57)
Median 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)	35 (58)
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

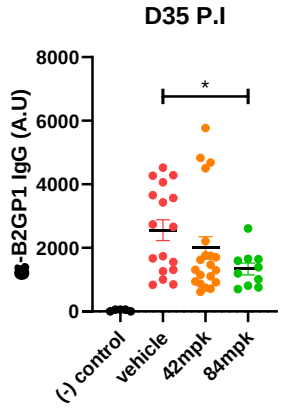
Endpoint	Description	Cevido Placebo	Cevido 200 mg		Cevido 400 mg		Fosta P3	Rilza P1/2	Efgar P3
		%	%	p-value	%	p-value	%	%	%
Primary	AVG_PLT ≥ 30,000 and AVG_PLT ≥ 2x baseline	33.3	46.2	0.504	63.6	0.151			
Ad hoc	PLT ≥ 30,000 and AVG_PLT ≥ 2x baseline	25.0	50.0	0.178	72.7	0.012			
Secondary	≥ 2 consecutive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

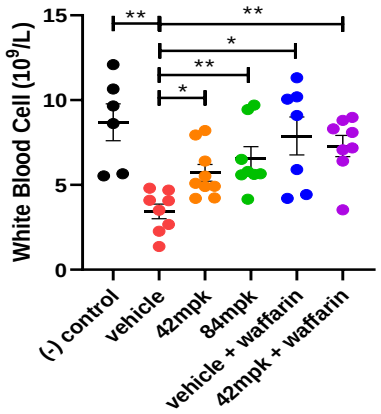
* Primary endpoint

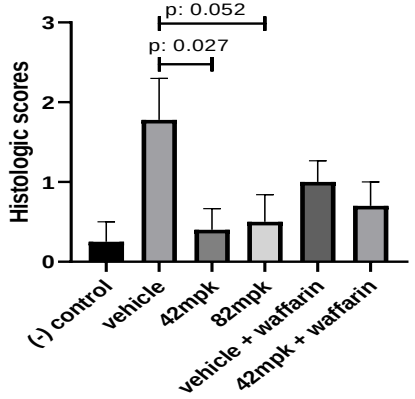
향후계획



* 항인지질항체증후군 (APS)
항체매개거부반응 (AbMR)
RA 병용투여 등







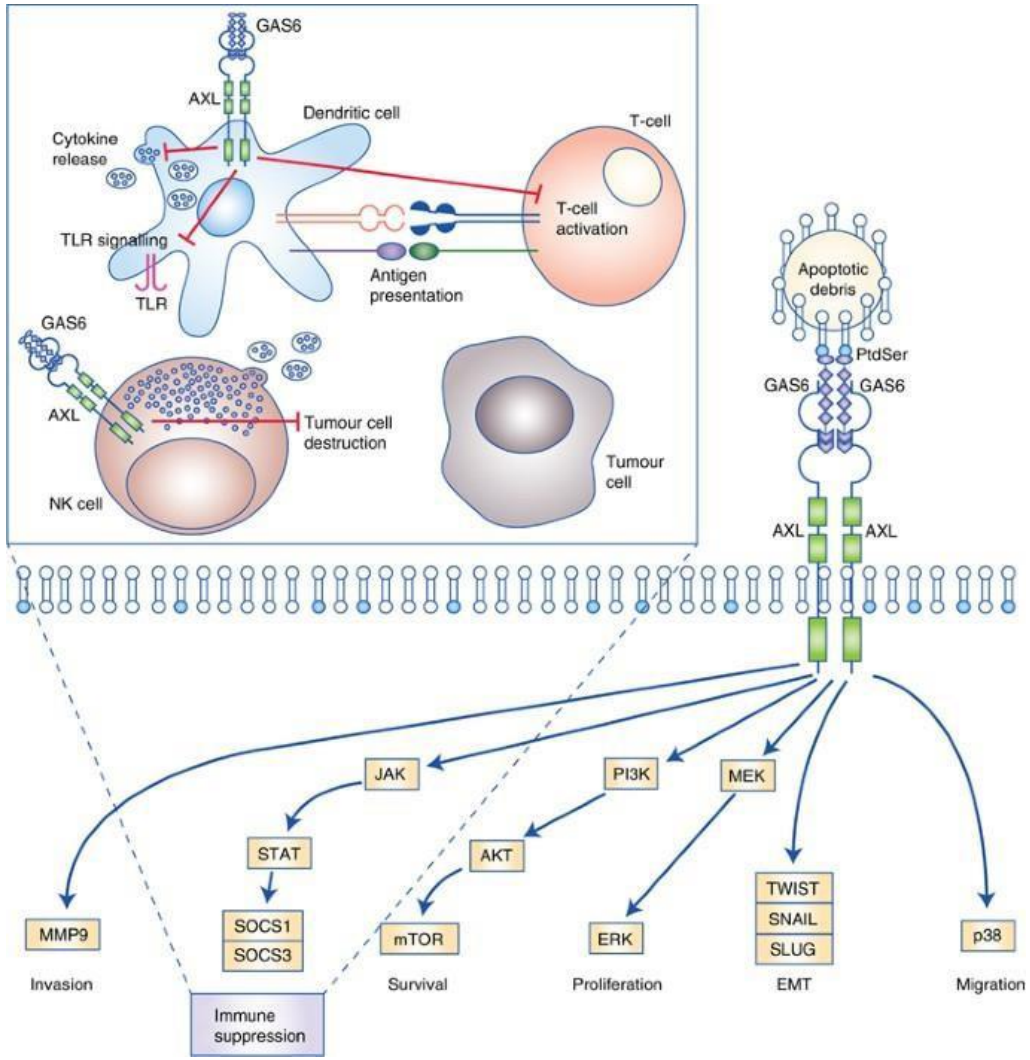
DS: Drug Substance, 원료의약품 / DP: Drug Product 완제의약품
BE: bioequivalence test 생물학적 동등성
IIT: Investigator initiated clinical trial 연구자 주도 임상
ODD: orphan drug designation 희귀의약품지정

SKI-G-801

The Best-in-class FLT3/AXL Dual Inhibitor

SKI-G-801 고형암 적용 배경

- AXL의 과발현은 **악성종양의 진행**과 관련이 있음
  - 여러 암종에서 좋지 않은 예후와 관련
  - Epithelial-mesenchymal transition (EMT)과 암의 전이를 촉진
  - 치료제 내성을 유도; 특히, **TKI-내성 EGFR 돌연변이 비소세포성폐암 (NSCLC)**
- **선천 면역관문 (Innate immune checkpoint)**
  - AXL은 대식세포 (macrophage)와 수지상세포 (dendritic cell)에서 apoptotic cell 유래 면역억제를 강화하는 종양미세환경 (tumor microenvironment)을 조성
  - AXL은 **면역관문억제제 내성 종양에서 과발현** 돼 있음

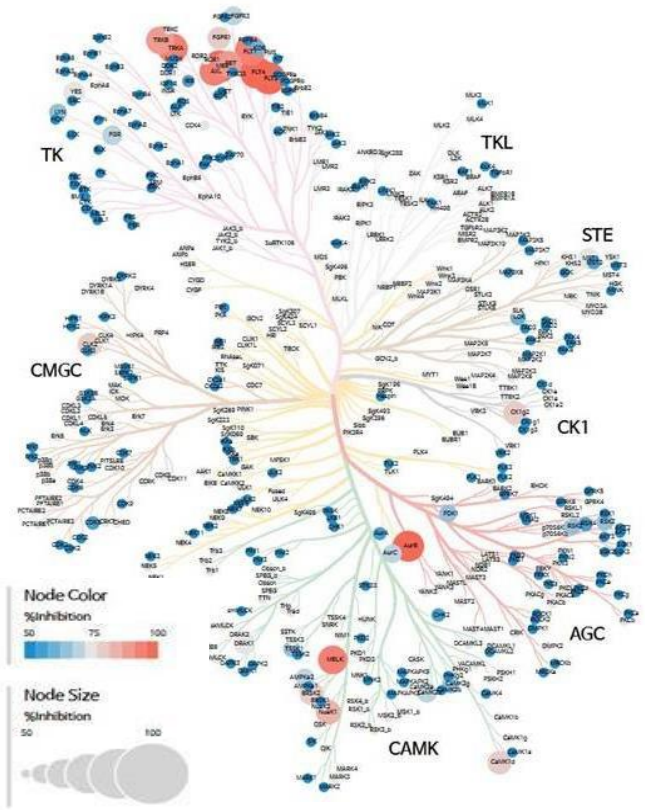


Gay et al., British J Cancer 2017

AXL Inhibitors; 경쟁사 현황

Asset	Company	AXL IC50	Others	Indication	Phase	Remark
Bemcentinib (R428, BGB-324)	BerGenBio	14nM		급성골수성백혈병 (AML), 골수이형성증후군 (MDS)	II	Completed
				COVID-19	II	Completed
				비소세포성폐암 (NSCLC), 키트루다 병용	II	
ONO-7475	Ono Pharma	0.7 nM	Mer (1.0 nM), FLT3 (147 nM)	불응성/재발성 AML/MDS 단독 혹은 벤클렉스타® (venetoclax) 병용	I/II	
				진행성 혹은 전이성 고형암 단독 혹은 옵디보 ® (ONO-4538, nivolumab) 병용	I	
AB-329 DS-1205	Daiichi Sankyo	1.3 nM		EGFR 돌연변이 NSCLC에서 이레사® (gefitinib) 병용 (n = 21)	I	Completed
				EGFR 돌연변이 NSCLC에서 타그리소® (osimertinib) 병용 (n = 13)	I	Completed ORR = 0%
Dubermatinib (TP-0903)	Sumitomo Dainippon	27 nM		진행성 고형암 (n = 177)	I	
				만성 림프구성 백혈병 (CLL) 단독 혹은 임브루비카® (ibrutinib) 병용	I/II	Terminated
				FLT3 돌연변이 AML (n = 80)	Ib/II	
HH30134	Haihe Biopharma	AXL	FLT3, NTRK	진행성 고형암 (n =50)	I	
Q702	Qurient	0.7nM	Mer (0.8 nM) CSF1R (8.7nM)	진행성 고형암 (n = 78)	I	

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



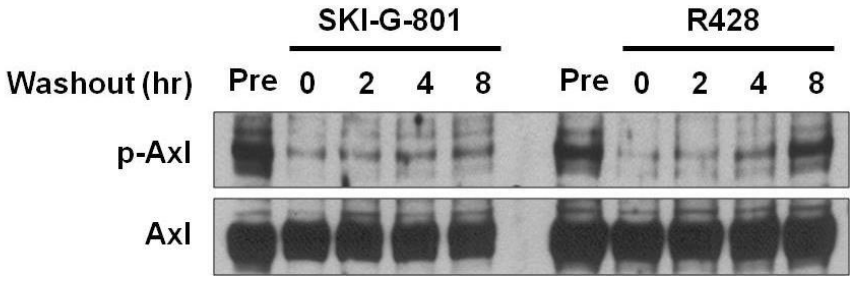
Kinase	IC50 (nM)
FLT3	1
Mer	1
Aurora B	6
Ret	9
FLT1	18
Fms	19
Axl	20
Aurora C	24
FGFR1	25
FGFR3	30
KDR	39
c-Kit	142
IGF-1R	300
PDGFRa	300
PDGFRb	300
EGFR	300

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

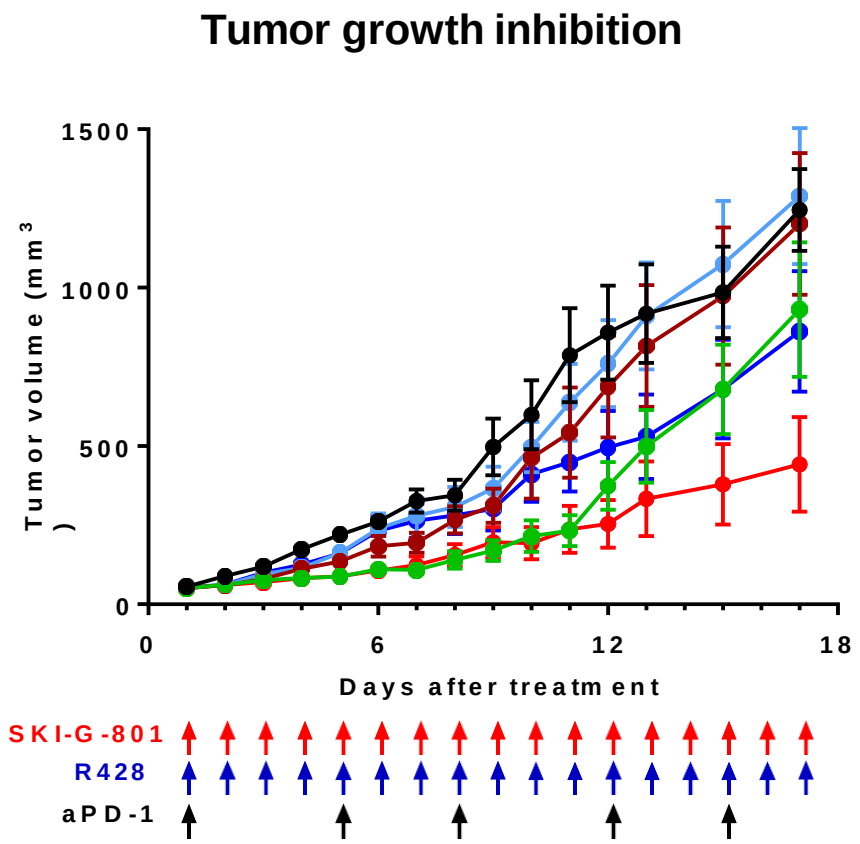
ATP dependency (in-house)

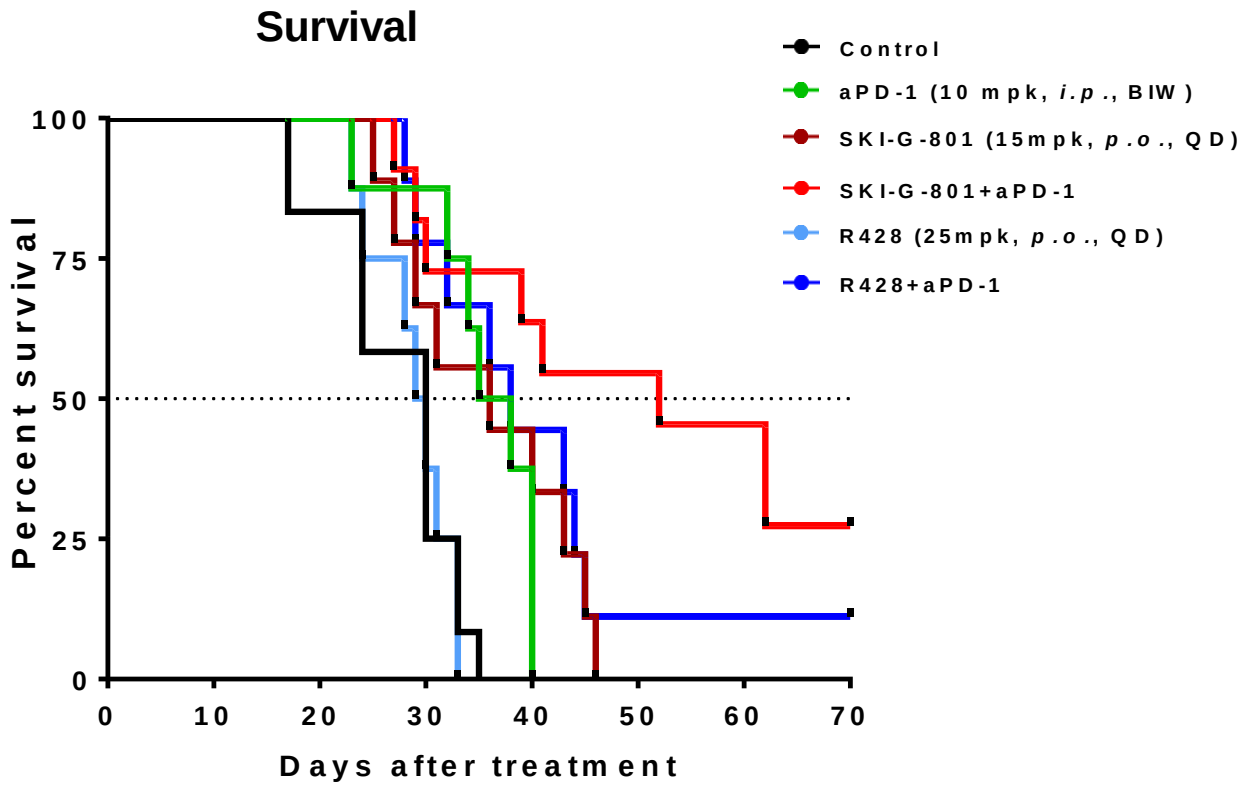
Compound	AXL (IC_{50}, nM)		
	ATP Km	1 mM ATP	Fold
SKI-G-801	12.5	113.9	9.1
R428	6.3	240.8	38.2



- 다수의 kinase들에 대해 뛰어난 선택성 확보
- 생리학적 ATP 농도에서도 좋은 potency를 유지
- 경쟁약물 대비 약물 처리 후 washout 이후에도 p-AXL 저해효과를 장시간 유지

SKI-G-801; Preclinical Efficacy Highlight 1

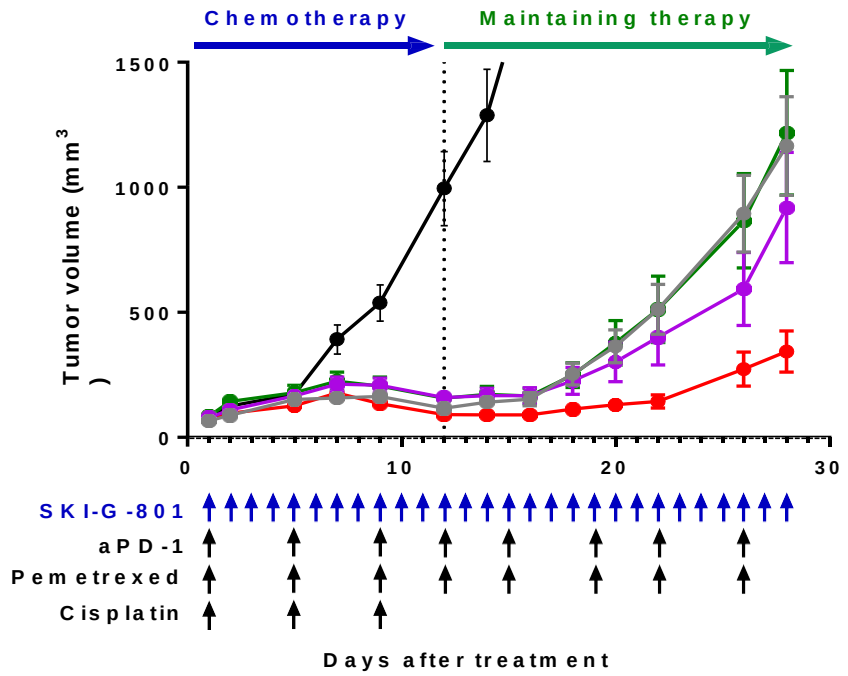


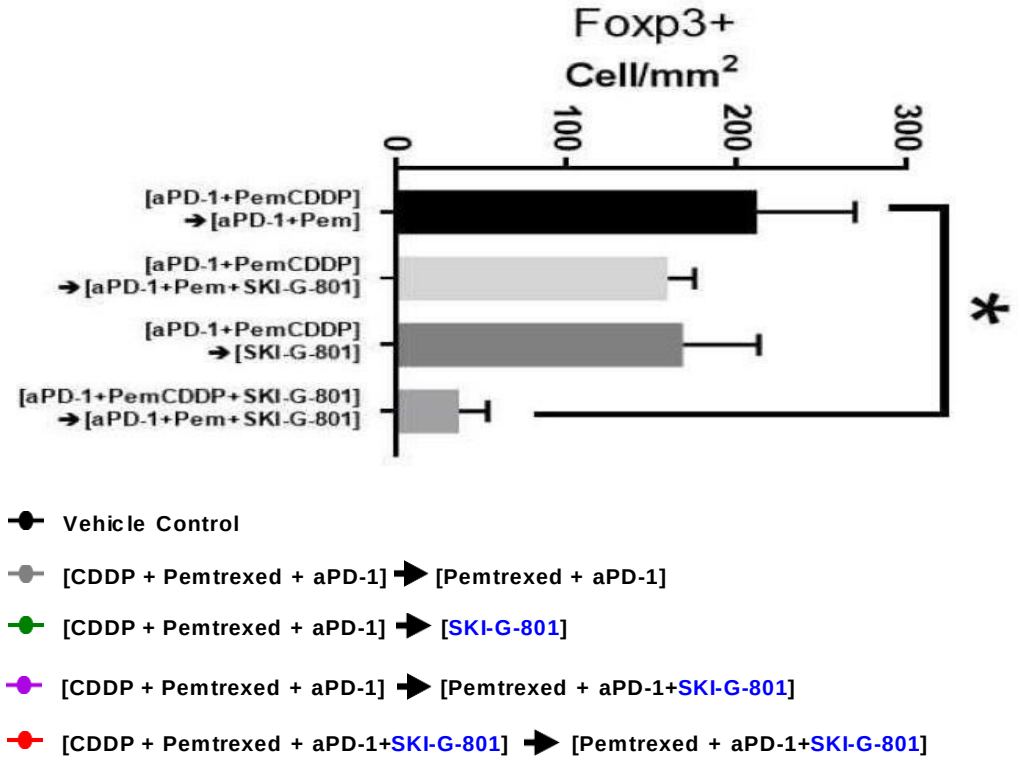


마우스 CT26 syngeneic 종양모델에서 단독요법 및 anti-PD-1과 병용투여 시 저용량에서도 경쟁약물인 bemcentinib보다 우수한 효능을 확인

SKI-G-801; Preclinical Efficacy Highlight 2

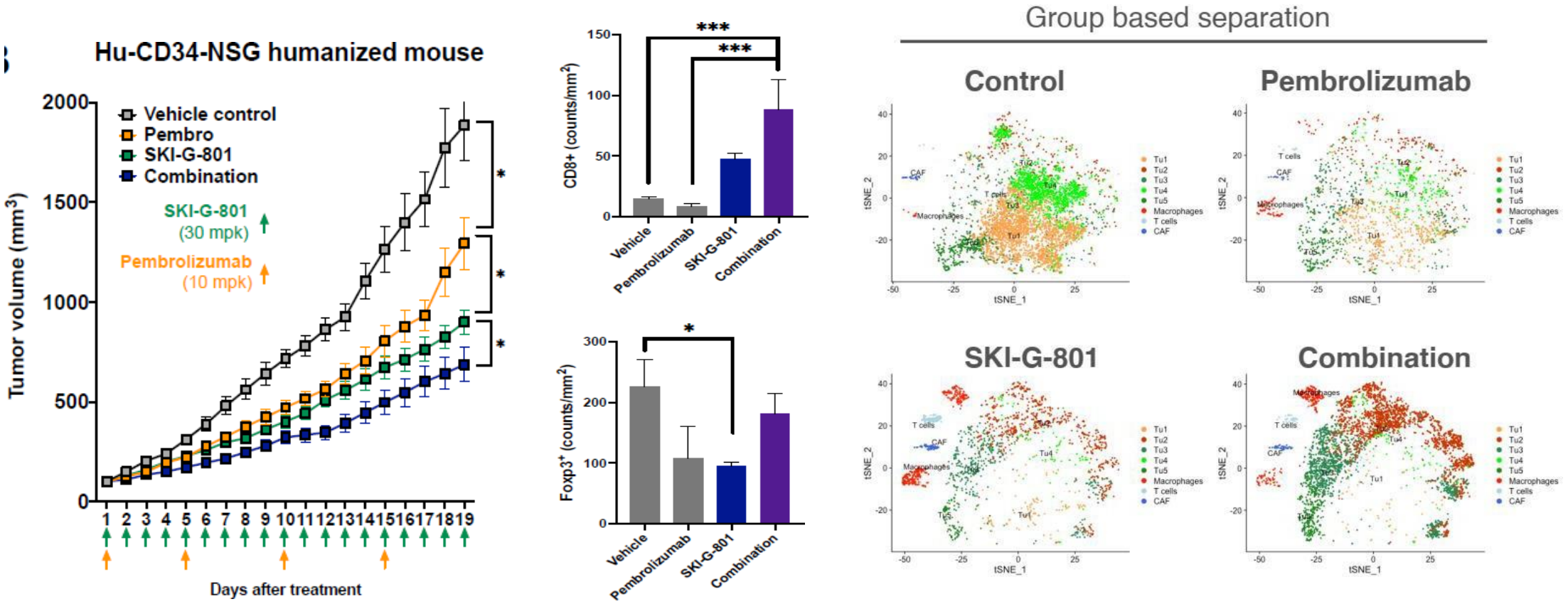
TC1 Lung adenocarcinoma model





SKI-G-801은 폐암 선암(adenocarcinoma) 모델에서 표준요법(standard of care)와 함께 투여 시 종양미세환경(TME)의 FoxP3+Treg 세포를 현격히 감소시켜 주고, 종양의 재성장 또한 크게 감소시켰으며, 마우스의 생존율을 증가시킴

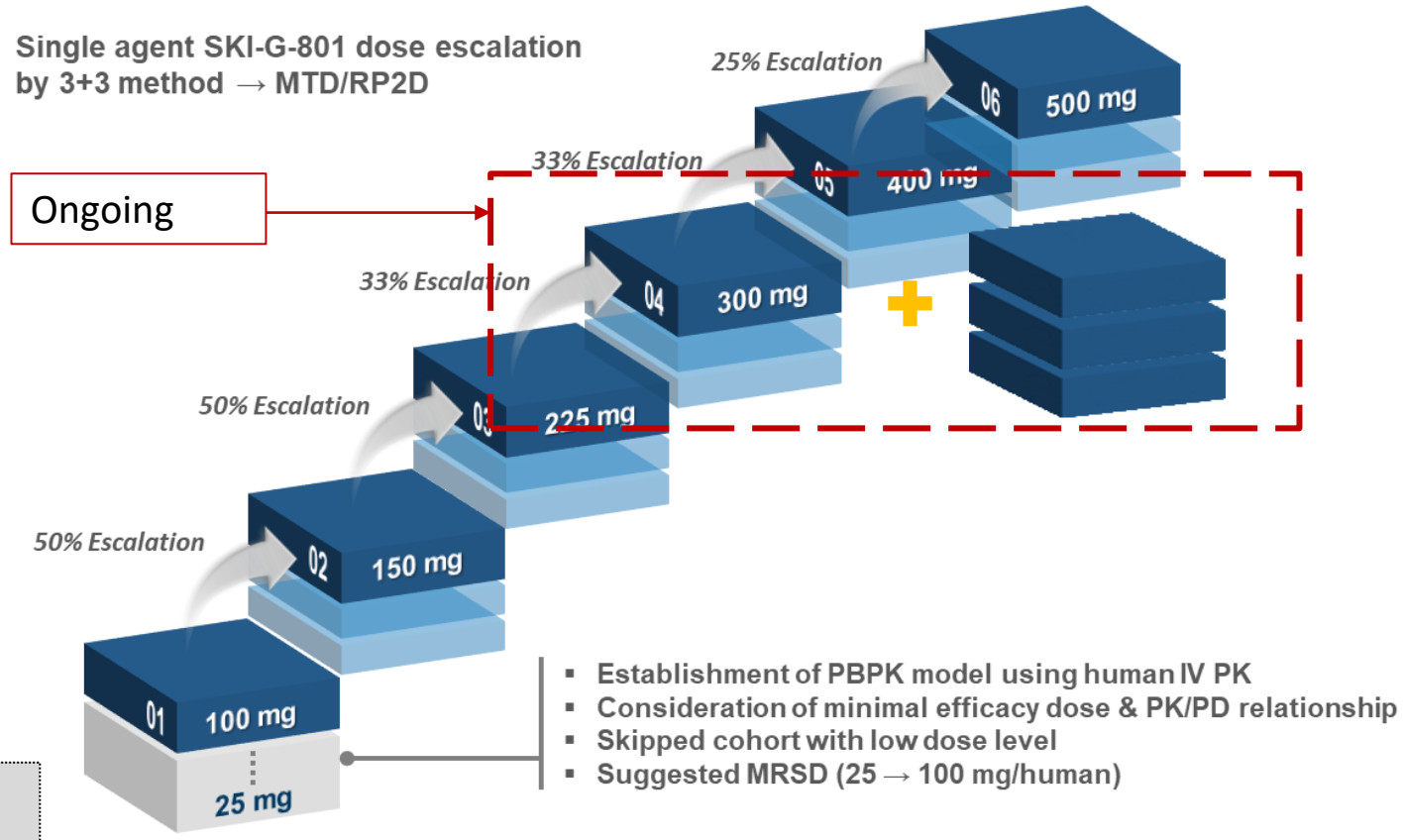
SKI-G-801; Preclinical Efficacy Highlight 3



소세포성폐암 PDX model on humanized NSG 마우스에서 종양성장 억제, 또한 anti-PD-1 병용투여군에서 시너지 효과 확인; CD8 T세포의 상당한 증가와 Treg 세포의 감소로 확인; 이는 anti PD-1 병용투여군에서 더 두드러짐을 single cell RNA sequencing으로도 추가 확인

SKI-G-801 for Solid Tumors; Clinical Development

- Open-label, 다기관, 고형암 환자에서 안전성, 내약성, 그리고 약물동태 (pharmacokinetics) 평가, 단독 투여 용량탐색시험
- 용량탐색 진행중, 100, 150, 225 mg 3가지 용량 완료
- 300 mg에서 DLT 관찰되어 추가 환자 등록
- 코호트 확장 예정



DLT: dose limiting toxicity 용량제한독성
MTD: maximum tolerated dose 최대내약용량
RP2D: recommended phase 2 dose 임상2상 권장용량
PBPK model: physiologically based pharmacokinetic model 생리학적약물동태모델
PK: pharmacokinetics 약동학 / PD: pharmacodynamics 약력학
MRSD: maximum recommended starting dose 최대임상시작용량

SKI-G-801; Clinical Development Timeline

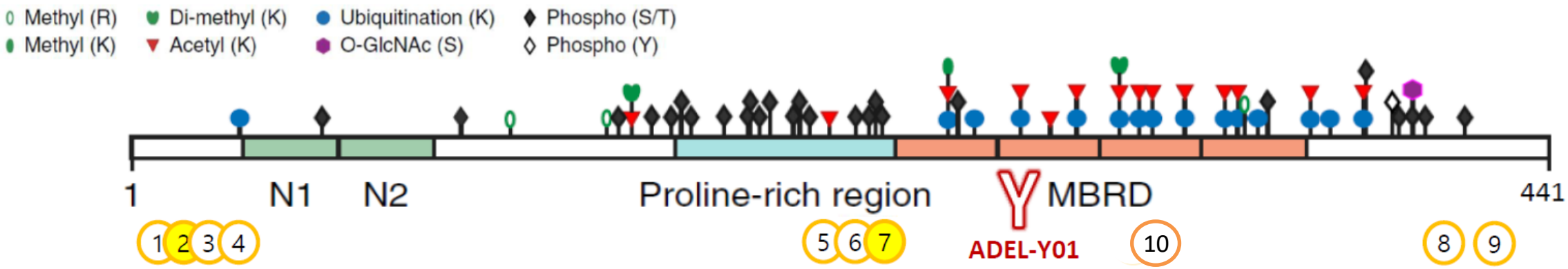
	2023				2024				2025			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Dose escalation												
IND amendment												
Combination Dose finding												
Cohort expansion PoC												

- Phase Ib/II 코호트 확장 스터디
- 면역관문억제제(ICB, immune checkpoint blockade) 치료에 불응하는 비소세포폐암 환자를 대상으로 Keytruda 병용

ADEL-Y01

Anti-tau AcK280 Antibody for Tauopathies including Alzheimer Disease

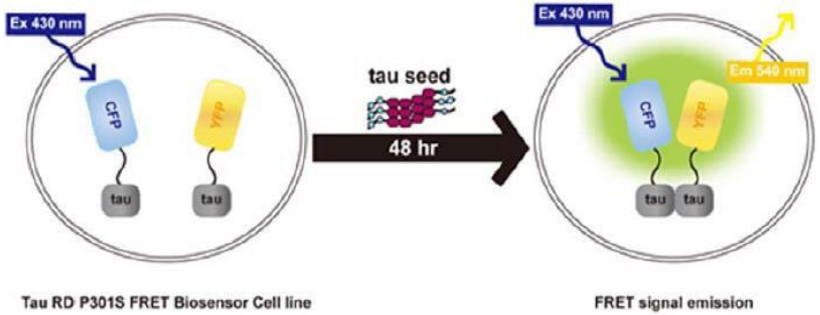
ADEL-Y01; 경쟁사 현황

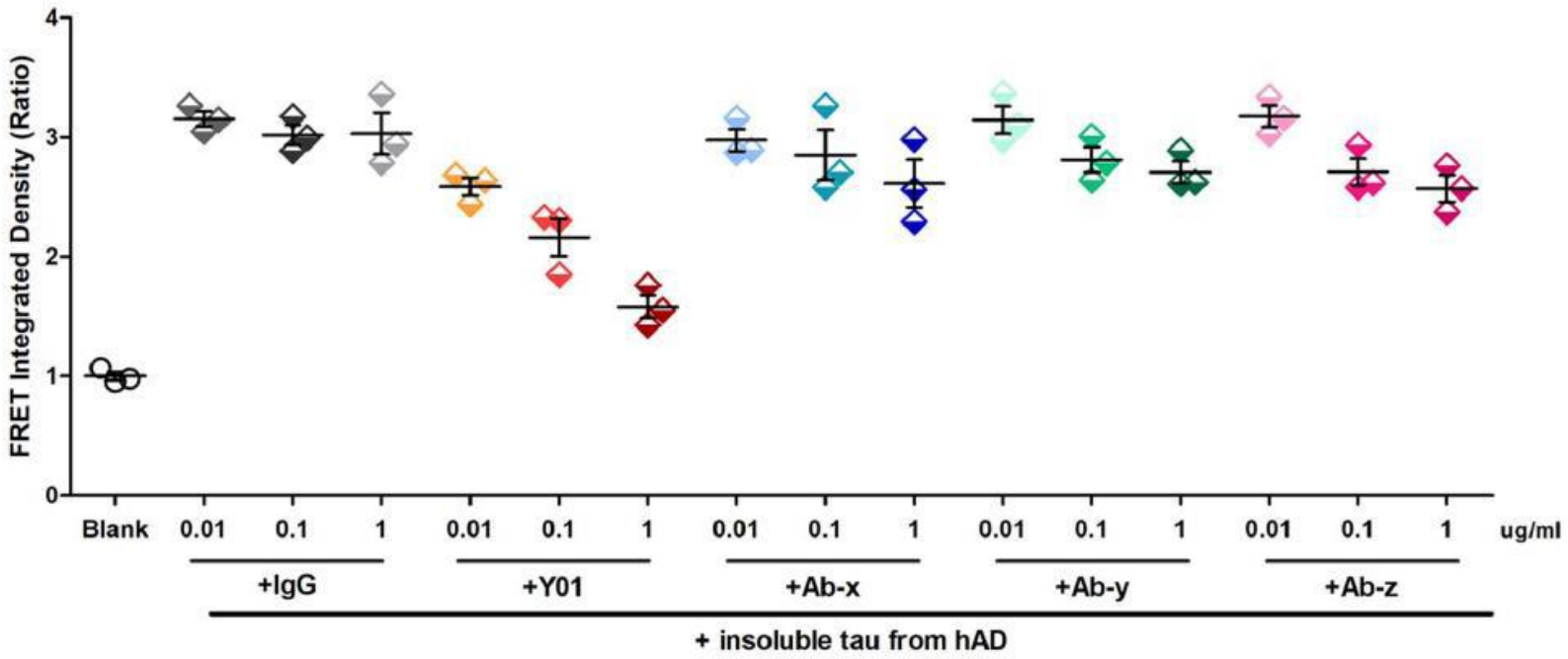


	Drug	Synoyms	Companies	Epitope	Clinical Trial Status
1	Zagotenemab	LY3303560, MC1	Eli Lilly	Tau aggregate (7-9:313-322)	Failed in P2
2	Gosuranemab	BIIB092, BMS-986168, IPN007	Biogen, BMS, iPerian	Secreted N-term fragment (15-24)	Terminated at P2
3	C2N-8E12	HJ8.5 (m)	Abbvie, C2N	Extracellular tau (25-30)	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

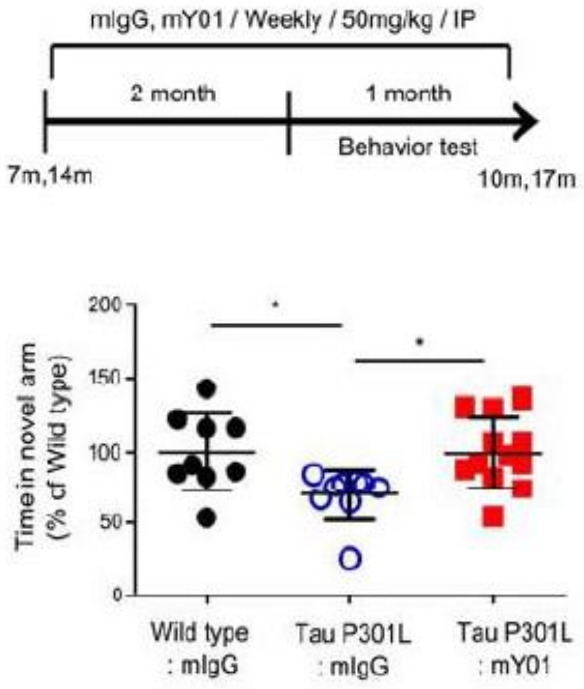
- Tau 단백질의 spreading과 seeding을 측정하기 위한 biosensor assay
- ADEL-Y01은 경쟁 항체보다 우수한 활성을 보임
- 알츠하이머 환자의 뇌척수액(CSF, cerebrospinal fluid)을 이용한 Ex vivo screening을 진행 중

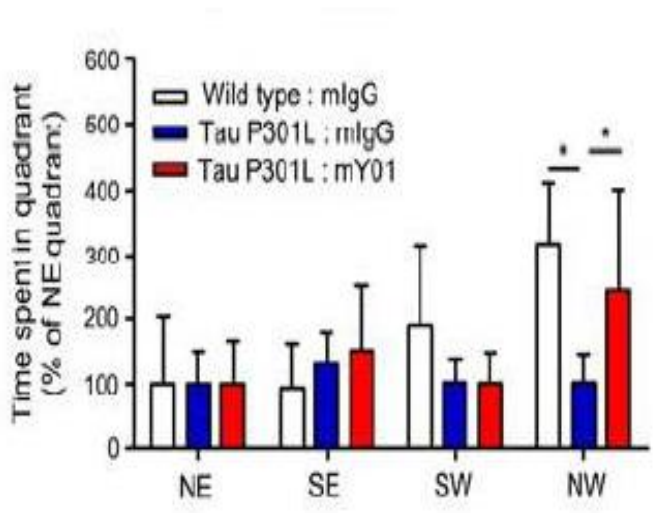


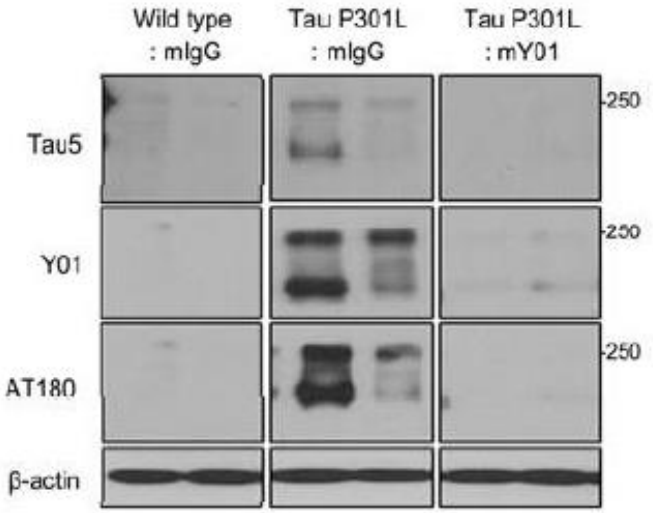


x = gosuranemab
y = bepranemab
z = E2814

ADEL-Y01; In Vivo 효능시험 (P301L 마우스 모델)

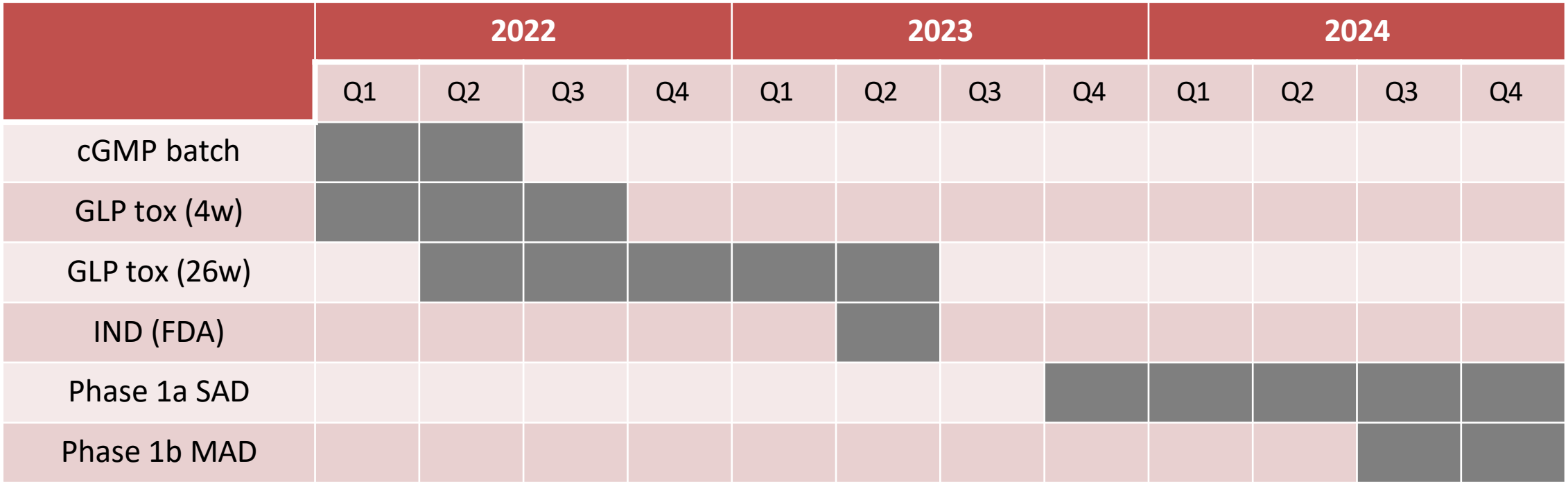






P301L Tau병증 마우스 모델에서 Y01 투여군은 대조군에 비해 뇌에서 타우 응집체의 축적을 방지하고 인지능력(Y-maze and water maze 시험)을 유의하게 개선함

ADEL-Y01; Development Timeline



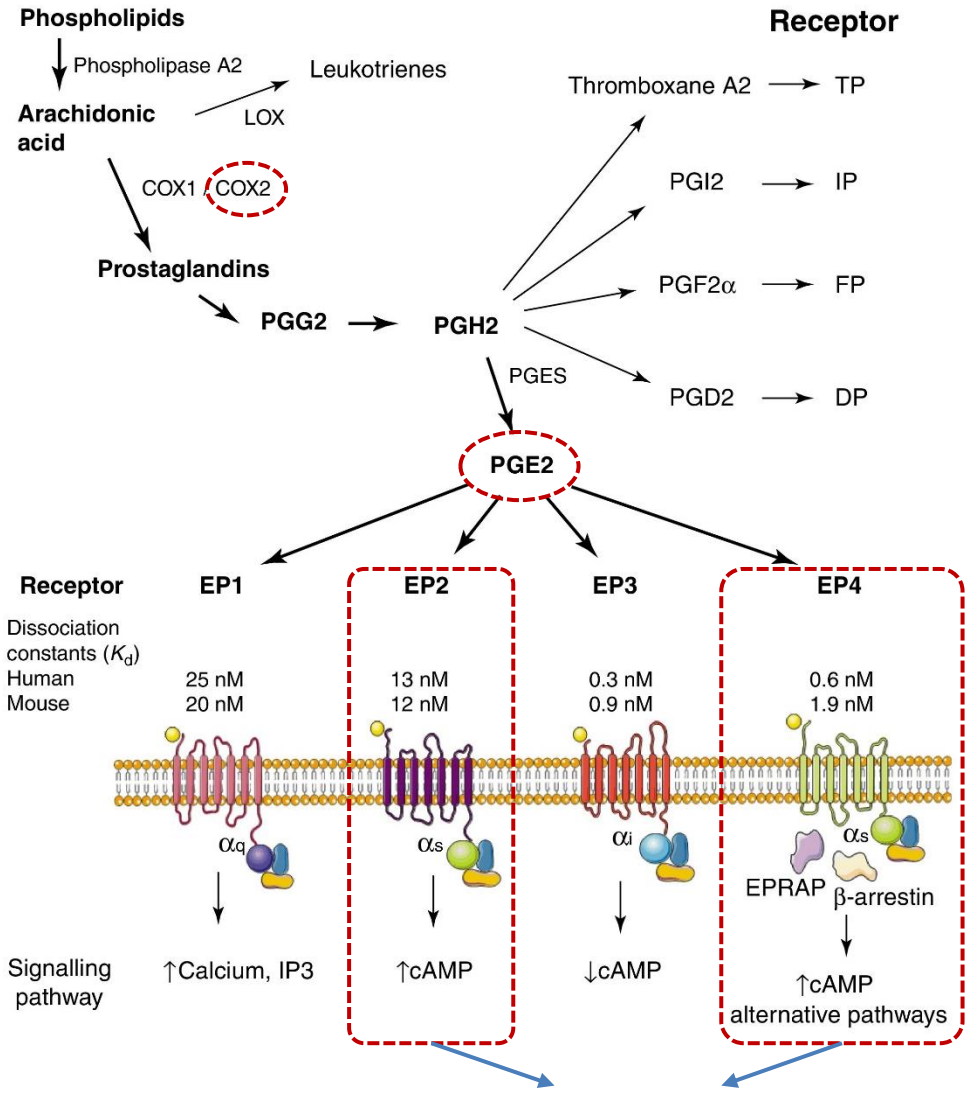
- GMP 생산 완료
- GLP 독성시험 (26주) 완료; 최대용량 (500mg/kg)까지 부작용 없음
- **2분기 미국 FDA IND 제출하여 4분기 임상1상 진입 예정**
- 폭넓은 전임상/임상 바이오마커 스터디 진행 혹은 계획중

SAD: single ascending dose study 단일용량상승시험 / MAD: multiple ascending dose study 다중용량상승시험

OCT-598

EP2/4 Dual Antagonist

Target Rationale



- **PGE2**와 PGE2 합성의 핵심적인 요소인 **COX2**는 결장암, 폐암, 유방암, 방광암, 피부암, 난소암 등 많은 암종에서 과발현 돼있는데, 이는 종양의 개시, 증식 전이 등에 기여함
- **COX2 억제제**에 의한 PGE2 생성 저해는 동물종양모델에서 종양의 성장을 억제했으나 **심혈관계와 위장관계에 위험성**이 있어 추가 약물 개발이 이루어지지 않음
- PGE2는 EP2와 EP4 수용체 활성화를 통해 세포내 cAMP level을 증가시켜 종양 형성을 촉진
- 유전적으로나 약리적으로 EP2와 EP4를 억제시켰을 때 동물모델에서 종양 성장을 억제

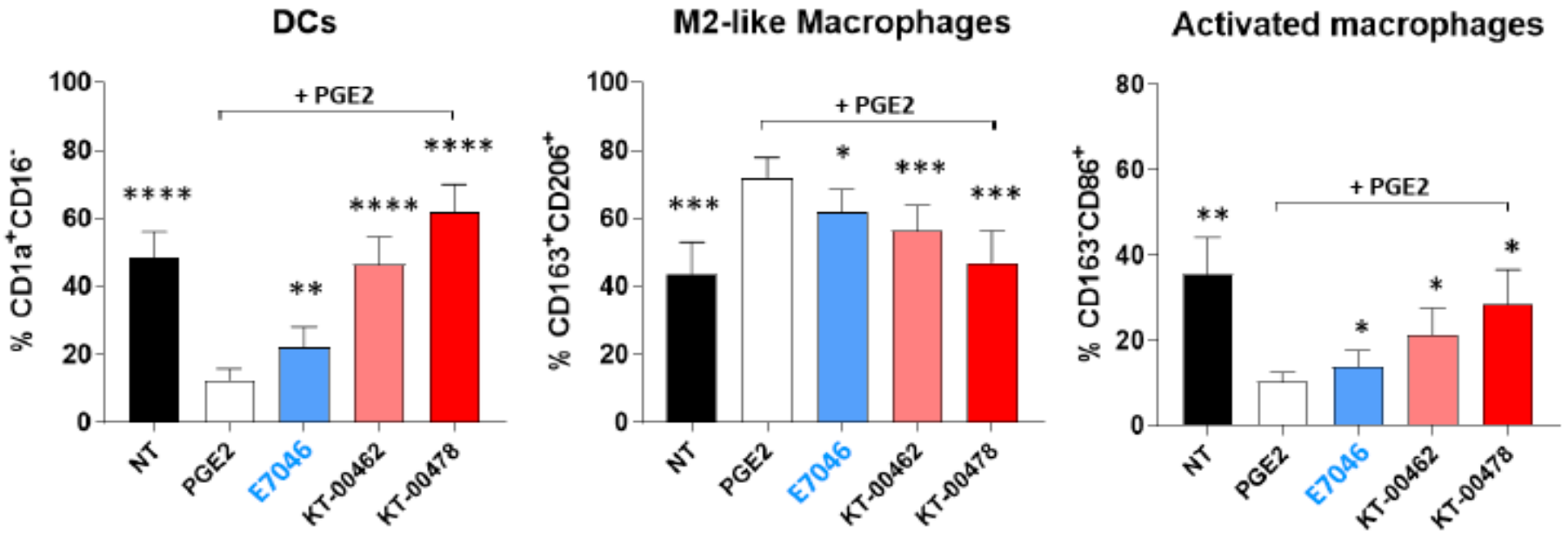
Pro-tumorigenic
(Tumor-promoting and immune-suppressive)

Kalinski P (2011) J.Immunology; Nakanish M et al (2013) Semin Immuopathol; 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	• NCT04344795 P1a/P2b (mono and with anti-PD-1)	• NCT03152370 P1 • NCT04432857 P1 (combo with anti-PD-1)	• NCT03155061 P1 (mono and combo with anti-PD-1) • NCT03661632 P1 (mono), P2 (combo with anti-PD-1	• NCT03696212 P1/2 (combo with anti-PD-1) • NCT03658772 P1 (combo with anti-PD-1)	• NCT04443088 P1 (mono)
Dose	BID	QD		300mg BID, 450mg q12h, 600mg q12h	QD

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

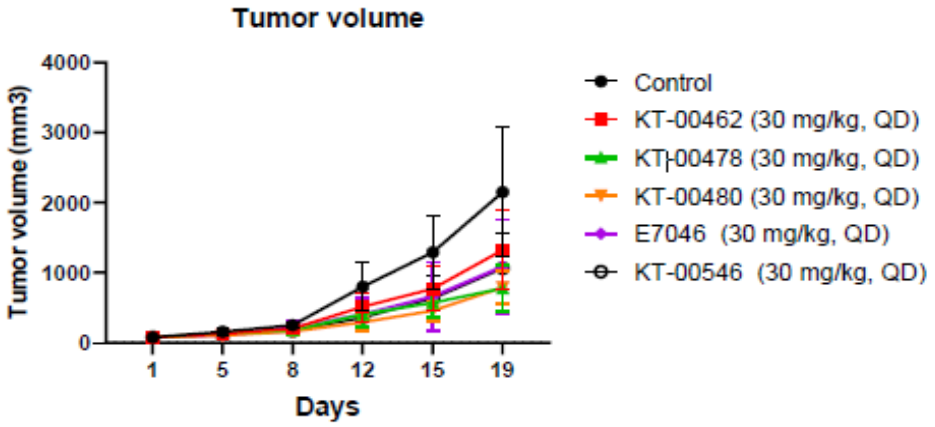


- PGE2: 100 nM
- Compounds at 500 nM

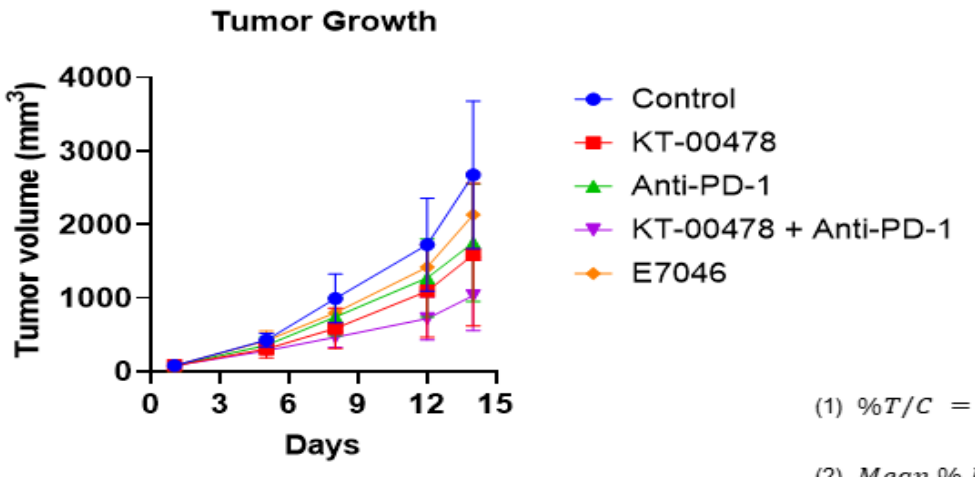
- OCT-598은 수지상세포와 M1 대식세포를 늘리고 M2 대식세포를 줄이는 등 PGE2로 유도된 인간 단핵구의 억제성 분화를 회복
- EP4 선택적 길항제인 E7046보다 우월한 효과 확인

In Vivo Efficacies in Syngeneic Mouse Tumor Models

➢ Single agent efficacy in MC38 model



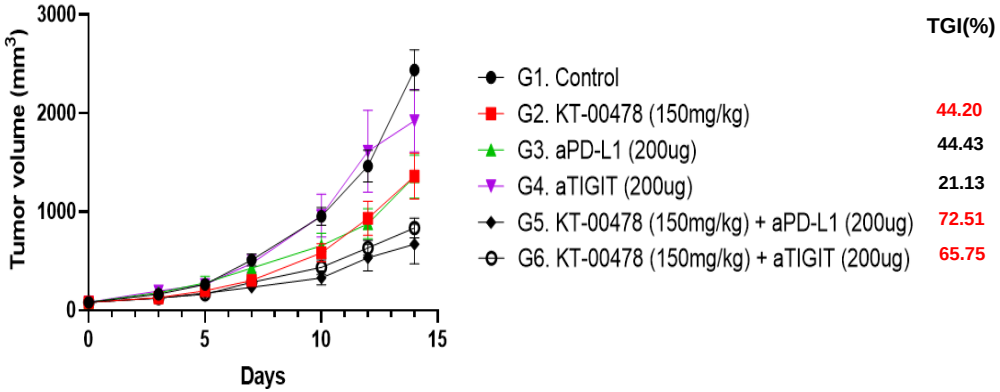
➢ Anti-PD-1 combination efficacy in CT26 model

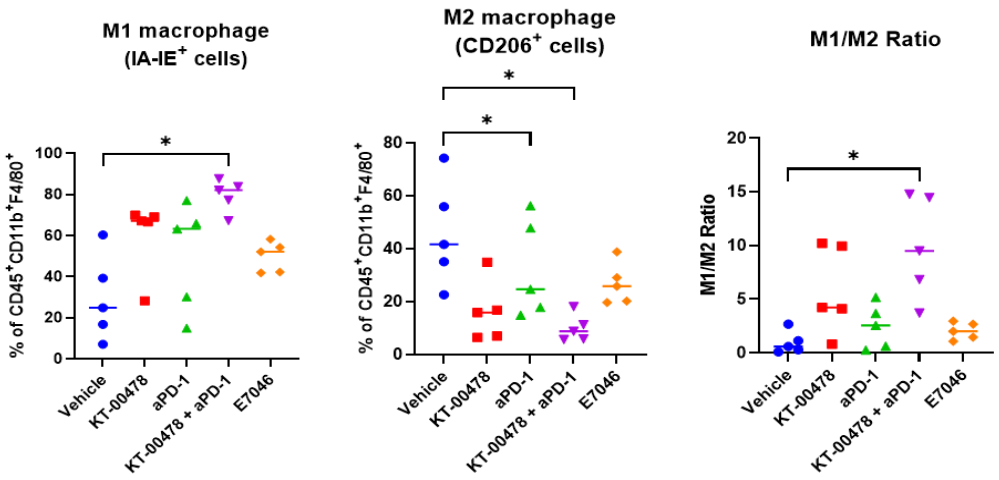


(1) $\%T/C =$

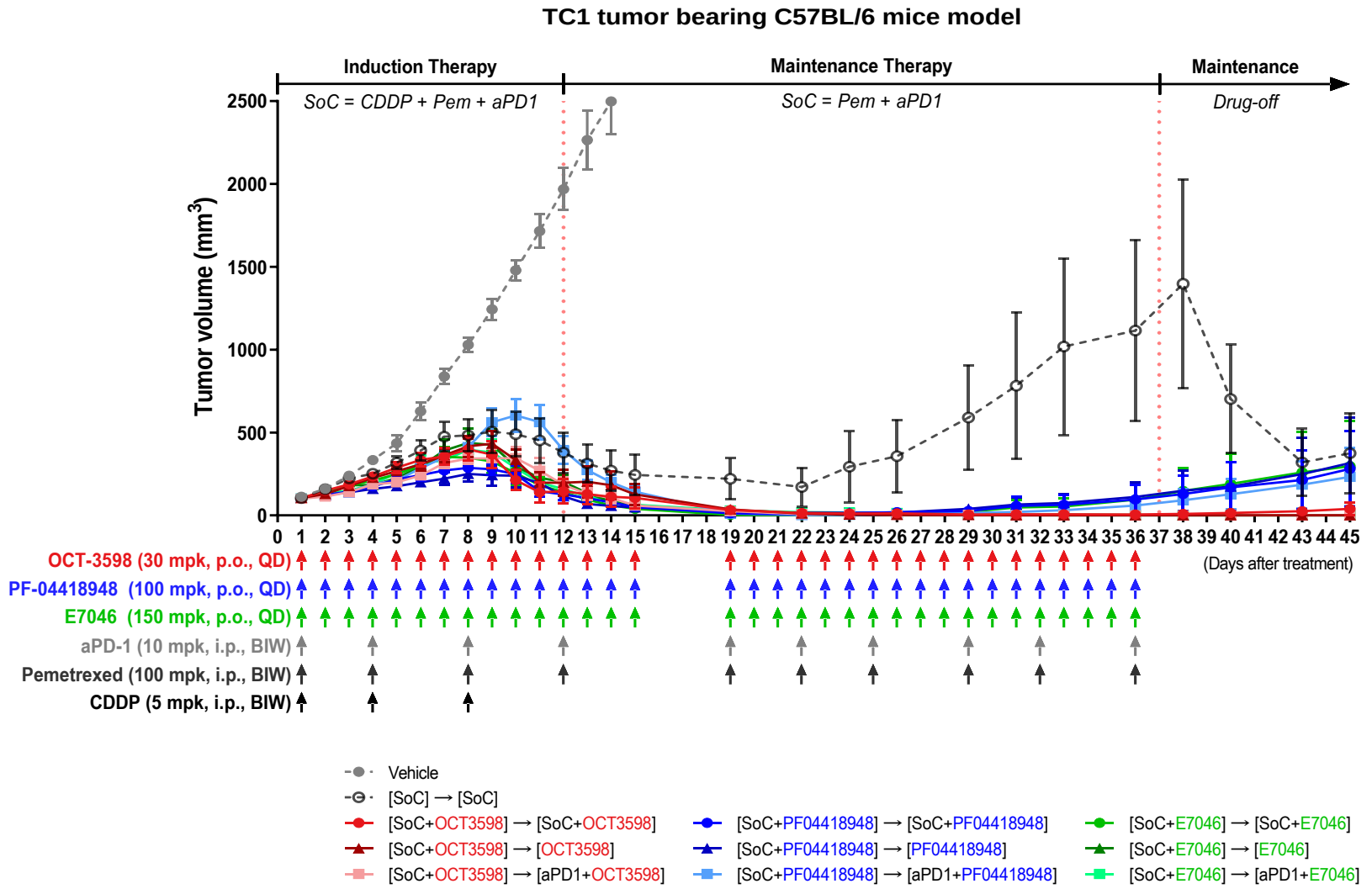
(2) $Mean\ \%\ I$

➢ Anti-TIGIT 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 진행중; AACR (2023년 4월) 발표 예정
- 공정개발, 시험생산, polymorph studies 착수
- DRF(dose range finding) 완료; GLP 독성을 비롯한 IND-enabling studies 3분기 진행예정
- 24년 2분기 IND 계획

Looking Ahead

Major Milestones in 2023

Cevidoplenib
ITP P2 Topline

Adel-Y01
FDA IND application

Adel-Y01
미국 임상 개시

1Q23

Cevidoplenib
- ITP P2 Topline

2Q23

Cevidoplenib
- ITP P2 CSR
- ITP P2 학회발표
- FDA ODD 신청

OCT-598
- AACR 학회발표

3Q23

SKI-G-801
- P1 Cohort expansion

Adel-Y01
- FDA IND application

4Q23

Adel-Y01
- 미국 임상 개시

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

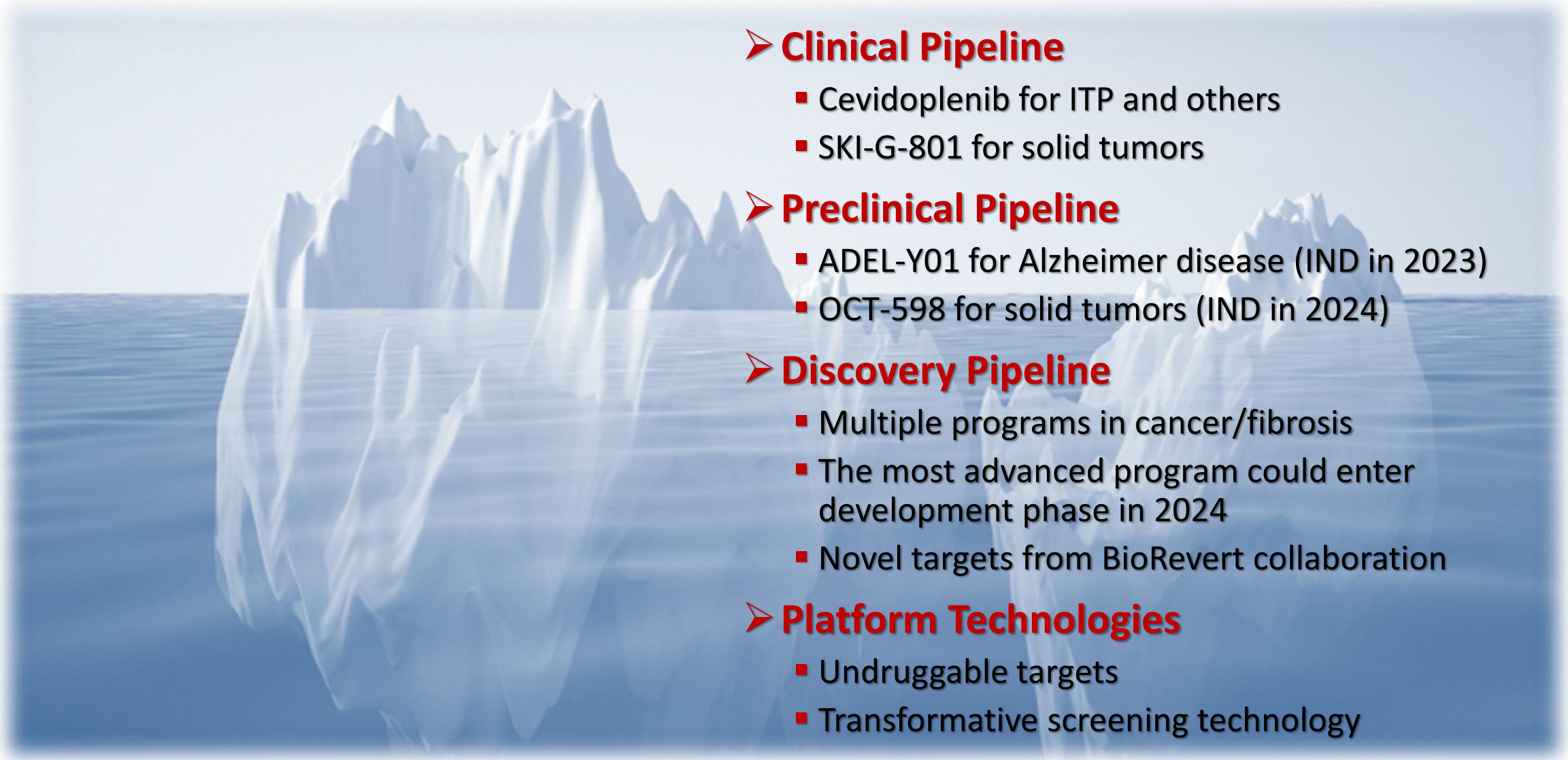
AACR
- OCT-598

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

3Q23

- **F/U BioEU and BioUSA**

The Best is Yet to Come



➢ 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 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