Oscotec Inc.

Translating Science into Medicine

March 2022

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Overview

About Oscotec Inc.

Overview

"At Oscotec, our mission is to create values by translating cutting edge science into innovative medicines for clinically unmet needs"

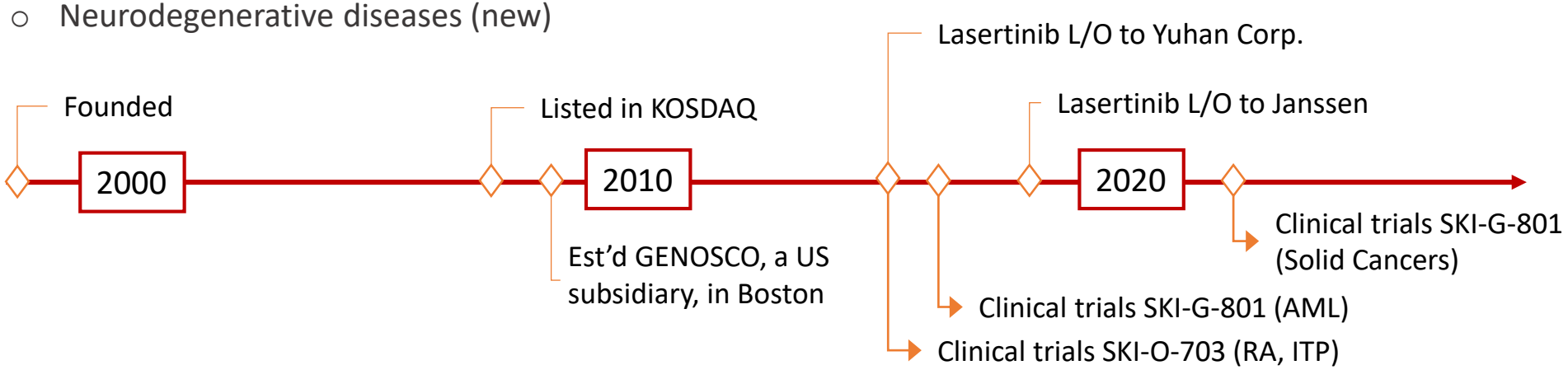
Profile

- Established in 1998, located at KoreaBioPark, Pangyo, South Korea
- Listed in KOSDAQ (2007); current market cap ~0.9B USD (as of February 2022)
- Paid-in Capital : 15B KRW (Outstanding shares : 30,206,525)
- No. of Employees : 54 (R&D – 29)
- Subsidiaries : Genosco (Boston), Ectodor (Boston)

Area

- Oncology and immuno-oncology
- Inflammation and autoimmune diseases
- Neurodegenerative diseases (new)

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 Chemistry, Pittsburgh Univ.
- Postdoc, California Inst. of Technology
- Sr. Research Fellow, Merck.
- Head 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

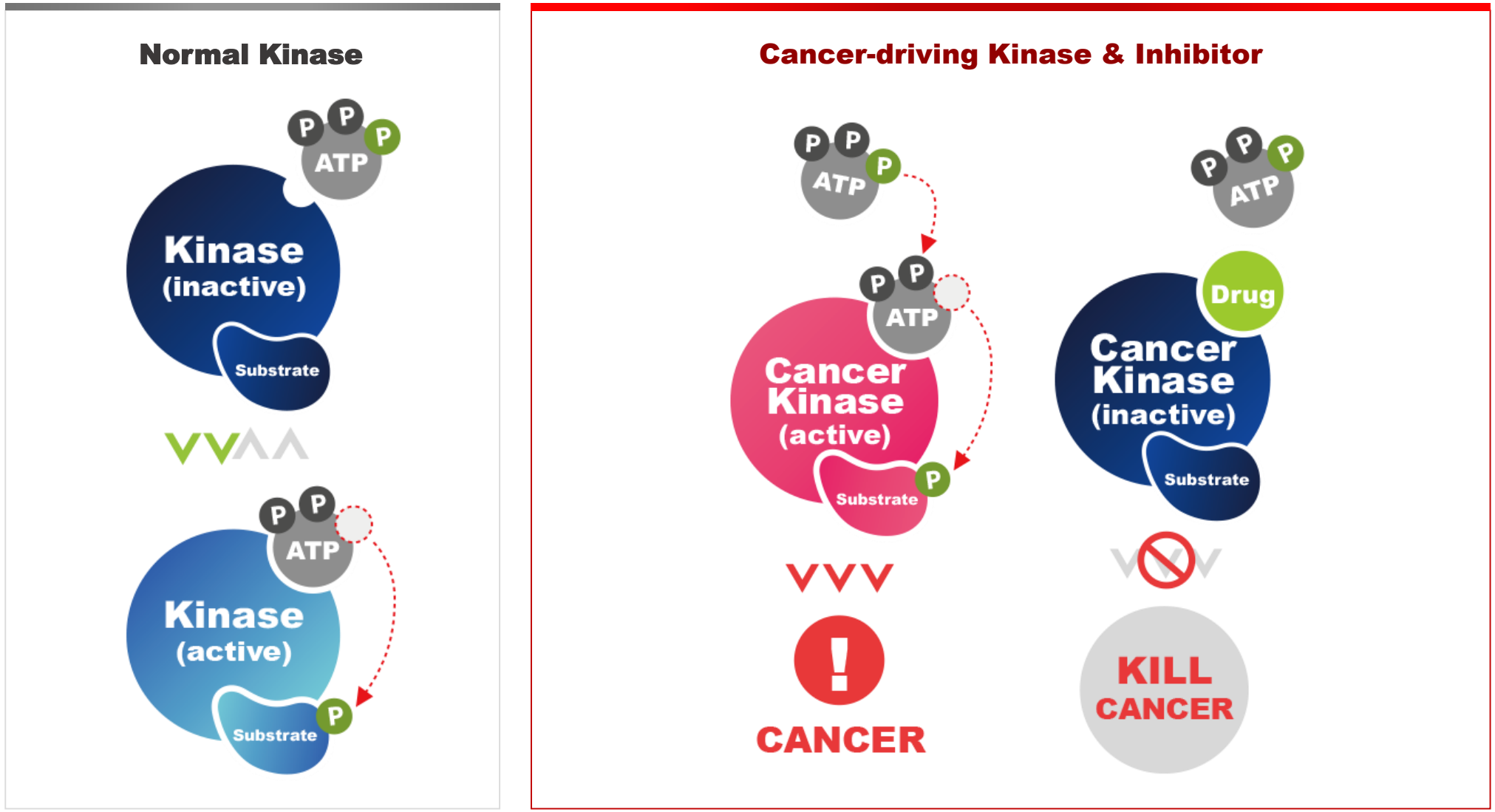
Katie Lee Ph.D. CEO

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

R&D Pipelines

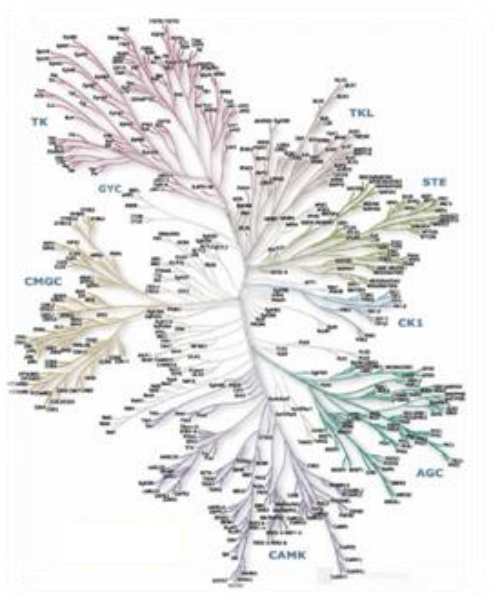
1) ***Lazertinib (GNS-1480, YH25448)***
   : EGFR Mutant Inhibitor › *NSCLC*
2) ***Cevidoplenib : SYK Inhibitor*** › *Autoimmune Diseases (RA, ITP, SLE..)*
3) ***SKI-G-801 : FLT3 Mutant Inhibitor*** › *AML*
4) ***SKI-G-801 : AXL Inhibitor*** › *Metastatic solid tumor (NSCLC, TNBC+)*
5) ***ADEL Y01 : Anti-Tau mAb*** › *AD, Tauopathies*

Kinase-Targeted Drug Discovery



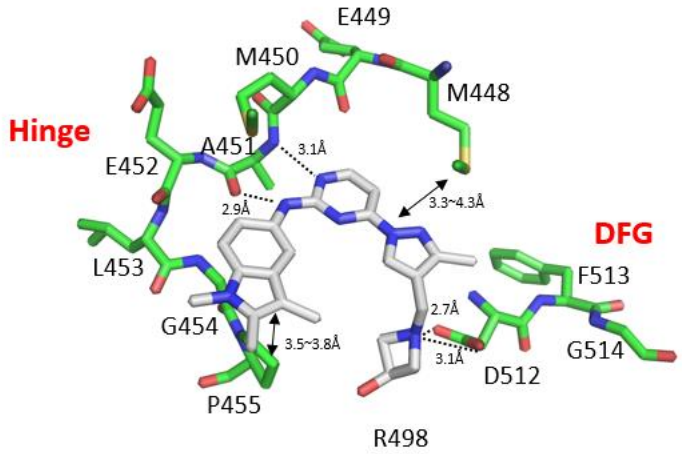
Focus on Selective Kinase Inhibitors

Kinase Selection



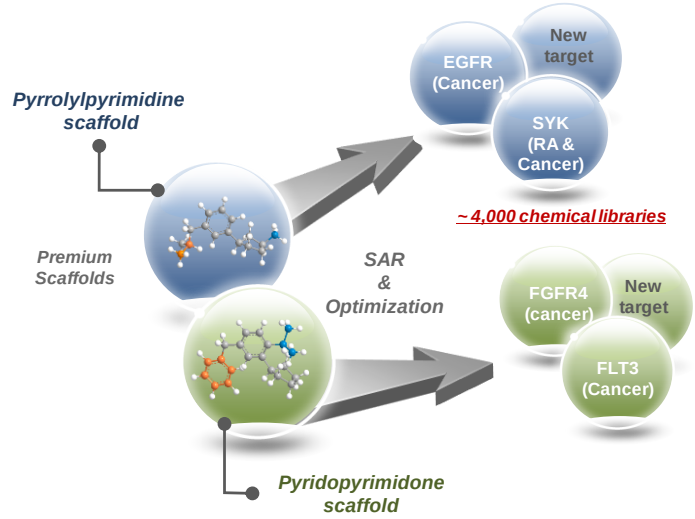
- 518 Kinases in the human genome
- Mediates critical signal transduction
- Selection of disease-relevant targets

Discovery Engine



- Expertise in structure-based drug design leading to high selectivity
- Rapid optimization of drug properties

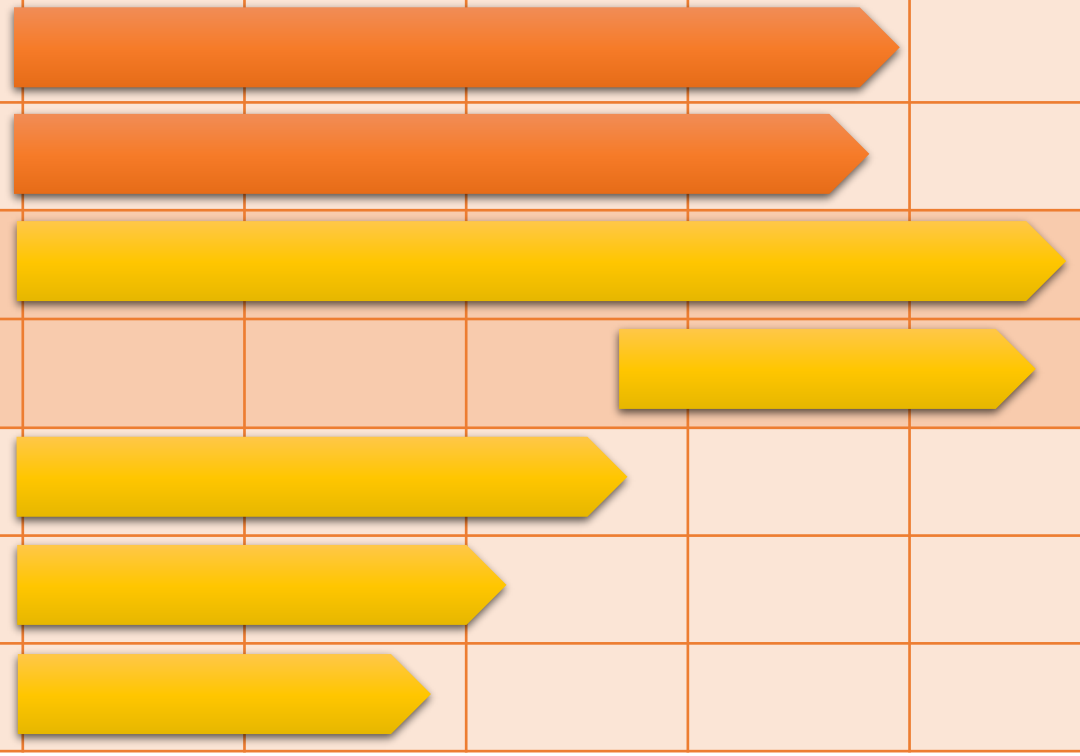
Focused Library



- Novel, proprietary scaffolds
- High quality compounds with narrow selectivity profile and inherently favorable drug properties

Clinical Development Pipeline

Disease Area	Program	Target	Indication	Development Phase					Partners
				Discovery	Preclinical	Phase I	Phase II	Phase III	
Immunology	**Cevidoplenib** (SKI-O-703)	SYK	RA						
			ITP						
Oncology	**Lazertinib** GNS-1480 YH25448	EGFR (T790M)	NSCLC (monotherapy)						Yuhan
			NSCLC (combination)						Yuhan/ Janssen
	SKI-G-801	FLT3/AXL	AML						
			Solid tumors						
CNS	**ADEL-Y01**	Tau	AD, Tauopathies						Adel

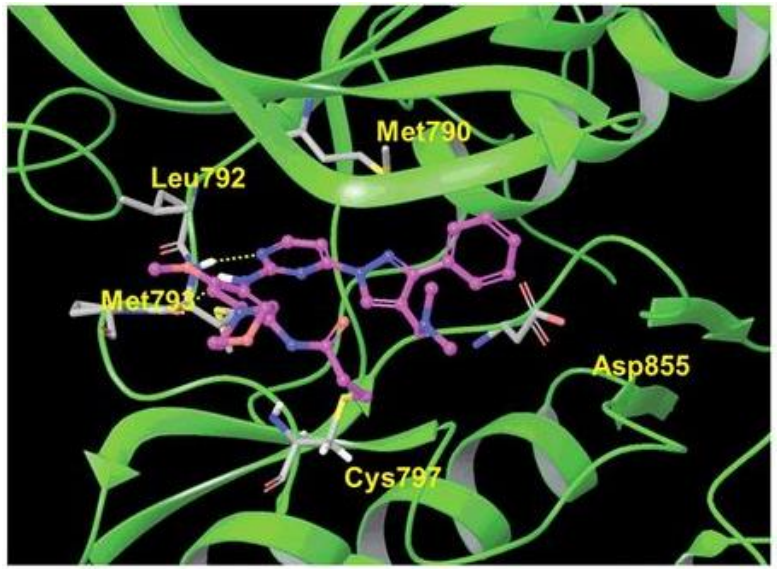


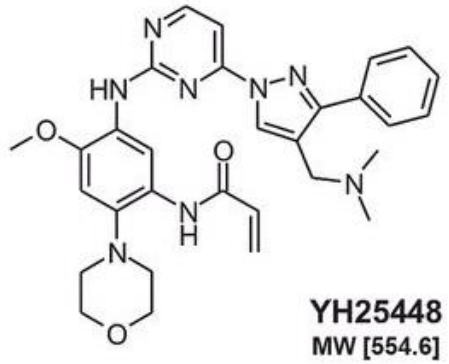
RA = Rheumatoid arthritis
ITP = Idiopathic thrombocytopenic purpura
NSCLC = Non-small cell lung cancer

AML = Acute myeloid leukemia
AD = Alzheimer Disease

Lazertinib | EGFR Mutant Selective Inhibitor

Indication	Non-small cell lung cancer (NSCLC)
Treatment Principle	Inhibition of EGFR double mutant (L858R/Δexon19)/T790M
Market Size	Up to $7B (2024 Est.)
Competitiveness	Superior efficacy with minimal side effects
Current Development Status	• Monotherapy; 2nd line Phase II completed, 1st line Phase III underway (Yuhan) • Combination with amivantamab; 1st line Phase III initiated in Q4 2020 (Janssen) & 2nd/3rd line Phase III in Q4 2021
Miscellaneous	Licensing deals • Oscotec to Yuhan (2015); 1.5B KRW upfront, 60:40 revenue share • Yuhan to Janssen (2018); 50M USD upfront, 1.205B USD total + royalties Expected approvals to market • Domestic Release in 3Q 2021 • NDA filings with US FDA expected in 1H 2022





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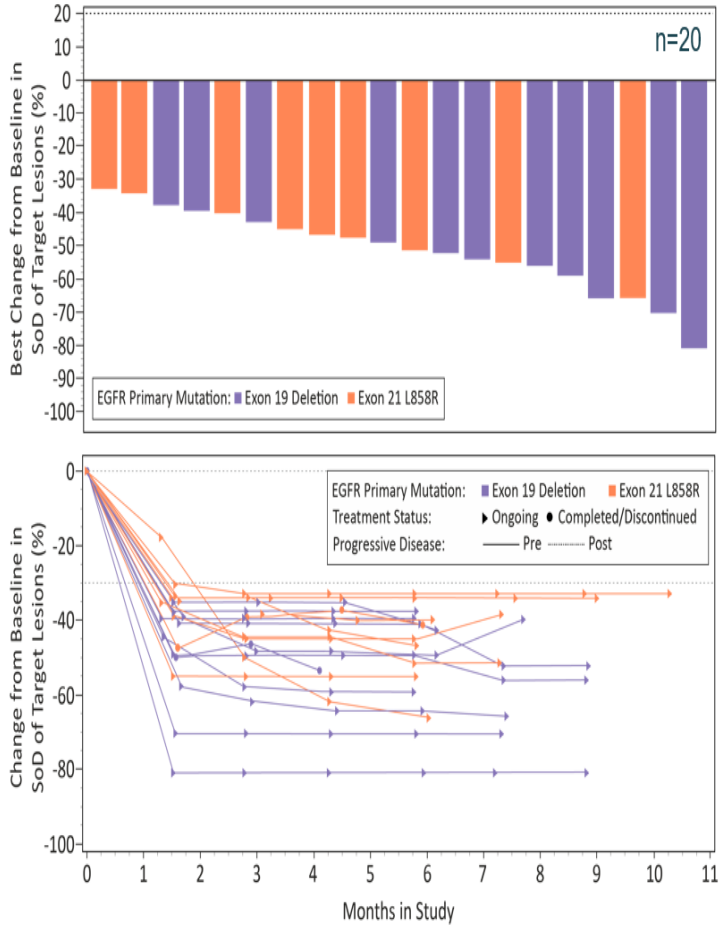
Lazertinib | Efficacy in Human – Combo.

Combination Efficacy in Treatment-naïve Patients



- **ORR: 100% (95% CI, 83 – 100)**
  - 20 PR
- **CBR: 100% (95% CI, 83 – 100)**
- **mDOR: not estimable**

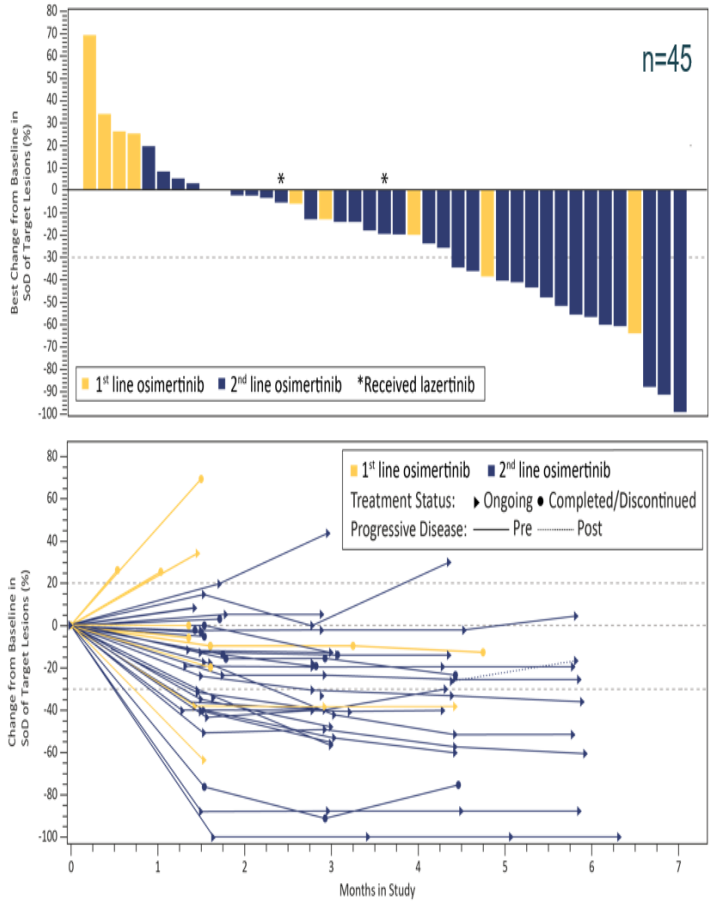
- **Median follow-up**: 7 mo (4 – 10)
- **Median treatment duration**: 7 mo (3 – 10)

Rapid time to first response: Median 1.5 months (1.2 – 2.6)

Responses were assessed by investigator per RECIST v1.1. mDOR, median duration of response.

Cho et al. 45th ESMO Congress 2020. Abstract #2172
CHRYSALIS Phase 1 in EGFRm NSCLC

Combination Efficacy: Osimertinib-resistant, Chemo-naïve Patients



- **ORR: 36% (95% CI, 22 – 51)**
  - 1 CR
  - 15 PR (1 pending confirmation)
- **CBR: 60% (95% CI, 44 – 74)**

Median follow-up: 4 mo (1 – 7)

Biomarker and CNS analyses ongoing and will be presented at future meeting

Four patients did not have post-baseline disease assessments and are not included. Responses were assessed by investigator per RECIST v1.1. CBR, clinical benefit rate (PR or better or stable disease SD for at least 2 disease assessments); CR, complete response; ORR, overall response rate; PR, partial response; SD, stable disease; SoD, sum of diameters

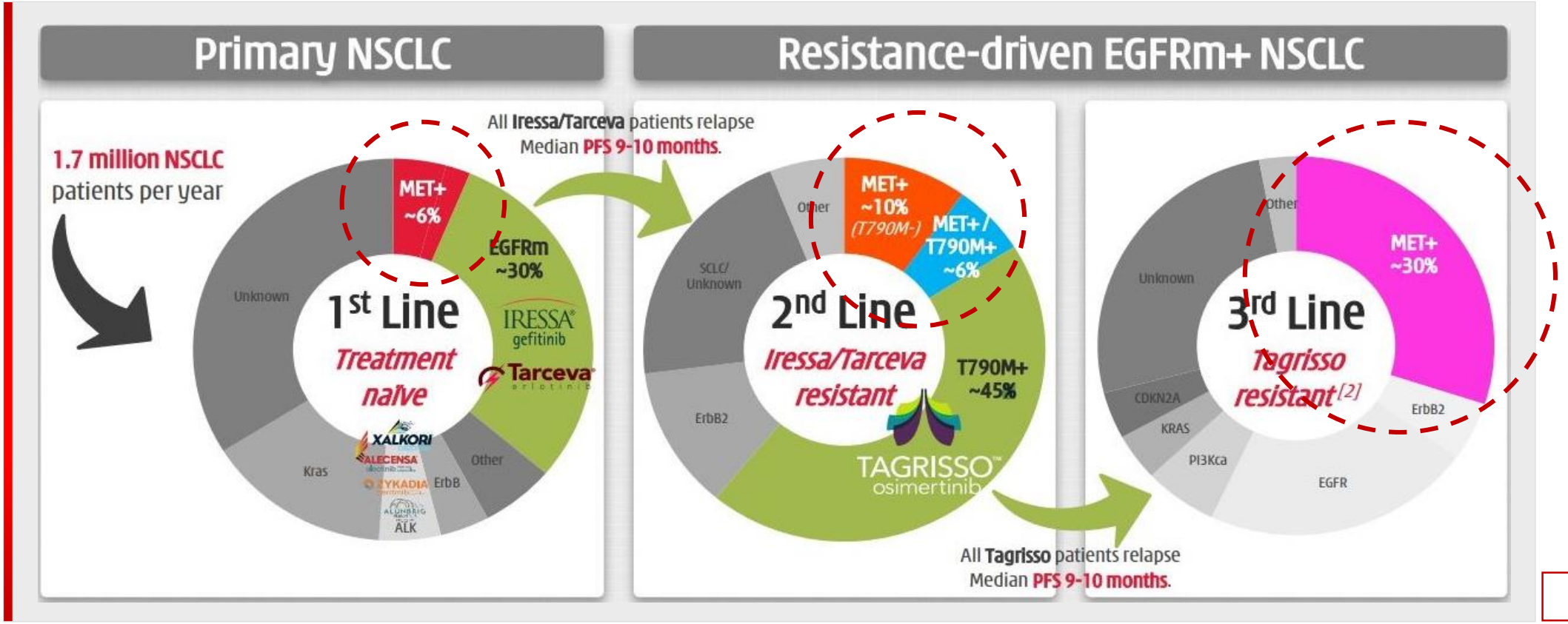
Cho et al. 45th ESMO Congress 2020. Abstract #2172
CHRYSALIS Phase 1 in EGFRm NSCLC

Oscotec Inc.

Drug-resistant MET Amplifications

- EGFR mutation in approx. 30% of NSCLC patient
- T790M mutation in 45~50% of drug-resistant patient after 1st Line Treatment
- MET amplification in approx. 30% of drug-resistant patient after 2nd line Treatment

Source : Chi-Med presentation.

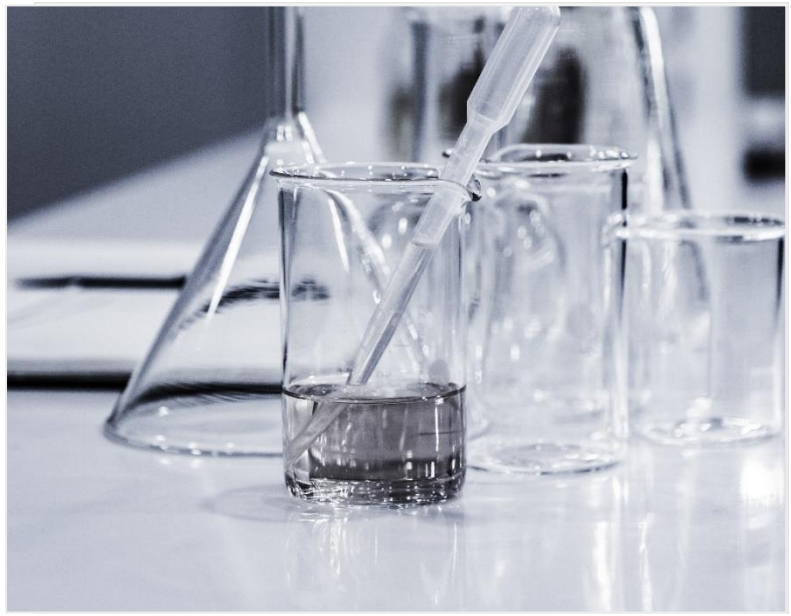


Link

Lazertinib | Phase II, Phase III & Release Est.

Cevidoplenib | Selective SYK Inhibitor

Indication	Inflammatory autoimmune diseases – Rheumatoid arthritis (RA) – Immune Thrombocytopenia (ITP) – Systemic lupus erythematosus (SLE) – Other autoimmune dermatitis, vasculitis, colitis, etc
Treatment Principle	Blocking inflammatory signals downstream of B cell receptors, γδT cell receptors, and Fc receptors
Market Size	ITP; $520M (2020)
Competitiveness	Superior safety due to excellent selectivity The first-in-class, bona fide SYK inhibitor
Current Development Status	• Phase IIa in RA wrapped up, CSR in Feb 2021 • Phase II in ITP ongoing
Miscellaneous	• Sponsored by KDDF (Phase IIa study) • Multiple preclinical studies ongoing in preparation for indication expansion • Global partnering opportunities explored from 2021 for further development



Cevidoplenib

SYK Inhibitor

Cevidoplenib | Superior Efficacy in a Mouse ITP Model

Mouse ITP model

- Platelet count lowered by stimulation of aCD41 Antibody (2μg)

Day-1

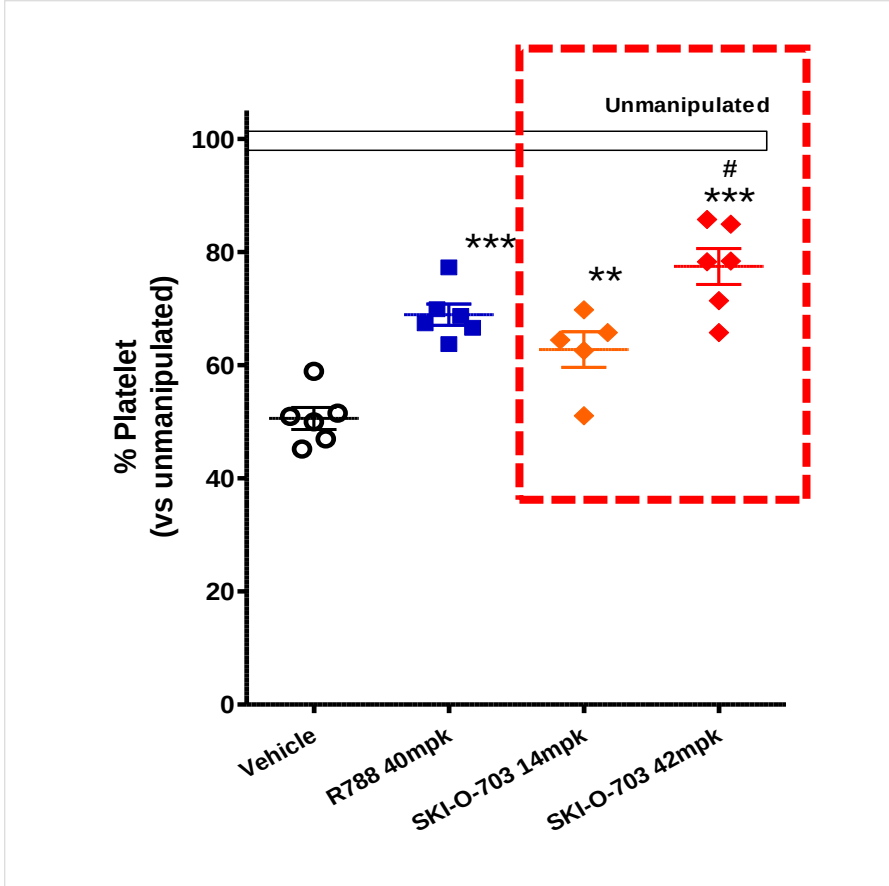
- 9 am : collecting bleed & analyzing platelet count
- 1 pm : inhibitor oral dosing

Day 1

- 1 pm : inhibitor oral dosing
- 2 pm : aCD41 Ab, i.p. dosing

Day 2

- 1 pm : inhibitor oral dosing
- 2 pm : collecting bleed & analyzing platelet count

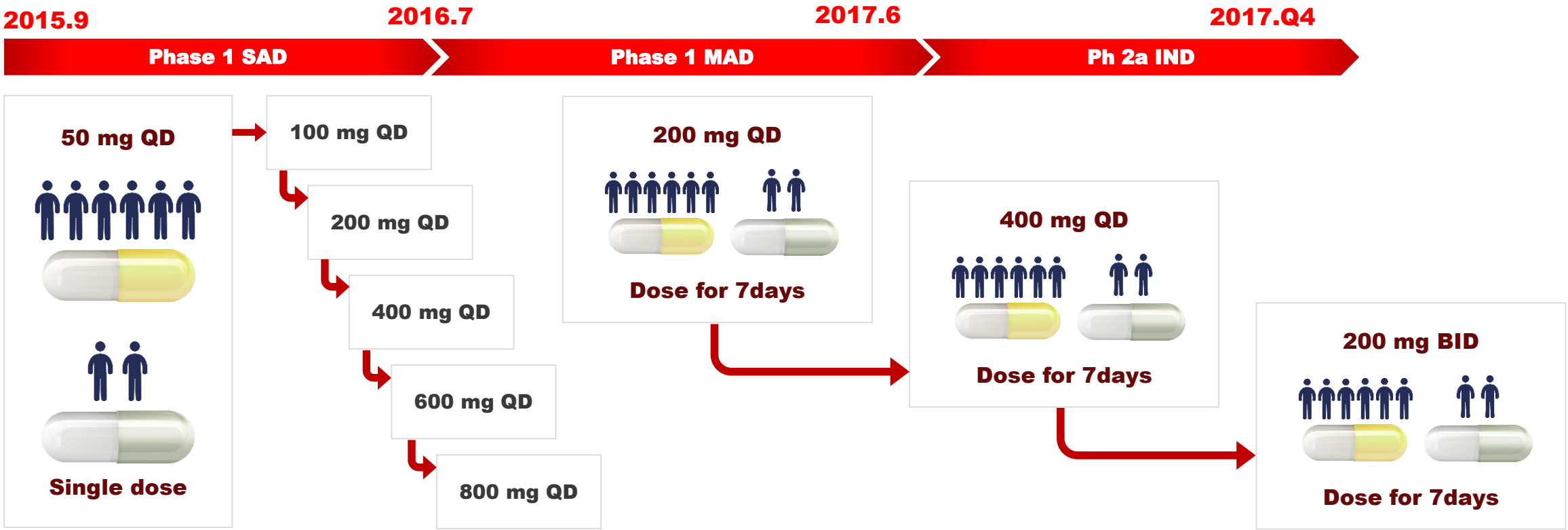


- Platelet count rescued in the presence of SYK inhibitor
- SKI-O-703 exhibits superior efficacy to R788
- R788 (fostamatinib; Rigel) approved for ITP (Apr 2018)

*Two tailed Student *t-test* vs Vehicle group, * p<0.05, ** p<0.01, ***p<0.001

Two tailed Student *t-test* vs R788 group, # p<0.05,

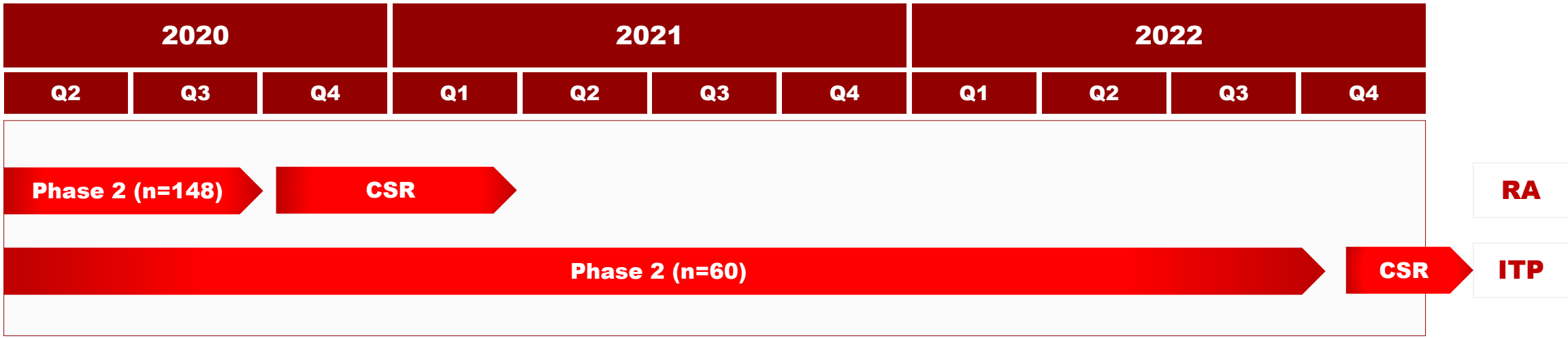
Cevidoplenib | Phase I Clinical Trial



- Healthy adult volunteer : 48 subjects
- Safe and well tolerated by both male and female subjects
- No significant findings in vital signs, ECG, and lab safety tests
- Dose proportional PK (AUC and Cmax)

- Healthy adult volunteer : 24 subjects
- Dosing period : 7 days
- Safe and well tolerated in all doses
- No significant findings in vital signs, ECG, and lab safety tests
- Dose proportional PK (AUC and Cmax)

Cevidoplenib | Phase IIa Proof-of-Concept Studies



I. Rheumatoid Arthritis (RA)

- RA with inadequate response to csDMARDs or anti-TNFa biological agent(s)
- Dose : placebo, 100, 200, 400 mg (bid)
- Dosing period : 12 weeks
- 163 patients of 58 sites in 7 countries – US, EU, Korea
- FPFV : April 2019

II. Immune Thrombocytopenia (ITP)

- ITP failed to respond or relapsed after at least 1 prior therapy
- Dose : placebo, 200, 400 mg (BID)
- Dosing period : 12 weeks
- 60 patients of 26 sites in 5 countries – US, EU, Korea
- FPFV : December 2019

SKI-G-801 | FLT3/AXL Dual Inhibitor

Molecular Target	FLT3	AXL
Indication	• FLT3-positive AML (acute myeloid leukemia ; FLT3-ITD 20-30%, FLT3-TKD 8-12%)	• Solid tumors incl. NSCLC and SCLC (immuno- and chemo-combinations)
Treatment Principle	• Blocking FLT3 mutation-driven proliferation of AML blasts and drug resistance	• Reversing AXL-mediated immunosuppression in the tumor microenvironment • Thwarting development of therapy-resistance
Market Size	$1B (2021 est.)	$39B (2025 est.)
Competitiveness	• Superior potency and selectivity • Clinically proven tolerability	• Remarkable efficacies shown in various preclinical models incl. humanized mouse PDX model
Current Development Status	• Phase Ia dose escalation study completed (CSR in 1Q 2022) • Phase Ib PoC studies under review	• Phase I studies initiated in Jan. 2022
Miscellaneous	• Sponsored by MOHW • HK Lee et al., Blood 2014 (IF 9.8) • FDA Orphan Drug Designation (2018)	• Presented at AACR (2019, 2020, 2021) • Publication in CTI 2021(IF 6.8) and Frontiers in Oncology 2022 (IF 6.2) • Bemcentinib (BerGenBio) in multiple PII clinical trials (AML, NSCLC, melanoma, and COVID-19)

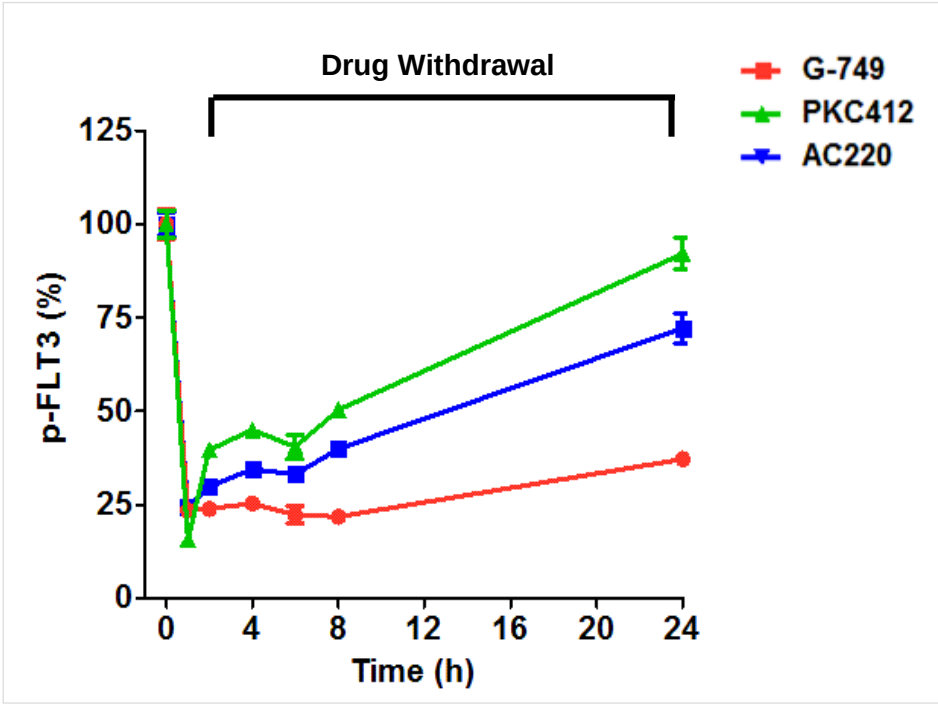
SKI-G-801 | Drug-resist. mutations / Sustained Inhibition

A Potent anti-leukemic effect of drug-resist. FLT3 mutants

Compound	BaF3 cells with FLT3 mutation (IC_{50}, nM)			
	ITD	ITD/F691L	N676D	D835Y
G-749	8.0	38.3	20.4	3.4
Quizartinib (AC220)	1.1	858.5	14.2	73.8
Gilteritinib (ASP2215)	16.0	163.6	25.4	4.1
Midostaurin (PKC412)	21.6	16.1	128.7	11.4

- G-749 (free base of SKI-G-801) potently inhibits proliferation of tested drug-resistant cells.

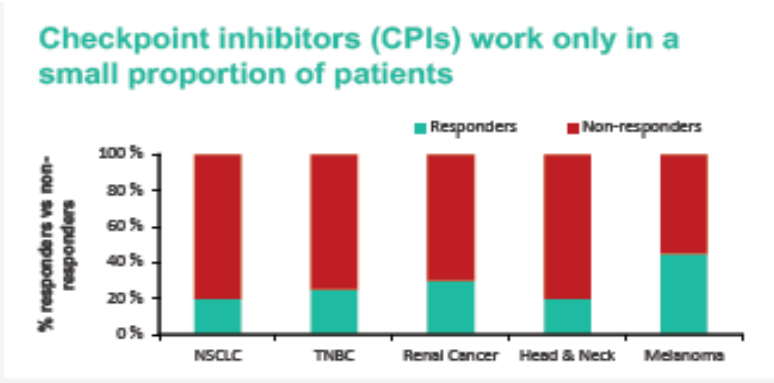
B Persistent anti-leukemic activity

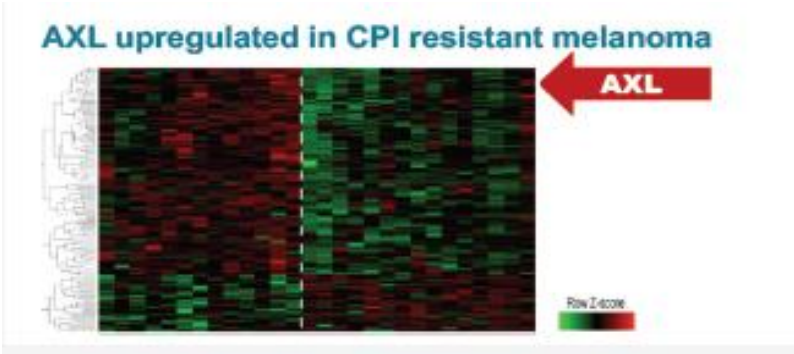


- After short incubation and wash-out, the inhibition of p-FLT3 is sustained by G-749 for 24 hours, whereas it is gradually reduced by AC220 or PKC412 in a time dependent manner.

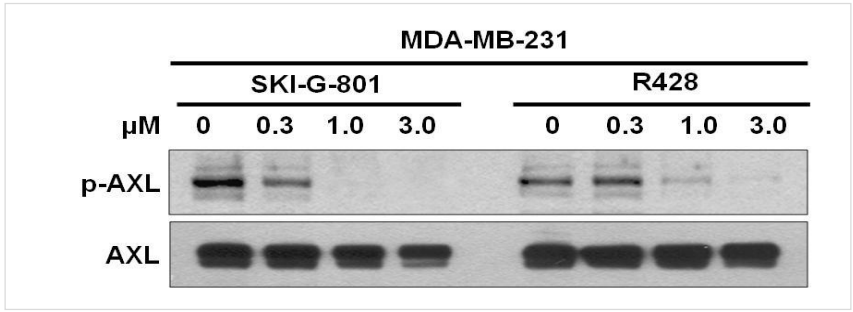
SKI-G-801 | AXL Inhibition – Rationale/Differentiation

A CPI response vs AXL upregulation

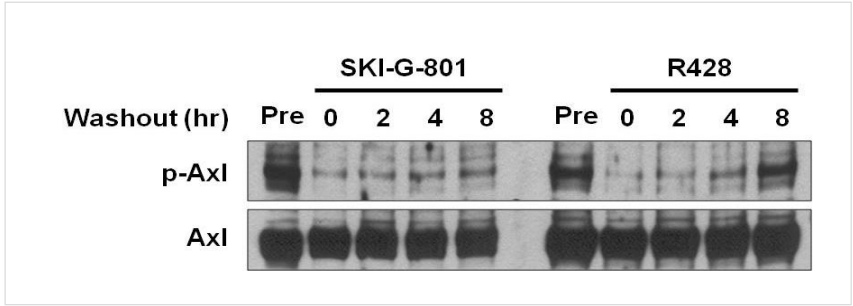




B P-Axl inhibition (vs R428)



C Prolonged p-Axl inhibition (vs R428)

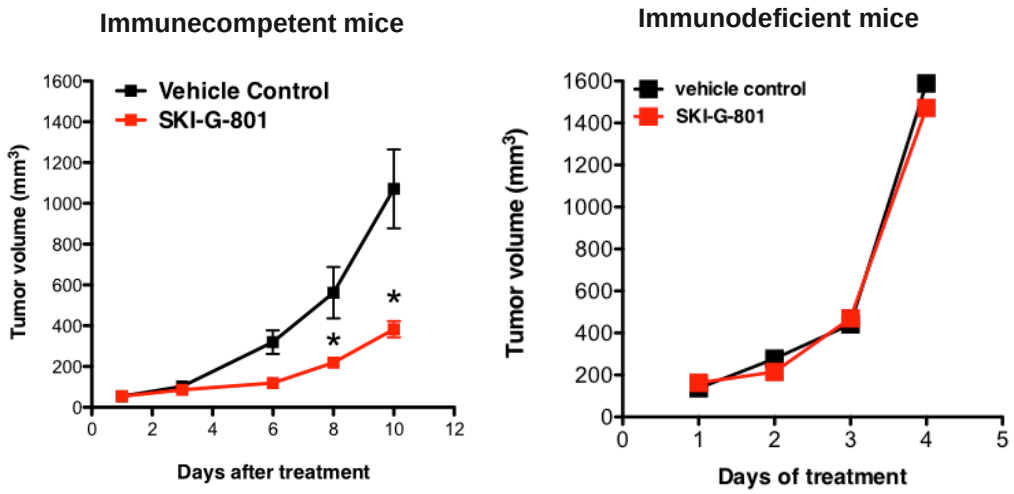


- AXL activation is thought to be an important resistant mechanism to immune checkpoint blockade
- SKI-G-801 inhibits AXL in MDA-MD-231 cells as potently as R428
- SKI-G-801 maintains AXL inhibition for 8 hours after wash-out, while R428's activity gradually declines

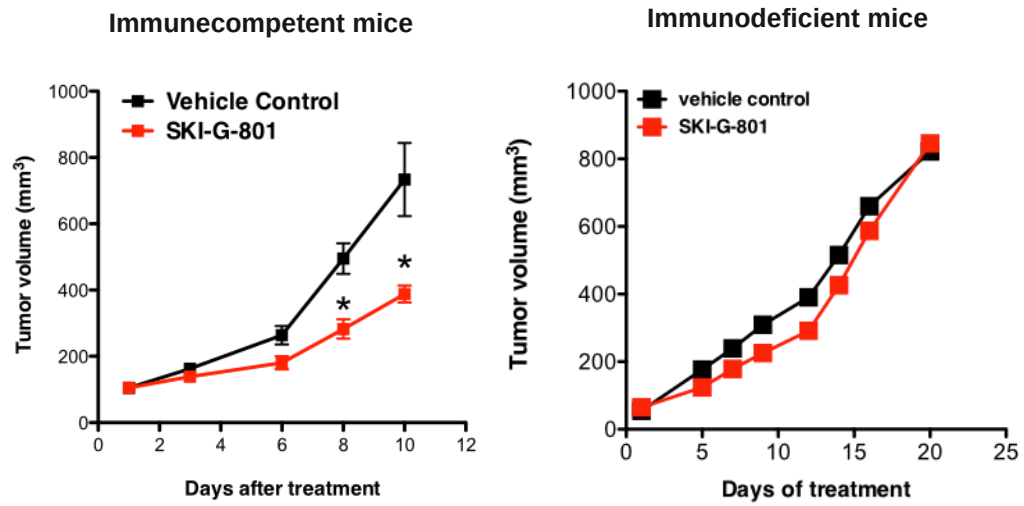
SKI-G-801 | Immune-mediated Anti-tumor Effect

Anti-tumor effect dependent on immune response

B16F10 tumor



4T1 tumor

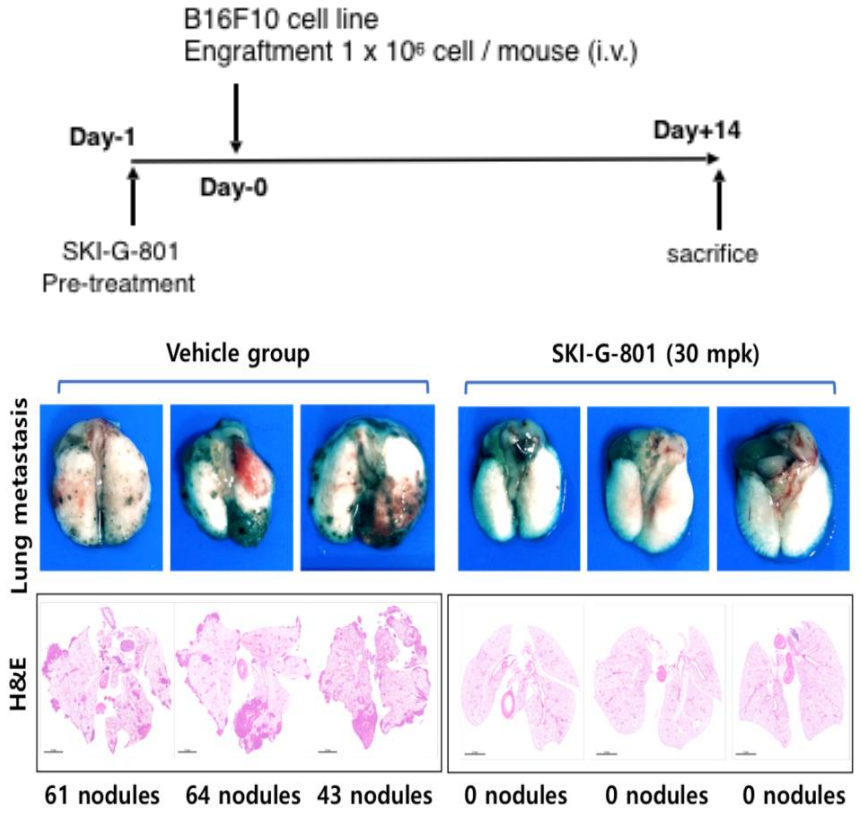


- Tumor growth inhibition in syngeneic mouse tumor models considered to be less immunogenic and unresponsive to immunotherapy
- The efficacy is mediated by anti-tumor immune response – no activity in immune-compromised mice

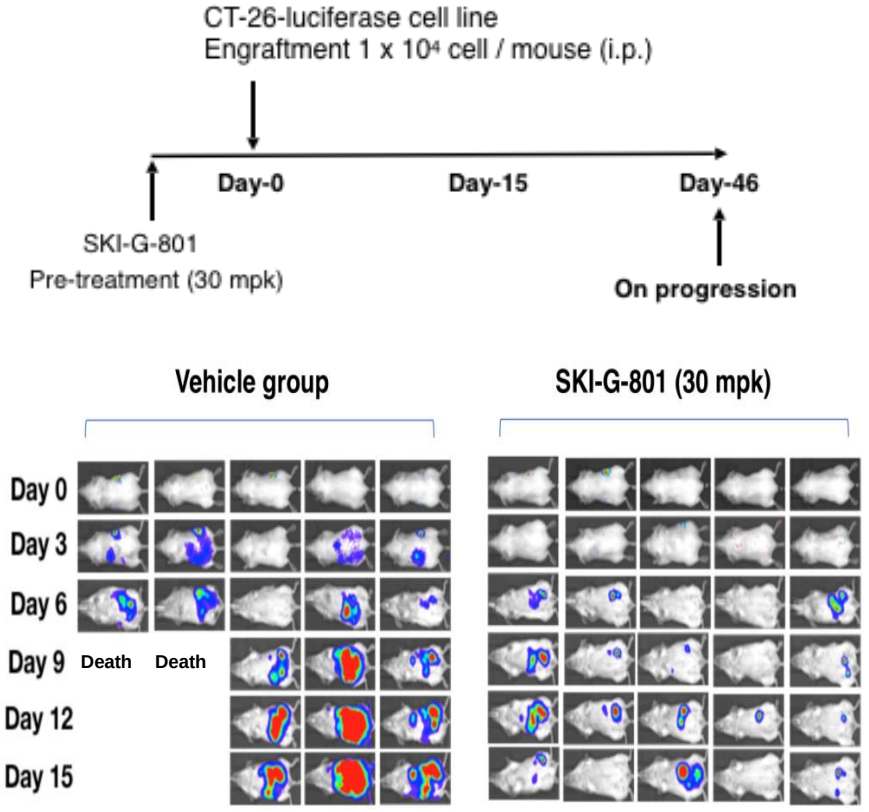
SKI-G-801 | Suppression of Metastasis

Excellent in vivo Efficacy in Metastatic models

A Lung metastasis models (B16F10)

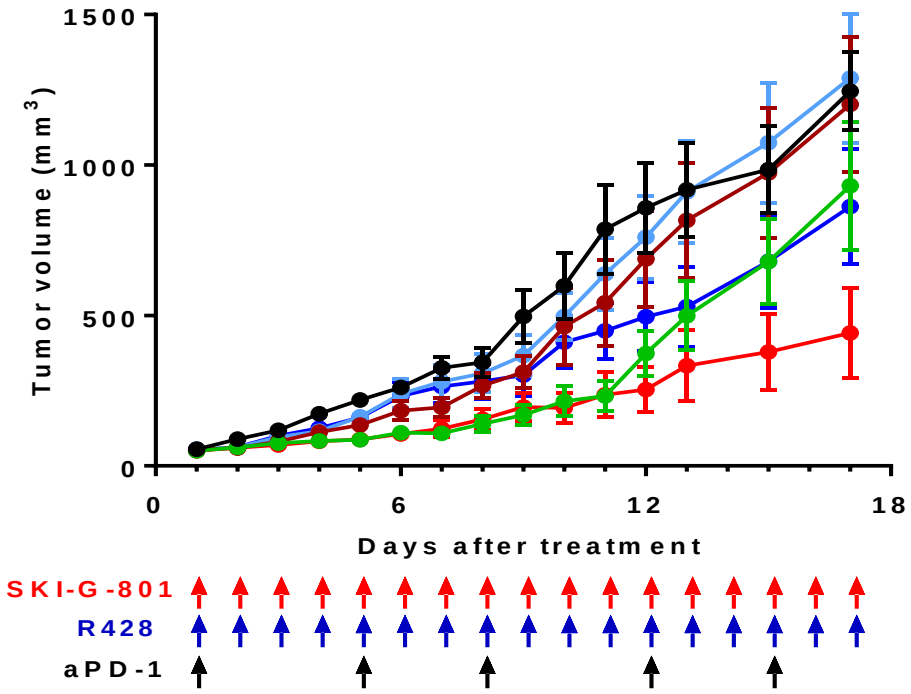


B Peritoneal metastasis models (CT-26)

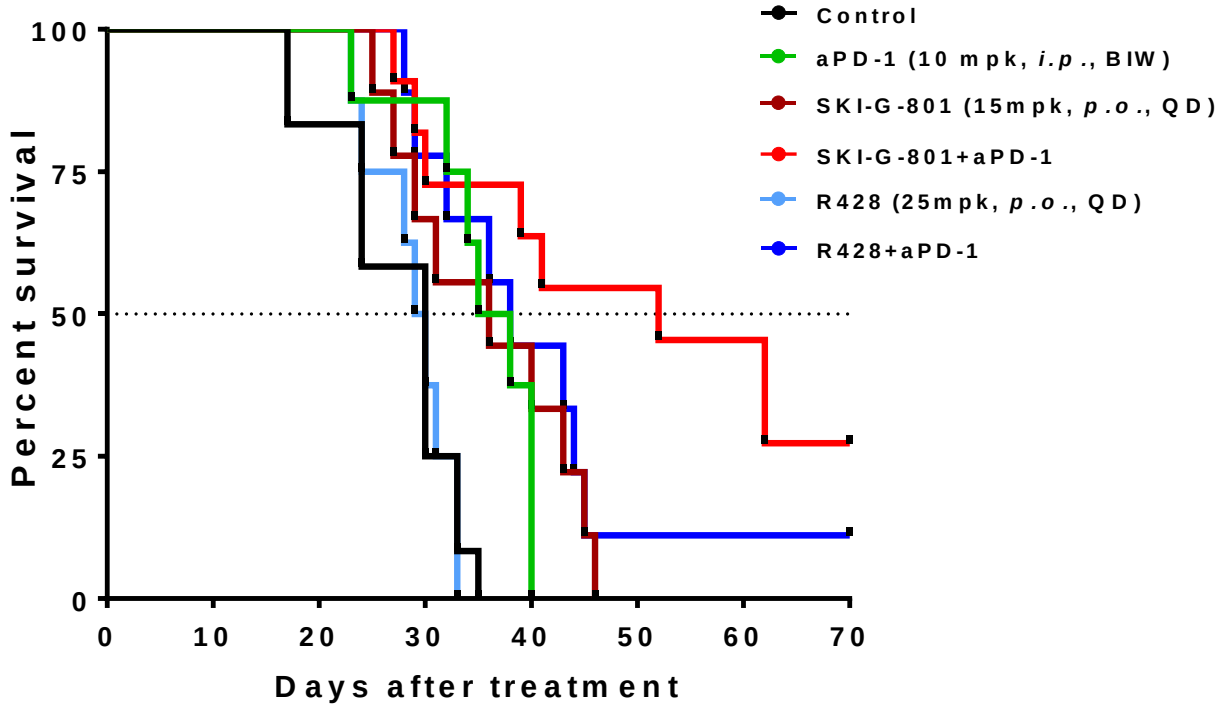


SKI-G-801 | Preclinical Efficacy Highlight

Tumor growth inhibition

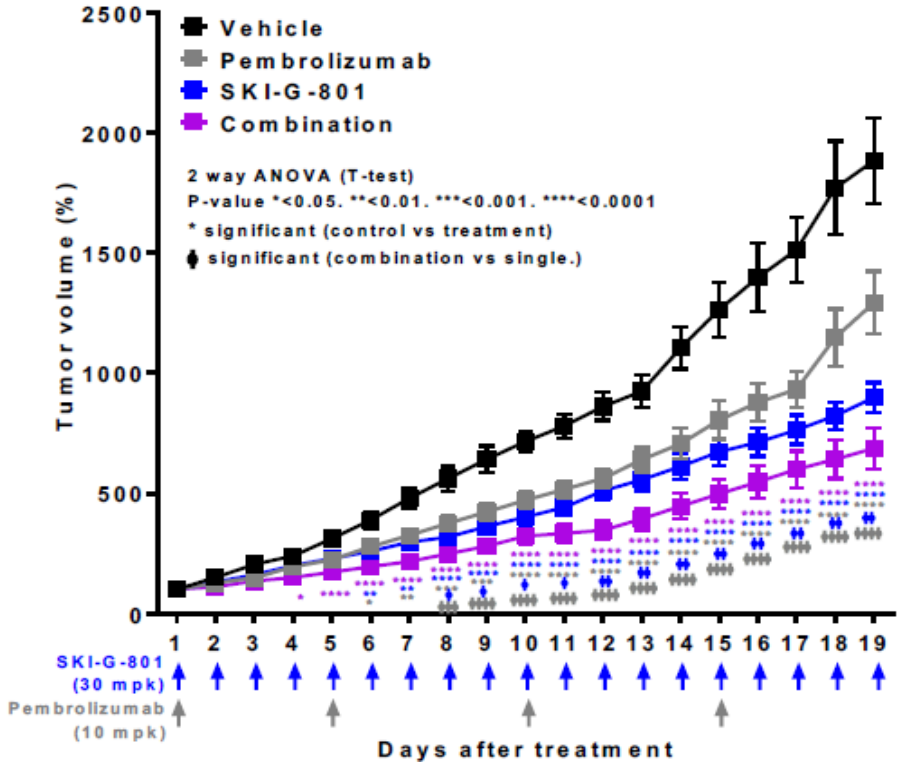


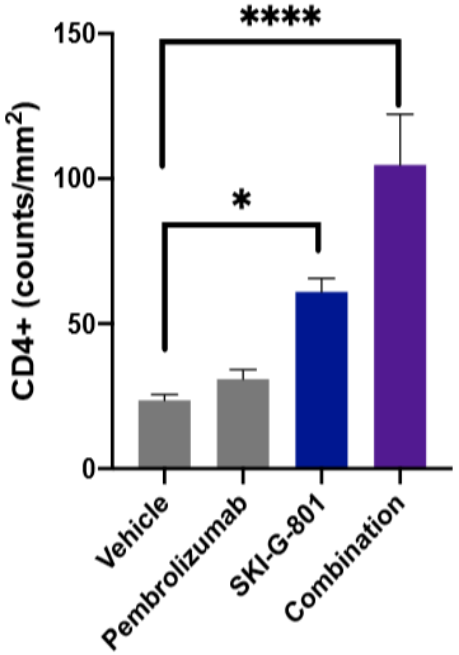
Survival

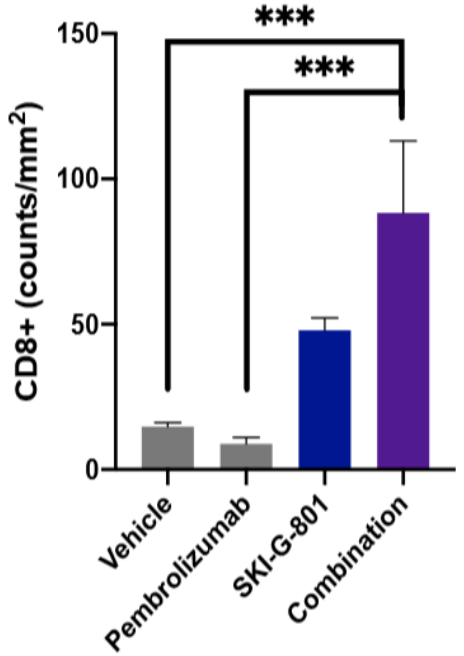


- Efficacy superior to bemcentinib (R428) at a lower dose as monotherapy as well as in combination with anti-PD-1 antibody in CT26 mouse syngeneic tumor model.

SKI-G-801 | Efficacy in PDX Model on Humanized Mice





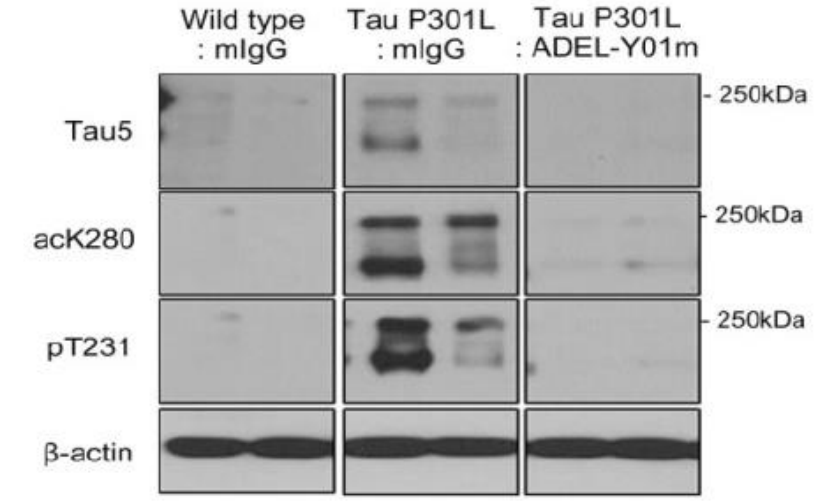


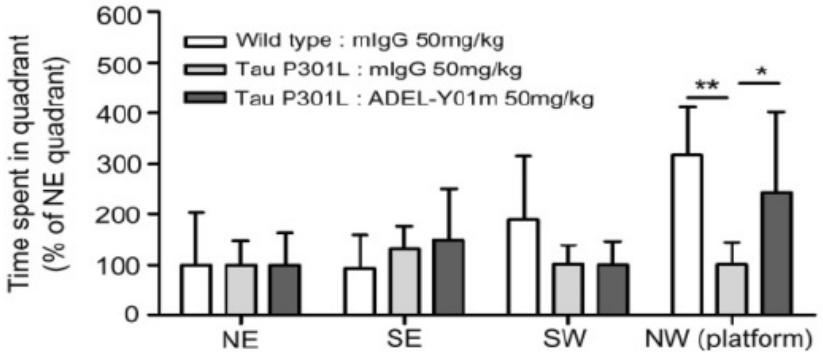
- Lung SCC patient-derived xenograft tumor engrafted on hu-CD34-NSG mice
- Significant tumor growth inhibition by SKI-G-801; further enhanced by combination with pembrolizumab
- Significantly increased T cell infiltration; esp. in combination with pembrolizumab

ADEL-Y01| Anti-Tau mAb

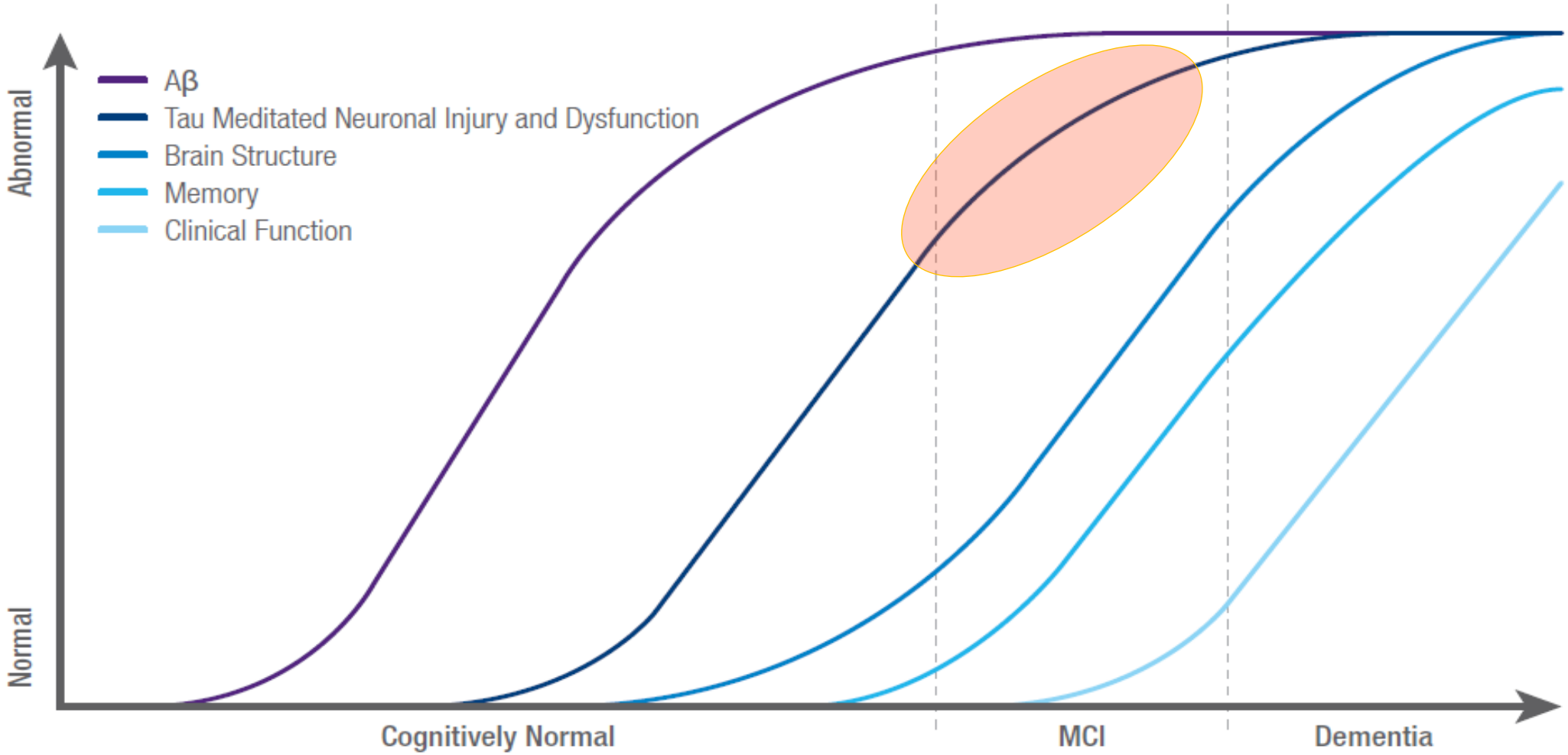
Molecular Target	Acetylated Tau
Indication	• Alzheimer's disease, Tauopathies (FTLD, PSP, CBD..)
Treatment Principle	• Impedes disease progression by blocking cell-to-cell transmission of Tau oligomers (seeds) that are capable of inducing aggregation and thereby inhibiting tau propagation
Market Size	$12B (2024 est.)
Competitiveness	• Differentiated MOA – targets the pathologically modified (acetylated) epitope of Tau protein that is thought to possess enhanced ability to propagate • Proven to be superior to competitors' in inhibiting tau aggregation and propagation
Development Status	• GLP Tox study (2Q 2021~) • IND Filing for Phase I studies by 4Q 2022
Miscellaneous	• Joint development agreement execution with ADEL Inc. in Oct 2020.

- ADEL-Y01m (50 mg/kg ip, qw for 3 mo) blocks pathological tau aggregation and improves cognition in P301L mice

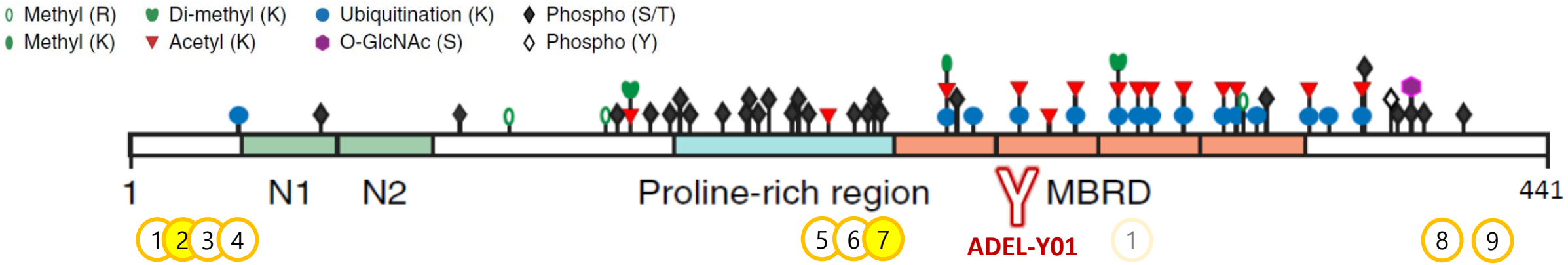




ADEL-Y01| Tau in Alzheimer`s Disease



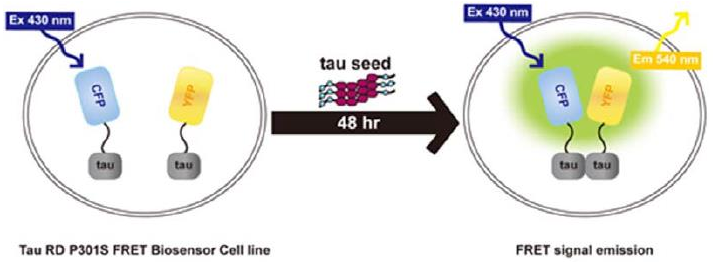
ADEL-Y01| Competitive Landscape and Differentiation

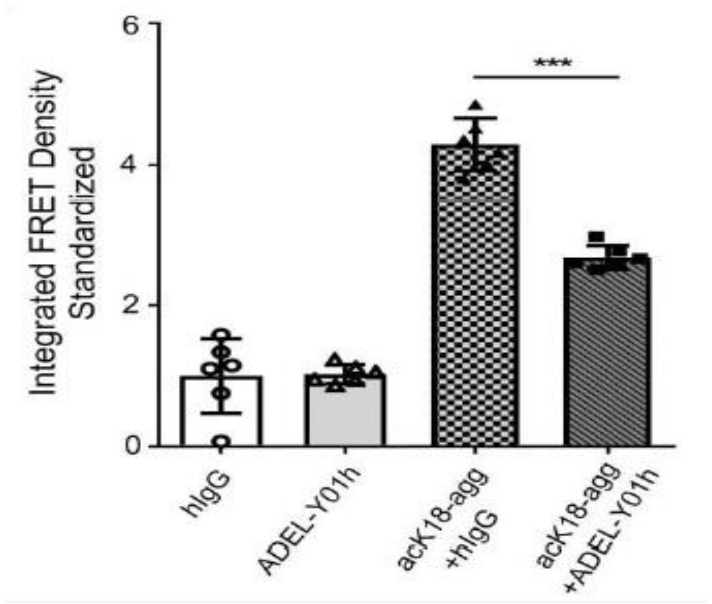


	Drug	Synoyms	Companies	Epitope	Clinical Trial Status
1	Zagotenemab	LY3303560, MC1	Eli Lilly	Tau aggregate (7-9:313-322)	P2 (early AD)
2	Gosuranemab	BIIB092, BMS-986168, IPN007	Biogen, BMS, iPerian	Secreted N-term fragment (15-24)	P2 (early AD), Stopped (PSP)
3	C2N-8E12	HJ8.5 (m)	Abbvie, C2N	Extracellular tau (25-30)	P2 (early AD), Stopped (PSP)
4	Semorinemab	RO7105705, RG6100	Roche, AC Immune	Tau N-term	P2 (AD)
5	JNJ-63733657		Janssen	Phospho tau PRR (pT217)	P1
6	PNT001		Pinteon	Phospho tau PRR (cis-pT231)	P1
7	UCB0107		UCB	Tau PRR (235-246)	P2 (PSP)
8	Lu AF87908		Lundbeck	Phospho tau C-term (pS396)	P1 (AD)
9	RG7345	RO6926496	Roche	Phospho tau C-term (pS422)	Stopped (HV)
-	BIIB076		Biogen	Monomeric and fibrillar tau	P1

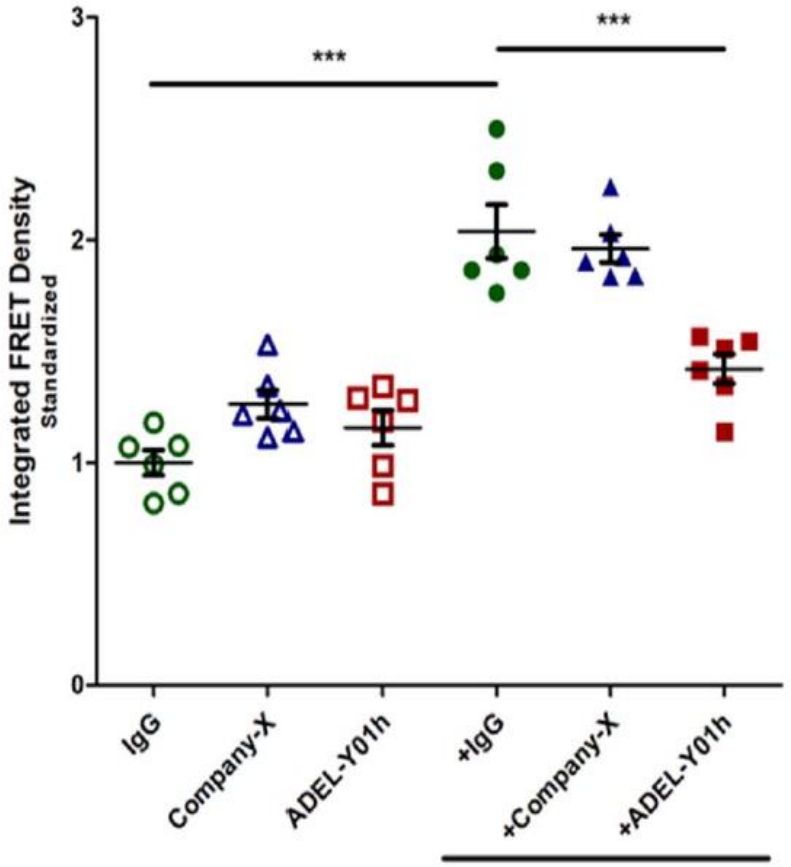
ADEL-Y01| Inhibition of Tau Propagation

A **Inhibition of Tau aggregation induced by AcK18 seeds in biosensor assay**



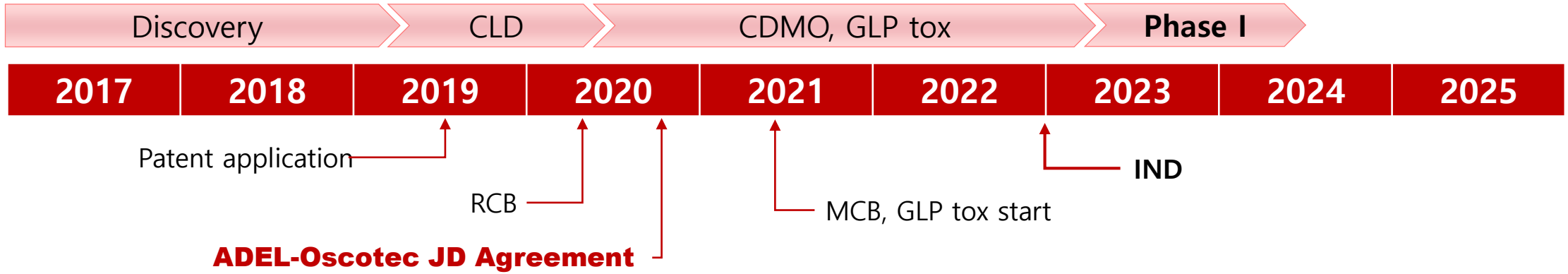


B **Activities superior to competitors' compounds under clinical development in the biosensor assay**



ADEL-Y01| R&D Scheme & Phase I Plan

- Rat PK; T1/2 = 175 h, CSF/Plasma = 0.275%
- Rat/monkey pre-Tox (up to 80 mpk, qw x 2); no overt toxicity, no tissue cross reactivity
- CMC manufacturing
  - Research cell banking (RCB) complete (yield ~4g/L)
  - USP/DSP development; MCB established, 200-L run ongoing
- GLP tox studies started in 2Q 2021 (26wk tox study is to be underway in 2Q 2022)
- Development timeline;



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