

Drug Discovery & Development

Oscotec Inc.

July 2020



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Overview

About Oscotec Inc.

1-1. Overview



Oscotec Inc.

“R&D – Based Biotech Company for Drug Discovery and Development”



Profile

- Company : Oscotec Inc. (PanGyo, Gyeonggi-do, Korea)
- Establishment : Dec.8, 1998
- Listing : Jan.17, 2007 (KOSDAQ)
- Paid-in Capital : W15bn (Outstanding shares : 29,200,311)
- No. of Employees : 44 (R&D – 19)
- Subsidiary : Genosco (Boston, USA)



Area

- Autoimmune Disease
 - RA/ SLE/ ITP
- Cancer
 - AML/ NSCLC/ Breast cancer



History

- Dec. 2008 Establishment of US subsidiary (Boston Lab.)
- July 2015 L/O of EGFR-Targeted Anti-Cancer Drug (Oscotec→Yuhan)
- Sep. 2015 FDA Approval For SYK's Clinical Trial in US
- Apr. 2016 FDA Approval For FLT3's Clinical Trial in US
- Nov. 2018 L/O of EGFR-Targeted Anti-Cancer Drug (Yuhan→Janssen)

1-2. Key Personnel

Oscotec Inc.

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

- Ph.D. in Biochemistry from Seoul National Univ.
- Dankook Univ. Prof.
- Harvard Medical School, Visiting Prof.

Tae-Young Yoon Ph.D. **CEO**

- Ph.D. in Organic Chemistry from Yale Univ.
- California Inst. of Technology, Post-Doc
- Novartis Pharma., Principal Scientist
- Dong-A ST Inc., SVP, Head of Research Center

Jung-Ho Kim Ph.D. **CTO**

- Ph.D. in Organic Chemistry from Univ. of Illinois at Urbana-Champaign
- Stanford Univ., Post-Doc
- Hanwha Chemical, Principal Scientist

Scott Lee MBA **CFO**

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

Genosco Inc.

John Koh Ph.D. **CEO**

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

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

- Ph.D. in Pharmacology from Seoul National Univ.
- Dankook Univ. Prof.
- Harvard Medical School, Visiting Prof.

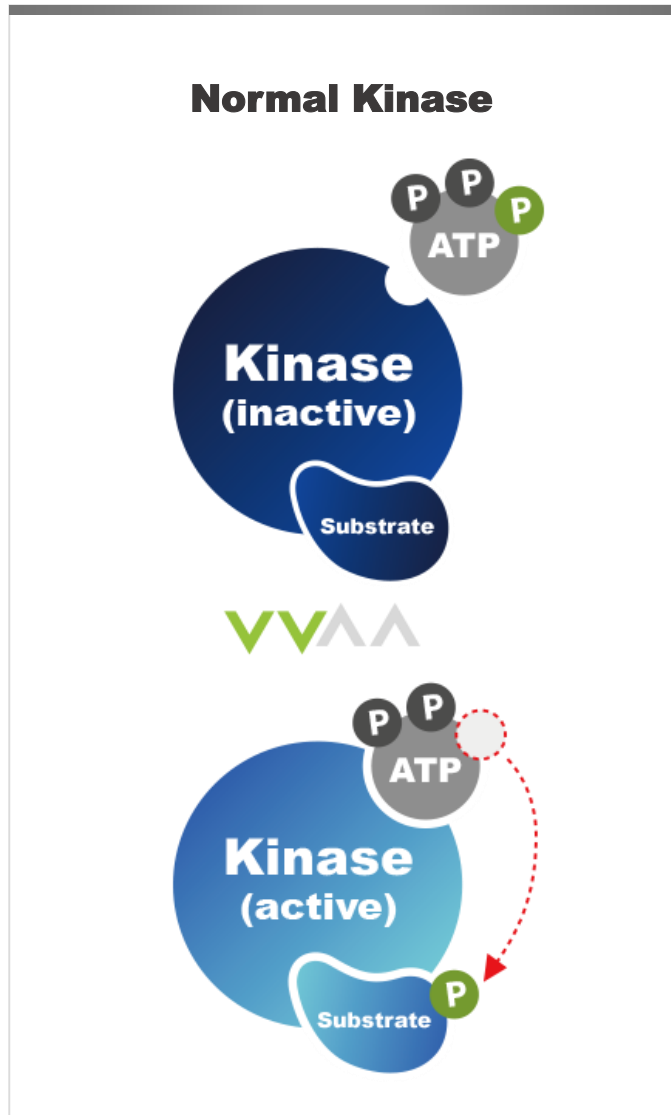
Kevin Yang B, Sc **CFO**

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

R&D Pipelines

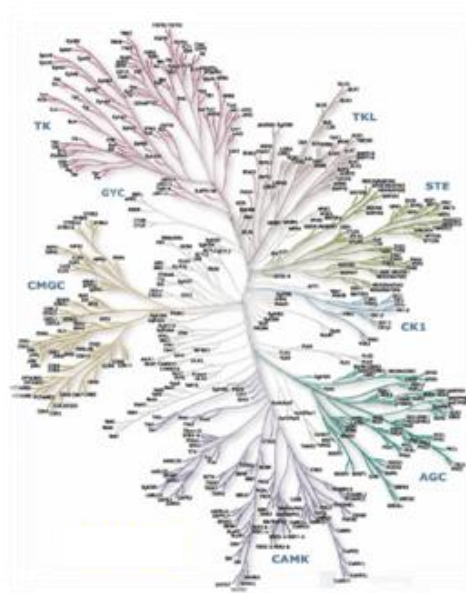
- 1) ***Lazertinib (GNS-1480, YH25448)***
: EGFR Mutant Inhibitor > NSCLC
- 2) ***SKI-O-703 : SYK Inhibitor*** > RA, ITP
- 3) ***SKI-G-801 : FLT Mutant Inhibitor*** > AML
- 4) ***SKI-G-801 : AXL Inhibitor*** > Metastatic solid tumor (NSCLC, TNBC+)

2. Kinase-Targeted Drug Discovery : Inhibitory Principle



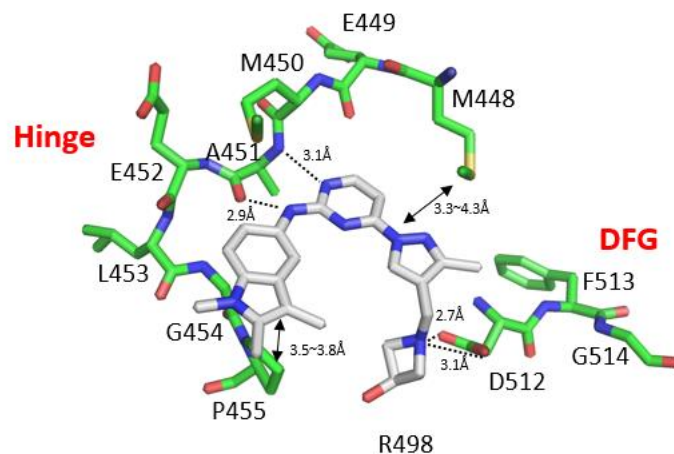
2. Focus on Selective Kinase Inhibitor

I. Kinase Selection



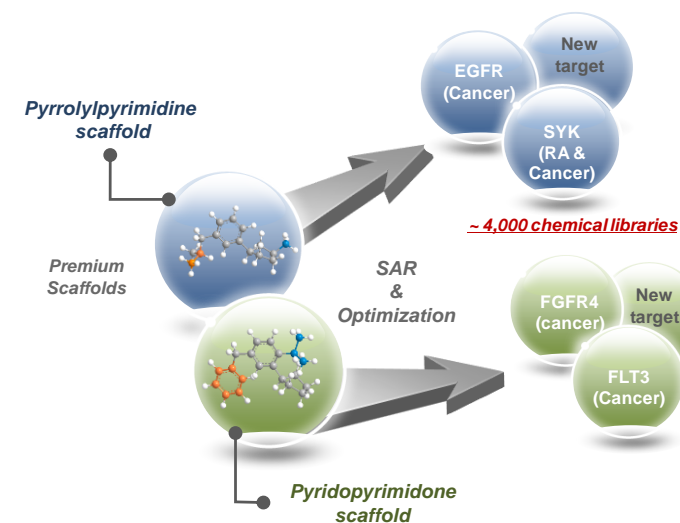
- One of 518 human Kinases
- High unmet needs for medicine
- Proven expertise in target selection

II. Discovery Engine



- Strong IP position
- Rational design
- *In silico docking* model

III. Company's Focused Chemical Library



- Novel proprietary compounds
- Structure-activity relationship
- Optimization

2. Drug Development Pipelines

Area	Product	Target	Discovery	Preclinical	Phase 1	Phase 2a	Phase 3	Developer
Immunology	SKI-O-703	SYK/RA						OCT
		SYK/ITP						
Oncology	Lazertinib GNS-1480 (YH25448)	EGFRdm+ / NSCLC						YH/ Janssen
		1 st line NSCLC						
		1 st line NSCLC (Combination)						
		SKI-G-801	FLT3m+/AML					
		AXL/NSCLC, TNBC						

OCT, Oscotec Inc.

GNS, Genosco

YH, Yuhan. Pharmaceuticals

RA, Rheumatoid Arthritis; SLE, Systemic Lupus Erythematosus; ITP, Immune Thrombocytopenic Purpura;

AML, Acute Myeloid Leukemia; NSCLC, Non Small Cell Lung Cancer; EGFRdm+, EGFR double mutants

2-1. EGFR Mutant selective inhibitor

● Indication	NSCLC
● Treatment Principle	EGFR(del19/L858R)/T790M Double Mutant Inhibition
● Market	\$6B (2023 Est.)
● Efficacy	Minimized Side Effects & Superior Efficacy
● Clinical Study Status	<ul style="list-style-type: none">■ Single treatment 2nd Line: Phase 2 Completed■ Combination treatment: Phase 3 (2020.2H~)
● Remarks	<ul style="list-style-type: none">■ L/O : 2015.7 Oscotec → Yuhan, 2018.11 Yuhan → Janssen ∴ 60/40 Share for All Income (Upfront US\$50M + Milestone US\$1.205B+ Running Royalty)■ MFDS` Conditional Approval expected by 2020 & NDA filing for FDA Approval expected by 2023



Lazertinib

EGFR Double Mutant Inhibitor

2-1. Lazertinib : Summary efficacy & safety in clinical trials

Excellent Efficacy

Oral, once-a-day 20mg-320mg dose of Lazertinib

	Lazertinib (ASCO, 2019)	Osimertinib # (AURA trial)
Overall Response Rate	60% (n=127)	51% (n=253)
A T790M (+) Patient (All doses)	64%	61%
> T790M (+) Patient (120mg) *	65%	-
> T790M (+) Patient (80mg) **	-	70% (n=43)
> Progression Free Survival	12.3mos	10.1mos
B T790M (-) Patient (All doses)	37%	21%
C Patient with brain metastasis (All doses)	50%	N/A

Excellent Safety

One cycle of treatment: 21 days

	Lazertinib (ASCO, 2019)	Osimertinib # (AURA trial)
Any AEs of grade 3-5	11%	32%
Any drug related grade 3-5	3%	13%

Safety

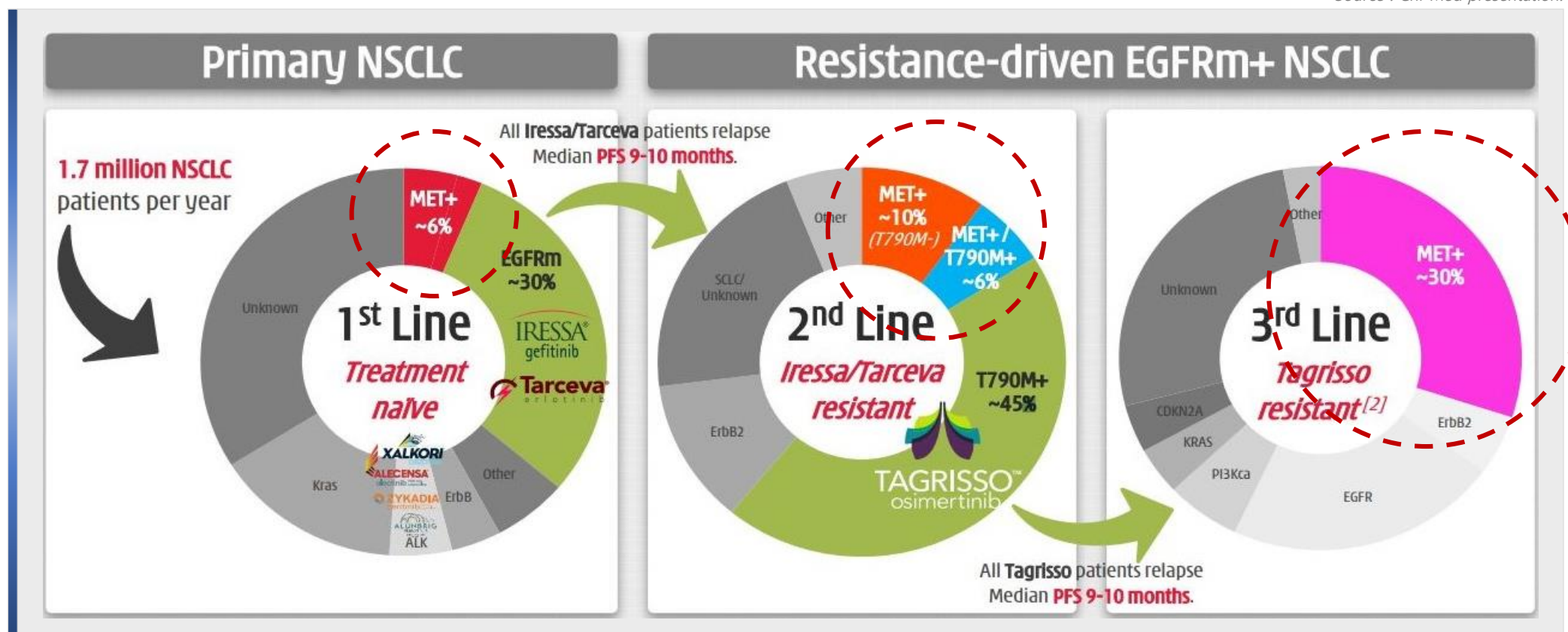
No dose limiting toxicity (DLT) from starting dose of 20mg QD up to 320mg QD. Lazertinib showed no dose-dependently increased TEAEs whereas Osimertinib did dose-dependent adverse events of diarrhea(47%) and rash(40%) in AURA trial.

2-1. MET amplification

Key issue

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

Source : Chi-Med presentation.



[Link](#)

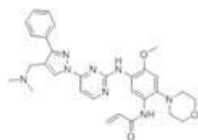
2-1. Combination effect with JNJ-6372 (EGFR/MET Ab)

An integrated EGFR pathway strategy to change the treatment paradigm



JNJ-6372
EGFRxcMET DuoBody®

A fully human, enhanced ADCC, bispecific antibody that targets EGFR and c-MET via novel MOA; currently being evaluated across the spectrum of EGFR and cMET altered tumors

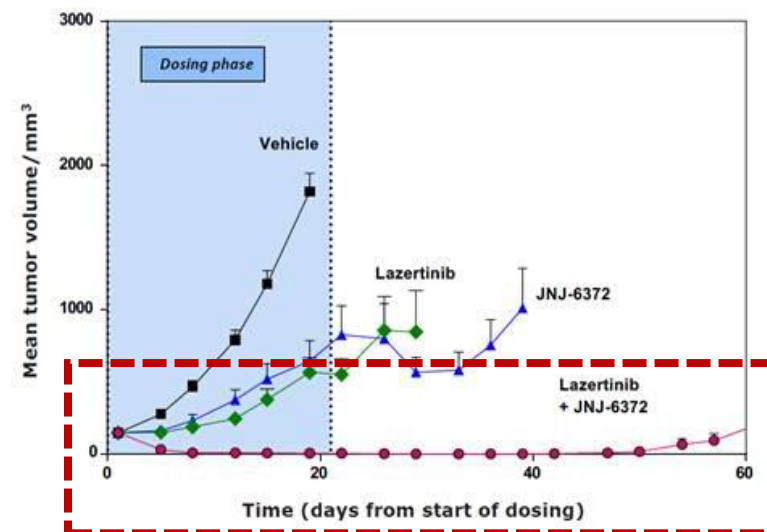


Lazertinib  **YUHAN**
3rd-generation EGFR inhibitor

A potent 3rd-generation EGFR TKI with highly favorable tolerability profile

In vivo preclinical activity: lung tumor xenograft driven by EGFR (T790M) and c-MET pathways;
JNJ-6372 in combination with Lazertinib prevents tumor growth more effectively than either agent alone
DD18058; Eln: DuoBody-EGFR x cMet-00570




**Triple blockade of EGFR and cMET
with JNJ-6372 and Lazertinib results
in superior activity in preclinical model**




2-1. Janssen – 10 Pipelines over 1 Billion Potential

Our robust pipeline is anticipated to deliver at least 10 new medicines with >\$1 billion potential*

Select NME approvals & filings in 2019–2023 timeframe

2019 approvals	Potential 2019–2023 filings	
 Spravato™ (esketamine)  nasal spray Treatment-resistant depression	JNJ-4550 cusatuzumab (Anti CD70 mAb) Acute myeloid leukemia	JNJ-7564 GPRC5D/CD3, JNJ-7957 BCMA/CD3 Regimens for multiple myeloma
	JNJ-4528 BCMA CAR-T Multiple myeloma	JNJ-6372 EGFR/c-Met (Bispecific EGFR and cMET receptor inhibitor) Solid tumor
 Balversa™ (erdafitinib) tablets Urothelial cancer	JNJ-1937 lazertinib (EGFR tyrosine-kinase inhibitor) Non small cell lung cancer	JNJ-4500 anti-NKG2D (anti-NKG2D mAb) Crohn's disease
	AAV-CNGB3/CNGA3/RPGR (Gene Therapy) Retinal disease	RSV Vaccine (Ad26.RSV.preF + preF Protein) RSV
	niraparib (PARP inhibitor) Prostate cancer	JNJ-7922 seltorexant (Orexin-2 receptor antagonist) Adjunctive treatment, MDD

 New since May, 2017

 Accelerated since May, 2017

* Peak non-risk-adjusted sales, including partner sales

Note: Filings/approvals are in the US or EU, unless otherwise noted. This information is accurate as of the date hereof to the best of Johnson & Johnson's knowledge. The Company assumes no obligation to update this information



2-2. SKI-O-703 : SYK selective inhibitor

● Indication	Autoimmune Diseases - Rheumatoid Arthritis (RA), Immune Thrombocytopenia (ITP)..
● Treatment Principle	SYK Inhibitor → Block abnormal activation of immune cells
● Market	RA : \$18.2B (2020), ITP : \$520M (2020)
● Efficacy	Superior Efficacy & Safety
● Clinical Study Status	■ RA – Phase 2a (Apr. 2019~) ■ ITP – Phase 2a (Dec. 2019~)
● Remarks	■ Sponsored by KDDF ■ RA – L/O promotion from 4Q 2020.



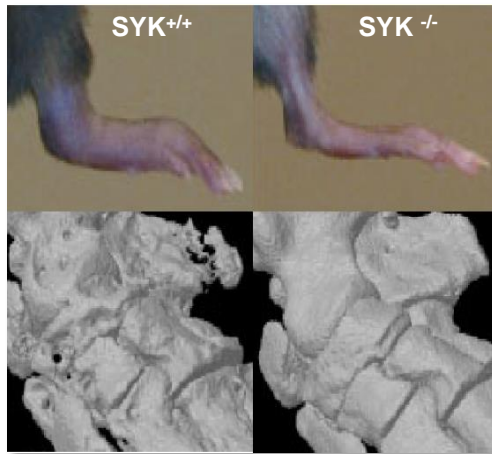
SKI-O-703

SYK Inhibitor

2-2. SKI-O-703: Rat Rheumatoid Arthritis Model

Rheumatoid Arthritis

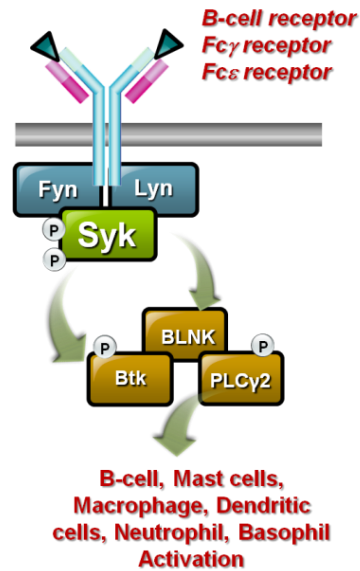
- Genetic evidence of SYK in RA



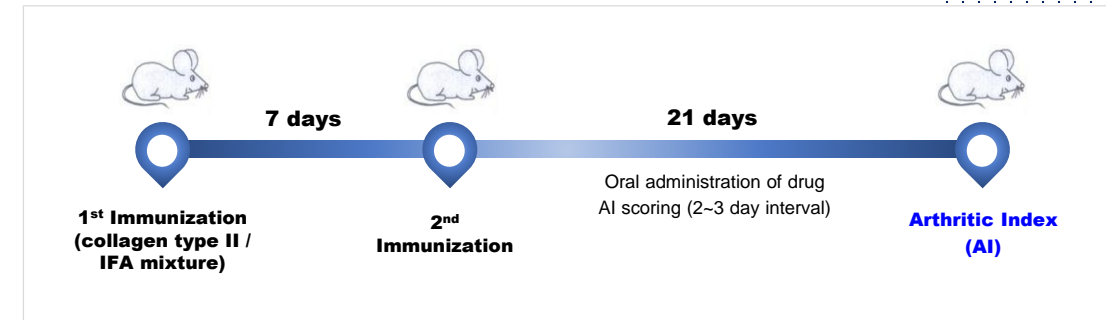
Jackus et al, 2010

Arthritis & Rheumatism 63: 1899-1910

- SYK deficient mouse : No sign of RA
- Novel mechanistic drug in RA market
- High potential to be first line therapy

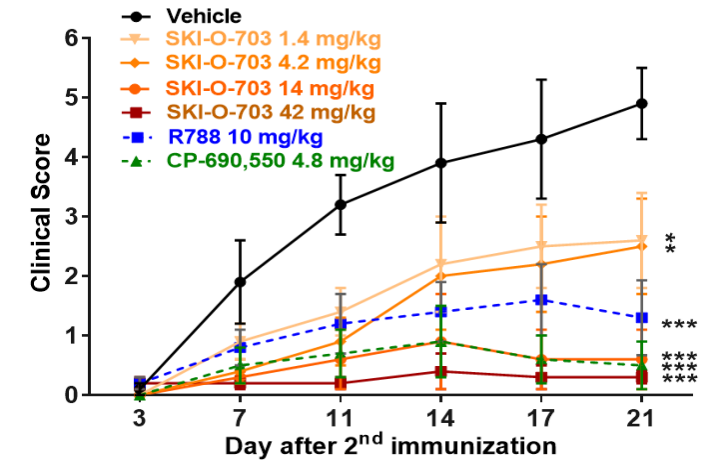


Collagen Induced Arthritis (CIA) Rat Model



Rat CIA model: evaluation of clinical score

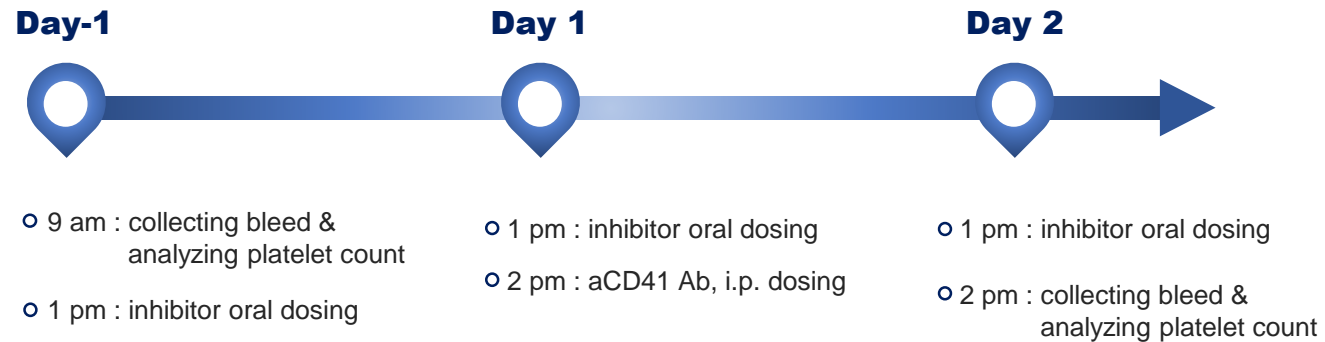
Note:
CP-690,550,
Tofacitinib



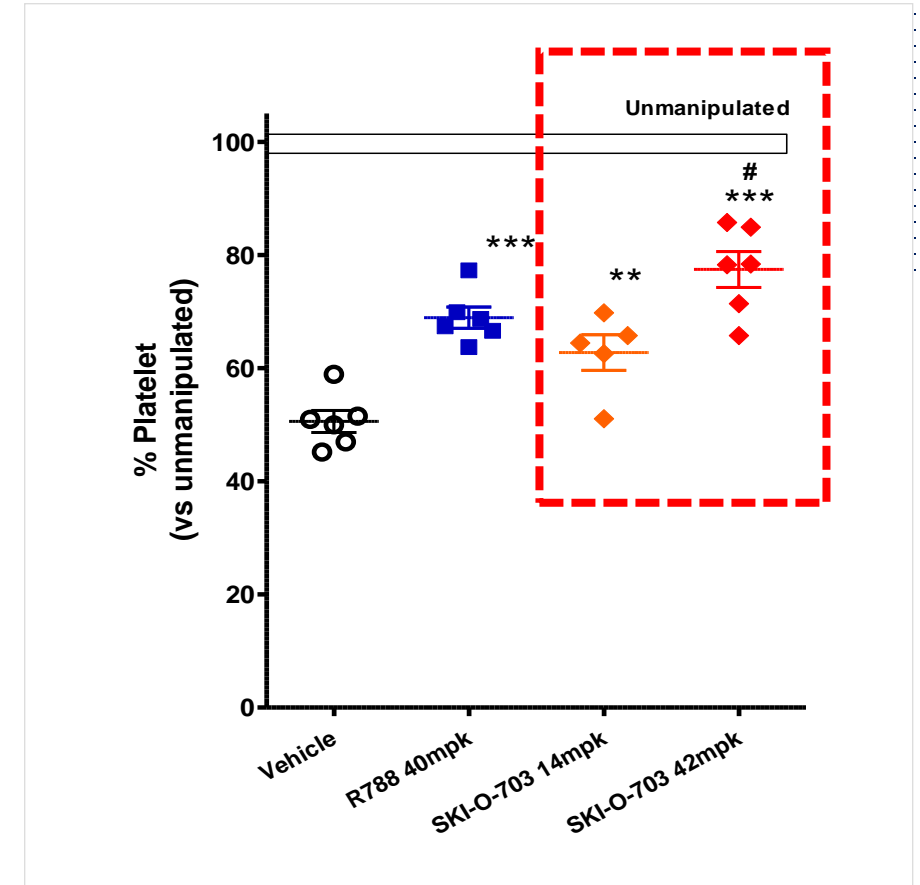
2-2. SKI-O-703: Great Efficacy in Mouse ITP Model

Mouse ITP model

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



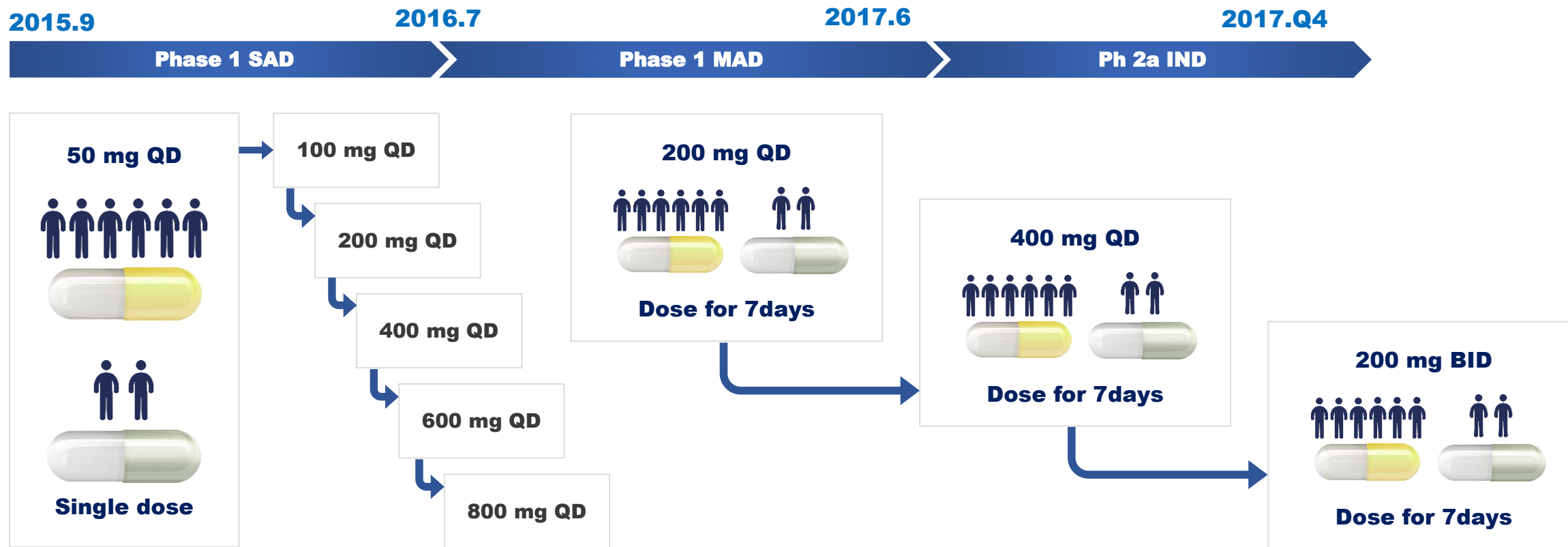
- › Selective and potent inhibition of SKI-O-703:
Restore platelet level to normal
- › SKI-O-703 : More efficacious than R-788
- › R788: NDA Approval for ITP (Apr., 2018)



*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, # $p < 0.05$,

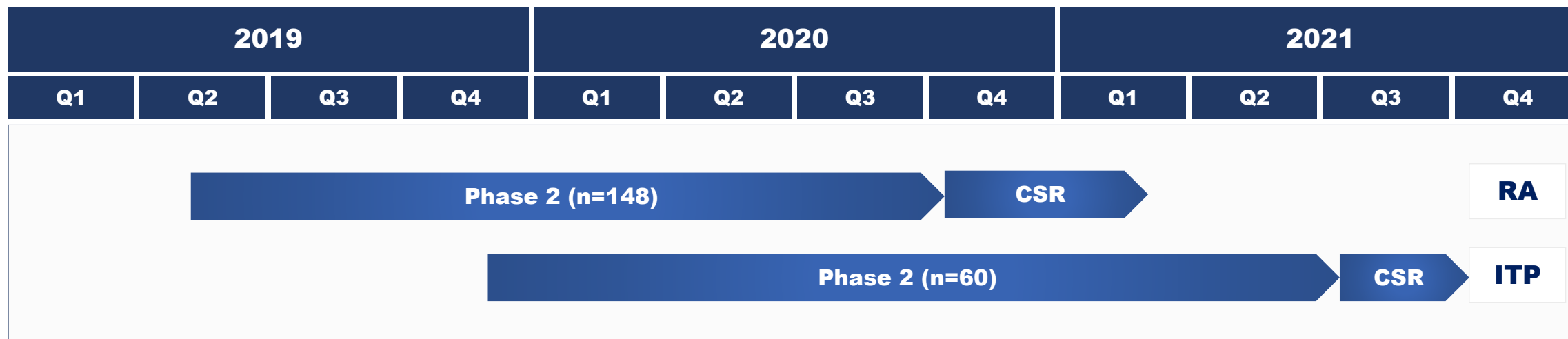
2-2. Phase 1 Clinical Trial



- Healthy adult volunteer : 48 subjects
- **Safe and well tolerated by both healthy male and female subjects**
- **No significant findings in vital signs, ECG, and lab safety tests**
- Increased in a dose proportional manner (AUC and C_{max})

- Healthy adult volunteer : 24 subjects
- Dosing period : 7 days
- **Safe and well tolerated in all dose**
- **No significant findings in vital signs, ECG, and lab safety tests**
- Increased in a dose proportional manner (AUC and C_{max})

2-2. Timeline for clinical trials



I. Rheumatoid Arthritis (RA)

- RA with inadequate response to csDMARDs or anti-TNFα biological agent(s)
- Dose : placebo, 100, 200, 400 mg (bid)
- Dosing period : 12 weeks
- 148 patients of 59 sites in 7 countries – US, EU, Korea
- FPI : 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
- FPI : December 2019

2-3. SKI-G-801 : FLT3 inhibitor

● Indication	Acute Myeloid Leukemia
● Treatment Principle	FLT3 Mutant Inhibition → Block FLT3 signal pathway and proliferation of blasts
● Market	\$1B (2020 Est.) : Demand expected to grow – Population aging, Progress in AML diagnostic, MKT entry of FLT3 inhibitors..
● Efficacy	Superior FLT3 Mutant Inhibition & Efficacy in drug-resistant environments
● Clinical Study Status	<ul style="list-style-type: none"> ■ May 2018~ Phase 1 Dose Escalation Study ■ 1H 2021~ Phase 1 Efficacy Study (planned)
● Remarks	<ul style="list-style-type: none"> ■ Sponsored by MOHW ■ Published in the Blood journal (IF=9.8), 2014 ■ ODD Designated by FDA, November 2018



SKI-G-801

FLT3 Inhibitor

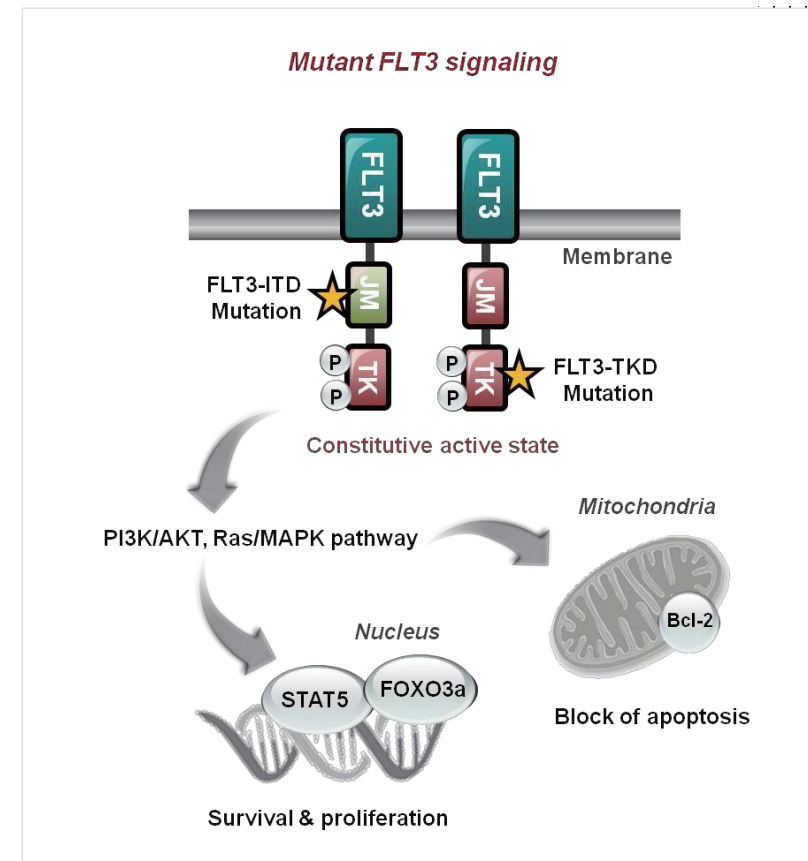
2-3. SKI-G801 : FLT3 Inhibitor for AML

Incidence of FLT3 mutations in AML

FLT3 mutants	Detail	Patients*
FLT3-ITD	20-30%	~8,400
FLT3-TKD D835Y	8-12%	~3,300

*, patient estimates represent new incidence in US

- > 65 AML patients: Low response and high relapse rate after first-line treatment (10% five-year survival rate)
- Occurrence of drug-resistant FLT3 mutants
e.g. gatekeeper (F691L) & kinase domain mutant (D835Y)
- No treatment options for FLT3 double mutant (ITD/D835Y)
- High unmet needs of FLT3 inhibitor to apply for Induction and maintenance therapy



2-3. SKI-G801 : Drug-resistant FLT3 mutation

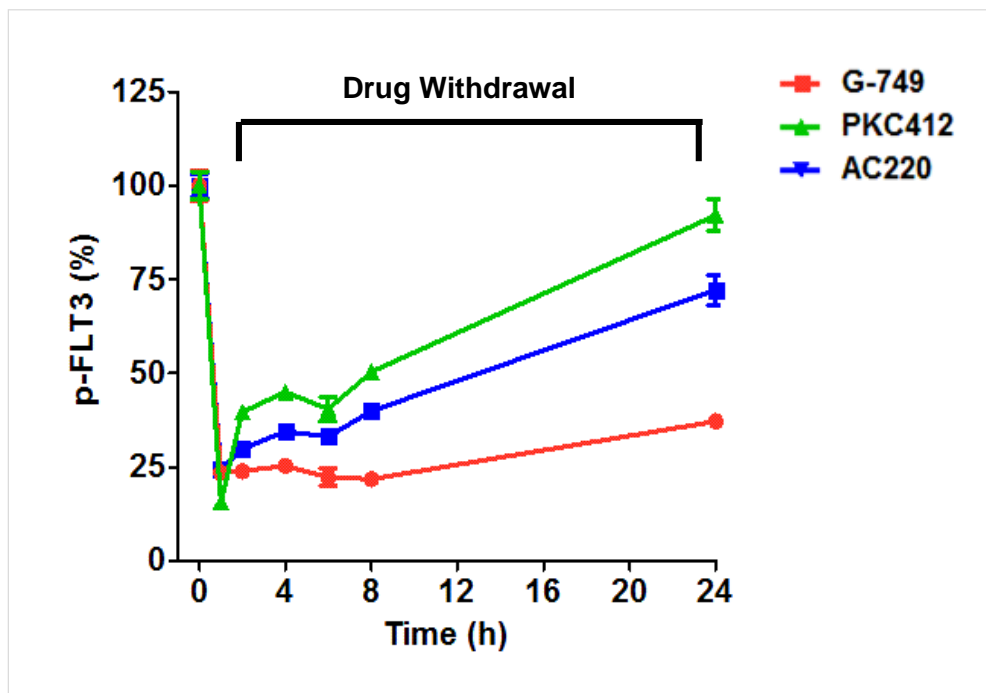
Potent anti-leukemic effect of drug-resistant FLT3 mutants

Compound	BaF3 cells with FLT3 mutation (IC ₅₀ , nM)			
	ITD	ITD/F691L	N676D	D835Y
G-749	8.0	38.3	20.4	3.4
AC220	1.1	858.5	14.2	73.8
ASP2215	16.0	163.6	25.4	4.1
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.

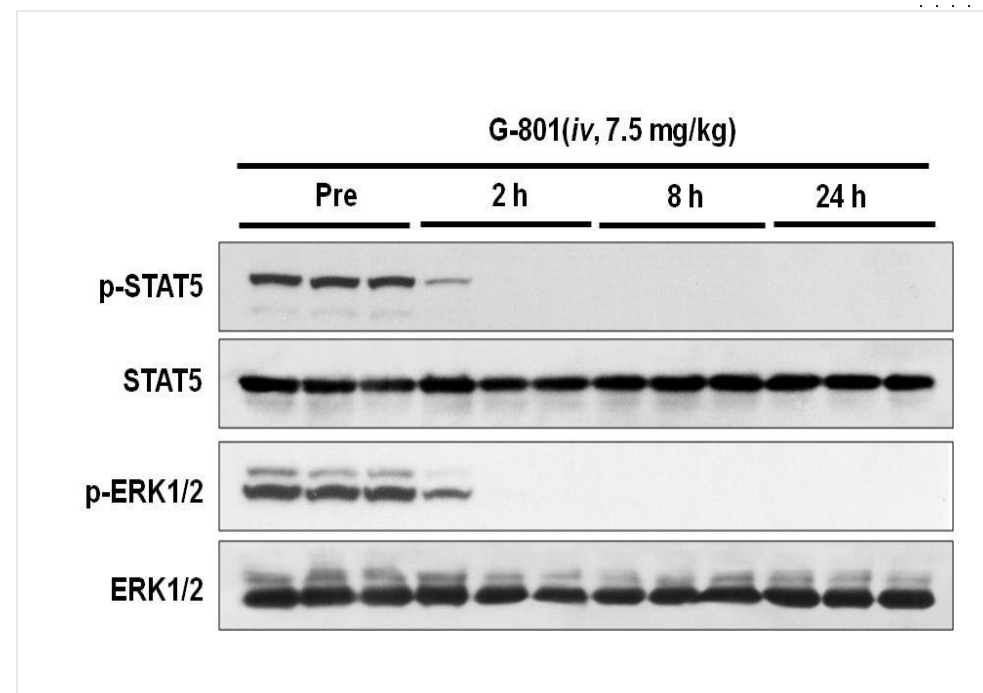
2-3. SKI-G-801: Persistent FLT3 inhibition

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.

Suppression of FLT3 downstream effectors



- Single SKI-G-801 (G-749 HCl salt) IV dosing at 7.5 mg/kg leads to complete inhibition of FLT3 downstream effectors (p-STAT5 & p-ERK1/2) within 2 hours and their activities lasts for 24 hours.

2-4. SKI-G-801 : AXL inhibitor

● Indication	Metastatic Solid Tumor (NSCLC, TNBC+)
● Treatment Principle	AXL Inhibition → Inhibition of metastasis and recovery immune response (e.g. cytotoxic T cell activation) → Cancer cell extinction & suppression of drug-resistance
● Market	>\$1B (2025 Est.) : Applicable for broad range of cancers
● Efficacy	Superior AXL inhibition and increased immune response
● Clinical Study Status	4Q 2020 IND Filing → 1Q 2021 Phase 1 (planned)
● Remarks	<ul style="list-style-type: none"> ■ Presented at AACR (April 2019, June 2020) ■ Joint research with Prof. Cho Byeong-Chul (Yonsei University College of Medicine) ■ Strategy for combination therapy with IO Drugs



SKI-G-801

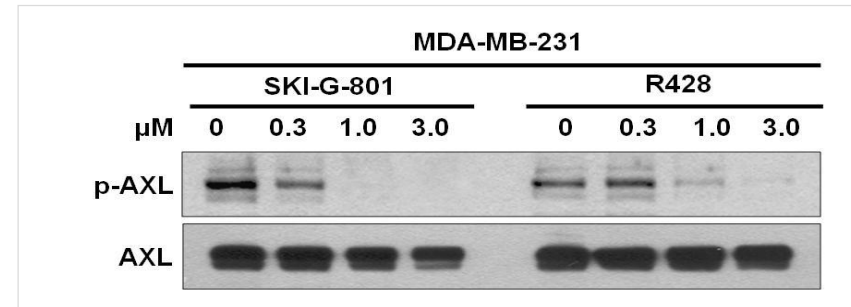
***AXL Inhibitor
(Immuno-Oncology)***

2-4. SKI-G-801: AXL Target expansion for solid tumors

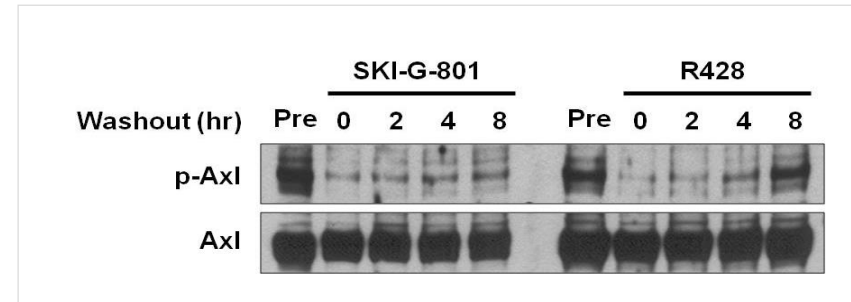
A CPI response vs AXL upregulation



B P-Axl inhibition (vs R428)



C Prolonged p-Axl inhibition (vs R428)

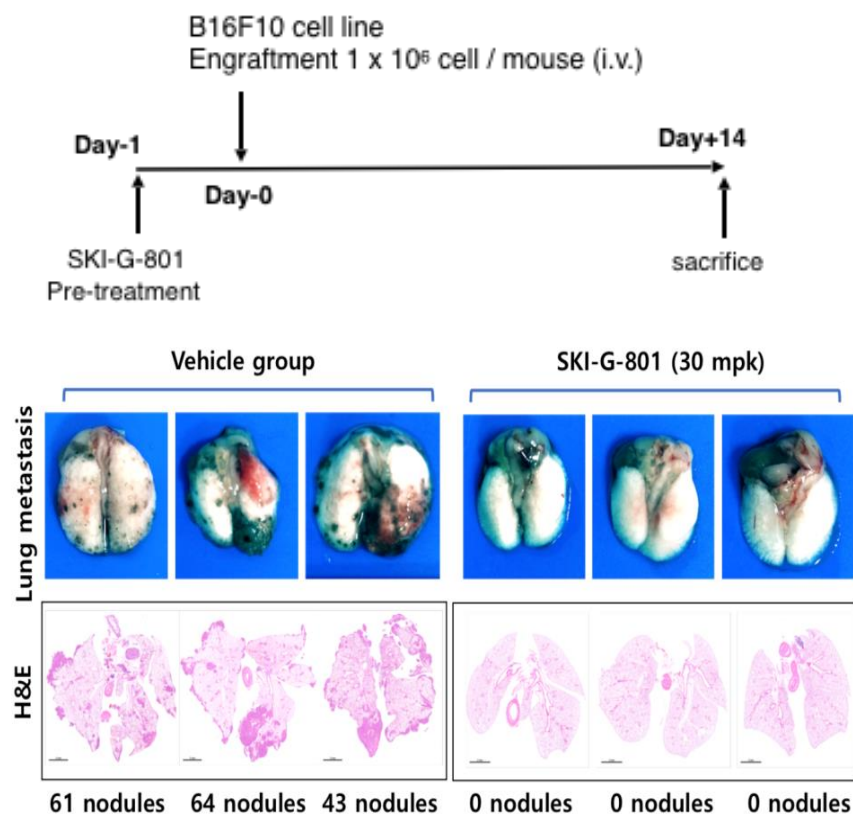


- AXL targeting would be highly beneficial to increase IO-drug's efficacy through blocking tumor immune escape
- Following GAS6 stimulation, SKI-G-801 inhibits p-AXL with a concentration-dependent manner in MDA-MD-231 cells, compared to R428
- The inhibition of p-Axl is sustained by G-749 for 8 hours, but the activity of R428 is gradually decreased

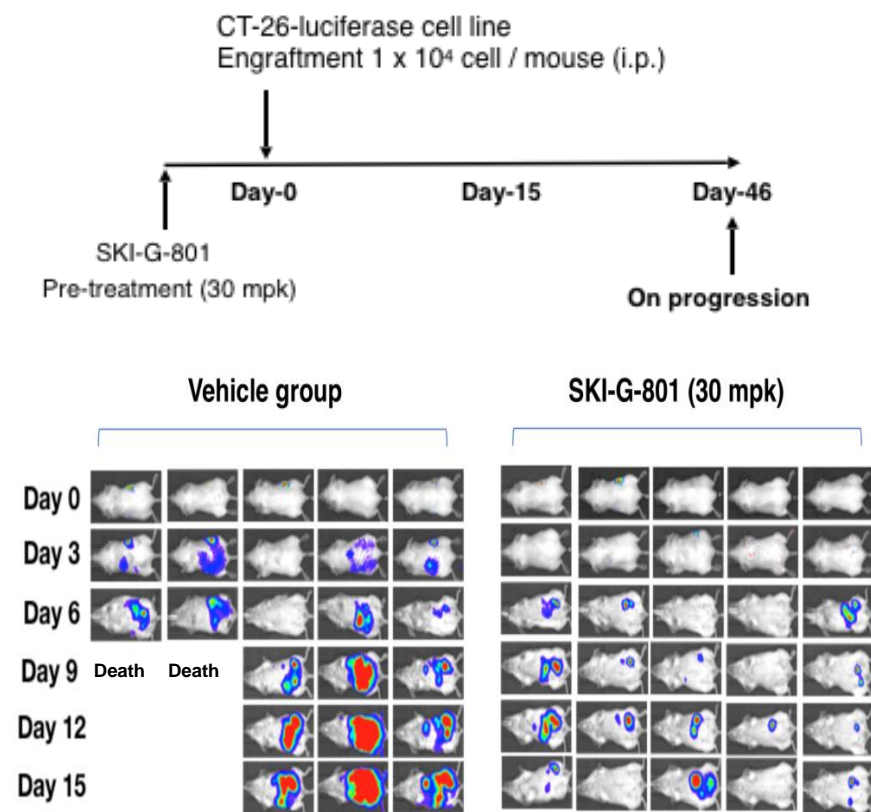
2-4. SKI-G-801: Suppression of Metastasis

Excellent in vivo Efficacy in Metastatic models

A Lung metastasis models (B16F10)



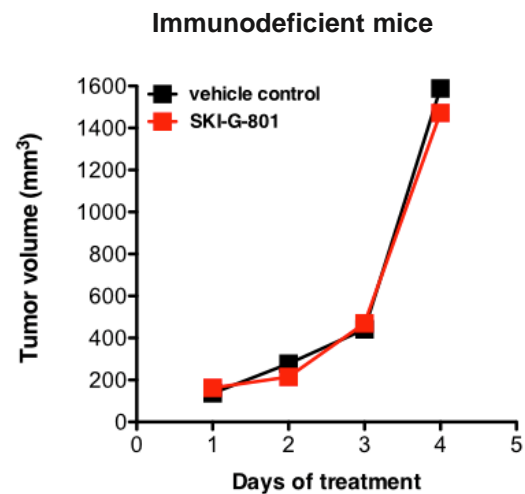
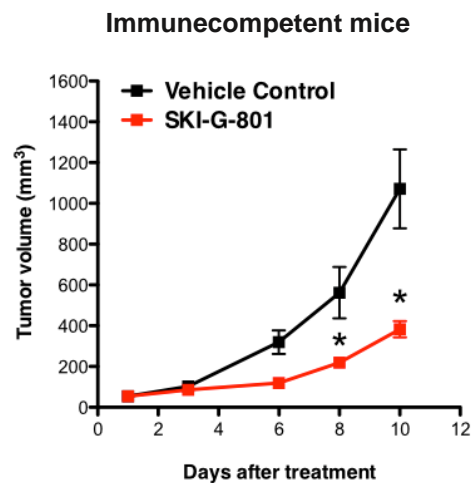
B Peritoneal metastasis models (CT-26)



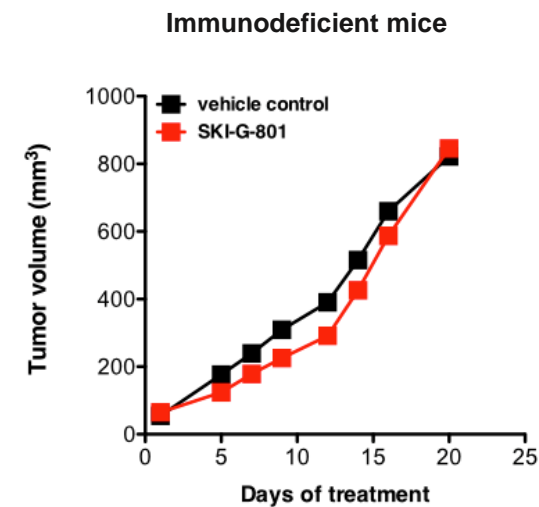
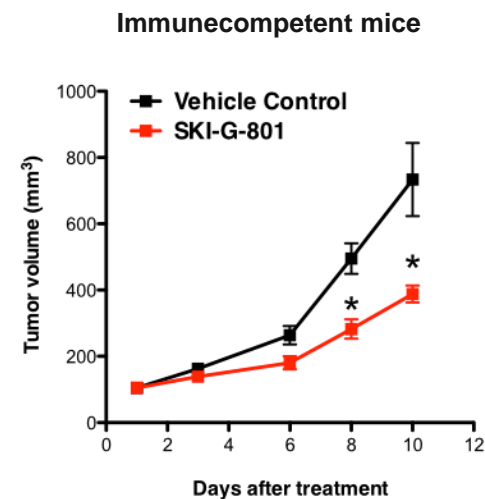
2-4. SKI-G-801 : Immune cell-dependent anti-cancer effect

Anti-tumor effect dependent on immune response

B16F10 tumor



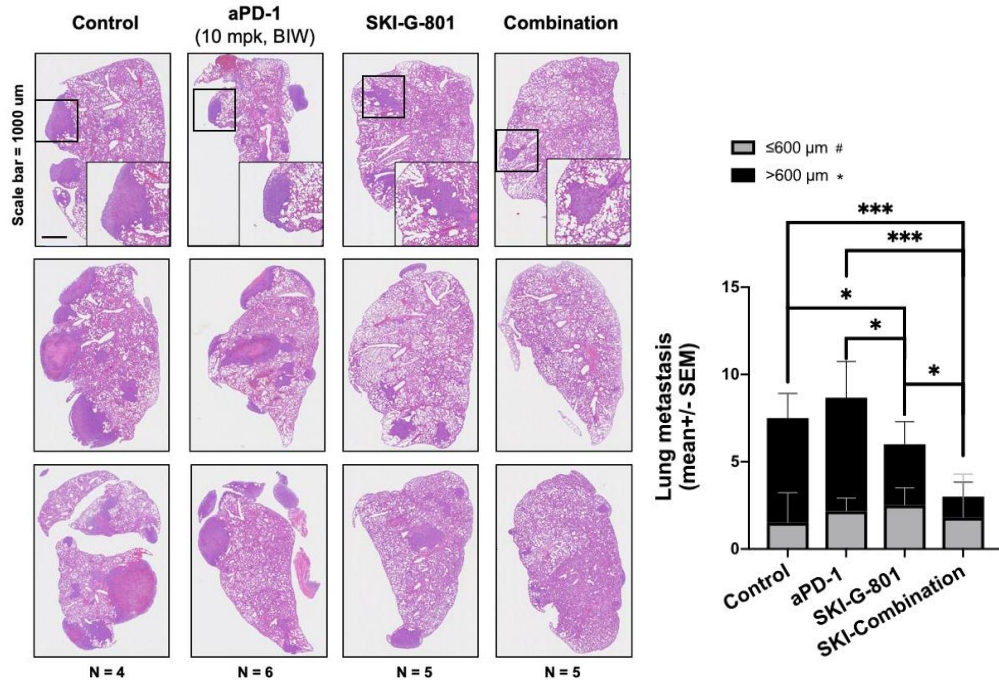
4T1 tumor



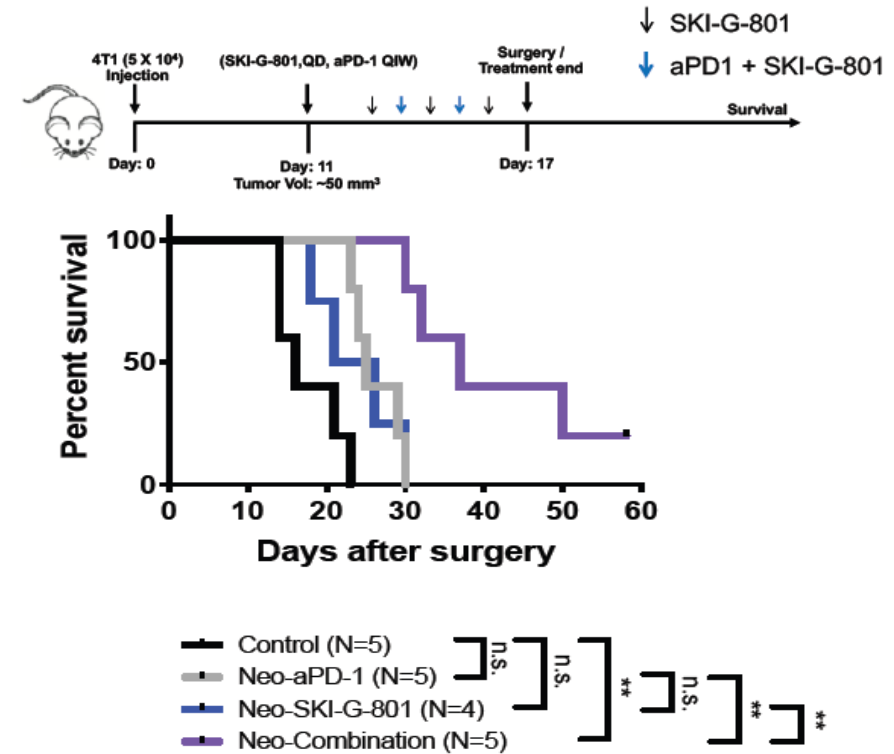
- There is no anti-tumor effect of SKI-G-801 in immunodeficient mice, indicating that SKI-G-801 may suppress tumor growth by directly engaging immune system

2-4. SKI-G-801: Combination effect with IO-drugs

A 4T1 spontaneous metastasis model



B Neoadjuvant therapy model

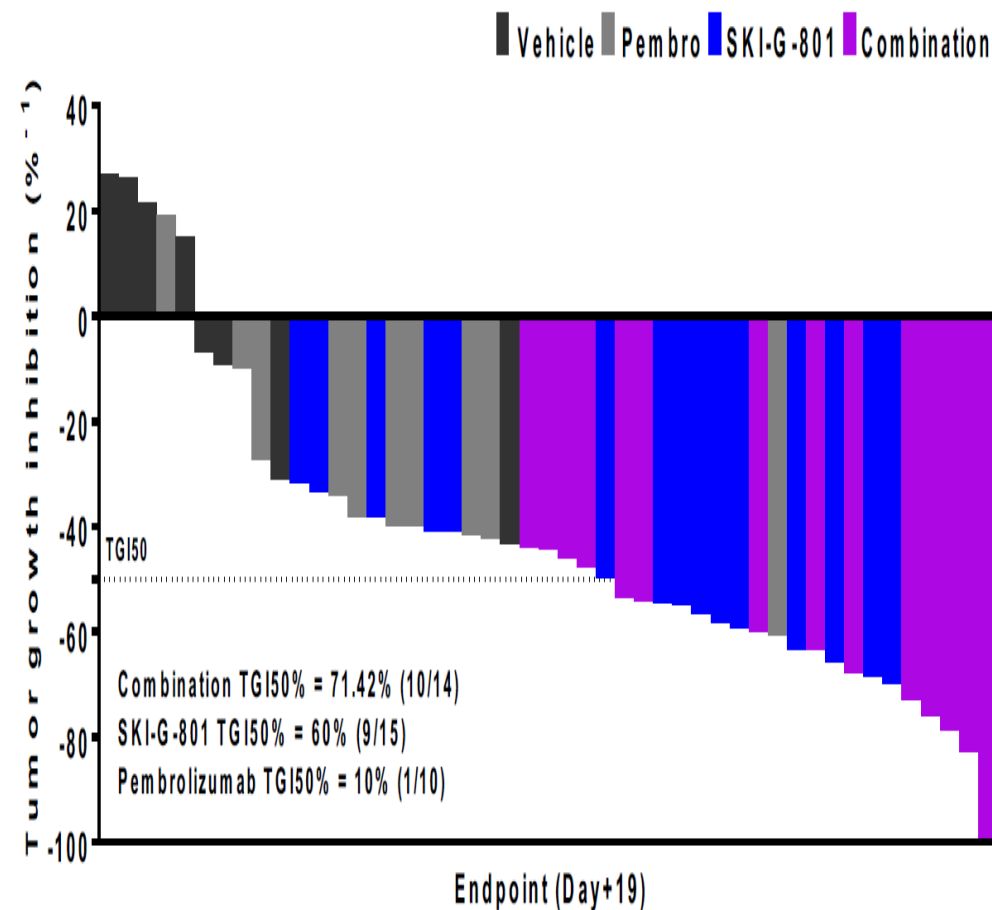
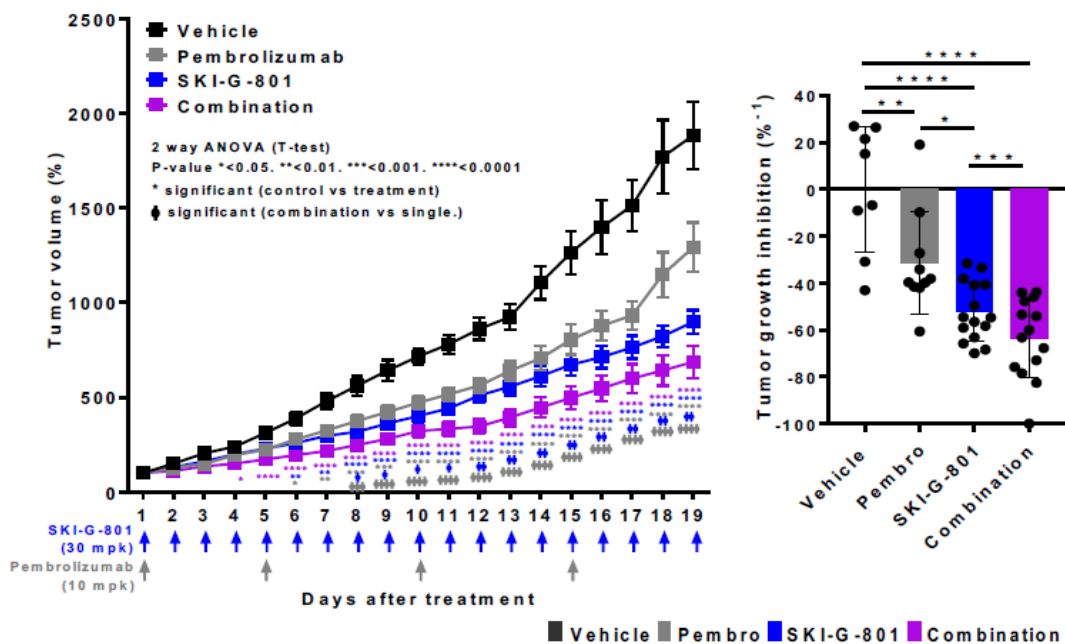
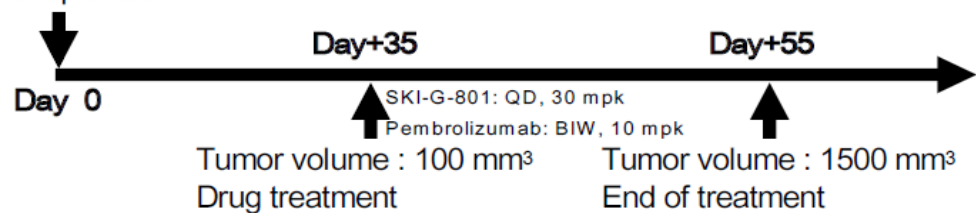


- The combination with SKI-G-801 and PD-1 shows greater inhibition of lung metastasis in the 4T1 spontaneous metastasis model (Figure A)
- Following neoadjuvant treatment for 6 days and tumor excision surgically, the combination-treated group increase overall survival rates in 4T1 syngeneic model (Figure B)

2-4. SKI-G-801: Combination effect with IO-drugs – PDX Model

The combination effect with SKI-G-801 and aPD-1 in Immuno-Avatars

*YHIM 2004 model represents lung squamous cell carcinoma.
*YHIM2004 (F3) tumor tissue
Transplantation



 | Oscotec Inc.

**Thank
you!**

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