㈜레고켐 바이오사이언스

Investor Relations 2022

3Q22

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ADC & 합성신약 분야의 차별적인 R&D 역량을 보유한 연구중심형 제약사!

기업개요 (2022.06월 기준)

회사명	㈜레고켐 바이오사이언스	
설립일/상장일	2006년 05월 / 2013년 05월	
자본금	121억	
주요사업	ADC(항체-약물 결합체) 연구개발	합성의약품 연구개발
본사	대전시 유성구 국제과학 10로 10	
임직원수	144명 (R&D 122명)	

CEO profile

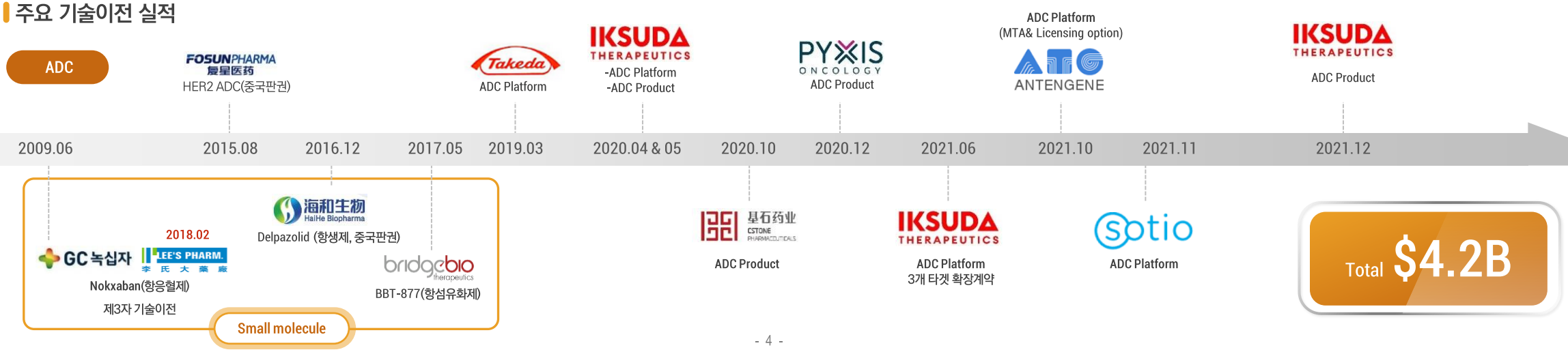
김용주 대표이사

서울대/KAIST, 유기화학 박사

㈜LG생명과학 신약연구소장

- 국내 최초 FDA승인 신약 " 팩티브 " 개발
- 항생제, 항응혈제, 간염치료제 등 다수 글로벌 기술이전 경험

주요 기술이전 실적

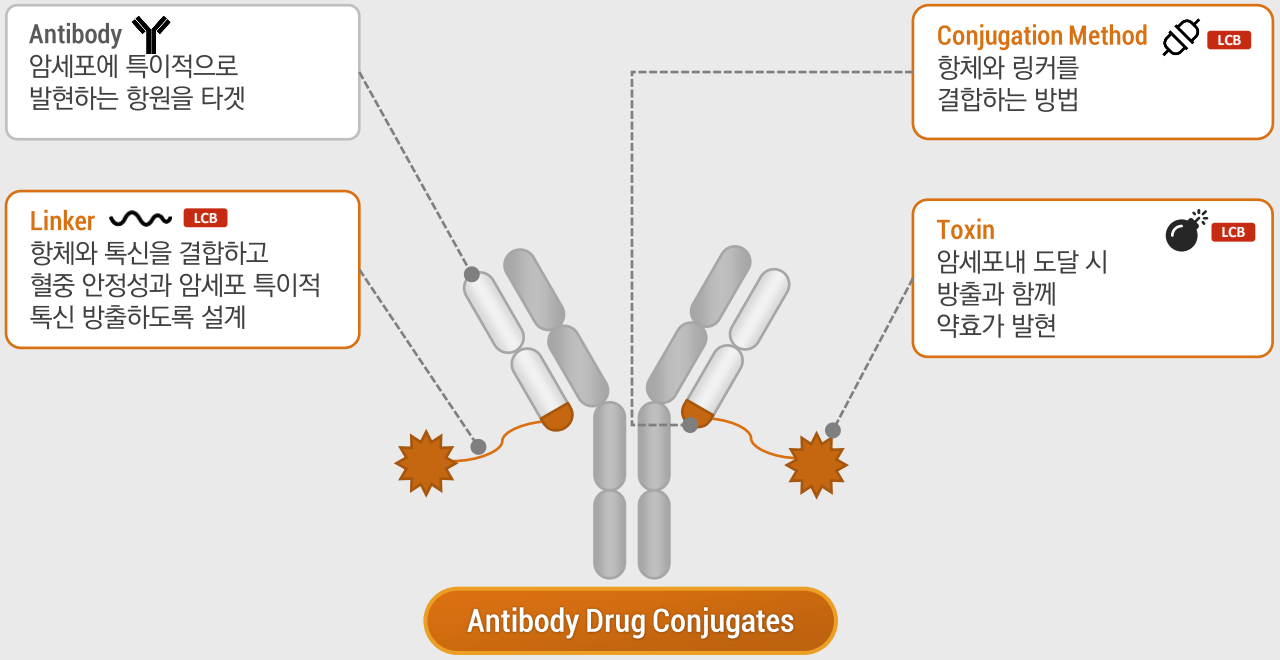


기술이전 계약현황

	계약 상대방	계약의 개요	계약체결일	선급금 (백만원)	계약금액 (백만원)
ADC	Fosun Pharma	• LCB14(HER2-ADC)/중국판권	2015년 08월	비공개	20,842
	Millenium Pharma (Takeda)	• ADC 원천기술	2019년 03월	비공개	454,823
	Iksuda	• ADC 원천기술	2020년 04월 2021년 06월	비공개	919,978
	Iksuda	• LCB73(CD19-ADC)	2020년 05월	6,132	278,370
	CStone	• LCB71(ROR1-ADC)	2020년 10월	11,276	409,883
	Pyxis (미국)	• LCB67(DLK1-ADC)	2020년 12월	10,517	325,487
	SOTIO Biotech	• ADC 원천기술	2021년 11월	비공개	1,212,656
	Iksuda (유럽)	• LCB14(HER2-ADC)/글로벌판권	2021년 12월	비공개	1,186,400
Small molecule	브릿지바이오	• BBT-877(ATX inhibitor)	2017년 05월	2,000	30,000
	Haihe Bio	• Delpazolid(옥사졸리디논계 항생제)/중국판권	2016년 12월	600	24,000
	GC녹십자	• Nokxaban(FXa inhibitor)	2009년 06월	비공개	비공개

ADC 플랫폼 원천기술을 활용한 다수의 파이프라인 확보

ConjuALL | 차세대 ADC 원천기술



1/ 혁신적인 결합방법과 안정적인 ADC 링커

- 항체의 특정부위 접합을 통한 **순도 높은 단일물질 구현**
- 암 특이적 톡신방출이 가능한 **안정적인 링커**
- 항체 변형 최소화를 통한 **탁월한 PK**

2/ 신규 MoA 독자개발 Payload

- 암세포에서만 활성화되는 PBD prodrug 및 신규 Toxin
- 면역항암기전 I/O payload –〉 단독 및 ADC 병용요법

파이프라인 : Antibody-Drug Conjugates

(주)레고켐바이오 LegoChemBio

ADC Products Pipeline

프로젝트	적응증/타겟	Discovery / preclinical / Phase 1 / Phase 2	Antibody Provider	License Status	Licensee
LCB14 HER2-MMAF	유방암		Herceptin Biosimilar	Fosun (China)	FOSUNPHARMA 复星医药
	위암(단독)				
	위암 (PD-L1 병용요법)				
	대장암				
	비소세포폐암				
	고형암				
	유방암	IND 1H23	Herceptin Biosimilar	Iksuda (ex-China)	IKSUDA THERAPEUTICS
LCB71 ROR1-pPBD	고형암, 혈액암		ablbio	CStone (ww)	基石药业 CSTONE PHARMACEUTICALS
LCB73 CD19-pPBD	혈액암		LIGHTCHAIN BIOSCIENCE	Iksuda (ww)	IKSUDA THERAPEUTICS
LCB67 DLK1	고형암, 혈액암		Y BIOLOGICS	Pyxis (ww)	PYXIS ONCOLOGY
LCB84 Trop2-MMAE	고형암, 혈액암		mediterranea	LCB (ww)	-
LCB07A bispecific ADC	고형암, 혈액암		ablbio	LCB & ABL	-
LCB02A	고형암, 혈액암		HARBOUR BIOMED	LCB (ww)	-
LCB04A AIC	undisclosed		ImmuneOncia Therapeutics Inc.	LCB (ww)	-
LCB12A bispecific ADC	undisclosed		Hanmi	LCB & Hanmi	-
LCB09A	undisclosed		LCB	LCB & Cellectar	CELLECTAR BIOSCIENCES

파이프라인 : Antibody-Drug Conjugates

(주)레고켐바이오 LegoChemBio

ADC Platform Pipeline

프로젝트	적응증/타겟	Discovery	preclinical	Phase 1	Phase 2	Antibody Provider	License Status	Licensee
LCB69	고형암, 혈액암					Takeda	Takeda (ww)	Takeda
LCB85 CanAg-pPBD	고형암, 혈액암		*IND 2023*			IKSUDA THERAPEUTICS	Iksuda (ww)	IKSUDA THERAPEUTICS
LCB20A	-					Sotio	Sotio	Sotio
LCB19A	-					ANTENGENE	Antengene	ANTENGENE
LCB91	고형암, 혈액암					undisclosed	undisclosed	undisclosed
LCB06A	-					undisclosed	undisclosed	undisclosed
LCB18A	-					undisclosed	undisclosed	undisclosed
LCB36A	-					undisclosed	undisclosed	undisclosed

파이프라인 : Small molecules

(주)레고켐바이오 LegoChemBio

	프로젝트	적응증	Discovery	preclinical	Phase 1	Phase 2	Phase 3	Partner	비고
Anti-biotics	Delpazolid (Gram +)	- DS-TB - MDR-TB - MRSA/ VRE	전임상 (USA) / ph 1, ph 2a (Korea)					-	- Orphan Drug - QIDP - Fast Track
			DS-TB : 임상 2b상 진행중(남아공, 탄자니아)						
			전임상 (USA) / ph 1, ph 2a (Korea)						
			MRSA 균혈증 : 임상 2상 진행중						
			China					海和生物 HaiHe Biopharma	- L/O for China ('16.12)
Anti-fibrotic	LCB17-0877 (ATX Inhibitor)	IPF, fibrotic diseases	USA					bridgebio therapeutics	- L/O for global (Profit Sharing)
Anti-coagulant	LCB02-0133 (Nokxaban, FXa Inhibitor)	항응혈제	USA					GC 녹십자	- L/O for global (Profit Sharing)
			China					LEE'S PHARM. 李氏大藥廠	- Sub L/O for China ('18.01)
Anti-cancer	ATX inhibitor (Next Gen)								- 미세종양환경 조절 - Combi with ADC
	Immuno-oncology (AIC payload & Combi therapy)								- AIC - Combi with ADC
									- AIC
									- AIC - Combi with ADC
									- Combi with ADC

ADC/항생제 분야 최고 전문가 활용, 글로벌 신약연구개발 추구

Scientific Advisory Board

Bob Lutz
ADC Development

- 30 years of pharma/biotech experience
- ImmunoGen VP, Translational Research & Development(23 years)
- Led '8'ADCs(including Kadcyla) to clinical trials
- Prensent CSO of Iksuda

Rakesh Dixit
ADC Toxicology/Safety

- 30 years of pharma/biotech experience
- AstraZeneca/Medimmune VP & Global Head of Biologics Safety Assessment, Merck, J&J
- The 100 Most Inspiring People in the Pharmaceutical Industry by PharmaVoice in 2015
- A key contributor to '10'different approvals <Imfinzi (anti-PD-L1 mab), Fasenra (anti-IL-5R afucsolytated mab), Brodalumab (anti-IL-17), etc>

Morris Z. Rosenberg
ADC Manufacturing/CMC

- 30 years of pharma/biotech experience
- Seagen EVP/Immunomedics CTO
- Led launch of Trodelvy, Adcetris, Avonex, Angiomax, Xigris, and Forteo

Lawrence Geiter
Antibiotics Development

- 30 years of tuberculosis drug R&D experience
- Otsuka VP, Head of Global Clinical Development of novel products-TB
- Led clinical trials of Deltyba(delamanid, Otsuka)
- Leading phase 2b of Delpazolid in Legochem

Vision 2030

Global Top ADC company

TOP 3

~ 2020

Platform

- Linker / PBD Toxins
- Conjugation

접근법

- 단일항체 (mAb)
- 암세포사멸 toxins

사업모델

- 후보물질 단계 기술이전

TOP 2

~ 2025

Platform

- Novel MoA Toxins
- I/O Payloads

접근법

- Bispecific Ab, AIC
- Payload 확장
- Combi (+ IO 등)

사업모델

- 독자 임상 파이프라인 확보
- 임상단계 기술이전 부가가치 확대

TOP 1

~ 2030

Platform

- Novel Ab/Ligand
- Non-cancer linkers

접근법

- 면역치료제, 항생제 등 다양한 분야 확대

사업모델

- 후기임상/허가단계 독자파이프 확보
- 기술이전 물질들의 허가를 통한 로열티 확보

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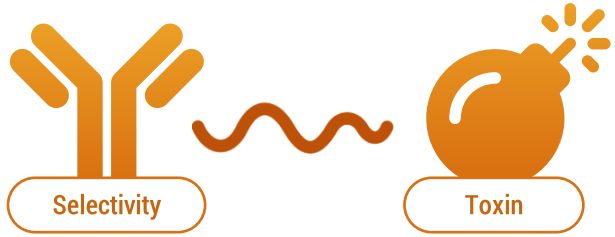
Antibody-Drug Conjugate(항체-약물 결합체)란?

(주)레고켐바이오 LegoChemBio

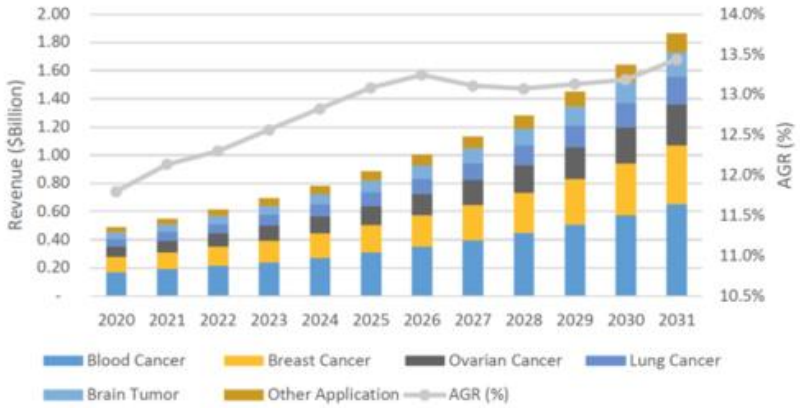
ADC concept



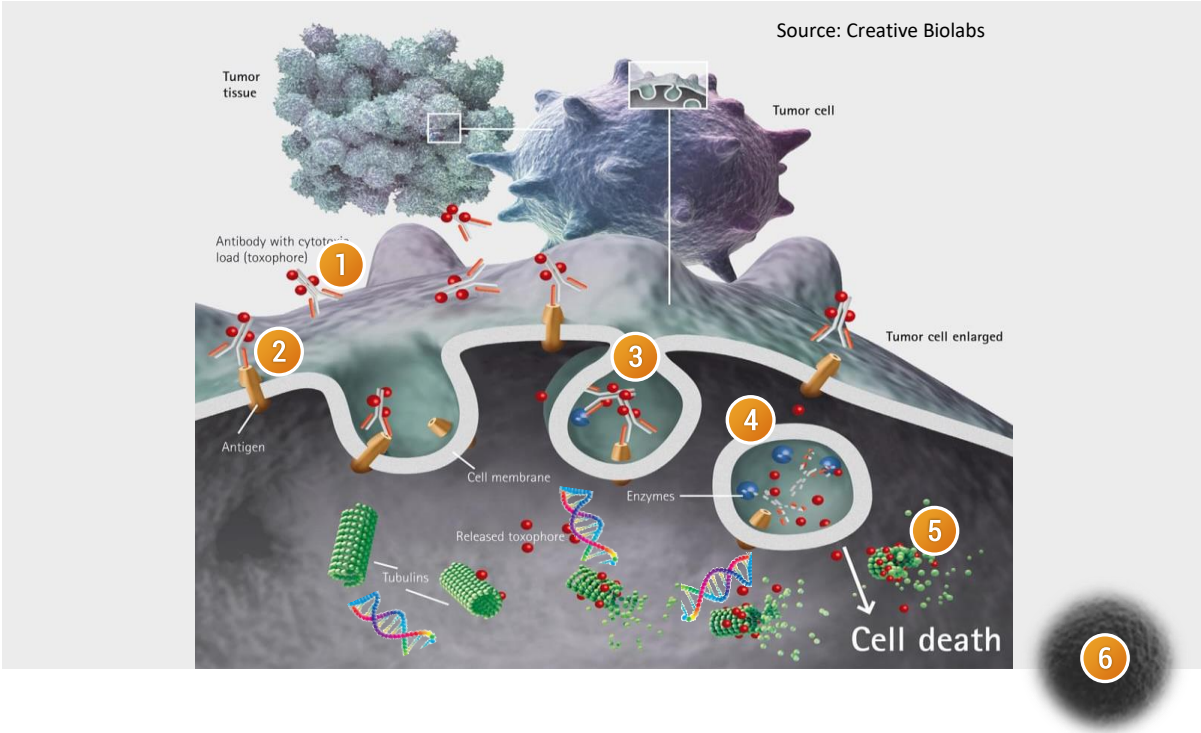
- ADC는 항체의 선택성과 합성의약품의 항암효과를 동시에 활용
- 항체를 통해 선택적으로 암세포와 결합, Toxin의 항암효과를 암세포에서만 나타냄

ADC market

Figure 10.36 LAMEA **Antibody Drug Conjugates Market** by Application Forecast 2021-2031(US $billion, AGR %)



Mode of Action



1. ADC travels through bloodstream
2. ADC binds to target antigen
3. ADC is internalized
4. Antibody portion removal in lysosome
5. Released cell-killing agent
6. Cell death(Apoptosis)

ADC 시장 현황

출시된 ADC 의약품

ADCETRIS (2011.08~)
- **호지킨림프종 (CD30)**
- 기술원천: Seagen 사
- 실시권자/판매자: Takeda(ex-US, Canada)

KADCYLA (2013.02~)
- **양성전이 유방암 (HER2)**
- 기술원천: ImmunoGen 사
- 실시권자/판매자: Roche /Genentech

BESPONSA (2017.08~)
- **급성림프구성백혈병 (CD22)**
- 기술원천: Pfizer
- 실시권자/판매자: Pfizer

MYLOTARG (2017.09~)
- **급성 골수성 백혈병 (CD33)**
- 기술원천: Pfizer
- 실시권자/판매자: Pfizer

POLIVY (2019.10~)
- **거대 B세포 림프종 (CD79b)**
- 기술원천: Genentech
- 실시권자/판매자: Genentech

ENHERTU (2019.12~)
- **양성전이 유방암 (HER2)**
- 기술원천: Daiichi Sankyo
- 실시권자/판매자: Daiichi Sankyo/Astrazeneca

PADCEV (2019.12~)
- **전이성 요로상피암 (NECTIN-4)**
- 기술원천: Seagen/Astellas
- 실시권자/판매자: Seagen/Astellas

TRODELVY (2020.04~)
- **삼중음성 유방암 (TROP2)**
- 기술원천: Immunomedics
- 실시권자/판매자: Immunomedics

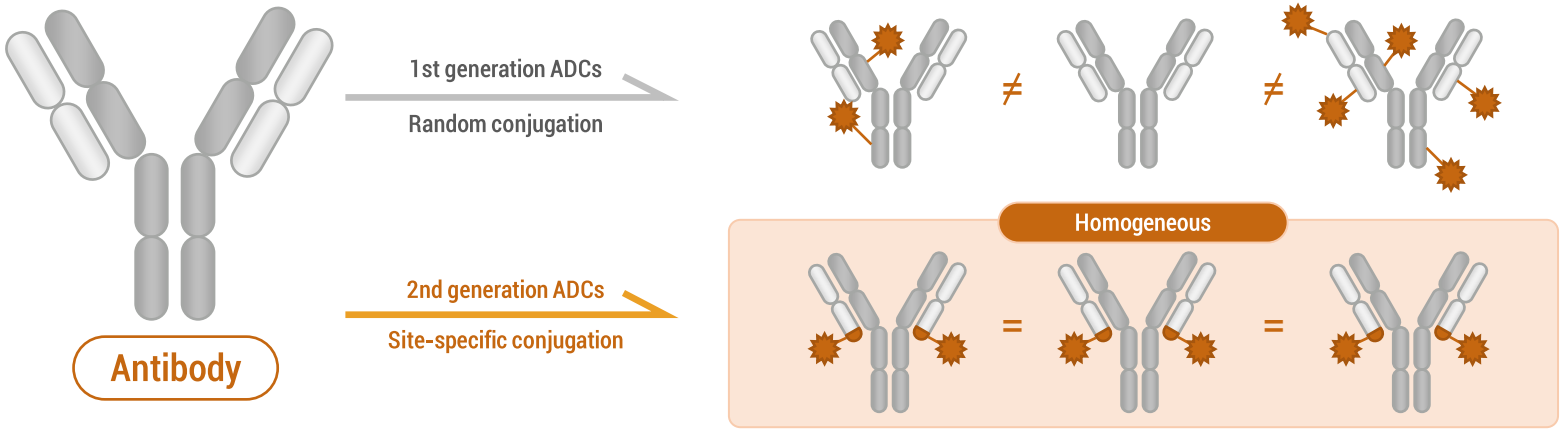
BLENREP (2020.08~)
- **다발성 골수종 (BCMA)**
- 기술원천: GSK
- 실시권자/판매자: GSK

ZYNLONTA (2021.04~)
- **거대 B세포 림프종 (CD19)**
- 기술원천: ADC Theranpeutics
- 실시권자/판매자: ADC Theranpeutics

TIVDAK (2021.09~)
- **전이성 자궁경부암 (TF)**
- 기술원천: Seagen/Genmab
- 실시권자/판매자: Seagen/Genmab

ADC Unmet Needs 및 해결 방안

"혈중에서
안정적인 링커를 활용,
암세포까지 약물을 직접 전달
할 수 있는 **단일물질 ADC 필요**"

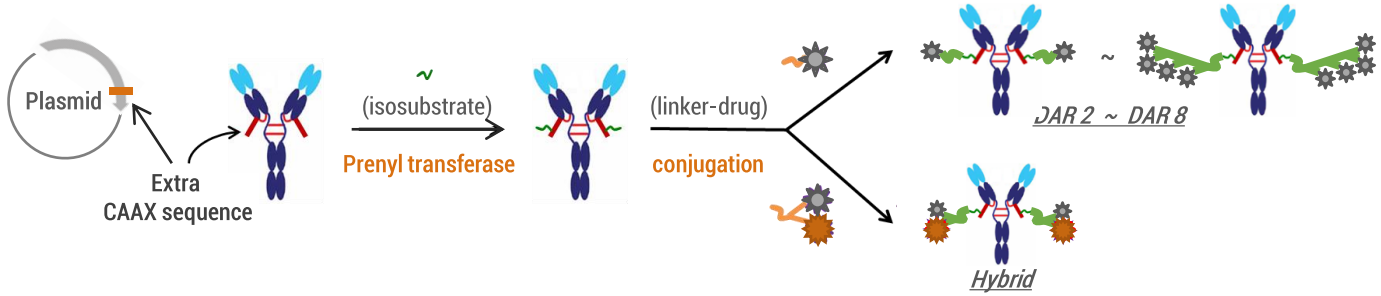


	미충족 수요 Unmet Needs	해결방안 Solutions
항 체	• **ADC 용 항체 변형에 따른 고유 물성 손실** – PK Profile – Binding Affinity	• **ADC용 항체 구조의 변형 최소화**
결합 방법	• **혼합물질 결합 방식** – 다수의 불순물 생성	• **단일물질 결합 방식** – 순도 높은 단일물질 생성
링 커	• **혈중 안정성** – 혈중 링커 분리에 따른 약효 및 안전성 감소 • **Toxin Release Rate** – 암세포 내 톡신 분리율 향상 필요	• **혈중 안정적인 링커** • **암세포 내 특정 효소에 의한 효율적 약물 유리**
Toxin	• **높은 항암효과 필요** • **암세포의 내성으로 인한 약효 상실**	• **신규 MOA 기반 Toxin**

ConjuALL : Linker platform

(주)레고켐바이오 LegoChemBio

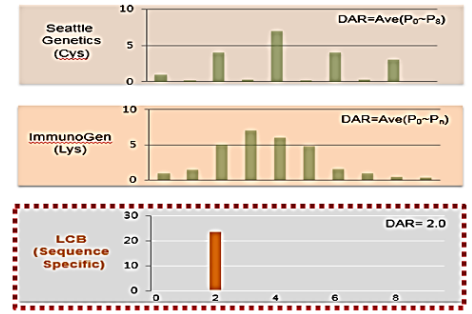
"혈중 안정적인 **Cleavable 링커**와 **고유결합 방법**을 **활용**, **약효**와 **안전성**을 **동시**에 **개선**"



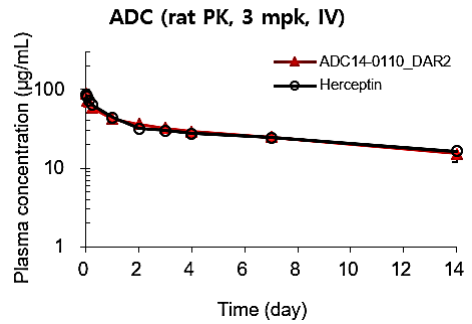
LCB's Approach

Site-Specific Conjugation (1, 2)	• 단일물질 (Defined DAR) • 우수한 PK 및 항체변형 최소 (PK of ADC = mAb PK) • 대량생산성 검증 완료 • 독자기술 ADC 특허 (미국)
Linker Stability (3)	• 우수한 혈중 안정성 • 링커와 다양한 접합기술 활용 항체 결합 가능 (기존 CaaX body를 활용하여 접합 → 현재 CaaX 없이도 접합가능)
Efficient Toxin Release (4)	• 효소(β-Glucuronidase)를 활용한 암세포 내에서 효율적인 약물유리
Universality (Ab carrier, Toxins)	• 항체 범용성 : Herceptin, ROR1, CD19, DLK1 • 다양한 독신 : MMAE, MMAF, PBD, etc. • 적용가능 기술의 확장 : Protein-Drug onjugates (PDCs)
Tailored DAR & hybrid toxins	• 맞춤형 DAR (DAR = 2, 4, 6, 8…) • 다양한 적응증 치료를 위한 이중 독신 접합 기술 • 독자 PBD 프로드러그 기술

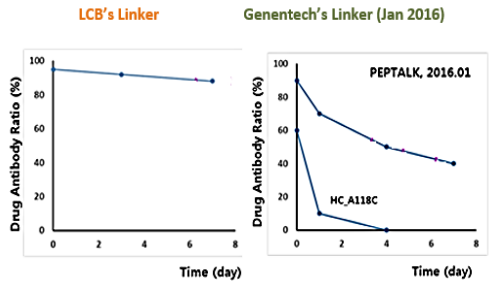
① 단일물질 ADC



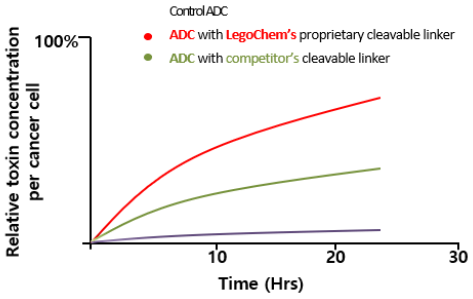
② 우수한 PK 프로필



③ 혈중안정적인링커



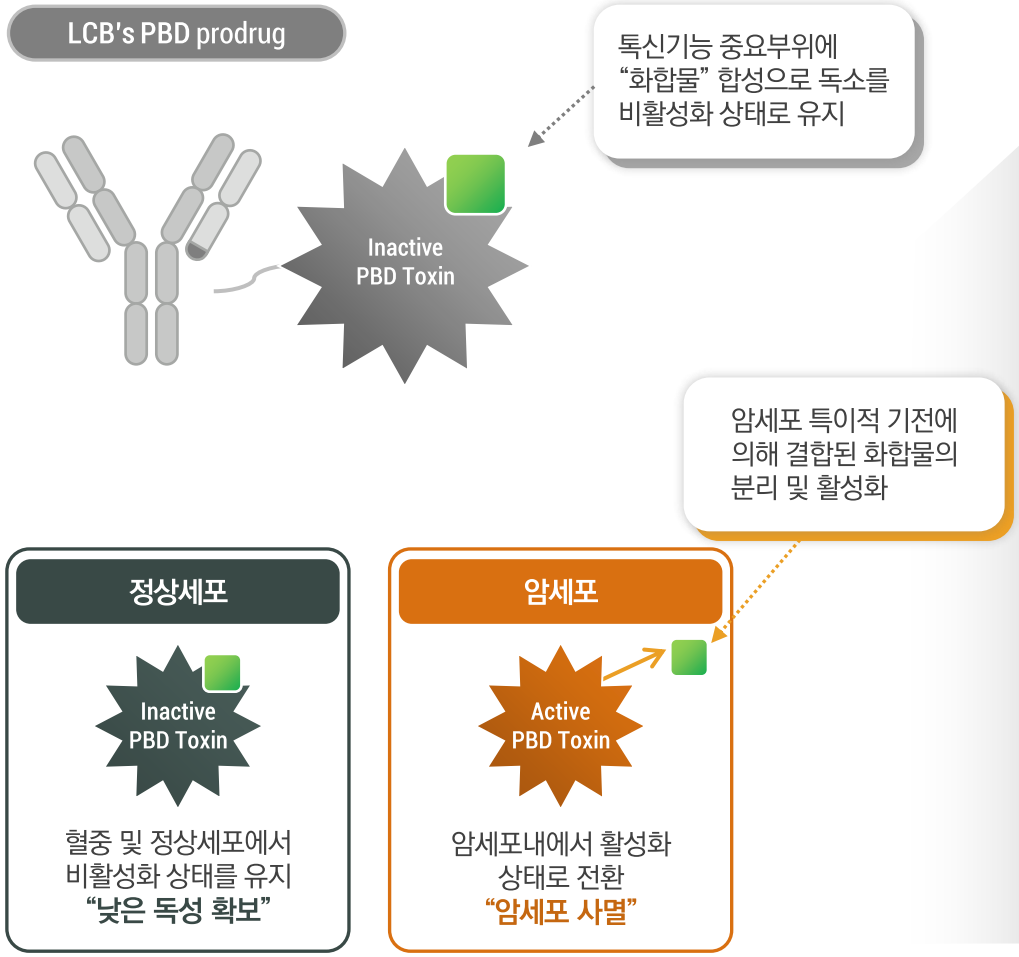
④ 효율적인약물유리



ConjuALL : Toxin platform(PBD prodrug)

(주)레고켐바이오 LegoChemBio

Mode of Action

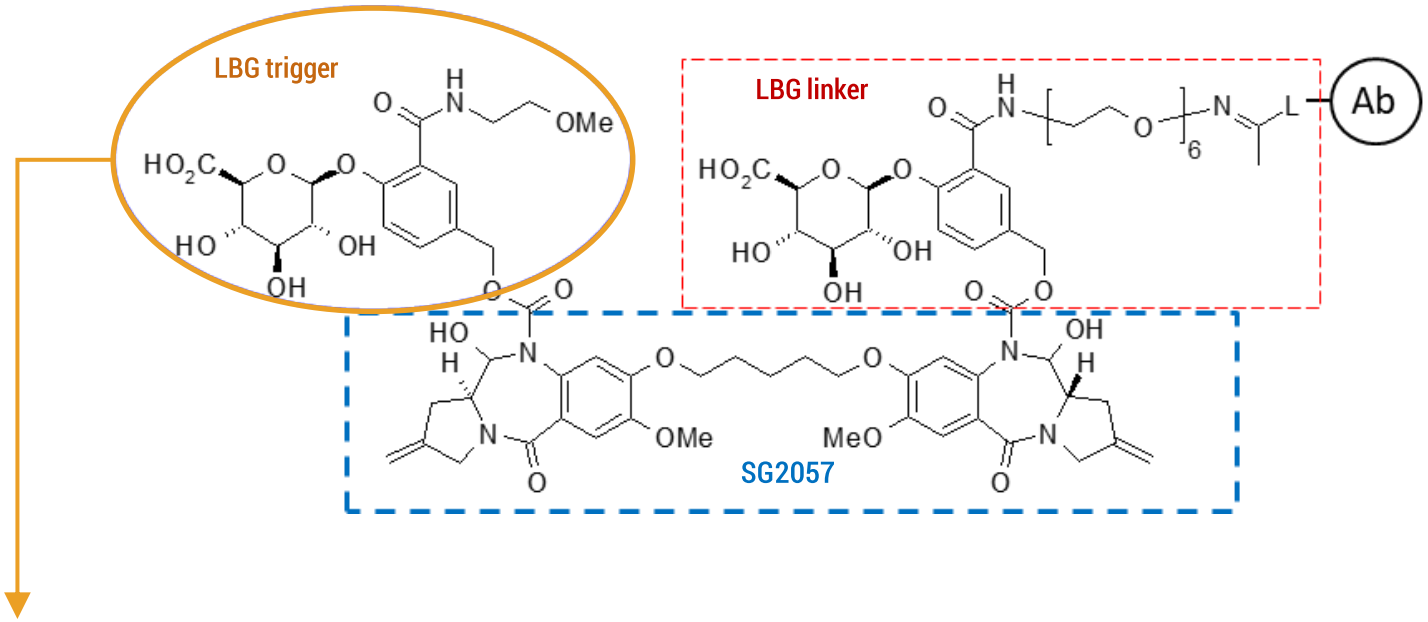


	Conventional PBD-ADC	LCB's PBD prodrug-ADC
효능	High	High (암세포 특이적 독소의 활성화)
독성	High	Low (혈중 및 정상세포에서 독소의 비활성화)
TI (Therapeutic Index)	Low	High (향상된 효능 및 낮은 독성)
생산성	Low	High (향상된 물성을 통한 생산수율 증가)

Chemistry and MOA of LCB's PBD prodrug

(주)레고켐바이오 LegoChemBio

"dPBD Prodrug" - *LBG linker



LBG hydrophilic masking moiety attached to PBD is removed predominately within cancer cells by its cognate enzyme, beta-glucuronidase, overexpressed in almost all of known solid and blood cancers, not in normal cells → same MOA as LCB linker cleavage

Beta-glucuronidase is predominately active and present in cancer cells' lysosome, which is the destination of ADCs after receptor-mediated endocytosis

LCB's approach in novel therapeutics development for oncology

1. HER2-ADC (solid cancers)
2. ROR1-ADC (solid and blood cancers)
3. CD19-ADC (various blood cancers)
4. TROP2-ADC (solid cancers)

01

LCB14

FS-1502; IKS014; HER2-ADC

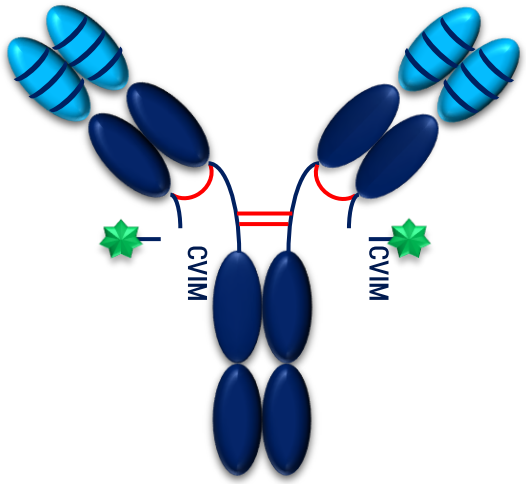
LCB14, anti-HER2 MMAF conjugate in solid cancers

(주)레고켐바이오 LegoChemBio

LCB14

anti-HER2_LBG-MMAF, DAR2

LCB14 is based on the clinical validated Trastuzumab & MMAF and LCB's proprietary beta-glucuronide linker



Overview

- HER2 targeting & MMAF bearing ADC
- Made by *ConjuAll*technology

Potential indications

- Various solid cancers (Advanced or metastatic HER2 positive solid cancers)
- Breast cancer, Gastric cancer, Ovarian cancer, Colorectal cancer, NSCLC, Urothelial cancer, Endometrial cancer....

Status / Next steps

Status

- Phase Ib for BC(in China)
- On going in Phase II (GC/CRC/NSCLC/Solid cancers/PD-1 combination in China)

Next steps

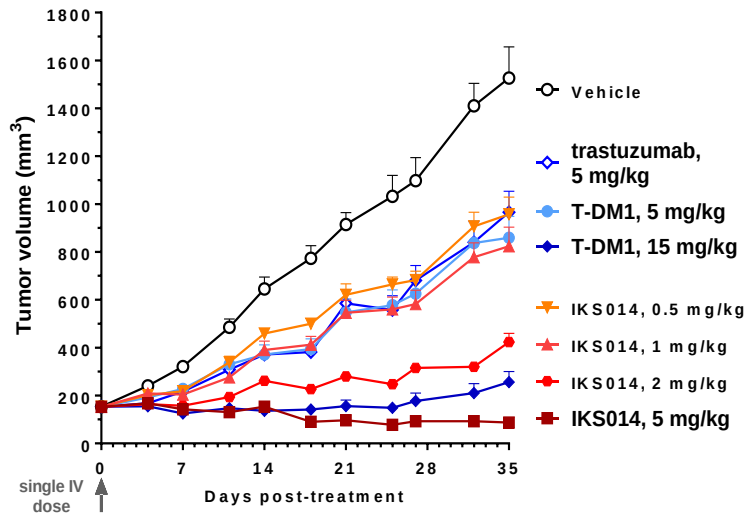
- Global Phase I planned, 1H 2023 (US IND by Iksuda)

* CRC, colorectal cancer; GC, gastric cancer; NSCLC, Non-small cell ling cancer

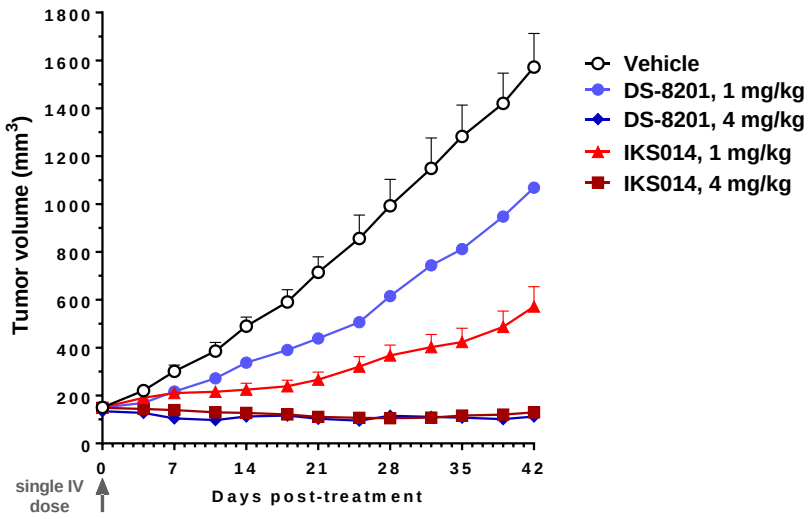
LCB14, anti-HER2 MMAF conjugate in solid cancers

(주)레고켐바이오 LegoChemBio

LCB14 was comparable to or superior to FDA approved drugs in HER2 positive gastric cancer xenograft model



- HER2 high gastric cancer model (IHC 3+)
- complete tumor growth inhibition at a single dose 5 mg/kg
- >3 fold greater activity than T-DM1 (DAR 3.5)



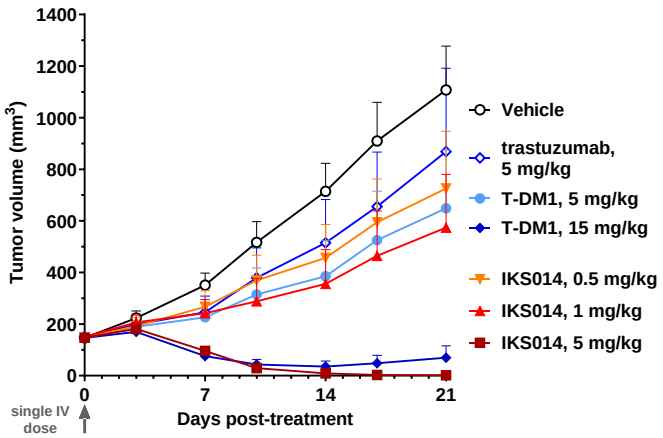
- HER2 high gastric cancer model (IHC 3+)
- effective tumor growth inhibition at 4 mg/kg
- comparable to DS-8201 (DAR ~8)

LCB14, anti-HER2 MMAF conjugate in solid cancers

(주)레고켐바이오 LegoChemBio

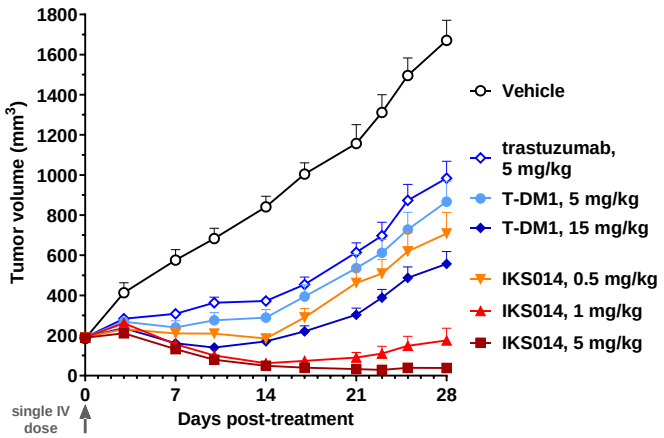
LCB14 was comparable to or superior to FDA approved drugs in HER2 positive breast & gastric cancer xenograft models

BT-474



- HER2 high breast cancer model (IHC 3+)
- complete tumor regression at a single dose 5 mg/kg
- Trastuzumab has marginal activity and T-DM1 only modestly inhibits tumor growth at a dose 3-fold higher

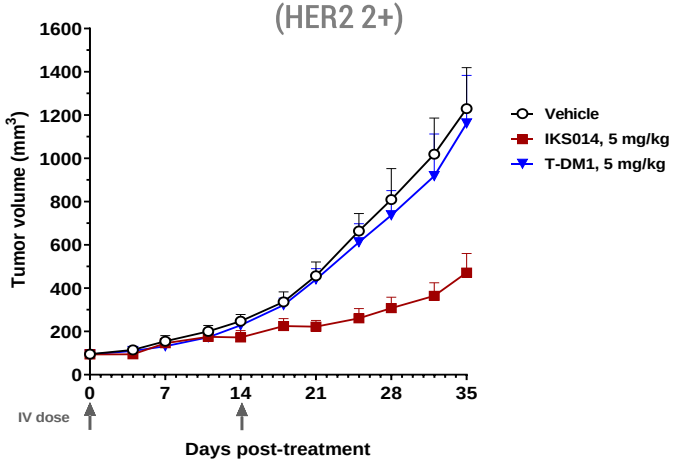
JIMT-1



- Trastuzumab & T-DM1 resistant, HER2 moderate breast cancer model (IHC 2+)
- complete tumor regression at a single dose 5 mg/kg & partial regression at 1 mg/kg
- T-DM1 only inhibits tumor growth at 15 mg/kg
- DS-8201a shows only marginal tumor regression at 10 mg/kg Q7d x 2 in this model (published data by DS)

gastric cancer PDX model

(HER2 2+)



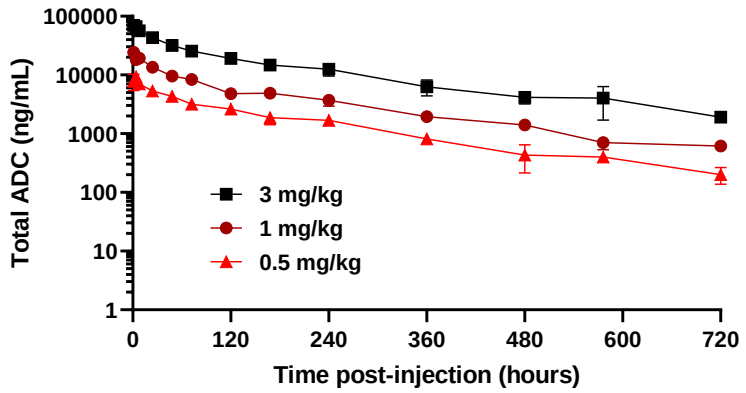
- HER2 moderate high gastric PDX model (IHC 2+)
- Tumor growth retardation at 5 mg/kg Q2W x2
- No efficacy for T-DM1 at same dosing schedule

LCB14, anti-HER2 MMAF conjugate in solid cancers

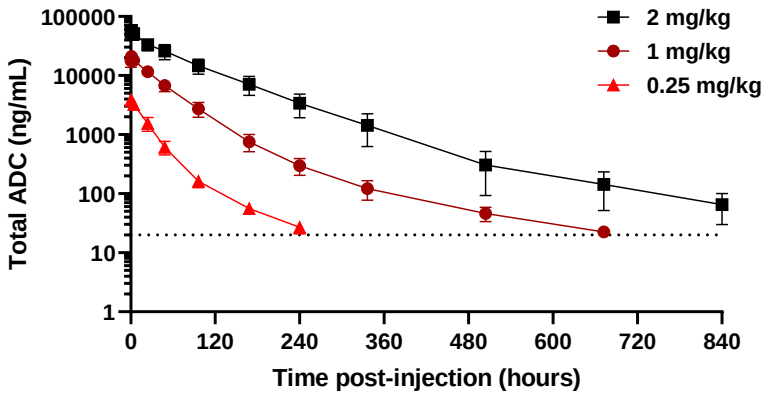
(주)레고켐바이오 LegoChemBio

IKS014 demonstrates stable ADC PK profile in vivo rats & cyno monkeys

Rat, IV, single dose



Monkey, IV, single dose



Safety assessment in preclinical study

- GLP-compliant single dose and repeat dose studies in cynomolgus monkeys yielded an HNSTD of 12 mg/kg for single dose; and 5 mg/kg Q3W x4 for repeat dose administration of LCB14 ADC
- Safety findings were limited to hematologic changes and serum chemistry including increase in liver function tests
- No ocular findings were noted

LCB's anti-HER2 ADC has very compelling TI value

	T-DM1 (Kadcyla)	DS-8201a	LCB14	XMT-1522
Company	Genentech / Roche	Daiichi Sankyo	LegoChem	Mersana
Payload (DAR)	DM1 (~3.4)	DX-8951 (~7.7)	MMAF (2)	Auristatin D (15)
MED (JIMT-1)	>20mpk	>10mpk	1mpk	1mpk
HNSTD	30 mpk^{S}	30 mpk^{R}	12 mpk	2.5 mpk
TI	<6	<12	48	10
Phase	FDA approved	Phase III	Phase I	Phase I (Terminated)

02

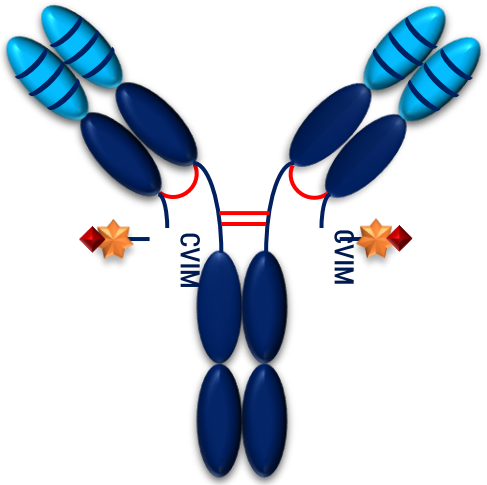
LCB71

CS5001; ABL202; ROR1-ADC

LCB71

anti-ROR1_LBG-proPBD, DAR2

LCB71 is a ROR1 specific ADC containing LCB's proprietary prodrug PBD



Fully human anti-ROR1 Ab with a CaaX motif that can be recognized by farnesyl transferase (FTase)

Overview

- ROR1 targeting ADC
- LCB's Proprietary Prodrug PBD bearing ADC

Potential indications

- ROR1 positive various cancers
  - solid cancers : TNBC, Gastric cancer, Ovarian cancer, NSCLC...
  - blood cancers : MCL, CLL, ALL, DLBCL...

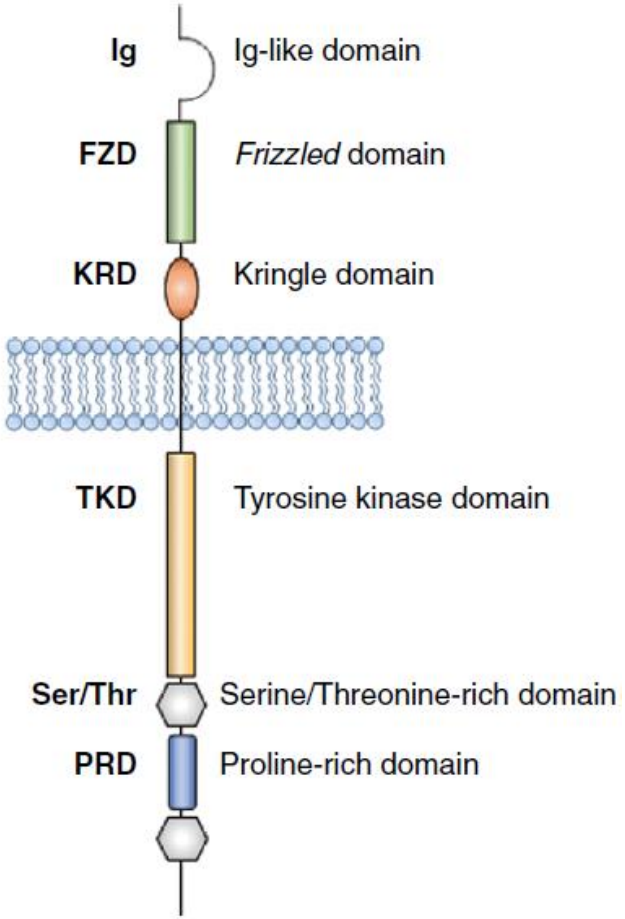
Status / Next steps

Status

- Phase I (US/China/Australia) ; First patient administration (2022.04.04)

* ALL, Acute lymphocytic leukemia; CLL, Chronic lymphocytic leukemia, DLBCL, Diffuse large cell lymphoma; MCL, mantle cell lymphoma; NSCLC, Non-small cell ling cancer ; TNBC, Triple negative breast cancer

ROR1 is a compelling oncology target



01

Cancer specificity

- ROR1 is overexpressed in various hematological and solid malignancies
- ROR1 is associated with cancer metastasis

02

Low normal expression

- ROR1 is an oncofetal protein important for embryonic development
- ROR1 shows no or low expression in healthy adult tissues

03

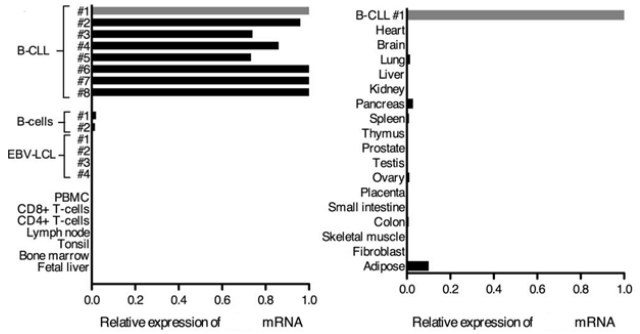
Drug resistance

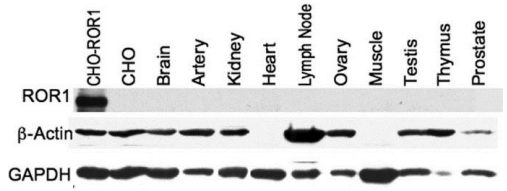
- Chemotherapy induces ROR1 expression
- Possibility of overcoming drug resistance of other TKIs such as erlotinib or ibrutinib

ROR1 expression in normal tissues

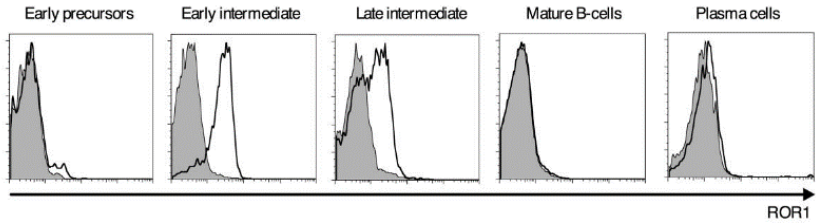
(주)레고켐바이오 LegoChemBio

ROR1 expression in normal tissues



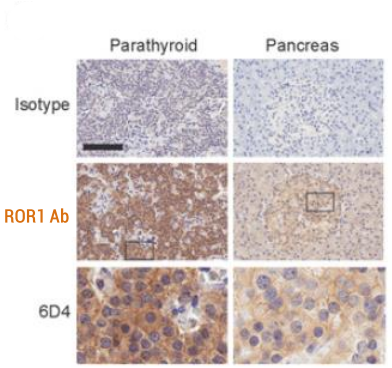


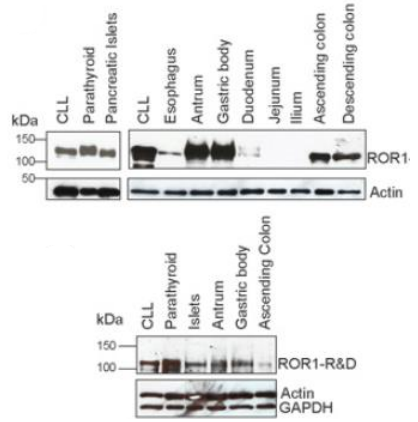
ROR1 & B cell development



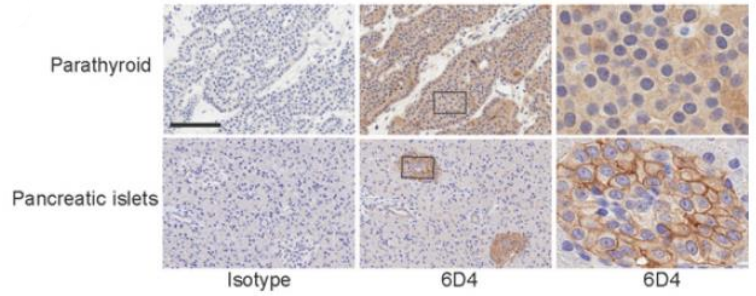
(2010) Blood 116(22) 4532-41, (2008) PNAS 105(8)3047-52

ROR1 expression in normal human parathyroid & pancreas





ROR1 expression in normal rhesus parathyroid & pancreatic islets



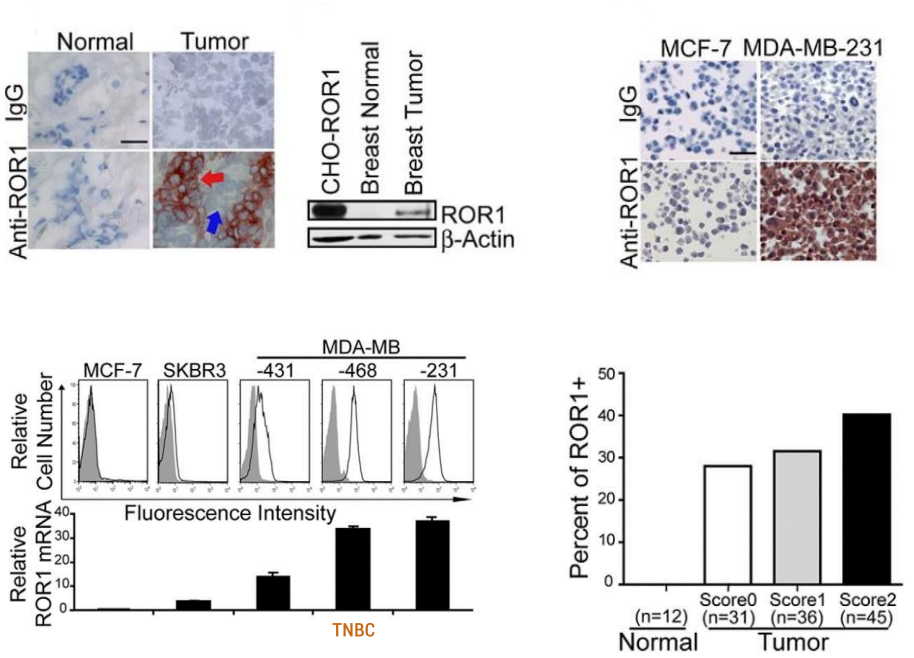
(2017) Clin Cancer Res 23(12)3061-71

ROR1 as a therapeutic target for TNBC

(주)레고켐바이오 LegoChemBio

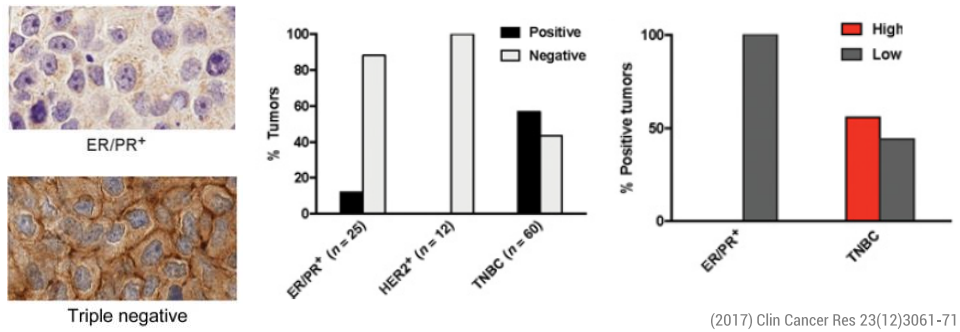
ROR1 expression is associated with poor prognosis in TNBC patients

ROR1 expression in Breast tumor



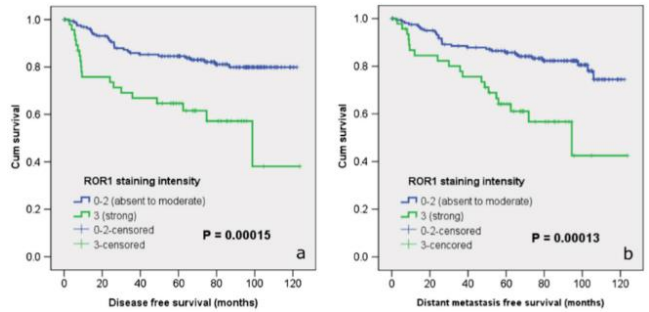
(2012) PLoS One 7(3)e31127

ROR1 expression in TNBC patient



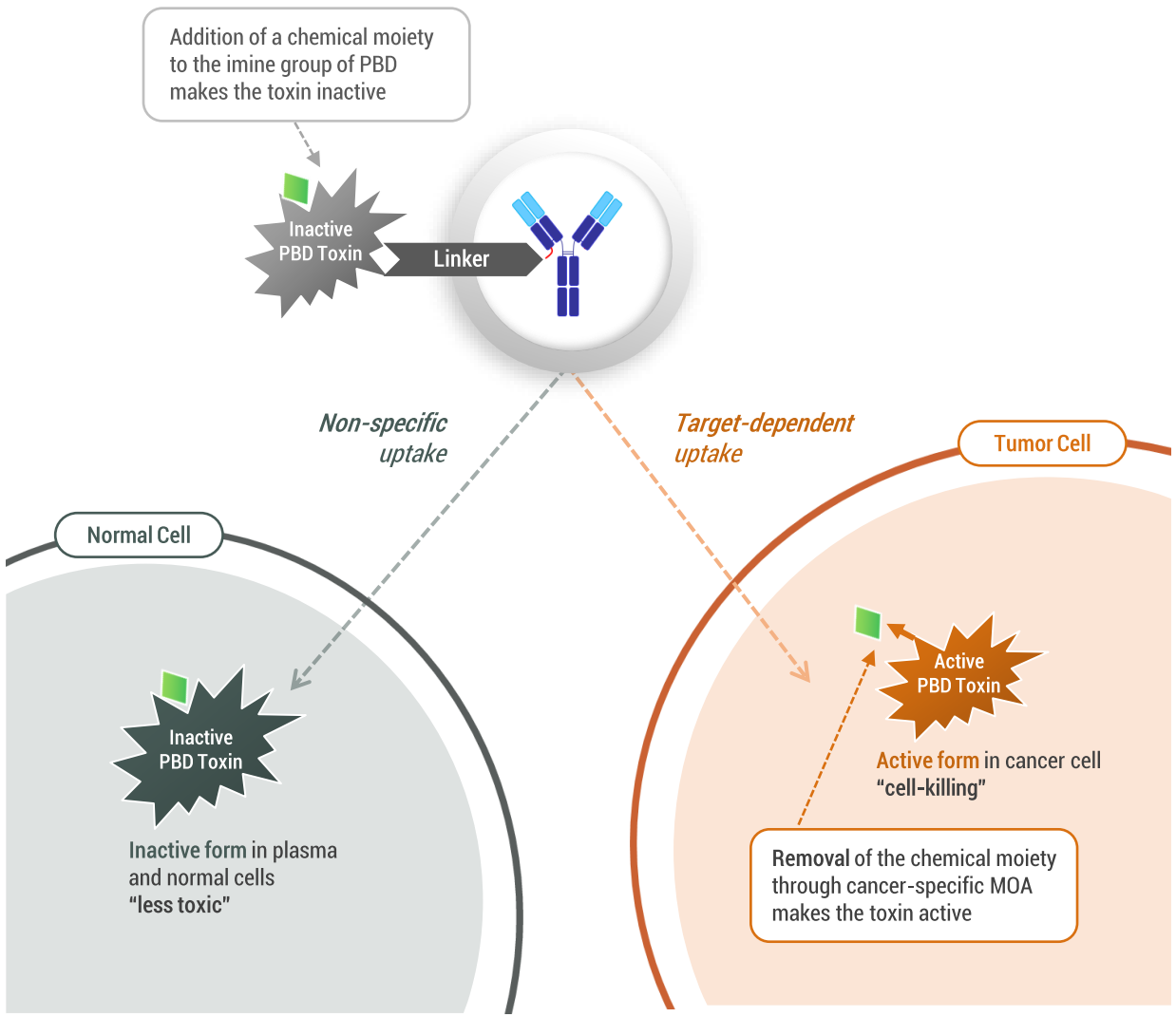
(2017) Clin Cancer Res 23(12)3061-71

ROR1 expression & poor prognosis in TNBC



(2016) Virchows Arch 468(5)589-95

LCB's proprietary PBD prodrug payload technology



	Conventional PBD-ADC	LCB's Proprietary PBD-ADC
PBD Characteristics	• Potent DNA damaging agent • Labile imine group leading to CMC challenges	• Potent DNA damaging agent • Protected imine with **improved CMC properties** • Improved hydrophilicity for **improved solubility** • Improved linker chemistry for **improved PK**
ADC Production	• Heterogeneous ADC even with site-specific approaches due to imine-adducts during manufacturing	• **Homogenous final ADC**
Antibody Conjugation Method	• Mostly unstable Cys-maleimide coupling (Thiomab approach)	• Highly stable oxime or Click ligation for **improved stability**
Toxicity	• Safety issues due to premature release of free PBD and non-specific uptake of ADC • Narrow therapeutic index • Delayed toxicity observed	• Stable tumor-activated prodrug technology prevents normal tissue damage for **reduced toxicity** • **Improved therapeutic index**

MOA (mode of Action)

(주)레고켐바이오 LegoChemBio

STEP 01 | ADC binds to ROR1 expressed cancer cell

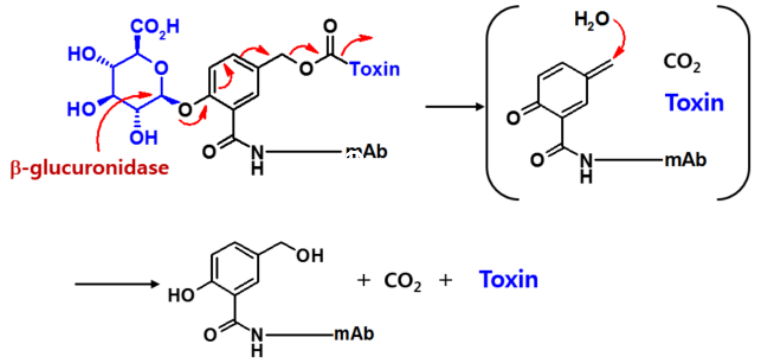
STEP 02 | ROR1 mediated endocytosis

STEP 03 | Lysosomal targeting (early endosome → late endosome → lysosome)

STEP 04 | Proteolysis : PBD release by β-glucuronidase

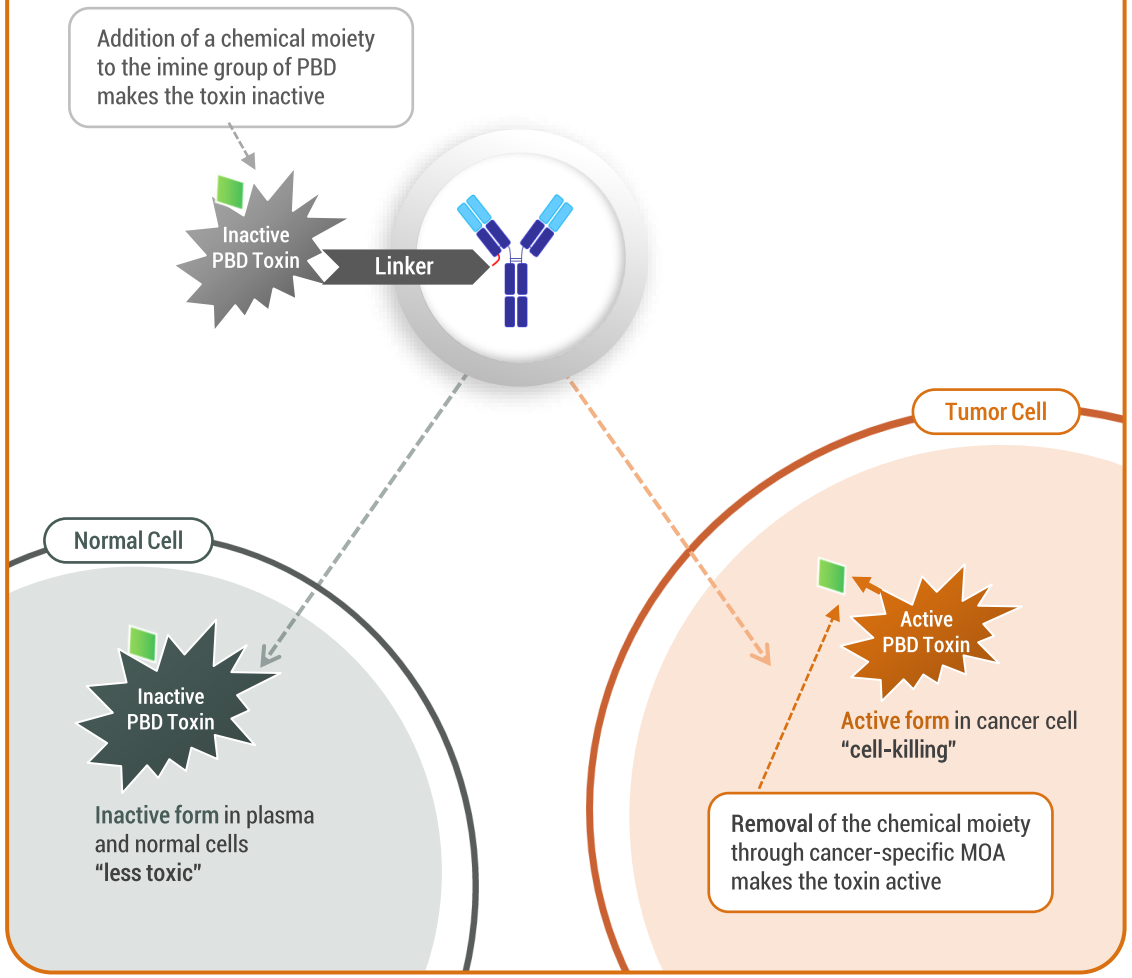
STEP 05 | DNA cross-linking → tumor cell death

Cancer-specific toxin release by proprietary β-glucuronide linker



Toxin release by β-glucuronidase trigger

LCB's proprietary PBD prodrug toxin

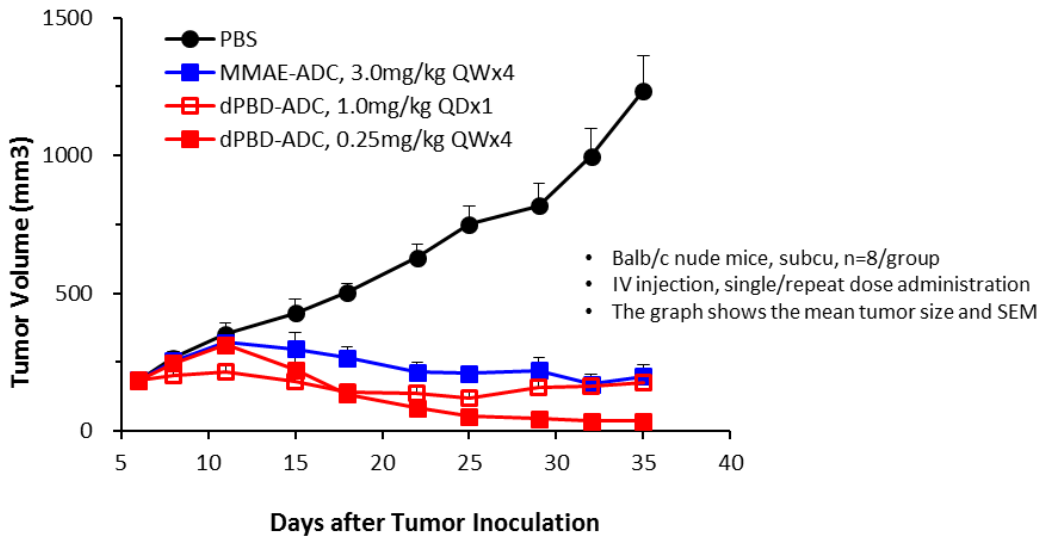


Preclinical Data

(주)레고켐바이오 LegoChemBio

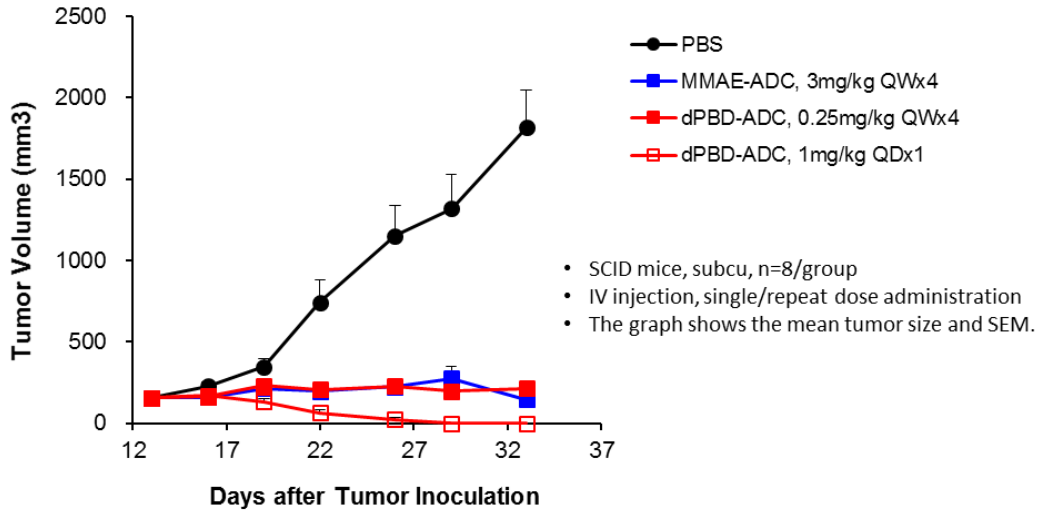
Calu-3 *in vivo* xenograft model

(IV administration)



Jeko-1 *in vivo* xenograft model

(IV administration)



03

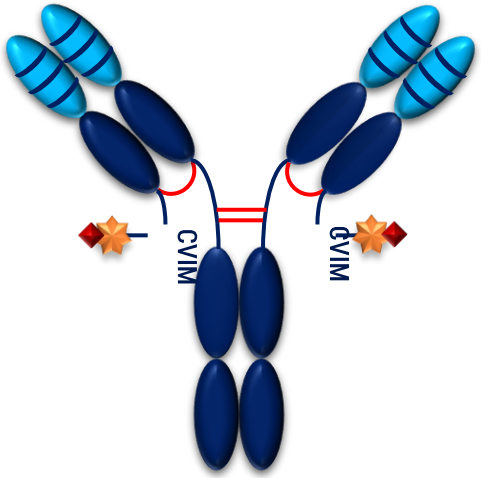
LCB73

IKS03; CD19-ADC

LCB73

anti-CD19_LBG-proPBD, DAR2

LCB73 is a CD19 targeting ADC containing LCB's proprietary prodrug PBD



Humanized anti-CD19 Ab with a CaaX motif that can be recognized by farnesyl transferase (FTase)

Overview

- CD19 targeting ADC
- LCB's Proprietary Prodrug PBD bearing ADC

Potential indications

- B-cell malignancies (NHL) : DLBCL, MCL, Burkkit Lymphoma,

Status / Next steps

Status

- New formulation confirmation studies on-going
- Completing IND-enabling preclinical studies

Next steps

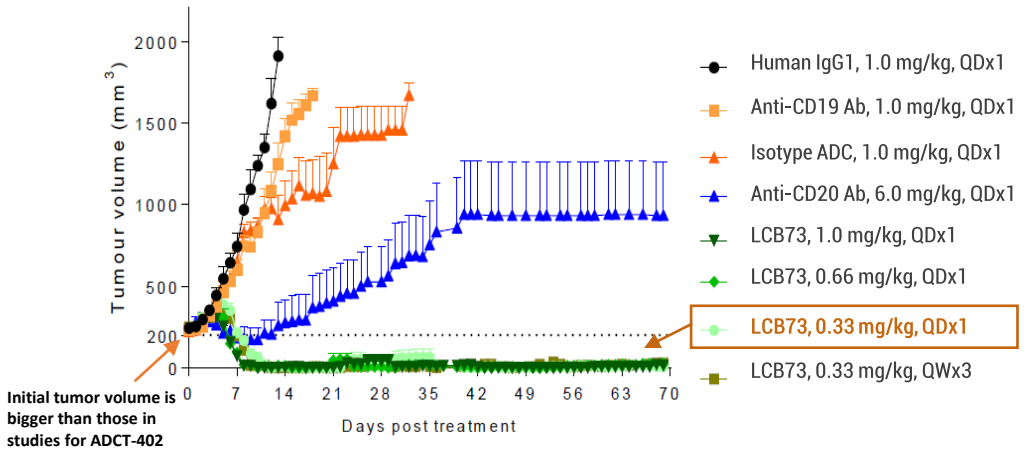
- Planed global Phase I, Q3 2022 (US IND)

* DLBCL, Diffuse larger cell lymphoma; MCL, Mantle cell lymphoma; NHL, Non-Hodgkin lymphoma

LCB73 has strong in vivo efficacy in Raji CDX model

(주)레고켐바이오 LegoChemBio

LCB73

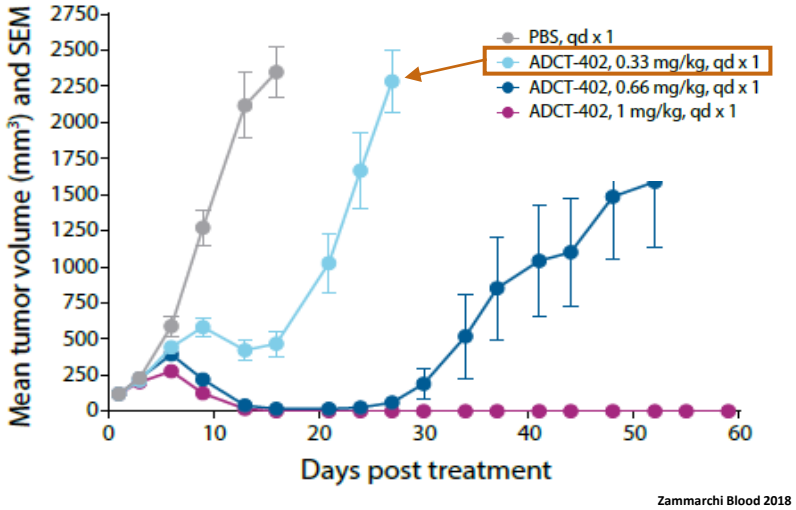


Initial tumor volume is bigger than those in studies for ADCT-402

- MED 0.33mg/kg
- No relapse until 70 days
- No efficacy of isotype ADC (target specific potency)

VS

ADCT-402



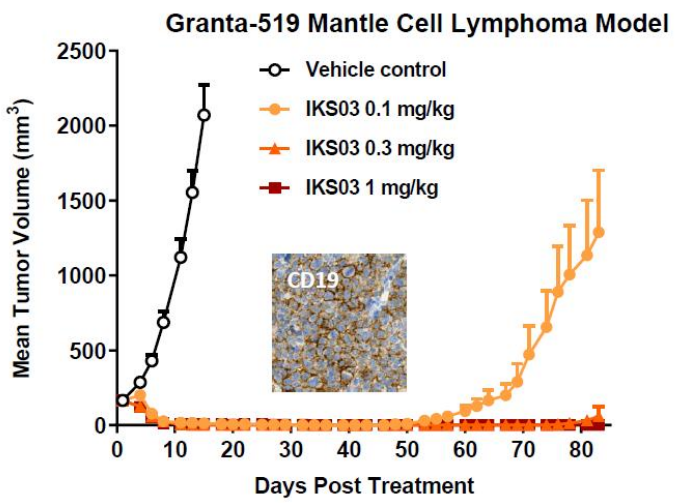
Zammarchi Blood 2018

- Restricted efficacy MED 0.33mg/kg
- No relapse in 2 mg/kg group until 60 days
- FDA approval April 2022, DLBCL (Zynlonta)

IKS03 demonstrates potent in vivo activity in lymphoma CDX models

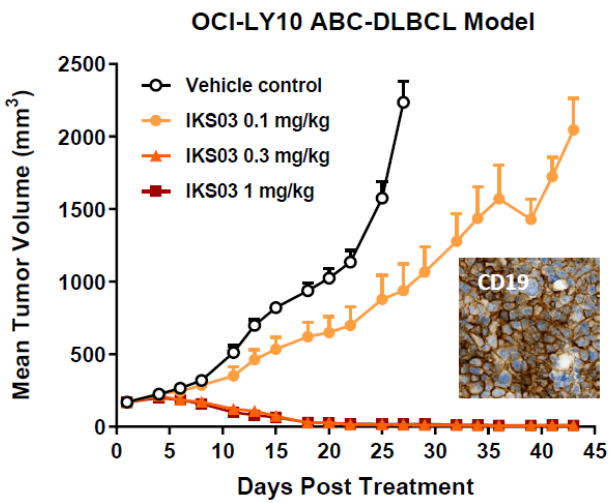
(주)레고켐바이오 LegoChemBio

Granta-519



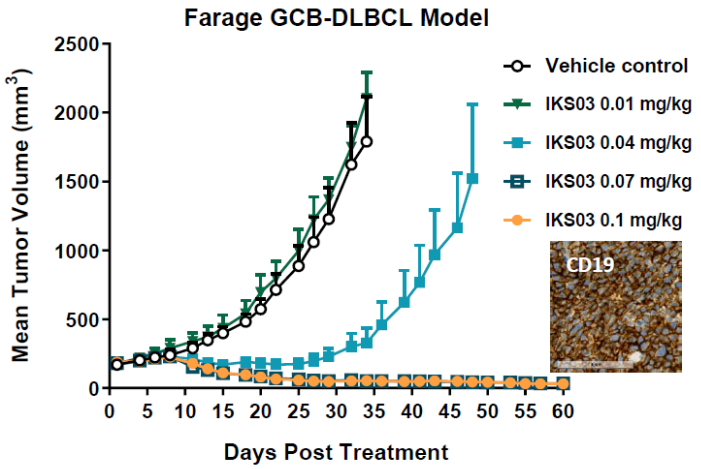
- Rare aggressive lymphoma subtype
- MED 0.1 mg/kg
- No relapse in 0.3 & 1.0 mg/kg groups until 80 days

OCI-LY10



- ABC DLBCL
- MED 0.3 mg/kg
- No relapse in 0.3 & 1.0 mg/kg groups until 43 days

Farage



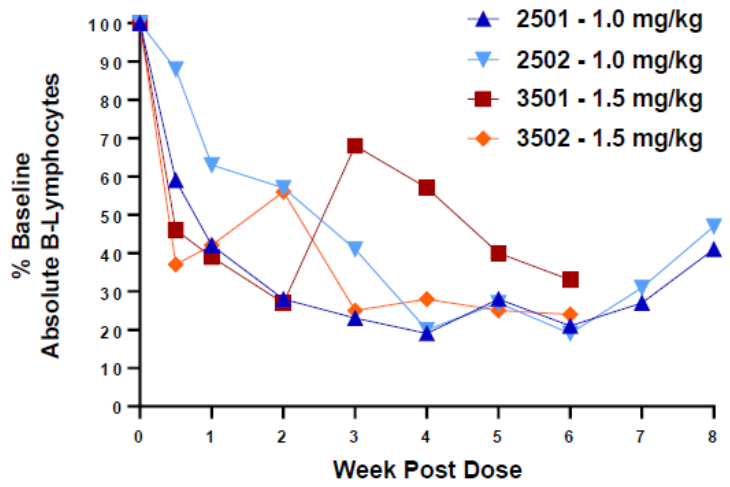
- GCB DLBCL
- MED 0.07 mg/kg
- No relapse in 0.07 & 0.1 mg/kg groups until 60 days

LCB73 shows well-tolerated in cynomolgus monkeys

(주)레고켐바이오 LegoChemBio

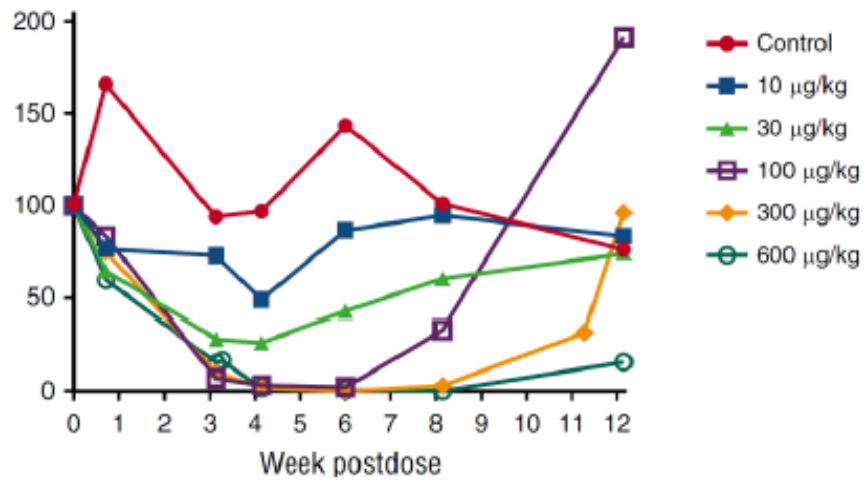
B-cell depletion in cynomolgus monkeys

IKS03 single dose



- LCB73 cross reacts with monkey CD19
- LCB73 was tolerated in monkeys at the highest dose tested of 1.5mg/kg (single dose)
- Limited depletion of normal B-cells in cynomolgus monkey supports the hypothesis of reduced linker-prodrug activation of LCB73 in normal tissues

SGN-CD19B single dose



- LCB73 cross reacts with monkey CD19
- LCB73 was tolerated in monkeys at the highest dose tested of 1.5mg/kg (single dose)
- Limited depletion of normal B-cells in cynomolgus monkey supports the hypothesis of reduced linker-prodrug activation of LCB73 in normal tissues

LCB73 (IKS03) shows potent in vivo anti-tumor activity in PDX models

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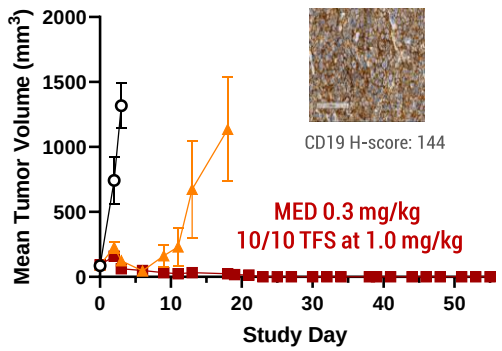
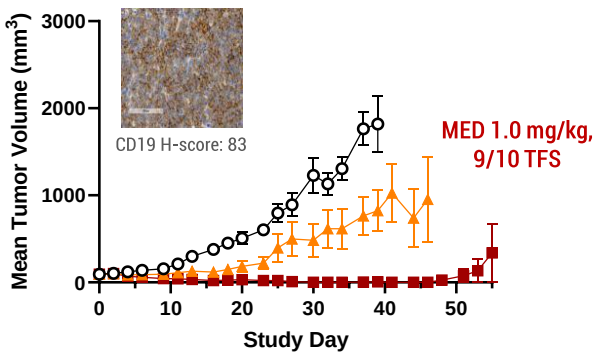
High-grade Lymphoma PDX CTG3794

Mean TV



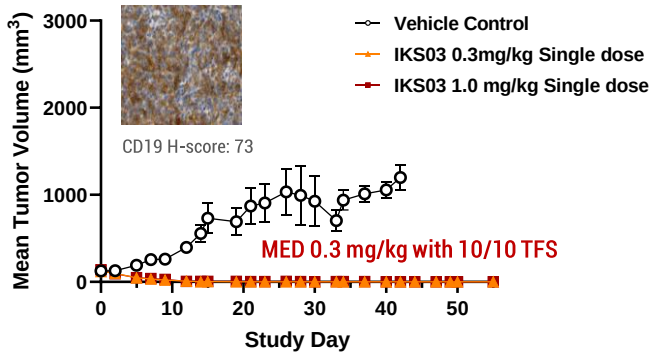
Lymphoma PDX CTG3799

Mean TV



Lymphoma PDX CTG397

Mean TV



Model	Histology	Cytogenetics/ IHC phenotypes	Treatment history	Treatment pre-collection	Response	Treatment post-collection	Response	CD19 H-score	MED (mg/kg)
CTG-3794	Non-germinal center (Triple Hit)	BCL2+; BCL6+; MYC+; XP01 amplified	Naïve			R-CHOP	Refractory. Responded (2m) then progressed	144	0.3
CTG-3799	Germinal center	MYC amplified (3 copies); IgH translocation on chr11 (unknown partner)	Pretreated	Rituximab	Pending	RCHOP +Ibrutinib	Responded	83	1.0
CTG-3797	Non-GCB (FCCL transformed; double expressor)	BCL6-; MYC-; split (65%) BCL2	Pretreated	CHOP	No response	EPOCH	No response	73	0.3

Superiority of Anticipated Therapeutic Index with the LCB's Pro-PBD Approach Over Other CD19-PBD ADCs

	ADCT-402	SGN-CD19B	LCB73
Company	ADC Therapeutics	Seattle Genetics	LegoChem Biosciences
Estimated HNSTD in cyno	0.6 mg/kg	0.25 mg/kg	>1 mg/kg
MED in mouse xeno study	1.0 mg/kg	0.33 mg/kg	0.33 mg/kg
TI	2.4	3.0	>12.0
Phase	Approval	Phase I (Terminated)	Preclinical (Phase I planned, Q3 2022)

04

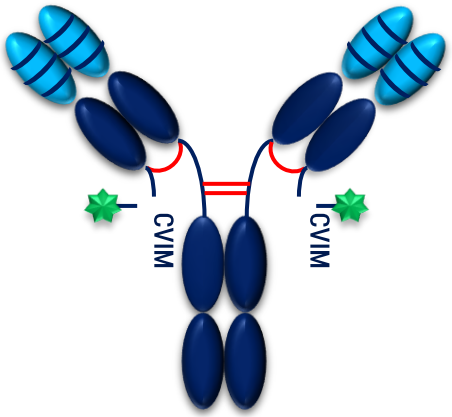
LCB84

TROP2-ADC

LCB84

anti-TROP2_LBG-MMAE, DAR4

LCB84 is based on the tumor selective mAb & MMAE and LCB's proprietary beta-glucuronide linker



h2G10 with a CaaX motif that can be recognized by farnesyl transferase (FTase)

Overview

- TROP2 targeting & MMAE bearing ADC
- Made by *ConjuAll*technology

Potential indications

- Various solid cancers (Advanced or metastatic TROP2 positive solid cancers)
- Breast cancer including TNBC, NSCLC, UC, PDAC, GC, OC, CRC....

Status / Next steps

Status

- GLP tox planned in Q3, 2022
- preparing GMP material for phase I study

Next steps

- Global Phase I planned, Q2 2023 (US IND by LCB)
- Potential to explore PD-1 combination

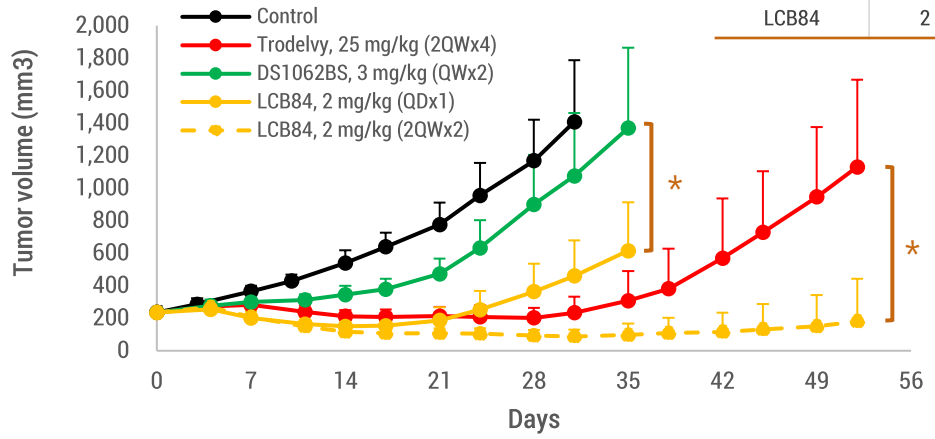
*TNBC, triple-negative breast cancer; CRC, colorectal cancer; GC, gastric cancer; NSCLC, Non-small cell ling cancer; OV, ovarian cancer; UC, urothelial cancer; PDAC, pancreatic ductal adenocarcinoma

LCB84, anti-TROP2 MMAE conjugate in solid cancers

LCB84 shows superior efficacy compared with FDA approved Trodelvy in TROP2 positive pancreatic cancer xenograft model

BxPC3 PDAC CDX

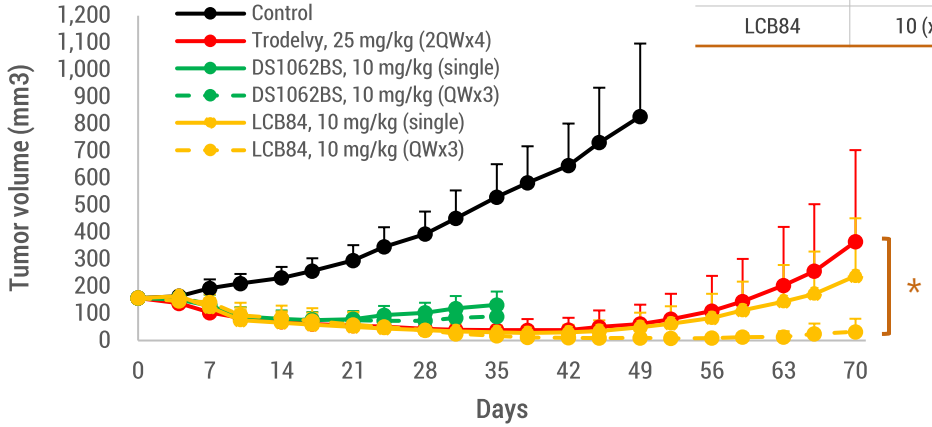
ADC	MED (mg/kg)
Trodelvy	N.D.
DS-1062BS	N.D.
LCB84	2 (x 1)



- TROP2 positive (high) pancreatic cancer model
- Effective tumor growth inhibition at 2 mg/kg (2QWx2)
- Superior efficacy than Trodelvy
- No efficacy for DS-1062 at higher dosing schedule

Capan-1 PDAC CDX

ADC	MED (mg/kg)
Trodelvy	25 (x 8)
DS-1062BS	10 (x 1)
LCB84	10 (x 1)

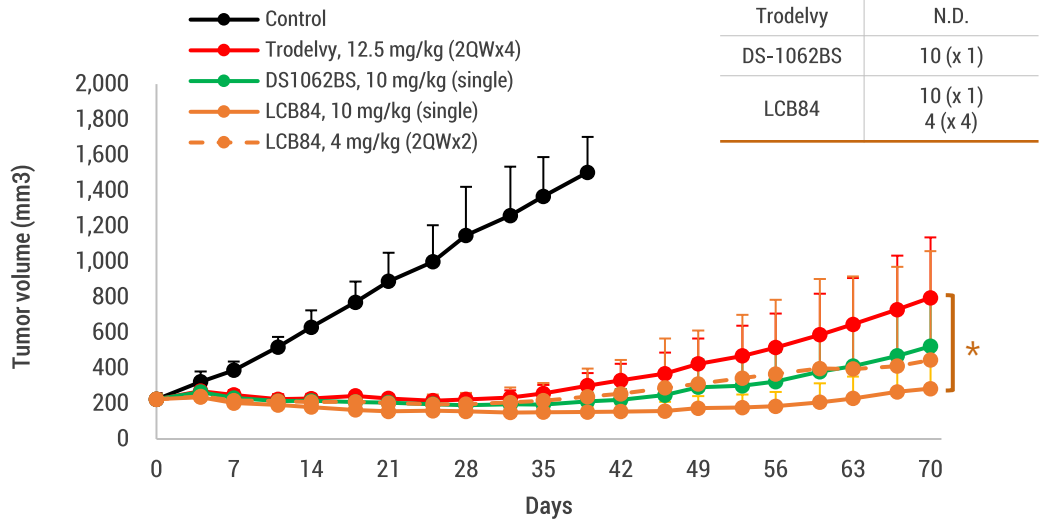


- TROP2 positive (high) pancreatic cancer model
- Effective tumor growth inhibition at 10 mg/kg (single)
- Superior efficacy than Trodelvy and DS-1062

LCB84, anti-TROP2 MMAE conjugate in solid cancers

LCB84 shows superior efficacy compared with FDA approved Trodelvy in TROP2 positive NSCLC xenograft model

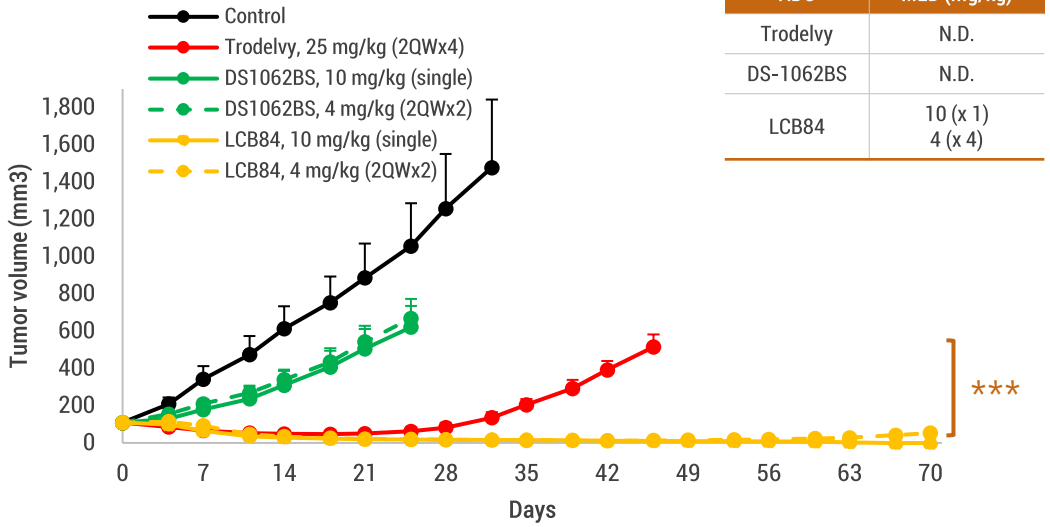
HCC827 NSCLC CDX



ADC	MED (mg/kg)
Trodelvy	N.D.
DS-1062BS	10 (x 1)
LCB84	10 (x 1) 4 (x 4)

- TROP2 positive (high) pancreatic cancer model
- Effective tumor growth inhibition at 4 mg/kg (2QWx2)
- Superior efficacy than Trodelvy

NCI-H2170 NSCLC CDX



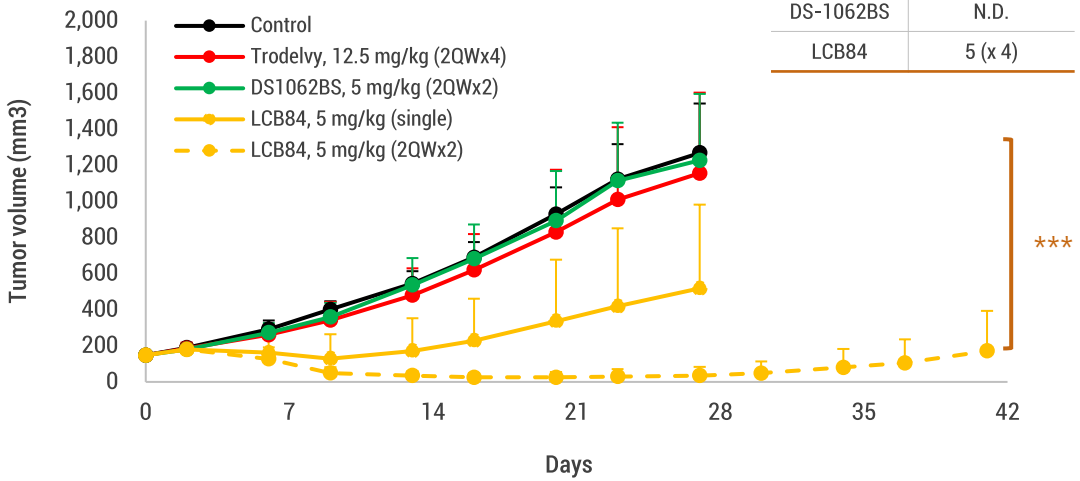
ADC	MED (mg/kg)
Trodelvy	N.D.
DS-1062BS	N.D.
LCB84	10 (x 1) 4 (x 4)

- TROP2 positive (moderate) pancreatic cancer model
- Effective tumor growth inhibition at 4 mg/kg (2QWx2)
- Superior efficacy than Trodelvy and DS-1062

LCB84 shows superior efficacy compared with FDA approved Trodelvy in TROP2 positive CRC and GC xenograft model

HT-29 CRC CDX

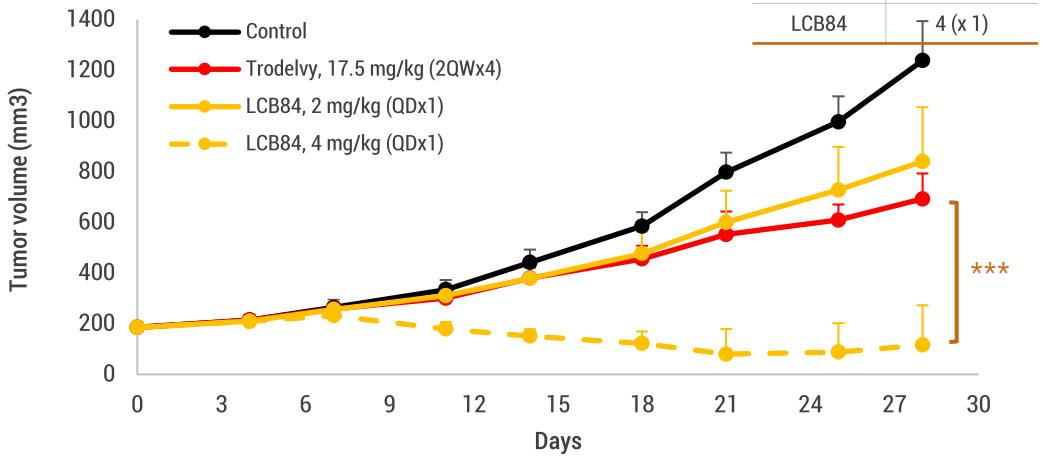
ADC	MED (mg/kg)
Trodelvy	N.D.
DS-1062BS	N.D.
LCB84	5 (x 4)



- TROP2 positive (high to moderate) colorectal cancer model
- Effective tumor growth inhibition at 5 mg/kg (2QWx2)
- Superior efficacy than Trodelvy and DS-1062
- No efficacy for Trodelvy and DS-1062 at higher or same dosing schedule

NCI-N87 GC CDX

ADC	MED (mg/kg)
Trodelvy	N.D.
DS-1062BS	-
LCB84	4 (x 1)



- TROP2 positive (moderate) pancreatic cancer model
- Effective tumor growth inhibition at 4 mg/kg (2QWx2)
- Superior efficacy than Trodelvy and DS-1062

LCB84, anti-TROP2 MMAE conjugate in solid cancers

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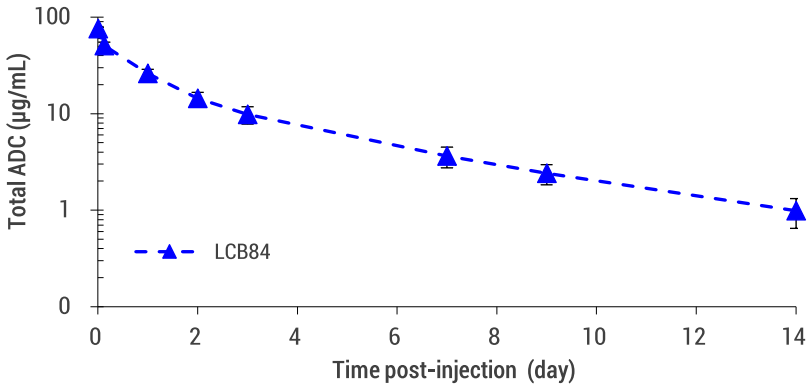
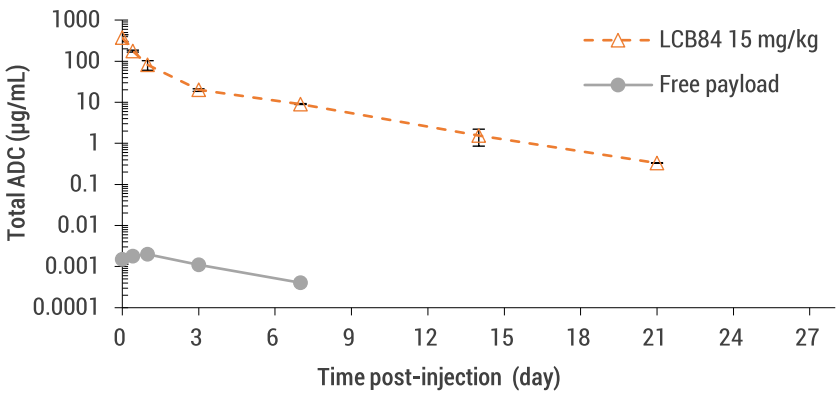
LCB84 demonstrates stable ADC PK profile *in vivo* rats & cyno monkeys

Rat, IV, single dose



Monkey, IV, single dose



Safety assessment in preclinical study

- Non-GLP repeat dose studies in cynomolgus monkeys yielded an HNSTD of 10 mg/kg Q3W x 2 for repeat dose administration of LCB84 ADC
- Skin toxicity seen in competitors and hematological toxicity such as neutropenia and thrombocytopenia, which are known as general toxicity of ADC, were not observed in tested doses

LCB's anti-TROP2 ADC has very compelling TI value

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	Trodelvy	DS-1062	LCB84
Company	GILEAD	Daiichi Sankyo / Astrazeneca	LegoChem
Payload (DAR)	SN38 (~7.6)	DXd (~4.0)	MMAE (4)
MED (BxPC3)	25mpk	10mpk	2mpk
HNSTD	60 mpk	10 mpk	10 mpk
TI	9.6	4	20
Phase	FDA approved	Phase III	Pre-clinical

Thank You!

Contact Info.

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