Introducing ABION INC

2024 KB Conference

Jun Young Choi (VP)

FORWARD-LOOKING STATEMENT

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OUR VISION & VALUE

ABION, pioneering precision oncology
In lung cancer and infectious disease solutions

ABION is the Korean drug discovery company with the pioneering spirit. Established in 2007, Abion (ks 203400) was the first Korean biopharma To advance the concept of precision oncology.

The company has robust pipeline for drug candidates in preclinical stage, clinical phase 1 and phase 2 to treat lung cancers and infectious diseases and is actively seeking research and clinical partnerships.

We have Integrity

At ABION, integrity is paramount. We prioritize data integrity, ensuring our medicines are developed based solely on reliable data.

We act Professional

Professionalism is central to our approach. Our R&D experts shine, driving professionalism in every aspect of our work.

We aim Innovative

Innovation is our engine. We relentlessly develop new bio-pharmaceutical drugs, pushing the boundaries of what’s possible.

We are Sustainable

Sustainability is key. We’re committed to socially responsible, sustainable practices in research, development, and growth.

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HISTORY OF OVERVIEW

2007
ABION INC.
Established

2009
Establishment of
R&D Center

2019
- ABION Australia Pty Ltd, Australia Subsidiary Established
- IND approval for ABN401 Phase 1/2 global trial by Australian FDA & Korean authorities

2021
- KOSDAQ (IPO) Listed
- US FDA IND approval for ABN401 Phase 1/2 Global (US)

2022
- ABN401 Phase 1 CSR readout
- ABION establishes U.S. subsidiary in San Diego

2023
- ABN401 Phase 2 Cut-off data release
- ABN401 Phase 2 Clinical trial First Patient In

2024
- ABN401 Phase 2 Cut-off data release
- ABN401 Phase 2 Clinical trial Last Patient In (expected)
- ABN202, ABN501 data release at AACR
- ABN401, ABN202, ABN501 oral presentation at ASCO IET
-

ABION LEADERSHIP

EXECUTIVES

YOUNG KEE SHIN
MD, Ph.D
Chief Executive Officer

JUN YOUNG CHOI
Ph.D
Chief Operating Officer

KEUNCHIL PARK
MD, Ph.D
External Director

SCIENCE ADVISORY BOARD

JÜRGEN WOLF
MD, Ph.D
Univ. Hospital Of Cologne

ABION'S STRATEGIC FOCUS AND KEY PIPELINE HIGHLIGHTS

Strategic focus

"Advancing precision medicine with a **biomarker-based strategy for patient selection** **from the pre-clinical stage**, ensuring targeted and effective therapies that maximize patient outcomes"

KEY PIPELINE : Lung Cancer Therapeutics

Indications		Pipelines	Target	Category	Discovery	Pre-clinical	Clinical trial	R&D Partner
Lung Cancer	NSCLC	VABAMETKIB	MET	Small molecule	Phase 2 Clinical trial for MET dysregulation (Global)			
		VABAMETKIB + Lazertinib	EGFR+MET	Small molecule	initiation of phase 2 Clinical trial for EGFR resistance with MET dysregulation (Global)			Johnson &Johnson
		ABN202	Multiple Targets [EGFR,MET..etc]	ACFP (Antibody-Cytokine Fusion Protein)	Pre-clinical			GENOPHARM
	SCLC	ABN501	Claudin-3 (CLDN3)	Antibody	Pre-Clinical(IND in 2025)			NIH NATIONAL CANCER INSTITUTE
				BsAb (CLDN3 x CD3)	Discovery			

KEY ADVANTAGES OF OUR MAIN PIPELINES

MET-TKI

VABAMETKIB|ABN401

"Potential Best-In-Class MET Tyrosine Kinase Inhibitor" With Opportunity Across Multiple Tumor Types

- Promising antitumor activity & superior safety profile
- Advantage to combination therapy
- Conducting phase 2 clinical trial

***Exceptional Safety Profile**

CLAUDIN-3

ABN501

"First-In-Class Novel Human Monoclonal Antibody For Claudin-3 (CLDN3)"

- High Specificity and strong affinity
- scRNA Analysis (SCLC patient samples) : Claudin-3 > DLL3
- Expansion of indications/modalities
- 2025 goal | Clinical Trial & IND packaging

***Promising target for SCLC**

CYTOKINE

ABN202

"Interferon-β-mutein Platform Technology"
Antibody Cytokine Fusion Protein

- Antibody targeting ability with IFN-β mutein ABN102)
- Superior Efficacy by direct & indirect anti- tumor effect
- ACFP platform > ADC | broader application
- Synergy with Immunotherapy Checkpoint Inhibitor

***Beyond ADC**

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VABAMETKIB ABN 401

VABAMETKIB : UNMET NEEDS OF c-MET

Unmet needs of c-MET targeting drug

HGF independent signal transduction in c-MET MOA

Due to limited efficacy of antibody therapeutics for targeting c-MET signaling, there are needs to develop small molecules-based TKIs (tyrosine kinase inhibitors)

Demand of high safety profile for c-MET targeting drug

TRAE		VABAMETKIB	Capmatinib (Tabrecta)	Tepotinib (Tepmetko)
Edema	All grade	< 30%	59%	70%
	G ≥ 3	N/A	3 ~ 40%	

The nature of c-MET allows the studies of various combination therapy.

- 3%* of NSCLC New Patient (1st Line therapy) : 50,000
- 17%* of Resistant Patient after 1st Line Tagrisso® : 90,000
- 50%* of Resistant Patient after 2nd Line Tagrisso® : 110,000

Estimate c-Met patient (10~15% of NSCLC)
250,000 Patients

Market size **US$ 5 Billion** 2022-2026 (CAGR 23.9%)

- Why c-MET?: In summary, c-MET mutation is the most frequent resistant mechanisms of Tagrisso®, which is the blockbuster EGFR Targeted therapy in lung cancer.
- Overall, Estimate 10% of NSCLC patients are c-MET target patients.
- Market size: 250,000 Target patients and US$ 5 Billion market
- Upside: The market grows with Tagrisso® sales

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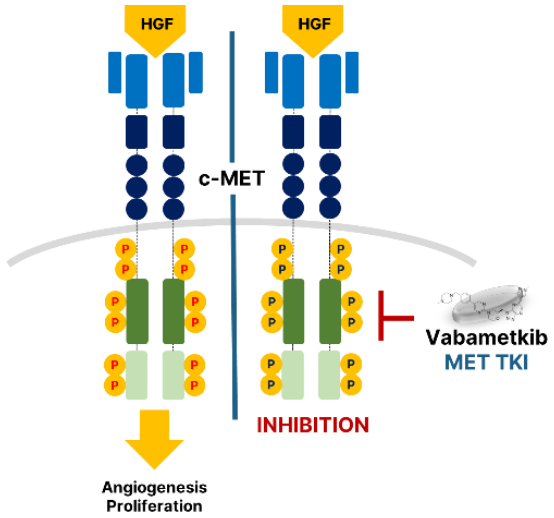
VABAMETKIB : ANTICANCER DRUG TARGETING c-MET

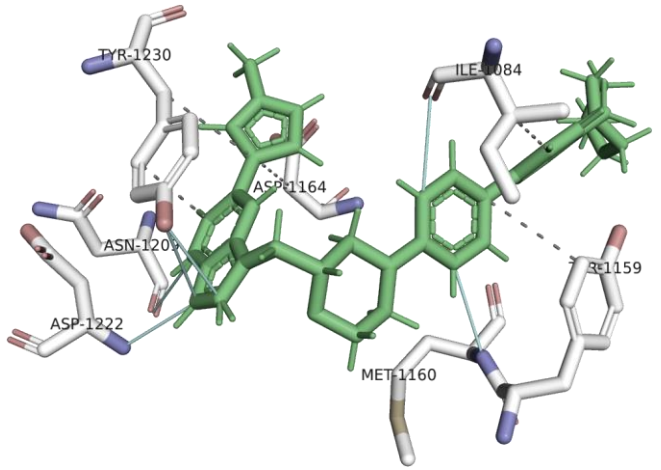
BEST-In-CLASS c-MET TKI: VABAMETKIB [ABN401]

VABAMETKIB Mode of Action (MOA)



- VABAMETKIB binds to ATP binding site and inhibits phosphorylation of downstream signaling.
- VABAMETKIB can stabilize the protein-inhibitor complex compared with other c-MET inhibitors because of differences in molecular size
- Plasma protein binding ability of VABAMETKIB is 4 to 9 times lower than that of approved competing drugs (Unbound fraction: VABAMETKIB, 18.2%; Capmatinib, 4%; Tepotinib, 2-3%)

VABAMETKIB Docking model



- A highly selective and potent c-MET kinase inhibitor that targets only c-MET
- PK/PD studies predicting clinical outcomes
- Superior safety compared to competitor drugs (Phase 1 and current Phase 2 results)
- Potential for indication expansion:
  - monotherapy or combination therapy in non-small cell lung cancer, gastric cancer, liver cancer, renal cell carcinoma, etc.

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VABAMETKIB : HIGHLY c-MET SELECTIVE

VABAMETKIB demonstrated the highest selectivity among the tested TKIs

<Highly selective c-MET TKI (for c-MET and other kinases)>

Items		VABAMETKIB (10 μM)	Capmatinib (10 μM)	Tepotinib (10 μM)
c-MET	> 99% inhibition	99.23%	-	-
	> 90% inhibition	-	98.84%	98.89%
Other Kinases	> 90% inhibition	0 Kinases	1 Kinase (AXL)	19 Kinases (ALKs, AXLs, TrkAs..etc)
	> 80% inhibition	1 Kinases (DYRK1B)	3 Kinases (TrkAs)	6 Kinases (ALKs, AXLs, TrkAs, PLT3..etc)
	50 ~ 80% inhibition	4 Kinases (CLK1, DYRK1, CLK4, AXL)	10 Kinases (c-MER, TrkA/Cs, AXLs, ROS1sm etc)	20 Kinases (c-MERs, ERBB2s, ALKs, TrkA/B/Cs, etc)

BRION W. MURRAY Ph.D

Chief Scientific Officer, and co-founder of Riva Therapeutics,

He was Vice President, Cancer Biology & Translational Research at Turning Point Therapeutics (acquired by BMS)

A database has been created that links kinase drugs, their kinase selectivity, and adverse events in

"The approved MET drugs capmatinib, tepotinib, and savolitinib all inhibit multiple kinases associated with edema. However, VABAMETKIB only inhibits one kinase by more than 90% at 10 μM (c-MET)."

Taken together, the high degree of selectivity of VABAMETKIB for cMET is consistent with its superior safety profile relative to capmatinib, tepotinib, and savolitinib

"Taken together, the high degree of selectivity of VABAMETKIB for c-MET is consistent with its superior safety profile relative to capmatinib, tepotinib, and savolitinib."

to engage these targets and therefore have less polypharmacology.

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VABAMETKIB : TARGET PRODUCT PROFILE

Target	c-MET RECEPTOR TYROSINE KINASE (RTK)
Mode of action	Inhibiting ATP binding to the active site of c-MET to block c-MET-associated signal transduction
Indication	MET Aberrated Solid tumors (**Exon 14 skipping**, MET overexpression, MET amplification)
Therapeutic areas	Solid tumors (**NSCLC**, Gastric Cancer, HCC and etc.)
Dosage	Oral administration (800mg, tablet), once daily(QD)
Clinical benefits	Monotherapy treatment for patients with solid tumors exhibiting c-MET alterations. Combination Treatment **with tyrosine kinase inhibitors (ex; EGFR) and others**

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OVERVIEW : CLINICAL PHASE 1 & 2 STUDY DESIGN

- Phase 1: Dose Escalation (all comer) and Pilot Expansion (NSCLC with MET dysregulation), completed.
- Phase 2: NSCLC patients with MET exon 14 skipping mutations (40 patients enrolled till now)

Phase 1 STUDY

Escalation — **All-comers patients**

- 1200mg, QD (N=4)
- 800mg, QD (N=3)
- 400mg, QD (N=4)
- 200mg, QD (N=3)
- 100mg, QD (N=1)
- 50mg, QD (N=1)

16 enrolled NO DLT,
NO ≥G3 TRAE
2 PR reported in
MET OVEREXPRESSION
NSCLC patients

Extension — **NSCLC with MET alteration**

NSCLC with MET Dysregulation → **800mg, QD**

8 enrolled 2 PR reported in MET EXON 14 SKIPPING NSCLC patients

Phase 2 STUDY

Phase 2 study design: multi-cohort study
Cohort 1 monotherapy in NSCLC with MET ex14skipping

Site: South Korea (14 sites) / Taiwan (6 sites) / USA (3 sites)

Patient with:
- NSCLC
- MET Exon 14 Skipping by tissue NGS/RNA ddPCR
- no previous MET-driven treatment
- N=40

ABN401 800mg Oral Once Daily

Primary Endpoint
- ORR by BICR

Secondary Endpoint
- DoR, PFS, OS, Safety, PK

Stage 1 Over 4 of 15 response
≥ ORR 25% → Stage 2 go (DRC)

Stage 2 Over 16 of 40 response
≥ ORR 40% → Study success

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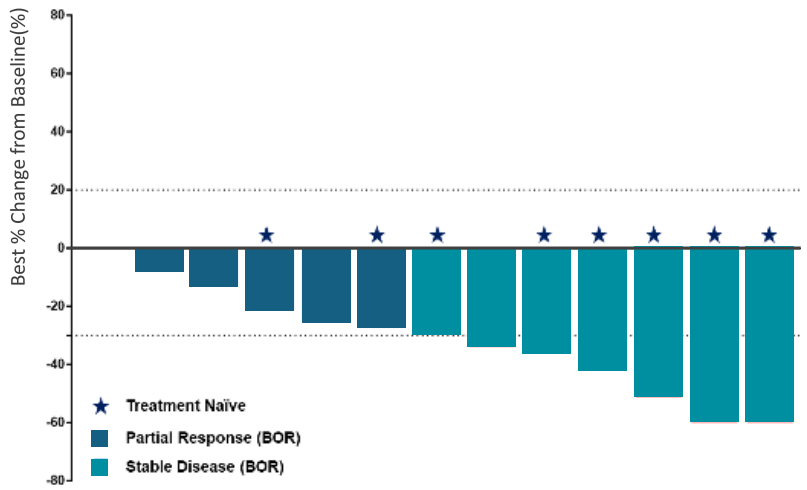
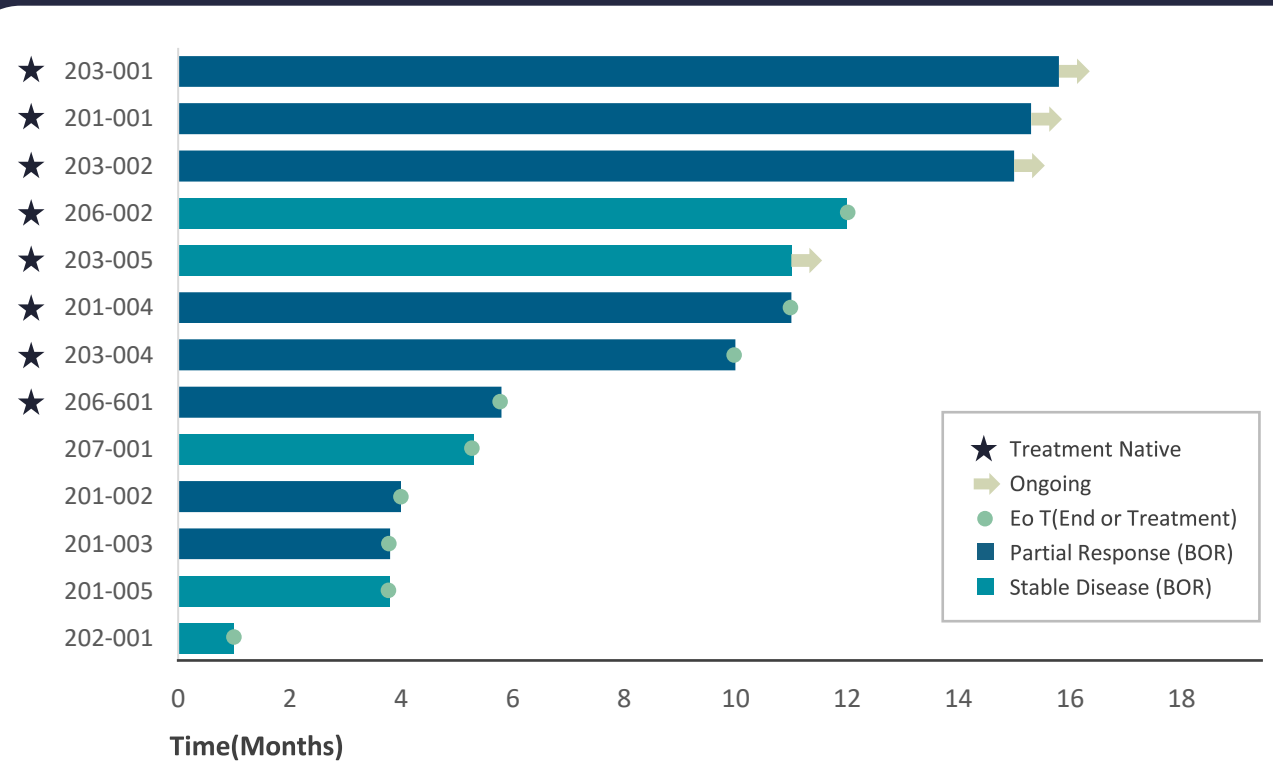
PHASE 2 COHORT 1 : CLINICAL OUTCOME

Phase 2, Stage 1 (As of 09May2024)

- All patients were MET inhibitor naïve. The objective response rate was 54% (7/13) in the evaluable population.
- In Treatment Naïve patient (n=8), the objective response rate was 75% (6/8)
- mPFS is 11.6 months and mDoR is 5.52 months, but the patients were still on treatments

Overall ORR 54%
Treatment naïve ORR 75%

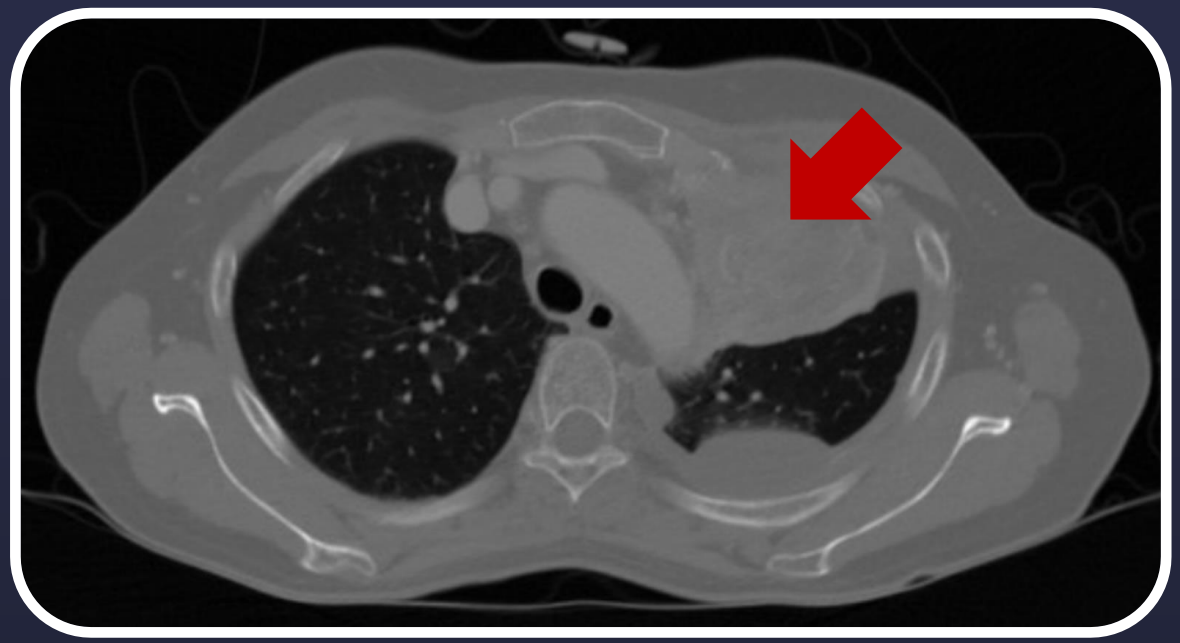


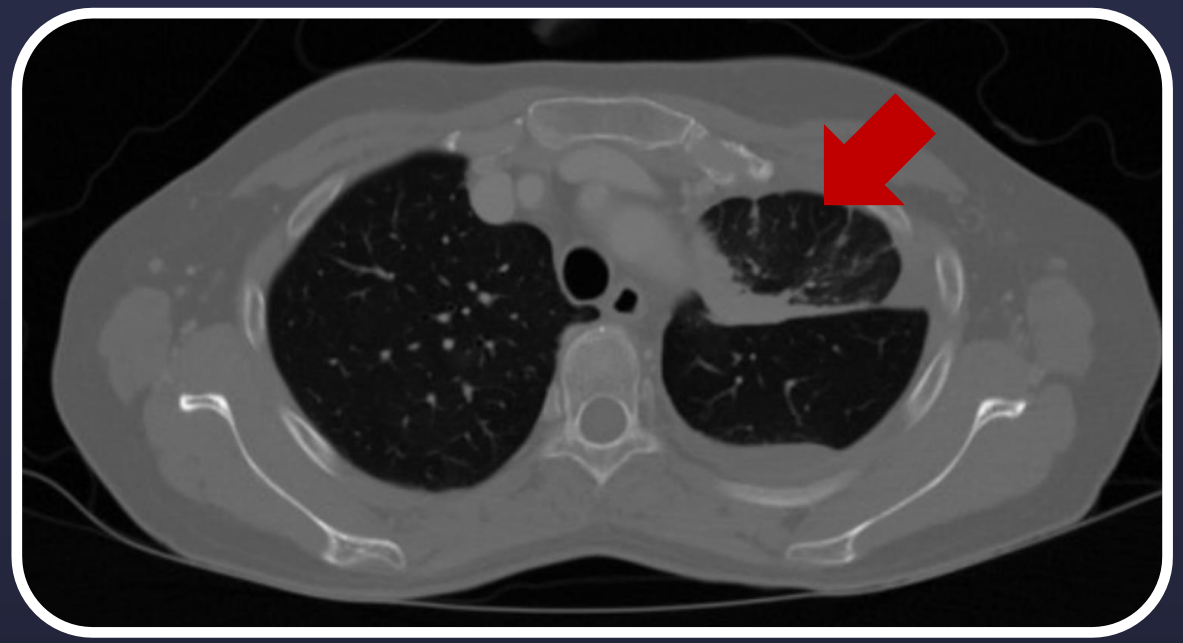


PHASE 2 COHORT 1 : PATIENT CT IMAGE

1st Image assessment

- Patient tumor regression after 1st Tumor Assessment (3wks) (LUL Expanded)
- 42.7% tumor reduction and PR confirmed in the patient, without any TRAE





ADVERSE EVENTS : COMPARISON WITH OTHER c-MET INHIBITORS

	VABAMETKIB[5] (N=30) ABN401-003	Capmatinib[1, 3] (n=364) GEOMETRY mono-1	Tepotinib[2, 4] (n=152) VISION
Treatment Emergent AE (TEAE)	86.7% (26)	98%	98%
TEAE, Gr 3 or higher*	**20% (6)**	**67%**	**54.6%**
TEAE, leading to IP discontinuation	10% (3)	15% (17%†)	20%
SAE	16.7% (5)	51% (53%†)	48%
Treatment Related AE (TRAE)	73.3% (22)	85.7%	89%
TRAE, Gr 3 or higher	**10.0% (3)**	**37.6%**	**28%**
TRAE, leading to IP discontinuation	10 % (3)	10.7%	11%
Treatment related SAE	3.3% (1)	13.2%	15%

- Gr 3 or higher: Gr 3 cerebral infarction (n=1, not related), Gr 3 COVID-19 (n=1, not related),
  Gr 3 Dyspnea (n=1, Related), Gr 3 Eosinophilia (n=1, Related),
  Gr 3 Hypoglycemia (n=1, not related), Gr 3 Ligament rupture (n=1, not related), Gr 3 pneumonitis (n=1, Related, Withdrawn), Gr 3 rash (n=1, Related).
- IP discontinuation: Gr 3 pneumonitis (n=1, Related), Gr 2 Hypersensitivity pneumonitis (n=1, related)
  Gr 1 Stomatitis (n=1, Related)
- SAE: Gr 2 Abdominal pain upper (n=1, Not related), Gr 3 cerebral infarction (n=1, not related), Gr 3 COVID-19 (n=1, not related),
  Gr 2 Hypersensitivity pneumonitis (n=1, Related), Gr 3 Hypoglycemia (n=1, not related), Gr 3 Ligament rupture (n=1, not related)
- **Edema (Gr 1/2) in 2 (6.6%)**

1. Wolf et al. NEJM 383:944-957, 2020, 2. Paik et al. NEJM 383:931-943, 2020, 3. TABRECTA® (Capmatinib, 2024.03, FDA Label),
4. TEPMETKO®(Tepotinib, 2024.02, FDA Label), 5. Investigator meeting – collected data (Apr-2024), †FDA label

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OPINION FROM PRINCIPAL INVESTIGATORS

JÜRGEN WOLF,
MD, Ph.D

University Hospital Of Cologne

The first impression of course this is an effective drug clearly of all response rates (75%) in the first line situation. But what I from the perspective of an oncologist who has treated really many patients with Capmatinib as well as with Tepotinib, **this (VABAMETKIB) is really remarkable is the toxicity profile.**
So, the low percentage of edema for me was the most impressive first signal because remember this patient population is not an average population.

XIUNING LE,
MD, Ph.D

MD Anderson Cancer

And then this ABION drug**(VABAMETKIB)** really is **potentially superior as a treating physician, I feel comfortable offering as a frontline treatment in the United States.** Yeah, I share the enthusiasm with Dr. Wolf and the rest of the panel. **I think the drug is very promising, not only offering good potential efficacy, but also mitigate the high toxicity we've seen with existing approved agents.** So, I'm very happy to offer those as an **opportunity for my patients in the frontline.**

TRAE	TABRECTA®	TEPMETKO®	VABAMETKIB
Grade≥3	37.6%	28%	**10%**
Discontinuation	10.7%	11%	**0%**
SAE	13.2%	15%	**4.2%**
ORR	**TABRECTA®**	**TEPMETKO®**	**VABAMETKIB**
Treatment naïve	68%	43%	**75%**
Overall	48%	43%	**53%**

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PHASE 2 COHORT 2 STUDY

Unmet needs for the combination therapy of EGFRi + METi in NSCLC

- Target patient population of EGFR inhibitor and MET after 1st line EGFRi treatment is 25% in total patient population
- Despite of newly approved 1st line treatment, such as Lazertinib + amivantamab, **EGFRi + METi combination therapy is still need in the 2nd line therapy** *(Wespiser, M. Lung Cancer (2024): 107895.)*
- It is implicated that METi safety is highly demanded from the recent EGFRi + METi combination study
- **The strength of Vabametkib in safety** is able to satisfy the unmet needs
- Abion is conducting the clinical trial of **EGFRi + METi combination therapy in collaboration with J&J**

에이비온-존슨앤드존슨, 병용임상을 위한 약물공급계약 체결

작성일 2024-06-28 11:48

2024년 6월 25일, 에이비온과 존슨앤드존슨 계열사 얀센은 EGFR 돌연변이에 의한 비소세포폐암(NSCLC)을 대상으로 하는 병용 임상을 진행하기 위해 약물 공급 계약을 체결하였습니다.

본 임상은 에이비온의 c-MET 억제제인 ABN401 (바바메킵)과 존슨앤드존슨의 EGFR 억제제인 레이저티닙(Lazertinib)의 유효성을 확인하는 임상이며, 해당 공동연구는 EGFR 돌연변이에 의한 NSCLC 환자에서 EGFR 저해제를 투여 받은 후 c-MET 변이로 인해 내성이 생긴 경우를 치료하는 것을 목표로 합니다.

해당 계약을 통해 에이비온은 임상연구의 스폰서로 연구를 주도하며, 존슨앤드존슨은 해당 임상시험에서 사용되는 레이저티닙을 무상으로 제공할 예정입니다.

Abion homepage

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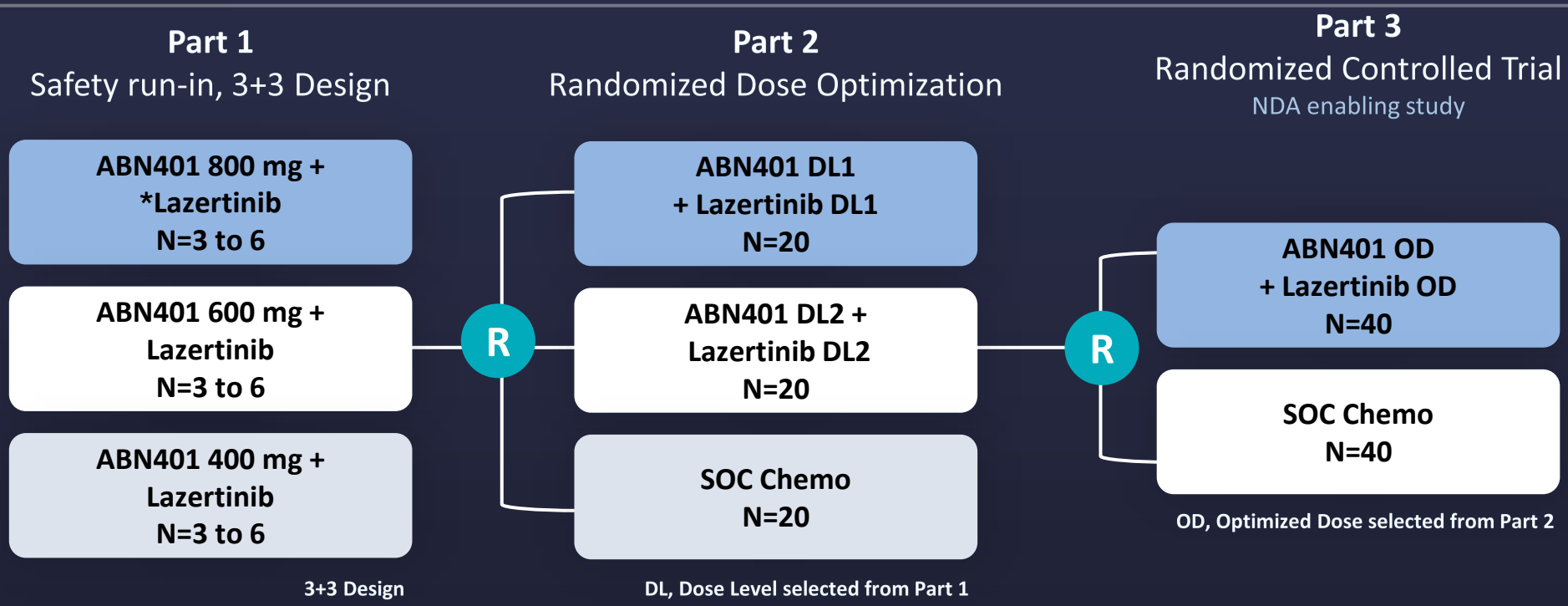
PHASE 2 COHORT 2 STUDY DESIGN

Cohort 2:
MET amp./ over exp + EGFRm [Combination Therapy]

Patients	Selection Method	Bio-marker	Administration
EGFRm pts who acquired resistance with either c-MET amp or over exp in NSCLC	[Tissue]NGS [Tissue]FISH, IHC	c-MET Amplification Overexpression	[3rd generation EGFR TKI] + [ABN401] 800mg



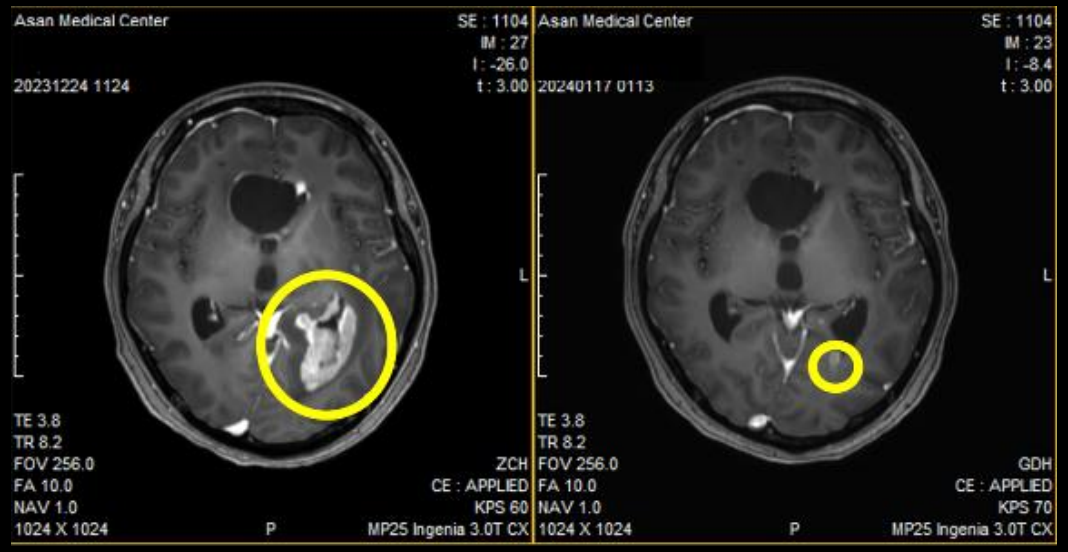
*Collaboration clinical study with Johnson&Johnson

VABAMETKIB : CASE STUDY RESULT

A very favorable response was confirmed on the brain MRI performed on the 16th day of treatment

Brain MRI

VABAMETKIB can expand the indication with GBM data



Patient: Female, 25 years old	
S/P EVD (July 13, '23 ~ July 30, '23)	
S/P Brain Tumor Resection NTR (July 19 '23)	GBM, WHO Gr4
S/P Postop. CCRTx (Aug 25 '23 ~ Oct 06 '23)	56 Gy
Op. bed growing (Oct 29 '23)	
S/P 2nd op. (Nov 09 '23)	Residual /recurrent GBM, WHO G4
EGOG	Surgical complexity observed.

Indication : GBM (Glioblastoma), MET X963_splice mutation, MET amplification 10 copies (cellularity 80%), CTTNBP-MET fusion

Study site : Seoul Asan Medical Center (AMC)

Tumor reduction (%) after treatment : 90%

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SUMMARY OF VABAMETKIB DEVELOPMENT

Secure excellent safety for BEST-IN-CLASS

- VABAMETKIB addresses significant unmet needs of existing c-MET TKI, with improved safety and tolerability profile
- Much improved safety profile in comparison to that in marketed Tabrecta®(Norvatis) and Tepmetko®(Merck)
- Confirmed efficacy in phase 1 clinical trial, and ongoing phase 2 clinical trial aims Breakthrough Therapy Designation/Accelerated Approval
- In MET exon 14 skipping patient, ORR was 53.9% (9/17) in the evaluable population and 75% (6/8) in treatment naïve patient
- With the given efficacy and safety data as a monotherapy, along with preclinical data, combination therapy with LAZERTINIB(J&J) is initiated for 3Q 2024

Expansion of c-MET-targeted anticancer drug market

- c-MET alteration is the most common resistance mechanism of 3rd Gen EGFR TKI in NSCLC market
- 250,000 Target patient market. $5B USD Market and expand every year

2023.1Q
Phase 2 Mono Trial
First-patient In

2024.3Q
Phase 2 Mono Trial
Last-patient In

2024.4Q
Phase 2 Cohort 2 Combi Trial
First-patient In

2025.1H
FDA/MFDS meeting for
BTD/Conditional approval

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ABN 202

BEYOND ADC

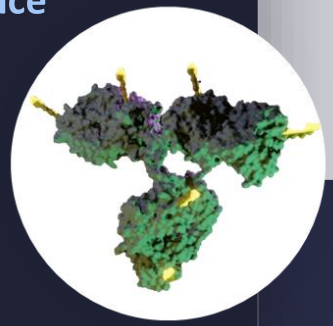
ACFP PLATFORM

ABN202 : PIONEERING TYPE 1 IFN ACFP PLATFORM TECHNOLOGY

Antibody-drug conjugates

Off-target toxicity
Aquired resistance

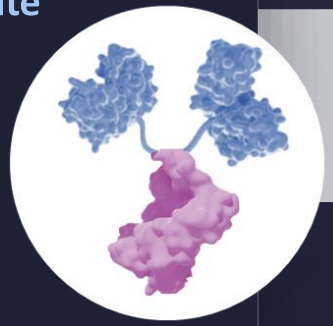
Limitation



Immunocytokines

Systemic toxicity
Low response rate

Limitation



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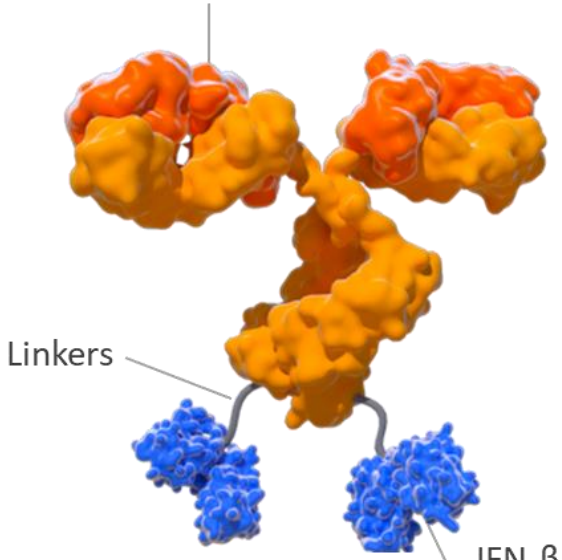
Tumor targeting antibody
(monoclonal, Bi-specific)



Mechanism Of Action

- Inhibits tumor cell proliferation directly
- Stimulates anti-tumor immune responses
- Maintains antibody effector functions (ADCC, ADCP)

Lead programs:

- MET, EGFR, TROP2, HER2, BsAbs

Lead Indications:

- ADCs resistant
- Immunotherapy/ TKIs resistant
- Novel target expressing solid cancer

Expected IND submission:

- 4Q 2026

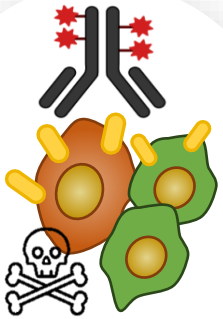
Key Features:

1. **High productivity and purity by glycoengineering**
2. **Reduced systemic toxicity by change of receptor binding kinetics**
3. **Beyond ADCs : Superior efficacy against Ag-low tumor and ADC resistance models**

ABN202 : AS "BEYOND ADC" THERAPEUTICS

Compared to ADC: Novel modality & Overcoming ADC Resistance

1st ADC

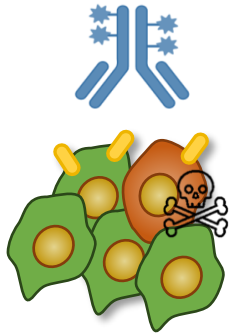


Post-ADC

2nd ADC **Low efficacy**

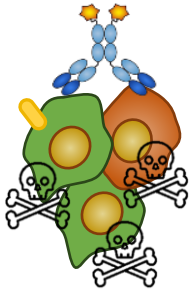
ADC resistance mechanisms

- Antigen expression ↓
- Payload resistance ↑
- Drug-efflux protein ↑



ABN202 **Potent efficacy**

- Non-redundant, Novel modality
- Direct tumor growth inhibition
- Boosting anti-tumor immunity



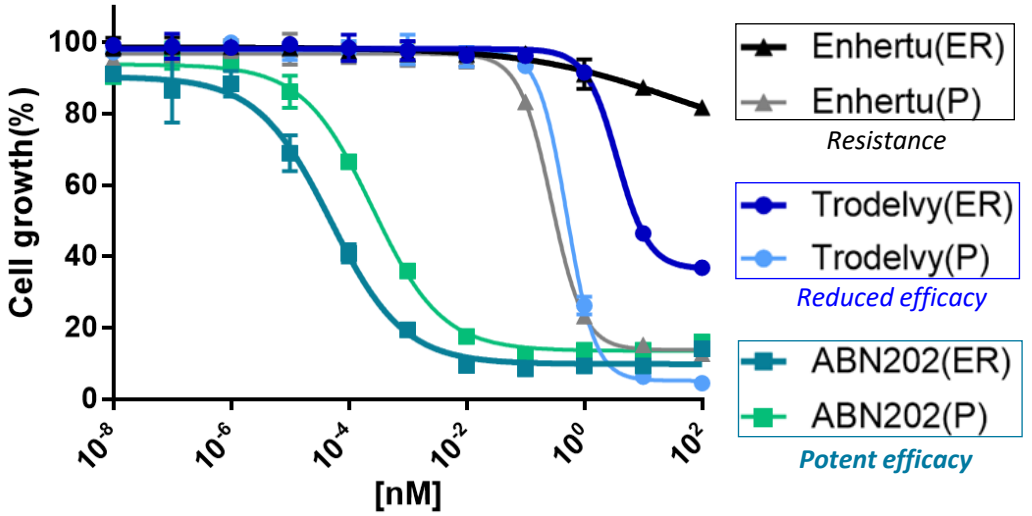
Overcoming ADC resistance

ADC-sensitive tumor

ADC-insensitive tumor

Superior drug efficacy compared to other ADCs in the **Enhertu-resistant cell model**

HCC1954 Enhertu resistance model



*(P) : Parental cell
*(ER) : Enhertu resistance cell

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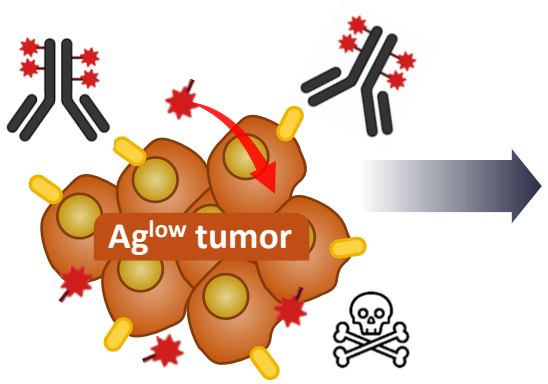
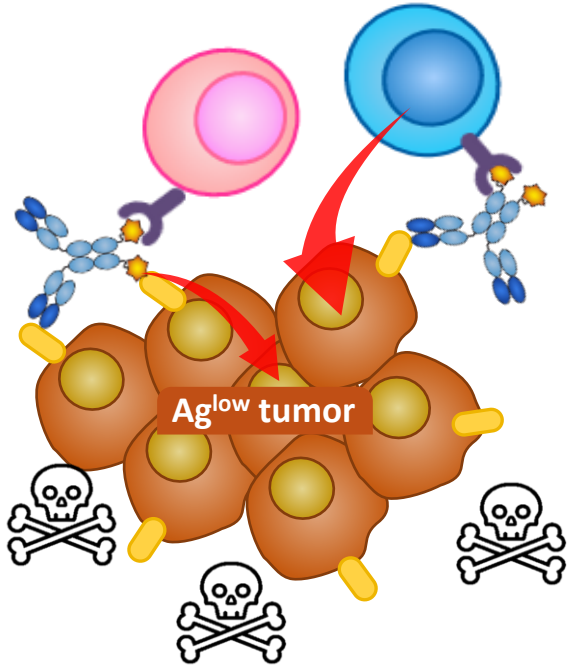
ABN202 : AS “BEYOND ADC” THERAPEUTICS

Potent Efficacy in Antigen-low mouse models Compare to other ADCs

ADCs :
Bystander effect



ABN202

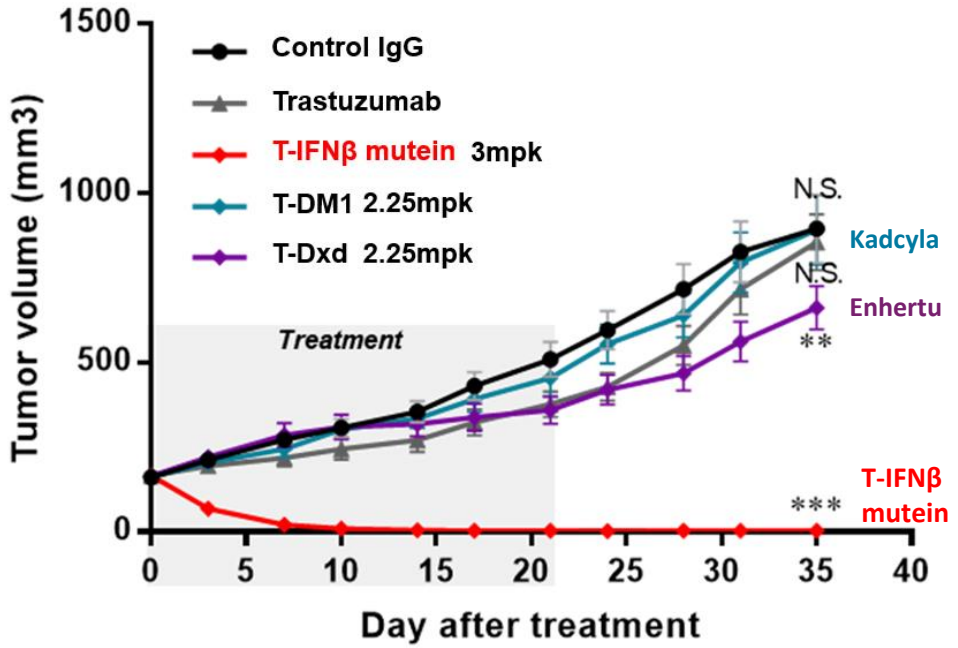


Potent efficacy + immune cell activation

Superior anti-tumor efficacy
compared to HER2 ADCs in **HER2-low model**

SNU620 Xenograft mouse model

HER2-low human gastric cancer cell line



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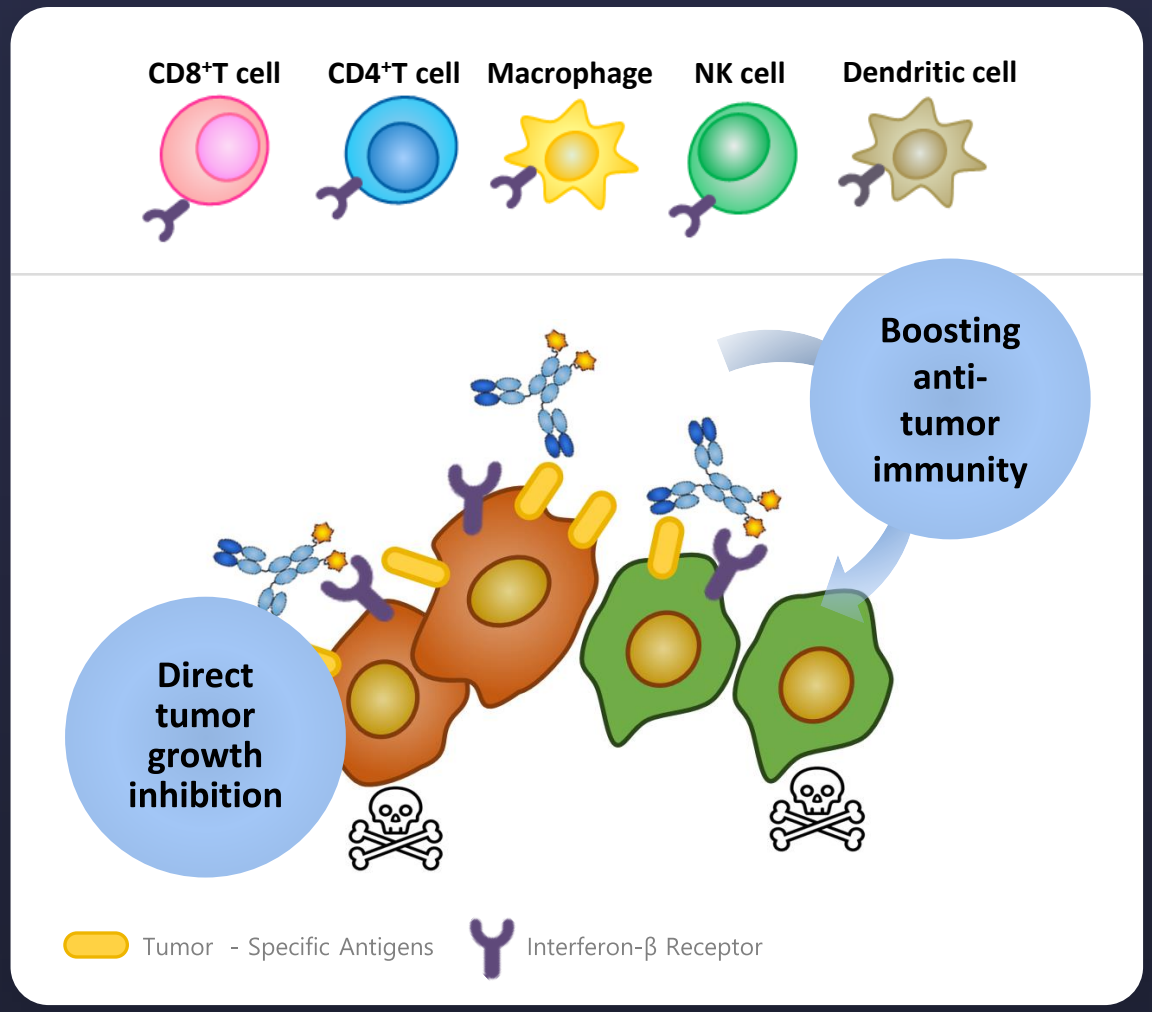
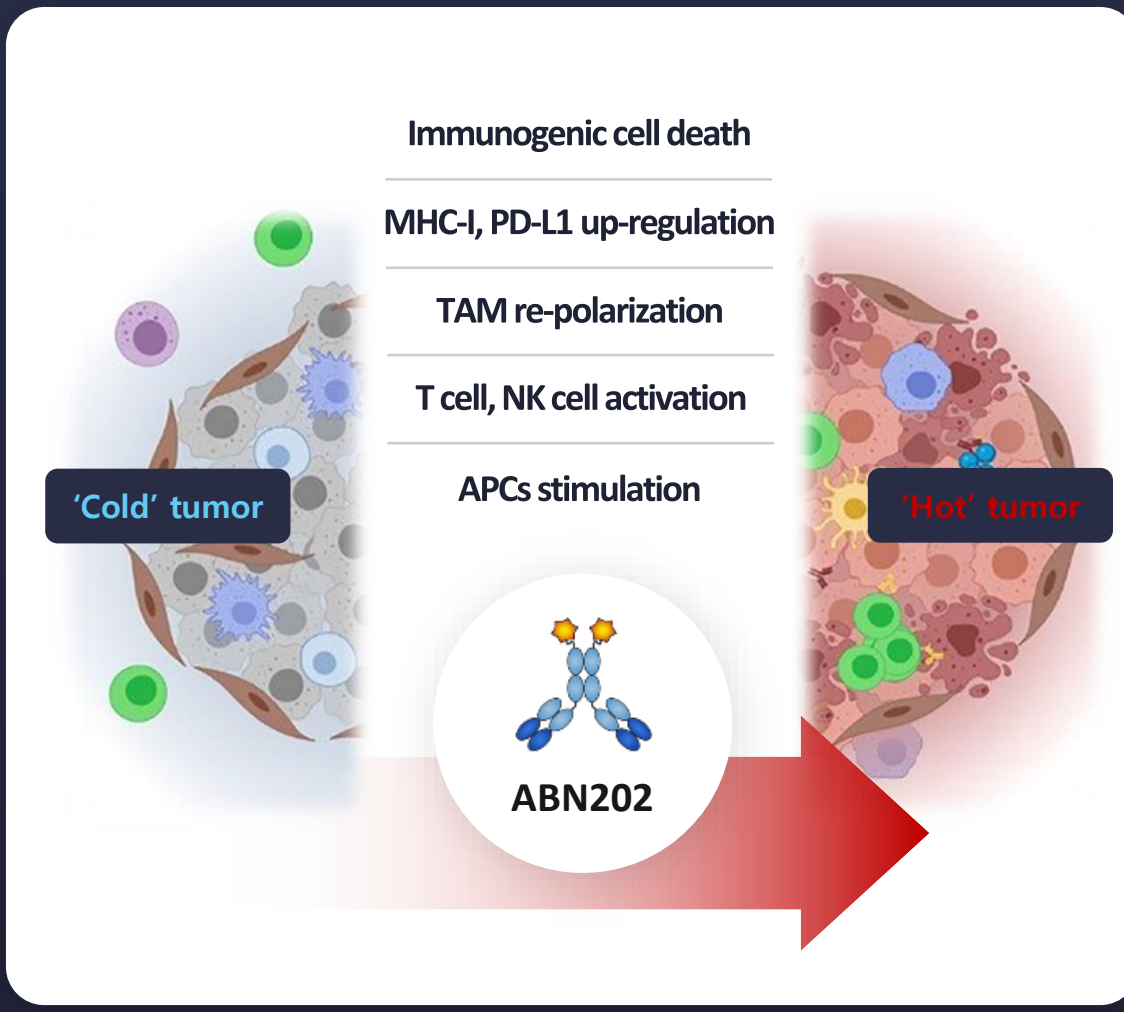
ABN202 : AS "COMBINATION POSSIBILITY WITH IMMUNE CHECKPOINT INHIBITORS (ICI)

ADVANTAGES of ABN202: Synergistic effects with ICIs and multiple anti-tumor mechanism

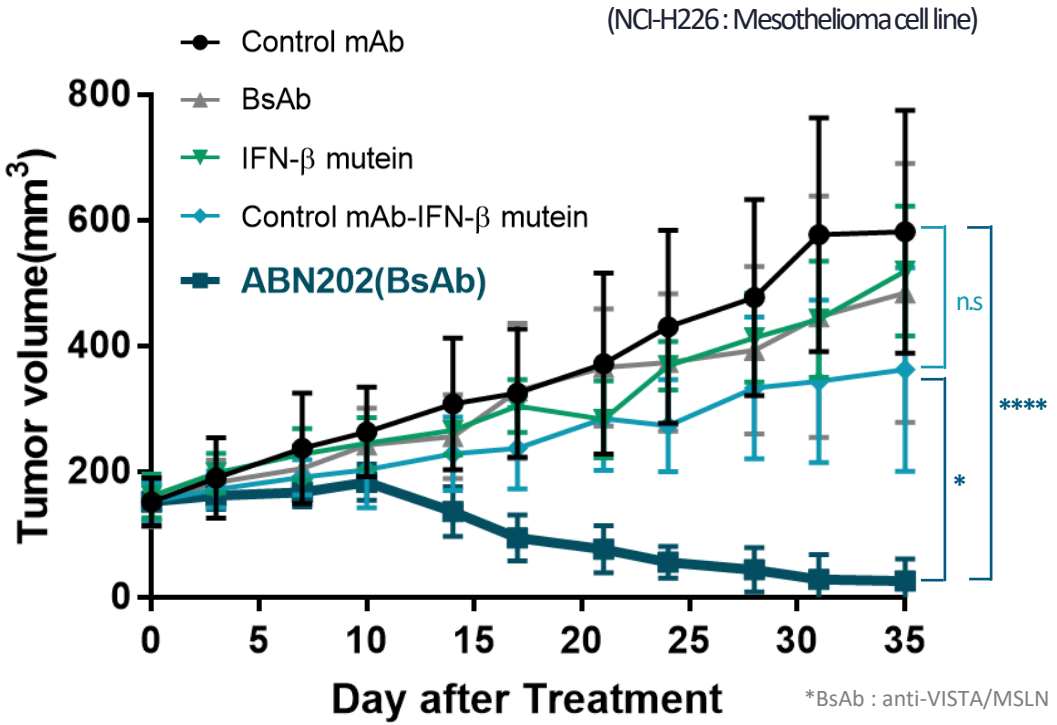




ABN202 : APPLICABILITY TO VARIOUS TUMOR-SPECIFIC ANTIBODIES AND MULTI-SPECIFIC ANTIBODIES

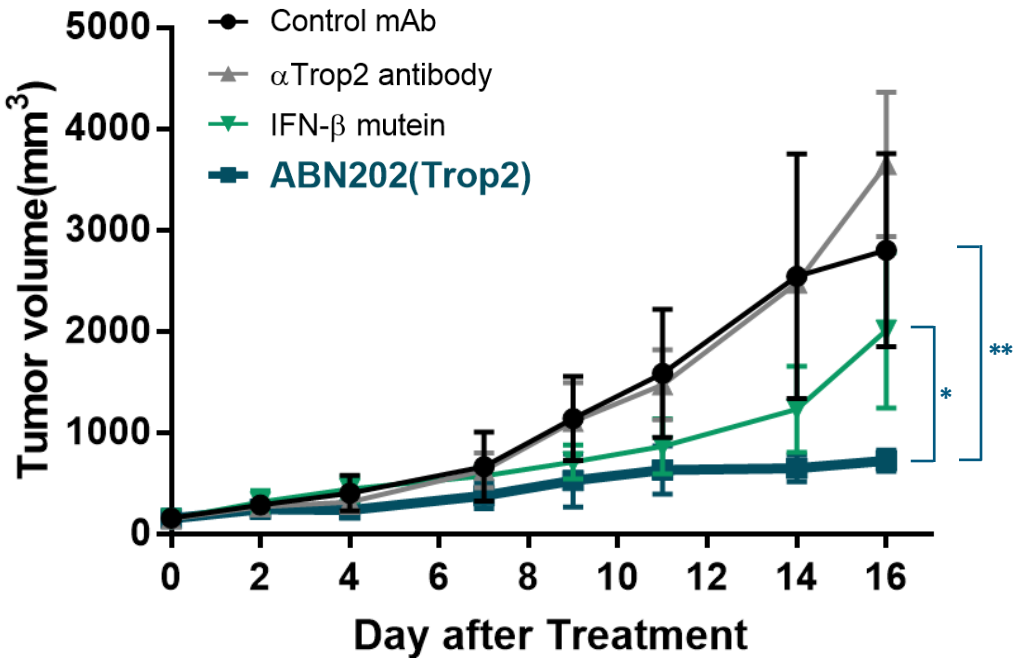
ABN202 inhibits tumor cell proliferation directly and stimulates anti-tumor immune responses

Human mesothelioma xenograft mouse model



ABN202 platform can be applied to
multi-specific antibodies because of the IFN-β mutein

Human IFNAR1/2 Knock-in* Mouse 'Cold tumor' Model



Potent anti-tumor efficacy through boosting
anti-tumor immunity in cold tumor model

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ABN202 : Advantages vs Other Platforms

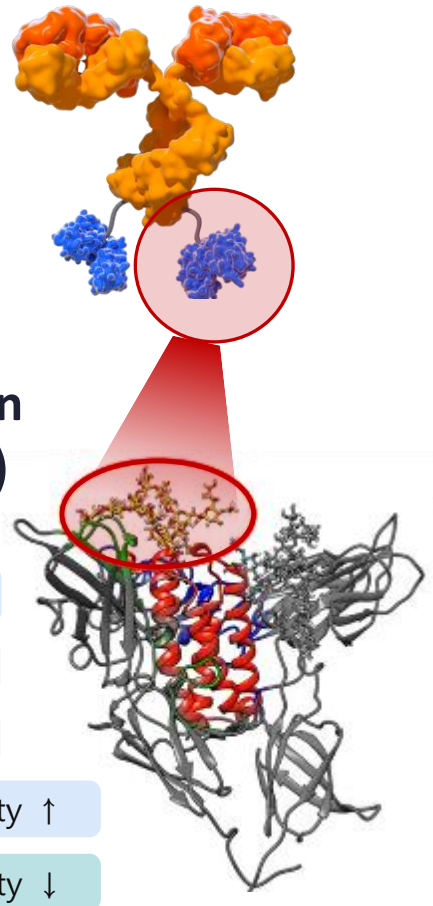
Differentiation and Competitive Edge Compared to Other Platforms

- ✓ Anticipating potent anti-cancer effects via Interferon-β mutation and immune response augmentation
- ✓ Introducing novel therapeutic strategies for ADC non-responsive/resistant patients
- ✓ ABN202, a versatile platform technology, applicable to single and bispecific antibodies, currently undergoing diverse indication research and

Drug	ADC (Ab-Drug-Conjugate)	Immunocytokine	ABN202
LEAD CANDIDATE	Enhertu, Trodelvy, Padcev etc.	PD-1-IL2v, IL-15 etc	EGFR, TROP2 etc
PAYLOAD	Cell Toxicity Payload (Dxd, SN38, MMAE etc)	Immune-activating Cytokines (IL-2, IL-15 etc)	**IFN-B-Mutein**
MODE OF ACTION	Topoisomerase I inhibitor	Cytokine signaling	Type I IFN signaling
DIRECT Anti-tumor Activity	**O**	**X**	**O**
Immunological Efficacy Anti-tumor Activity	**△**	**O**	**O**
BYSTANDER EFFECT	**O**	**△**	**O**
SYNERGISM OF ICI	**△**	**O**	**O**
Developed by	Roche, Daiichi-Sankyo, AstraZeneca	Bristol Myers Squibb, Roche, NEKTAR, GOOD, ImmunityBio	abion Perpetual Pharmaceutical Pearl Provider

ABN202 : PIONEERING TYPE 1 IFN ACFP PLATFORM TECHNOLOGY

ABN202 improved purity(monomer) and tumor-microenvironment specific activity compared to wild-type IFN-β

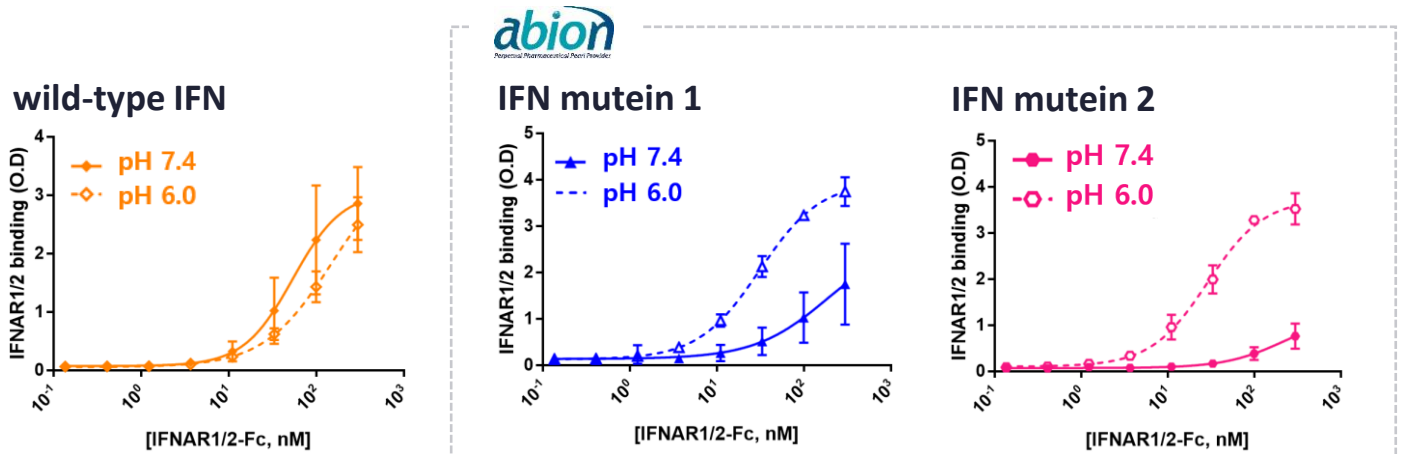


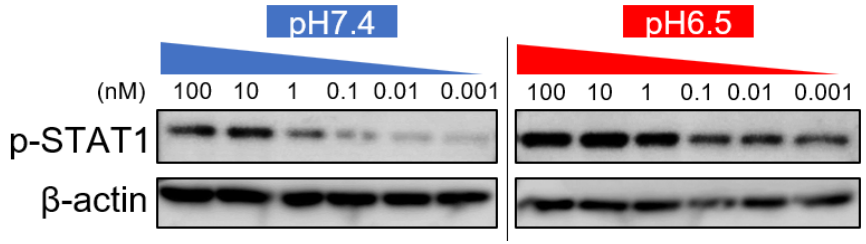
IFN-β mutein (C17S/R27T)

- Productivity ↑
- Solubility ↑
- Stability ↑
- Biological Activity ↑
- Peripheral toxicity ↓

Acidic pH-selective cytokine : Acidokine™ platform

Receptor binding and biological activity in acidic-pH condition





ABN202 : KEY TAKE AWAY

Synergistic Action with Immunotherapy Checkpoint Inhibitor

Superior Efficacy and Overcoming ADC Resistance

Versatility to Apply Various Antibodies

Pipeline	Target antigen	Indication	R&D	Pre-toxicity	Pre-clinical	Phase 1	R&D partner
ABN202	HER2	HER2-positive solid cancer					GENOPHARM
	EGFR	Non-small cell lung cancer					
	TROP2	TROP2-positive solid cancer					
	CLDN3	Small cell lung cancer					
	B7-H3	Small cell lung cancer					
Multi-specific ABN202	MET x EGFR	Non-small cell lung cancer					
	VISTA x MSLN	Mesothelioma, Pancreatic cancer, Ovarian cancer					

ABN 501

First-in-Class,
CLDN3 Targeting Antibody

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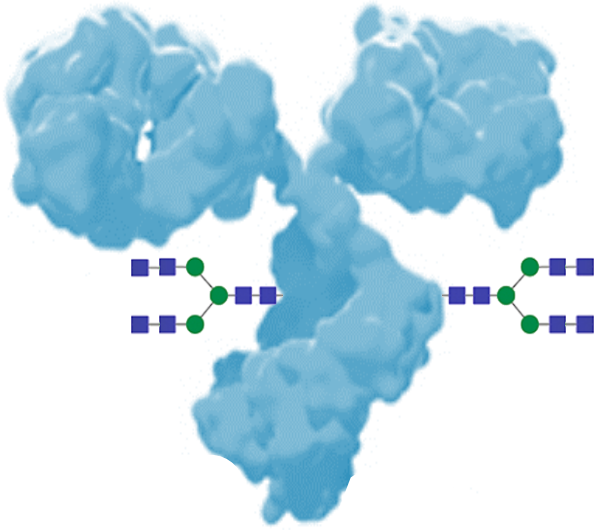
ABN501 : A NOVEL ANTI-CLDN3 ANTIBODY FOR CANCER TREATMENT

Antibody Form:
"Fully Human IgG1, Afucosylated"



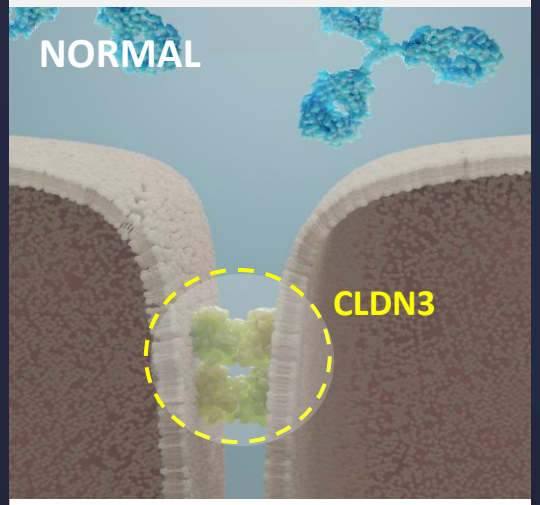
High Specificity
Binds Exclusively to Claudin-3 (CLDN3)

ABN501

Expected IND submission: 2H 2025

Normal cells

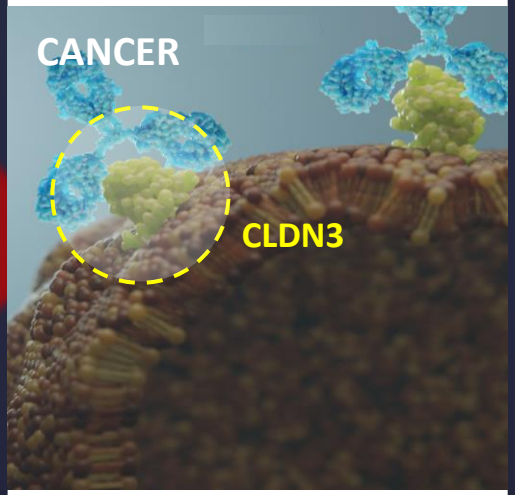
CLDN3: Not Exposed



Localized at Tight Junction

Cancer cells

CLDN3: Exposed



Abnormal Proliferation

Novel Target Antibody
CLDN3 Exclusive

High Affinity & Specificity
Towards CLDN3

Pan-Carcinoma Marker
Broad Applicability

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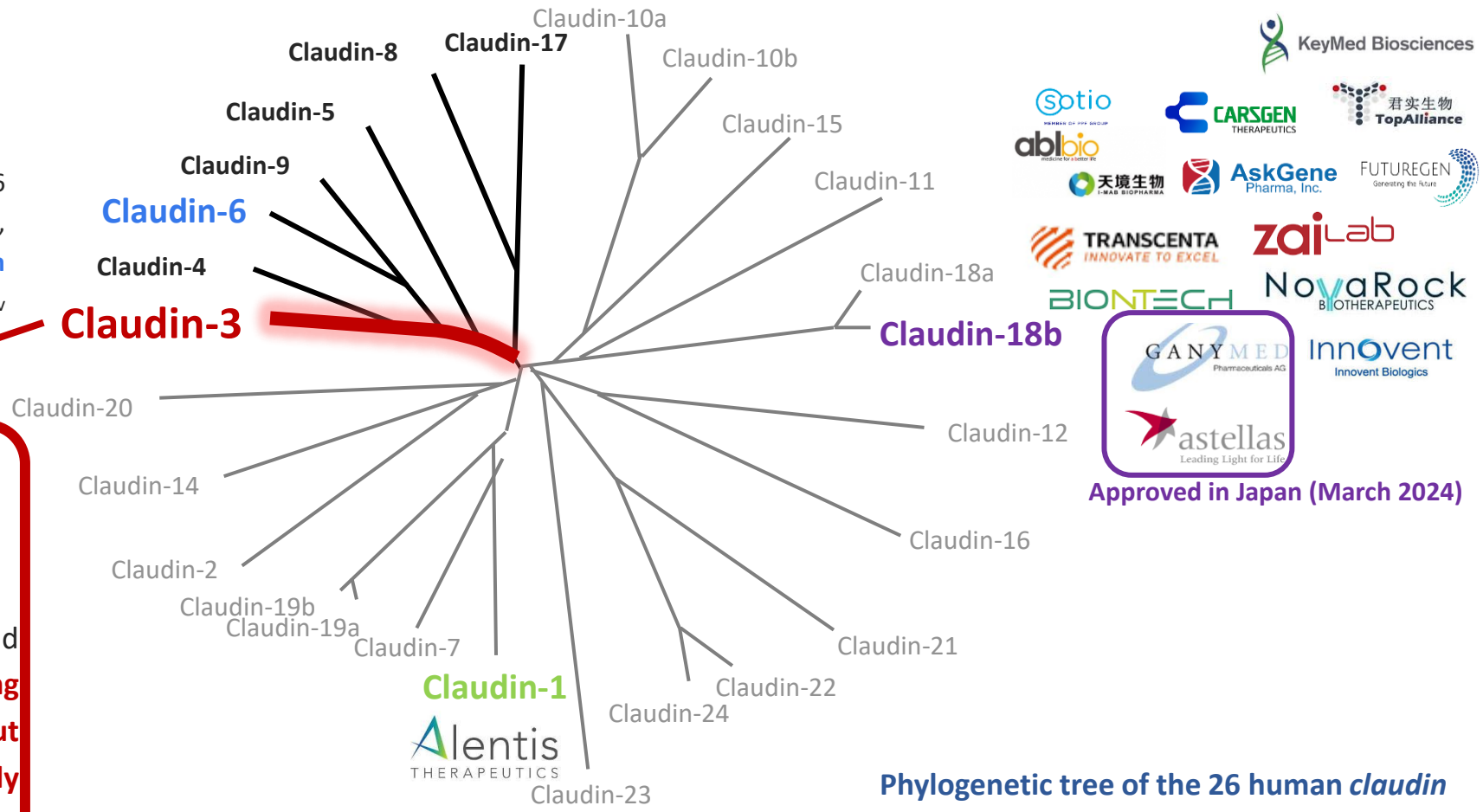
ABN501 : A NOVEL ANTI-CLDN3 ANTIBODY FOR CANCER TREATMENT

ABION is the exclusive holder of a fully human antibody targeting CLDN3

- **IMAB027** is an antibody targeting CLDN6 currently undergoing clinical development, **demonstrating cross-reactivity not only with CLDN6 but also with CLDN9** (Ref. iScience. 2022 Nov 24;25(12):105665.)

ABN501 exhibits high selectivity and strong binding affinity, **binding exclusively to CLDN3 without interacting with other Claudin family members** (Ref. Biomolecules. 2020 Jan; 10(1): 51.).

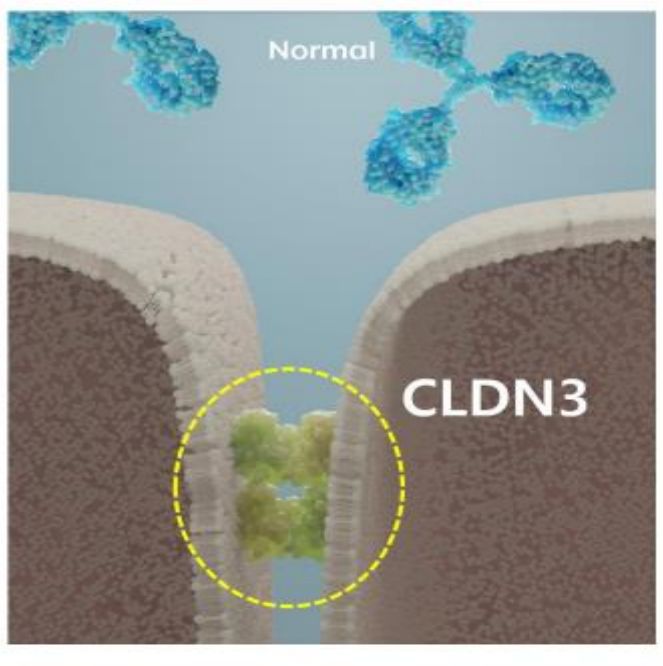


Phylogenetic tree of the 26 human *claudin* genes

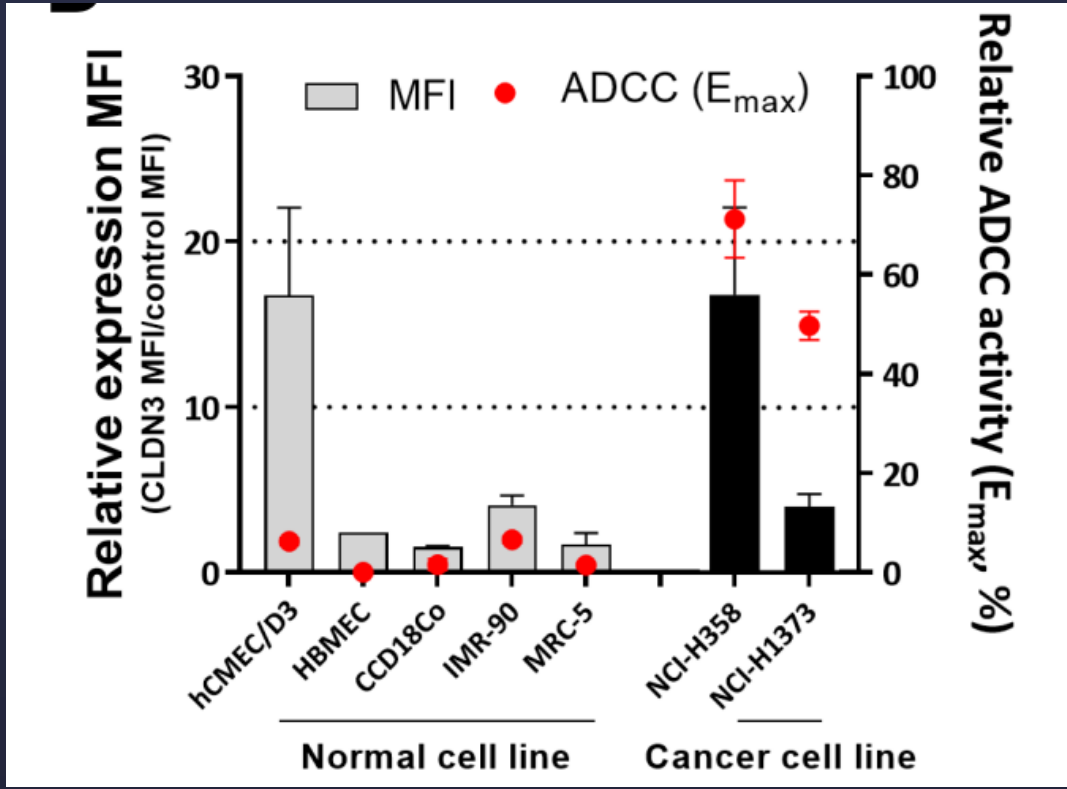
Approved in Japan (March 2024)

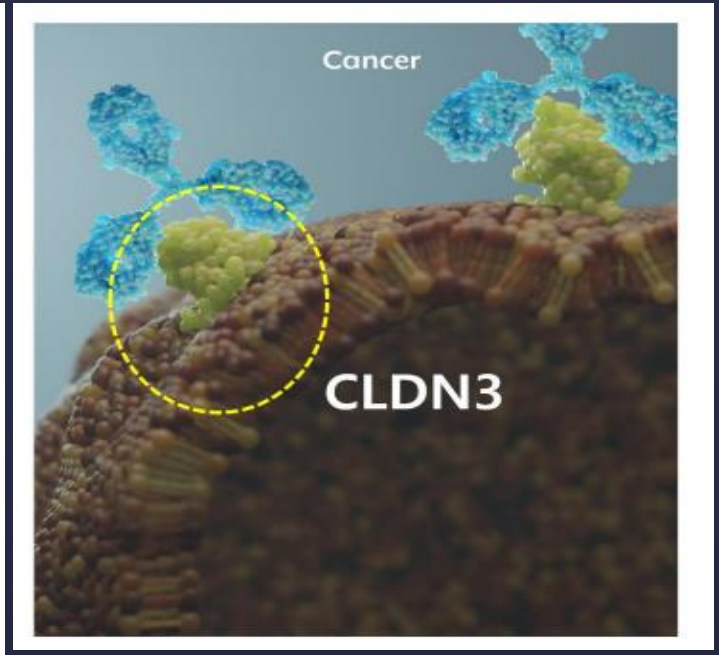
ABN501 : ABN501, highly selective anti-Claudin-3 antibody

Safety – ABN501 does not induce cytotoxicity in CLDN3-expressing normal cells



Normal cells
: CLDN3 is localized in TJ region
(No exposure)





Cancer cells
Tumor cells proliferate through out-of-plane division upon malignant transformation and **exposed outside the tight junction.**

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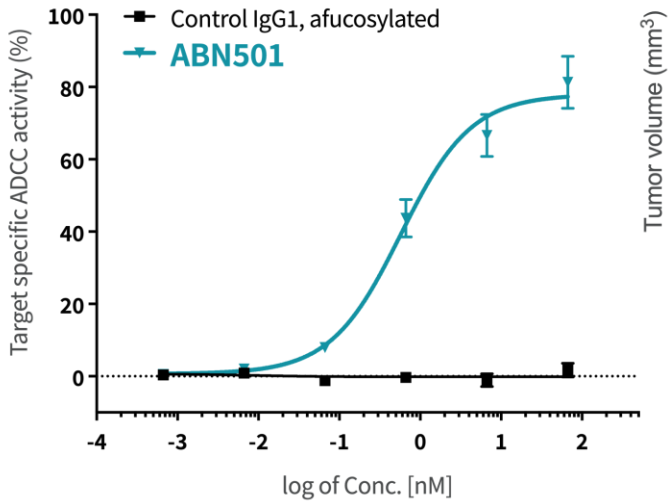
ABN501 : STRONG EVIDENCE OF ANTI-TUMOR ACTIVITY IN CLDN3+ CANCERS

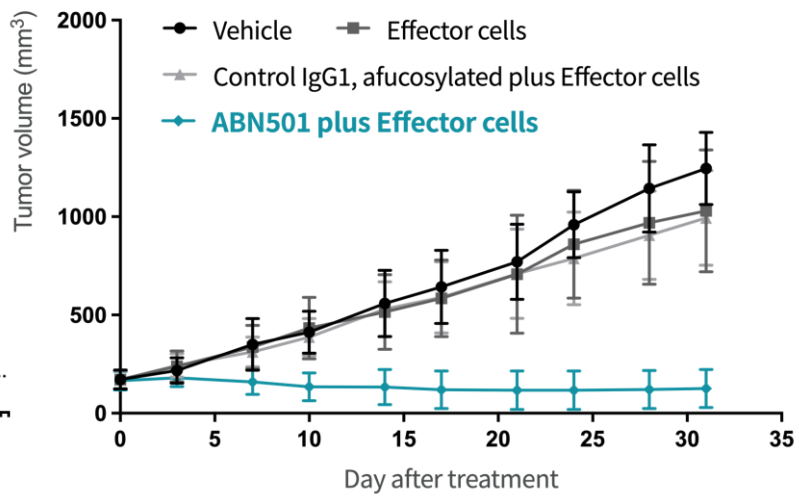
ABN501 demonstrates significant anti-tumor efficacy as a monotherapy in CLDN3+ cancer

Superior anti-tumor activity of ABN501 in CLDN3-expressing cancer

CLDN3$^+$ Cancer cells
Cell line : MDA-MB-453



CLDN3$^+$ Cancer cells
Cell line : MDA-MB-453



ABN501

New Therapeutic Options
for CLDN3-expressing cancer patients

Enhanced ADCC activity

Potent in vitro and
in vivo antitumor activity

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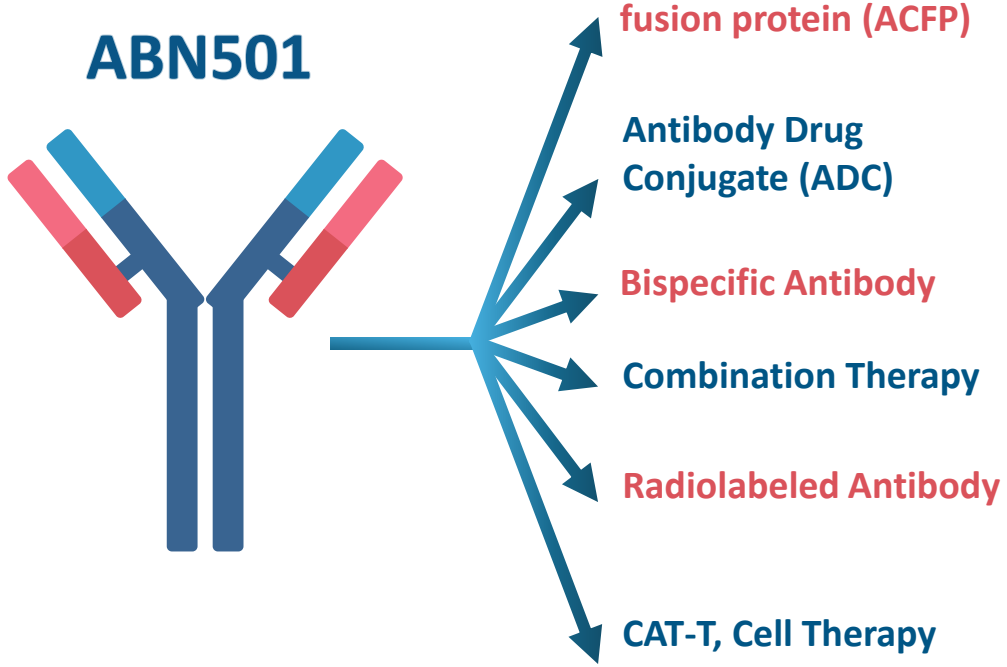
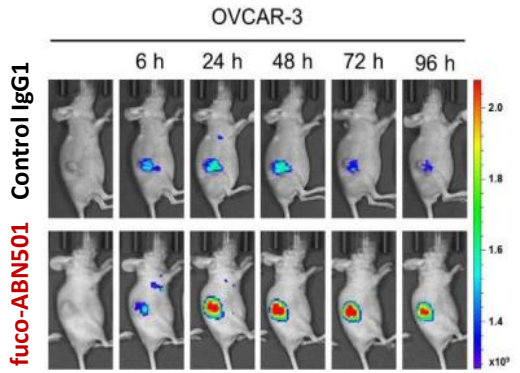
ABN501 : VARIOUS DRUG MODALITIES

ABN501 can be expanded to the other drug modalities

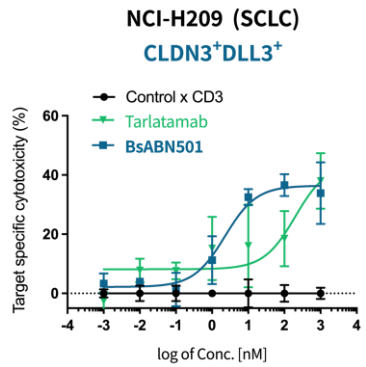


Expand the market with various of antibody engineering technique

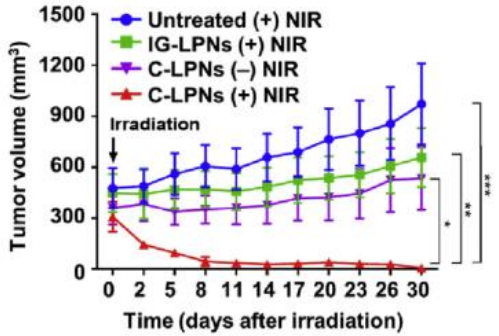
Monoclonal Ab 1



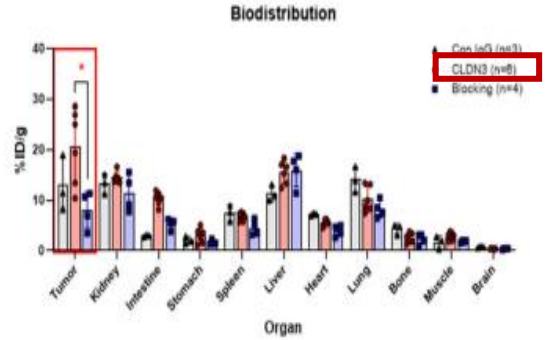
Bspecific T cell Engager CLDN3 x CD3



Photothermal ADC[2]



Radiolabeled Ab[3]



[1] Biomolecules 2019 Dec 28;10(1):51.
[2] Acta Pharm Sin B. 2020; 10(11):2021-2226.
[3] Nucl Med Biol. 2022;114-115:135-142.

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ABN501 : HIGH UNMET MEDICAL NEEDS IN SCLC

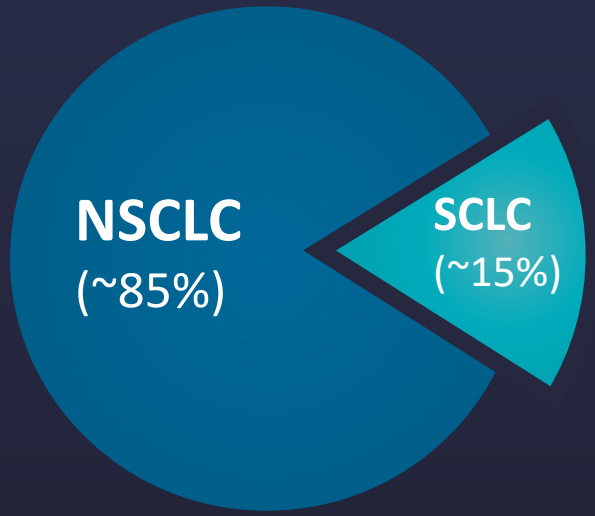
Potential Indications – Small Cell Lung Cancer

SCLC is an aggressive form of cancer with limited treatment options and significant unmet medical needs

SCLC (Small-cell-lung cancer)

5-Years
Relative Survival

7%
All Seer Stages Combined



~170K
New Cases Annually

LS-SCLC
(~30%, ~50K new cases)

ES-SCLC
(~70%, ~120K new cases)

Unmet Medical Needs

✓ ~ 20% of SCLC; Accelerated approval of Imdeltra (DLL3 X CD3 HLE-BiTE®, Amgen) in relapsed/refractory ES-SCLC patients

✓ Targeted therapy for 80% of patients still do not exist

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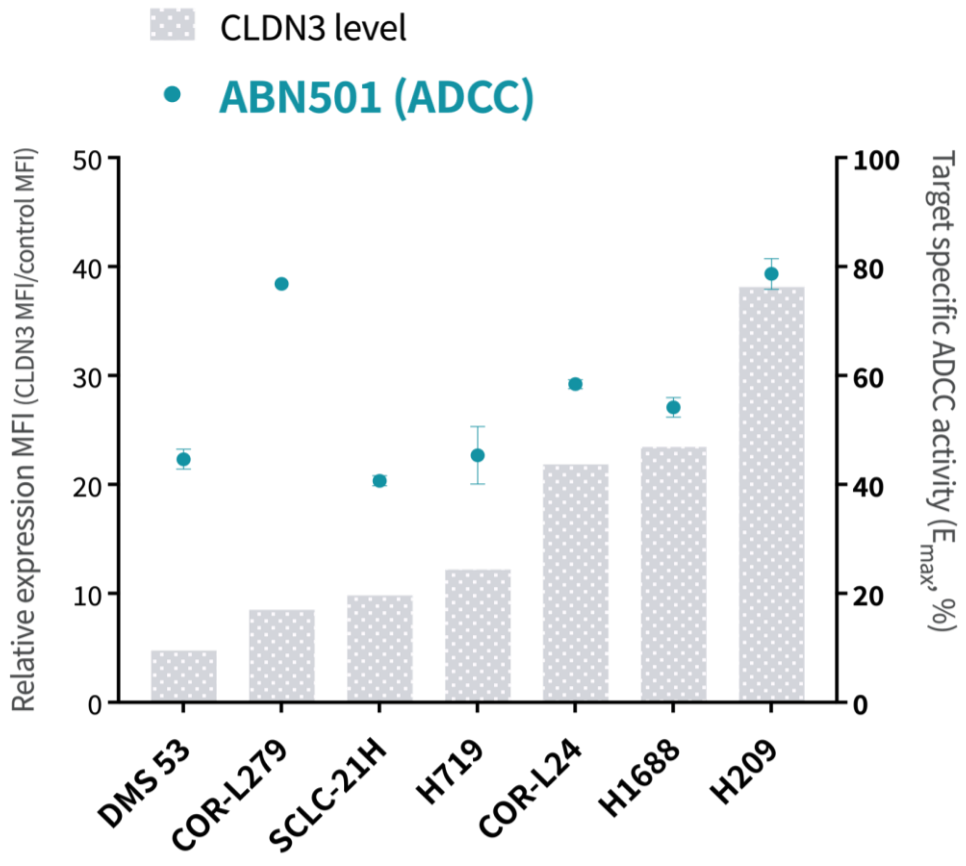
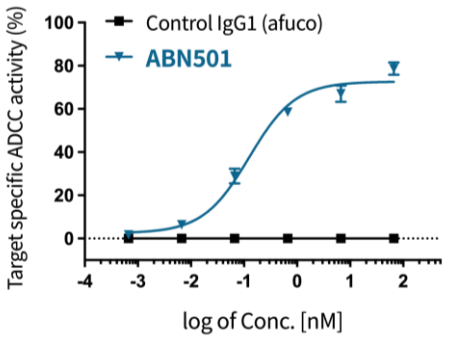
ABN501: PROMISING EVIDENCE OF ANTITUMOR ACTIVITY OF ABN501 IN SCLC

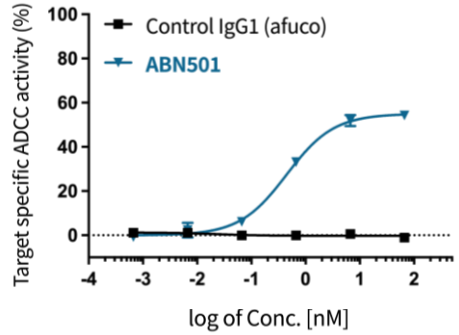
Potent in vitro Anti-tumor Activity in SCLC



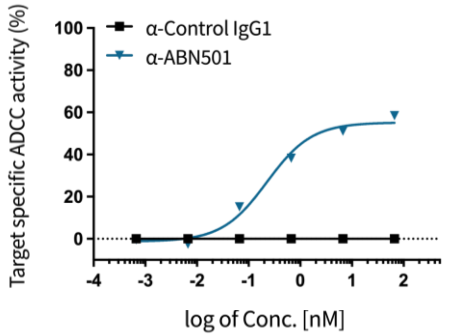
SCLC
NCI-H209



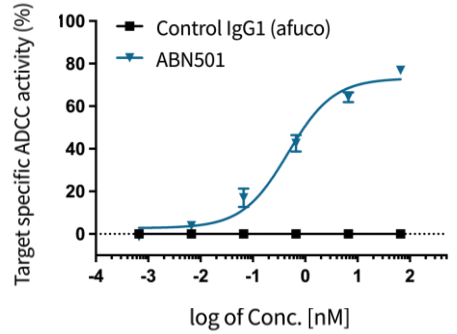
SCLC
NCI-H1688



SCLC
COR – L24



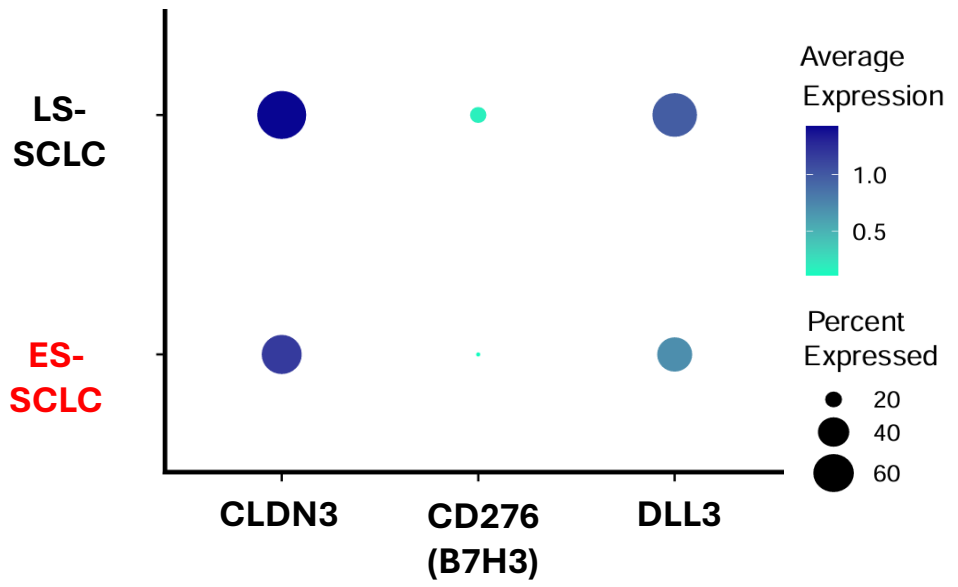
SCLC
COR – L279



ABN501: POTENTIAL TO BE A NEW THERAPEUTIC OPTION FOR SCLC

Notable Elevation of CLDN3 Expression Pattern in SCLC Compared to the Other Clinically Developing Targets

scRNA-seq data from SCLC patient samples



Date regenerated from Cancer Cell. 2021 Nov 8;39(11):1479-1496.e18

Research Collaboration (SCLC)

ABION Inc, U.S. National Cancer Institute (NCI) Signs Joint Research Agreement

Nonclinical studies in SCLC (PDX, CDX, etc)

ABN501 : KEY TAKE AWAY & TIMELINE

First-in-class antibody targeting CLDN3, showing promise for diverse solid tumors, with preclinical trials slated for 2024 and IND submission targeted by 2025.

First-in-Class Novel Human Monoclonal Antibody for CLDN3

- No competitor exist
- SCLC patient sample: CLDN3 > DLL3

Highly Specific and Robust Pre-clinical Results

- CLDN3, Tumor-specific biomarker
- High potency and safety in mouse model

Strong Potential for Expansion of Indication/Modality with ABN501

- CLDN3, Pan-carcinoma marker
- ABN501 : Applicable to various drug modalities

Pipeline	Target antigen	Indication	R&D	Pre-toxicity	Pre-clinical	Phase 1	R&D partner
ABN501	CLDN3	Solid tumor (SCLC, etc.,)					NIH NATIONAL CANCER INSTITUTE
	CLDN3 x CD3	Solid tumor (SCLC, etc.,)					

2024.1H
SCLC pre-clinical result release

2024.2H
Completed process Dev. Preclinical Tox (Non-GLP)

2025.1H
Preclinical Tox (GLP)

2025.2H
IND Packaging

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ABN101

Interferon-β Bio-Better

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ABN101 : Preparedness for Next Pandemic

Unmet Needs for New Anti-viral Drug

- Continuous threats of drug resistance strains and emerging viral pathogens (SARS, MERS, COVID-19, and influenza virus)
- According to WHO report in 2022, it is predicted that pandemic, such as COVID-19, may be emerging more frequently

CLINICAL DAILY NEWS

Resistance to COVID-19 antiviral drugs already evident: study

ALICIA LASEK

APRIL 3, 2023

SHARE

SARS-CoV-2 variants already are showing mutations that may make them resistant to the antiviral COVID-19 pill Paxlovid and at least one other approved antiviral drug, according to researchers from the University of Minnesota Medical School.

TOP STORIES VIEW ALL

NEWS
Owner of defunct Skyline chain pleads guilty in $39M fraud case

NEWS
Supreme Court spars over case that could limit power of CMS, other agencies

NEWS
CMS finalizes long-awaited prior authorization rule for Medicare Advantage

EDITORS' PICKS VIEW ALL

Concern as study says new covid sub-variant is resistant to all therapeutic antibodies

By Jim Cornall

November 23, 2022 - Updated on February 17, 2023

4 minutes • Share

Photo/Shutterstock

Medical countermeasures for new infectious diseases are needed by development of novel antiviral therapeutics in new paradigm

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ABN101 : Preparedness for Next Pandemic

Needs of broad-spectrum antiviral drug for biodefense

- Development of broad-spectrum anti-viral for emerging viral pathogens
- Inhibition of virus spread by convenient administration without hospitalization
- Reduction of quarantine period by ameliorating the symptoms
- Convenient storage in ambient temperature

- JPEO CBRND, the devices and medical countermeasures are developed and acquired to prepare for chemical and biological threats
- After COVID-19 pandemic, military is actively searching for medical countermeasure against viral pathogens

- Rapidly and widely spread of virus infection in military due to work as group
- Prophylactic drugs are critical for the defending forward against viral pathogens

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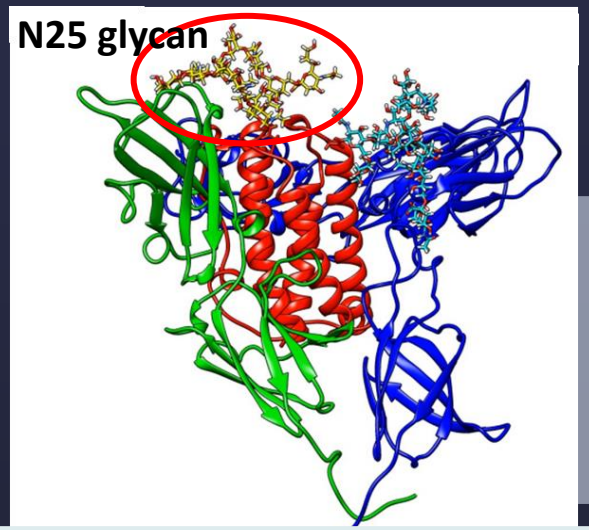
ABN101 : Various Formulation

ABN101_Various Formulation

- Syringe/Microneedle: Multiple Sclerosis and chronic viral infection, such as HBV and HCV
- Inhaler: **Broad-spectrum anti-respiratory virus drug (SARS-CoV-2, Influenza virus, and RSV)**
- Formulation study is completed
- **GMP manufacturing of Dry powder is ready**

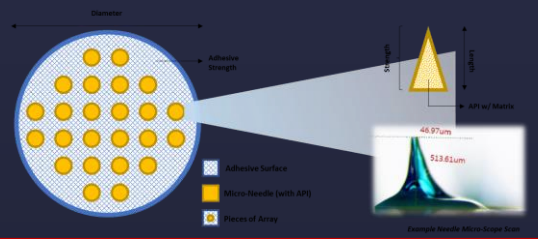


- Improved physicochemical properties
- Better pharmacokinetics(PK) and biological activity
- High productivity

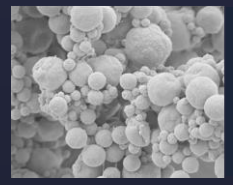
Various Formulation

Applicable to many indications with various formulation

Syringe



Microneedle



Inhaler

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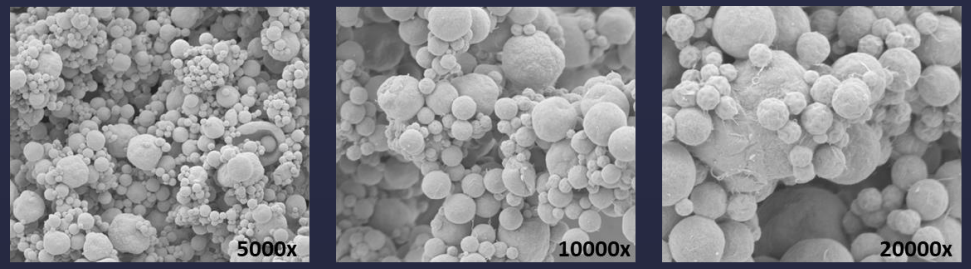
ABN101 : Anti-viral Activity_Influenza virus

ABN101 dry powder

- Direct delivery to lungs
- Convenient storage and treatment

First-in-class, Interferon-β dry powder for prophylaxis



	Yield (%)	D90 (mcm)	Water content (%)
ABN101 Dry Powder	82%	~5.4	~2.1

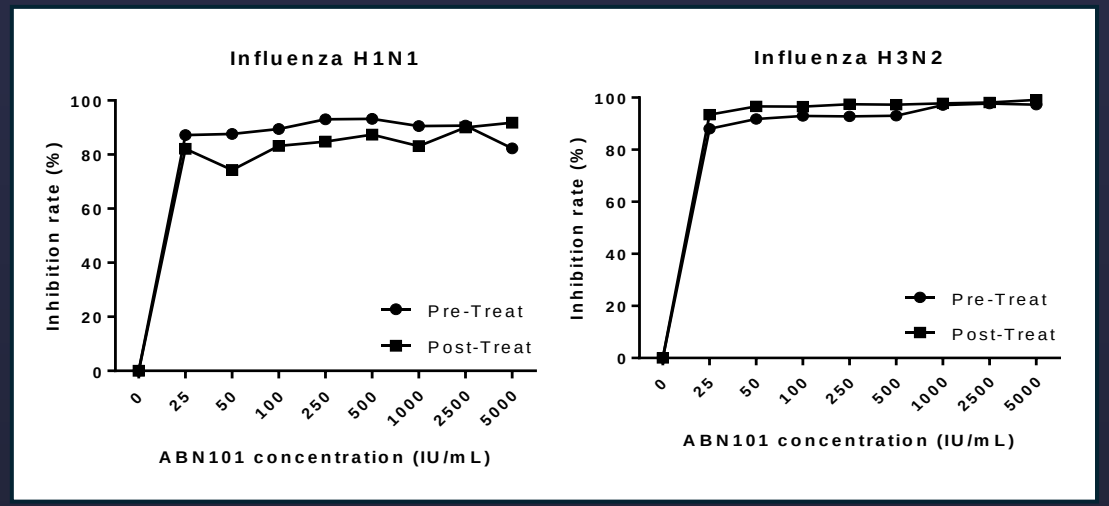
Biological activity of ABN101 in dry powder is well maintained

ABN101 : Broad-spectrum anti-respiratory virus drug

Antiviral efficacy of ABN101 dry powder

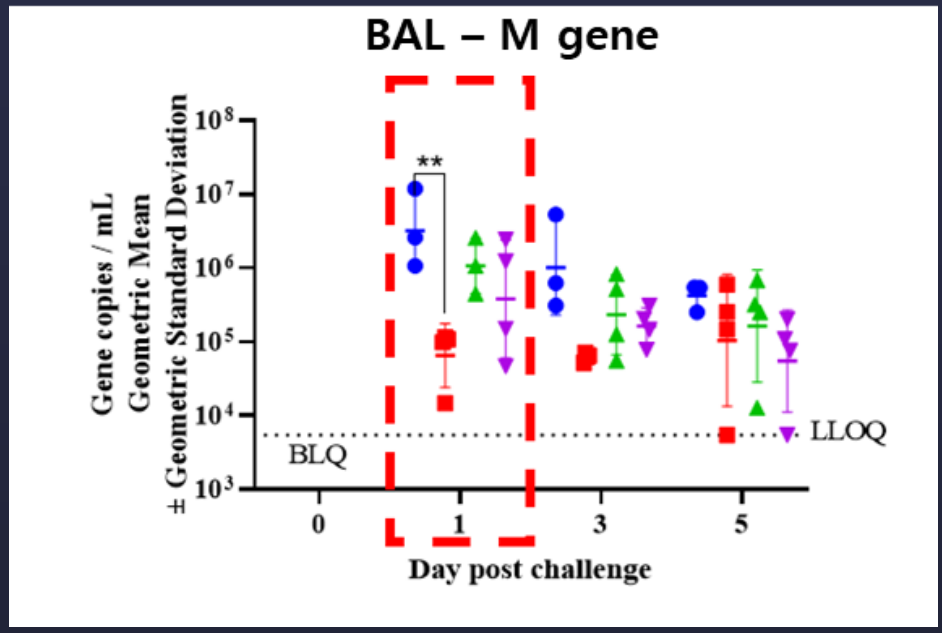
- Broad-spectrum anti-viral
- Confirmed for respiratory viruses, such as SARS-CoV-2, influenza virus and RSV

In vitro efficacy - Influenza virus



Effective for SARS-CoV-2, RSV as well as influenza virus

In vivo efficacy - Influenza virus



Untreated Control
ABN101(12 MIU) INH 24 h pre-infection
Positive control
ABN101(12 MIU) INH 8 h post-infection

abion

ABN101 : Broad-spectrum anti-respiratory virus drug

Development Collaborators

ABN101 : Summary

Interferon-β Bio-better

Interferon-β Bio-Better

- Superior physicochemical properties
- Capability to develop in various formulations
- Higher biological activity

Dry Powder Inhaler

- Efficient and convenient administration into lungs
- Storage in ambient temperature
- Minimizing systemic exposure

Broad-Spectrum Antiviral Prophylaxis

- Proven efficacy to inhibit respiratory viruses
- Immediate medical countermeasure for emerging viral threat

Pipeline	API	Indication	R&D	Pre-clinical	Phase 1
ABN101	Interferon-β	Broad-spectrum Infectious viruses (esp. Respiratory viruses)			

2024.4Q
GLP (Dry powder) production
GMP (Liquid) production

2025.1Q
Toxicology study
(GLP-Dry powder)

2025.2Q
GMP (Dry powder) production

2025.2H
IND Packaging

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Thank you

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Q&A