

## HLB Life Science

**Investor Relation 2024** 

Mar 2024



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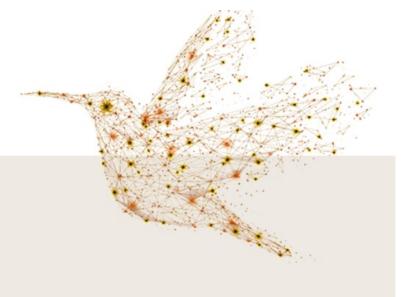


## Company Overview









### Vision

No.1 Cancer-specialized company through achieving 5 global L/O deals by 2030

## **Mission**

**Human Life Better** 

### **Core Values**

Concentration, Challenge, Communication, Collaboration, Change, Creation



HLB has acquired excellent pharmaceutical & biotechnology professionals and established a global network in the drug development.

We are ready to grow into the leading new drug development company based on the 'Global Integrated New Drug Development Platform'

## History



Date of Establishment

July 24, 1998

Sales Revenue

97.990 billion won ('23)

Number of Employees

153

## 1998~2018

1998. Establishment of Energy Solutions Co., Ltd.

2008. Listing on KOSDAQ

2015. Change of company name; HLB Life Science Co., Ltd.

Approval of Phase 3 for Rivoceranib in Gastric cancer (progressive or metastatic gastric cancer)

2016. Stake Acquisition of Shinhwa Advance, Co., Ltd.

Approval of Phase 1 for Rivoceranib in Gastric cancer (for standard therapy failure and unresectable progressive recurrent gastric cancer)

2017. Approval of Phase 2 for Rivoceranib in Colon cancer (for metastatic colorectal cancer)

Approval of Phase 3 for Rivoceranib in Gastric cancer (optimal supportive therapy for progressive or metastatic gastric cancer)

2018. Acquisition of exclusive domestic license for Rivoceranib and partial profit rights in Japan/Europe.

Stake Acquisition of Life River Co., Ltd. (Present, HLB Cell)

Approval of Phase 1/2a for combination therapy of Rivoceranib+Paclitaxel (for progressive gastric cancer or gastroesophageal joint cancer) / Approval of Bio-artificial liver

## History



Date of Establishment

July 24, 1998

Sales Revenue

99.591 billion won ('23)

Number of Employees

153

### 2019~2023

2019. Change of Headquarter location (Pangyo, Gyeonggi-do)

Approval of Phase 2 for Rivoceranib in Adenoid cystic carcinoma (Reoccurring or metastatic adenoid cystic carcinoma)

2020. Exclusive Licensing in Korean for Pyrotinib / Change of Headquarter location (Dongtan, Hwaseong, Gyeonggi-do)
Approval of Phase 3 for Pyrotinib in non-small cell lung cancer / Approval of Phase 3 for Rivoceranib/Camrelizumab in Hepatocellular carcinoma Approval of Phase 1b/2 for the combination of Rivoceranib or Rivoceranib/Trifluridine/Tipiracil in Colorectal cancer)

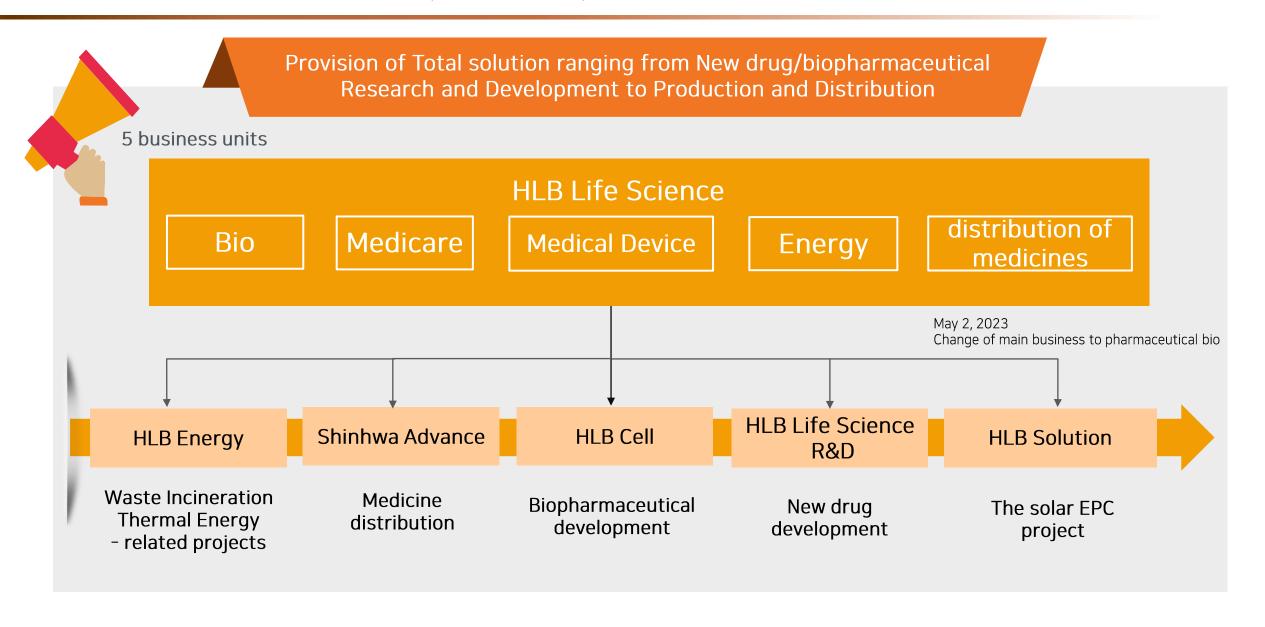
2021. Establishment of HLB Life Sciences R&D New Drug Research Institute Approval of Phase 2 for Rivoceranib/Camrelizumab in Primary gastric cancer

2022. HLB Life Science R&D Spin-Off, Exclusive Licensing for a New Anticancer Drug Technology from LSK NRDO → G2M inhibitor
AlM M&A, Transfer to Medicare Division
Approval of Pyrotinib as an orphan drug in non-small cell lung cancer, Clinical approval of Rivoceranib for canine anticancer drugs

2023. Exclusive Licensing for the New Anticancer Drug Technology from LDC (German) → CDK inhibitor
Rivoceranib - Application of U.S. NDA (Liver cancer), Acquisition of conditional NDA in Korea (adenoid cystic carcinoma)
Approval of Phase 3 for Pyrotinib in Breast cancer

## **HLB Life Science Subsidiary Company Status**







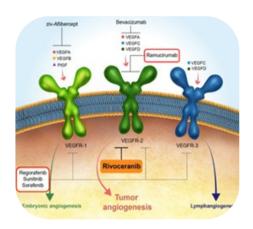
## HLB Life Science R&D Platform

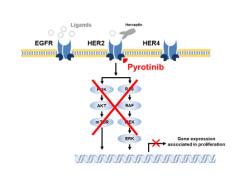
### HLB Life Science R&D Platform

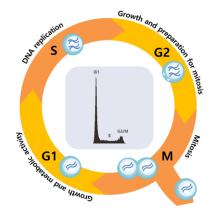


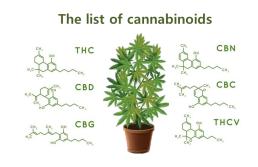
Rivoceranib VEGFR-2 Inhibitor Pyrotinib
EGFR/HER2/HER4 Inhibitor

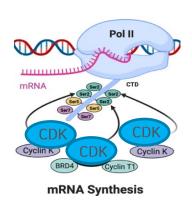
HLS221-N01 G2M Inhibitor HLS231-N01 Cannabinoids HLS232-N01 CDK inhibitor











- Rivoceranib inhibits tumor growth by selectively blocking signaling of the VEGF Receptor-2, limiting new blood vessel formation (angiogenesis)
- Pyrotinib is an irreversible dual pan-ErbB receptor tyrosine kinase inhibitor developed for the treatment of HER2-positive advanced solid tumors
- G2M inhibitor interferes with the progression of G2 ► M stage during the cell division cycle (inhibiting the growth of cancer cells and inducing death)
- Cannabinoids have anticancer properties, which can improve cancer therapy. This project determines the potential utility of cannabinoids in the treatment of cancer
- CDK is Ser/Thr protein kinases that regulate transcription and co-transcriptional processes through the activation of RNA Polymerase II



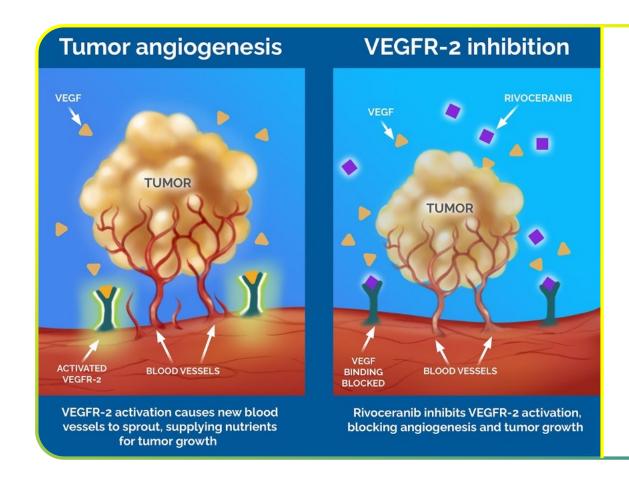
## Pipeline Status

## Pipeline



Project	Indication	Exploration	Preclinical	Phase 1	Phase2	Phase 3	Approved
Rivoceranib	Liver cancer (1st Line, Camrelizumab combination)						FDA NDA May 2023
	Gastric cancer (1 <sup>st</sup> Line, Camrelizumab combination)						
	Gastric cancer (2 <sup>nd</sup> Line, Paclitaxel combination)					>	
	Gastric cancer (3 <sup>rd</sup> Line, Mono)						
	Adenoid cystic carcinoma (1st Line, Mono)						r conditional approval ec.2023
	Colorectal cancer (3 <sup>RD</sup> Line, Capecitabine combination)				<b>&gt;</b>		
	Canine solid Tumor						
Pyrotinib	Metastatic breast cancer	Phase 3 IND approval (Mar. 2023)					
	Non-small cell lung cancer						
G2M Inhibitor	Solid Tumor	LSK NRDO L/I					
CBD Derivatives	Solid Tumor	1501 >	<b>∠</b> NeoCannBio				
CDK Inhibitor	Solid Tumor	455	Discorery Center				
Medicinal cannabi	is Epilepsy						



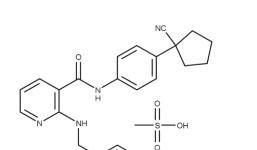


## Angiogenesis is a hallmark of tumor development <sup>1</sup>

- Tumor releases vascular endothelial growth factor (VEGF)
- VEGF binds to VEGF receptors on existing blood vessels
- New blood vessels sprout
- Nutrients are supplied to tumor, allowing for rapid growth

Sources: Feng G, Chun Y. Current Cancer Drug Targets. Anti-VEGF/VEGFR2 Monoclonal Antibodies and their Combinations with PD-1/PD-L1 Inhibitors in Clinic. Volume 20, Issue 1, 2020, DOI: 10.2174/1568009619666191114110359

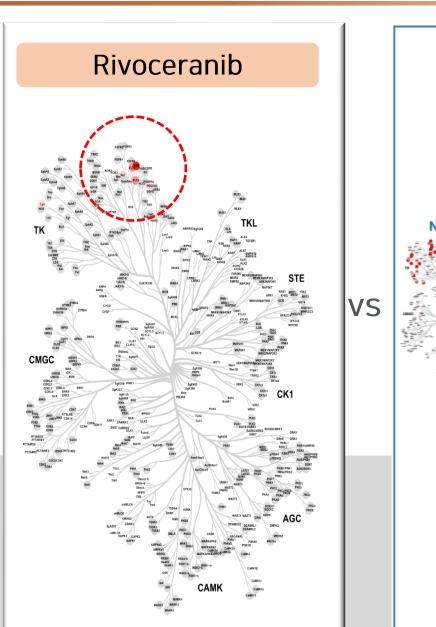
## Rivoceranib: Potent & Selective on clinically validated target, VEGFR2 HLB Life Science

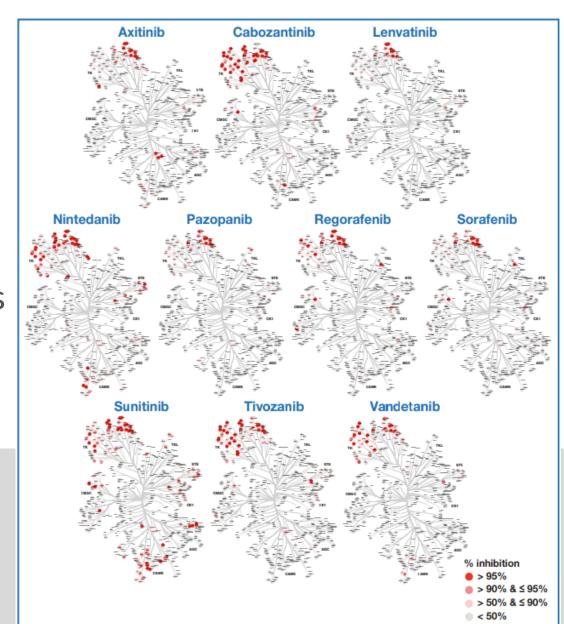


Rivoceranib inhibits

tumor growth by
selectively blocking
signaling of the VEGFR2,
limiting new blood vessel
formation (angiogenesis)

Best-in-Class Anti-cancer Drug





## Rivoceranib: Development Status



- ✓ Phase 3 completion in gastric cancer (2020)
- ✓ NDA submission in AAC (2023, Korea)
- ✓ Liver Cancer NDA Application (2023, US)

✓ Optimized efficacy/toxicity (Best-in-Class)

✓ Value generation through

indication Expansion

✓ Orphan drug designation (GC: US/EU/KR, ACC: US/KR)

- ✓ First Approval in China (2014)
- ✓ Sales in 2021: US\$505M¹

Ref 1. Hengrui 20121Annual Report

 ✓ Market expansion through combination prescriptions in China
 Expected US\$11.4B in 2024 <sup>2</sup>

Ref 2. Datamonitor Healthcare, 2017

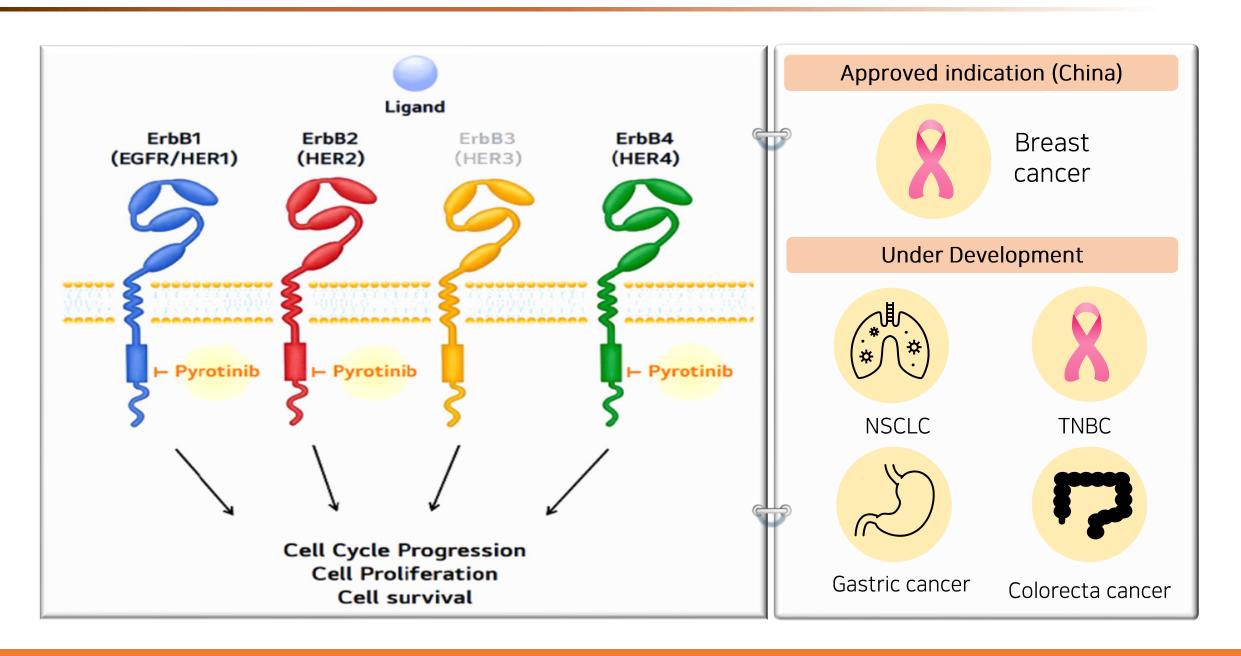
## Future Plan

- Promotion of New Drug Approval in Korea market
- > Global market entry and visualizing product sales by alliance with HLB Life Science affiliates or partners
- > Indication expansion based on the medical unmet needs (e.g : Combination therapy research etc.)

Rivoceranib

## Pyrotinib: EGFR/HER2/HER4 inhibitor





## Pyrotinib: Development Status



### "First approval in China in 2018 → Introduction of exclusive Korean license in 2020 "

**Pyrotinib** 

- ✓ Conditional approval of HER2-positive Breast cancer (2018, Jiangsu Pharmaceuticals, China)
  - → Approval completion in 2020
- ✓ Global sales in 2021: US\$1.0B¹

Ref 1. https://dataintelo.com/report/pyrotinib-market

 ✓ Approval of Phase 3 clinical trial IND for HER2-positive breast cancer
 (March 2023, Korea)

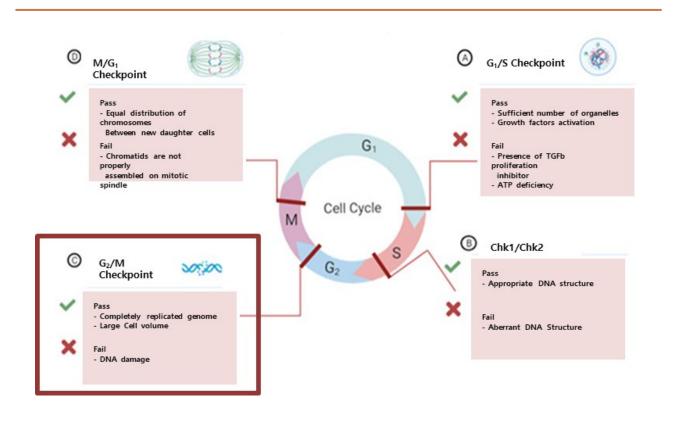
- ✓ Phase 3 clinical trial for Non-small cell lung cancer
  - Orphan drug Designation in Development stage (Korea)
  - Currently conducting global clinical trials in collaboration with Jiangsu Pharmaceuticals

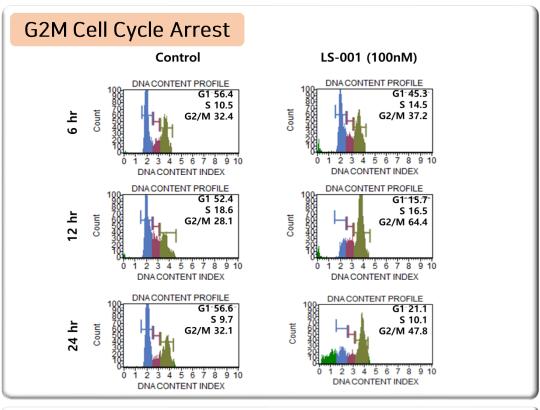
 ✓ Planning to confirm the Anticancer effect through various solid cancers and combination prescription

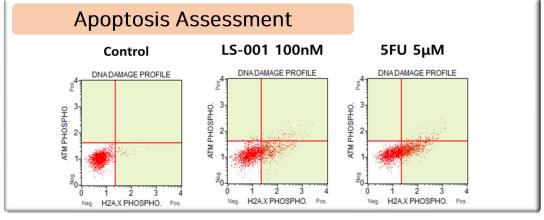
## G2M Inhibitor (New Anticancer Drug)



- Cell cycle is the lifetime of a mother cell from its division into two daughter cells until it passes on genetic materials
- Cell division progresses through a cycle of 4 phases (G1  $\rightarrow$  S  $\rightarrow$  G2  $\rightarrow$  M) repeating itself.
- Cell division is activated in cancer cells
- A G2M inhibitor inhibits the growth of cancer cells and induces apoptosis by interfering with the progression from the G2 to M phase in the cell division cycle







## G2M Inhibitor (New Anticancer Drug)



#### Colony formation Assay in Colon cancer cells

Compound

Control

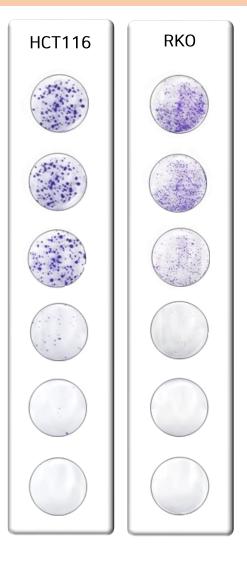
6.25 nM

12.5 nM

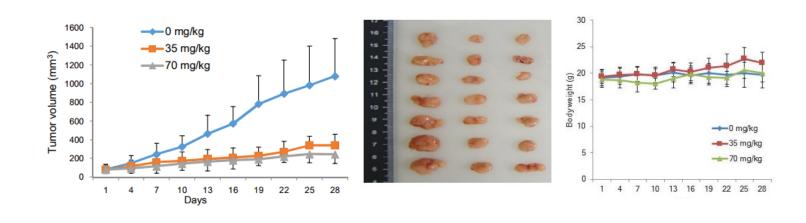
25 nM

50 nM

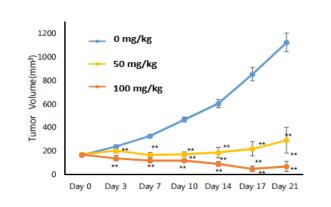
100 nM

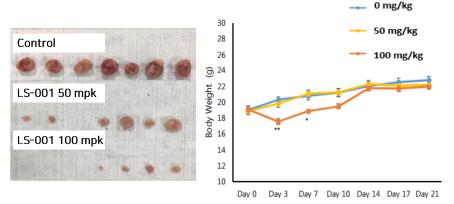


#### Anticancer efficacy in colon cancer cell transplantation Xenograft model



#### Anticancer efficacy in blood cancer cell transplantation Xenograft model





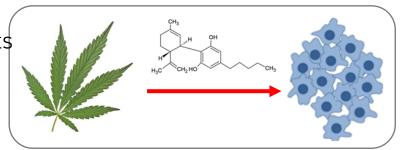
### Cannabinoids derivatives

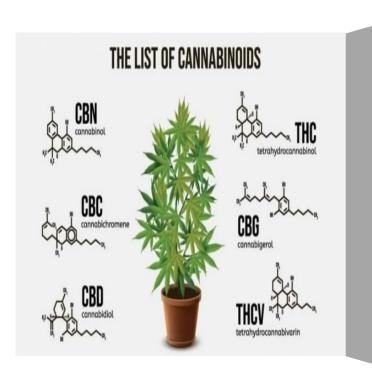


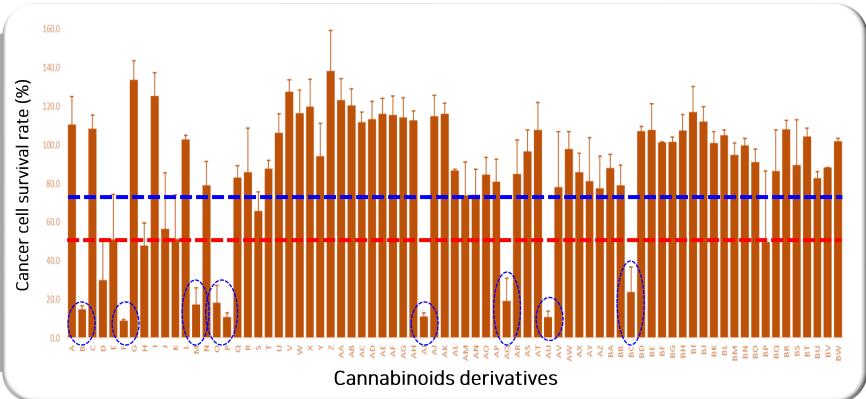


Cannabinoids have been extensively studied for their potential anticancer effects and symptom management in cancer patients.

→ Screening underway of cannabinoids and their derivatives against cancer





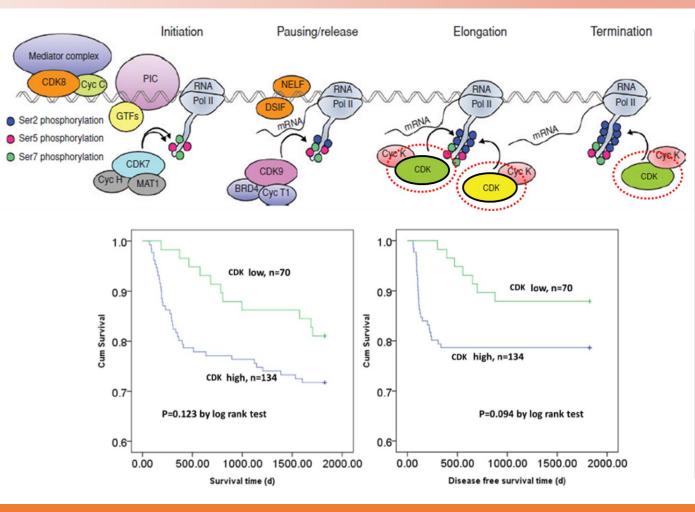


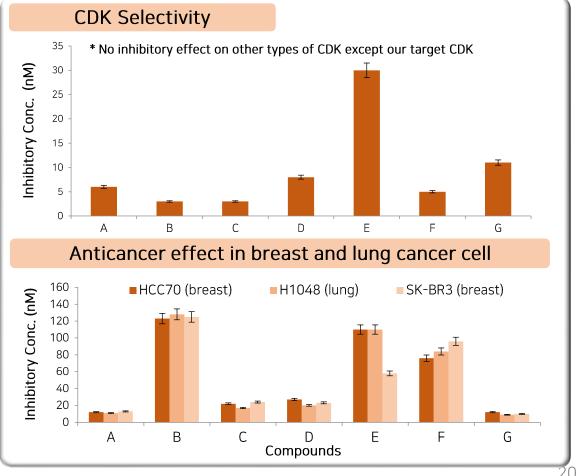
## **Newly Introduced Anticancer Drug**



First-in-Class Anti-cancer drug Licensing (Aug 2023)

- First-in-Class Anti-cancer Drug from LDC
  - Induction of cell damage by blocking self-repair mechanisms of cancer cells
- Development underway; in pursuit of global development and licensing out



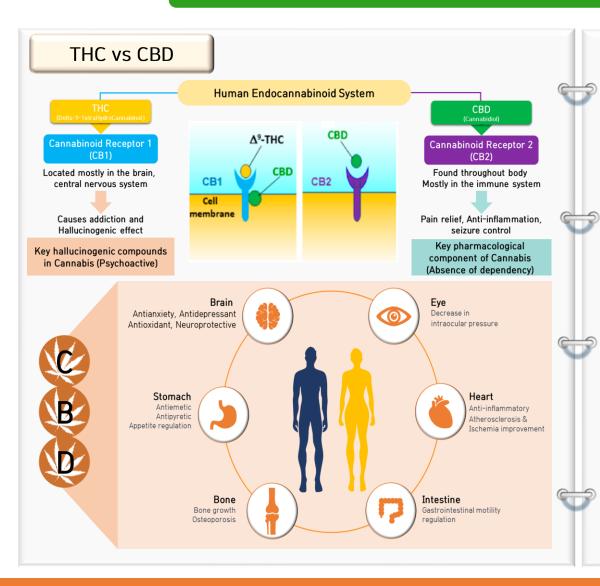


### **Medicinal Cannabis Business**

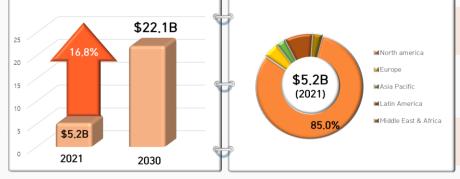


#### Cannabis: Globally acclaimed as the uncharted green biomaterial !!!





#### Global Cannabidiol Market Size



North America Market Value (2021) USD4.4B



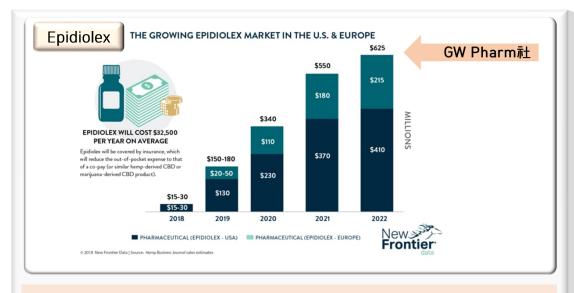
Market Value (2030) USD17.4B

#### **Drug Development Status**

)	Drug Name		Generic Name (API)	Manufacture	Country	Approval status Approved country	Efficacy	
	MARINOL	335	Dronabinol (delta-9-THC)	AbbVie Inc.	U.S	FDA (1985)	Relief for cancer treatment	
						US	patients' nausea and vomiting  • Anorexia in AIDS patients	
)	05044457	CHARGE COMMISSION IN THE PROPERTY OF THE PROPE	Nabilone (delta-9-THC)	Bausch Health (fka Valeant Pharm.)	Canada (US)	FDA (1985)	Relief for cancer treatment patients' nausea and vomiting	
	CESAMET					US, UK, Germany	Sedative and antipsychotic effects	
	SATIVEX		Nabixmols (delta-9-THC, CBD)	Jazz Pharm (fka GW Pharm.Ltd.)	UK	EMA (2016)	Relief of spasticity due to	
						UK, Germany, France, Australia	multiple sclerosis	
	EPIDIOLEX	*Epidolec	Cannabidiol (CBD)	Jazz Pharm (fka GW Pharm,Ltd.)	UK	FDA (2018)		
						US, EU, Canada, Japan, Korea	Alleviation of seizure symptoms	

### Medicinal Cannabis Business





In Korea, following the 2018 revision of the Narcotics Control Act, medical use of cannabis for specific purposes has been conditionally approved.

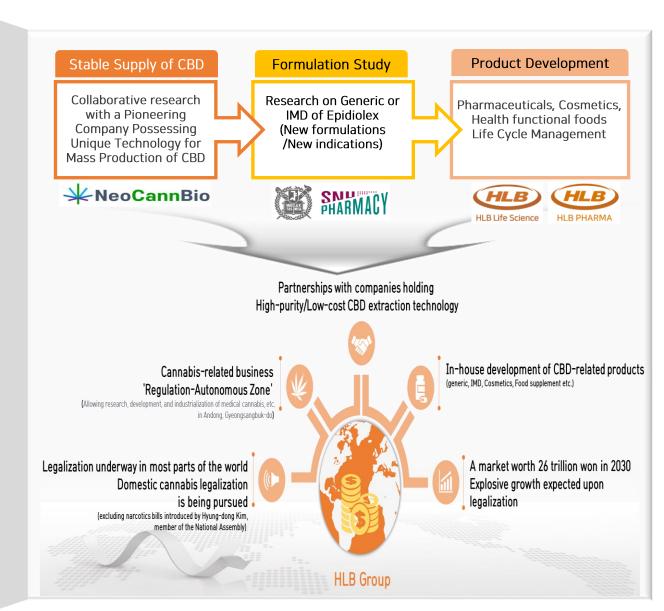
This allows for purchase through the Korea Orphan & Essential Drug Center.

However, it is very expensive!

Although covered by insurance, the high price has a negative impact on the financial situation of National Health Insurance Service



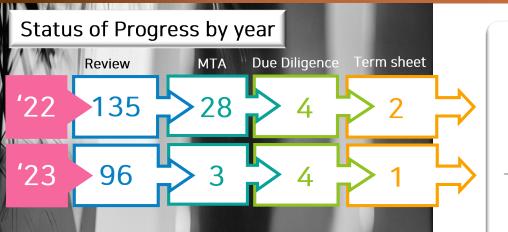
Needs for Domestic Cannabidiol products



## Open Innovation









HLB생명과학R&D, 獨 LDC와 '표적항암제' L/I 계약

기사입력: 2023-08-09 11:19 | 수정: 2023-08-09 11:19

바이오스펙테이터 서윤석 기자

계약금 등 상세내용 비공개..특정 유전자 전사 억제기전





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NOVEMBER 6-8, 2023 | MUNICH, GERMANY

2024. 02. 21

HLB Life Science contracted MOU with Atheonbio for the co-development of cancer diseases



2024. 03. 06

HLB Life Science contracted business promotion agreement for commercialization of Rivoceranib-Camrelizumab







## HLB Life Science Roadmap

## HLB Life Science Roadmap



#### HLB Life Science Bio Business

## HLB-LS New Compounds

Development of new anticancer drugs
Planning of L/O

#### Rivoceranib

Continuous Indications expansion
Animal anticancer drugs

Cannabinoid

Treatment of Epilepsy

Discovery of new indications (anticancer drugs)

#### Research-Oriented Global Pharmaceutical Company

- Development of targeted anticancer drugs with global competitiveness
- Collaboration with global partners through R&D-focused development capabilities
- Leading the Development of Innovative and Differentiated Anticancer Drug

## ~2035

Visualizing Achievements with New anticancer drugs

- Entering Clinical Trials with New Anticancer Drugs
- Successful Global L/O

~2030

#### Visualizing Product Sales and Global expansion

- Visualizing sales of Rivoceranib/Pyrotinib
- Entering Clinical Trials with new anticancer drugs and Pushing for L/O
- Expansion of CBD business

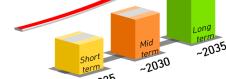


**Pyrotinib** 

Expansion of new indications

#### Life Cycle Management (LCM)

- Successful launch of Rivoceranib/Pyrotinib and indication expansion
- Establishment of novel anticancer pipelines







Human

Life

Better

Thank you



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