



**Human Life Better**

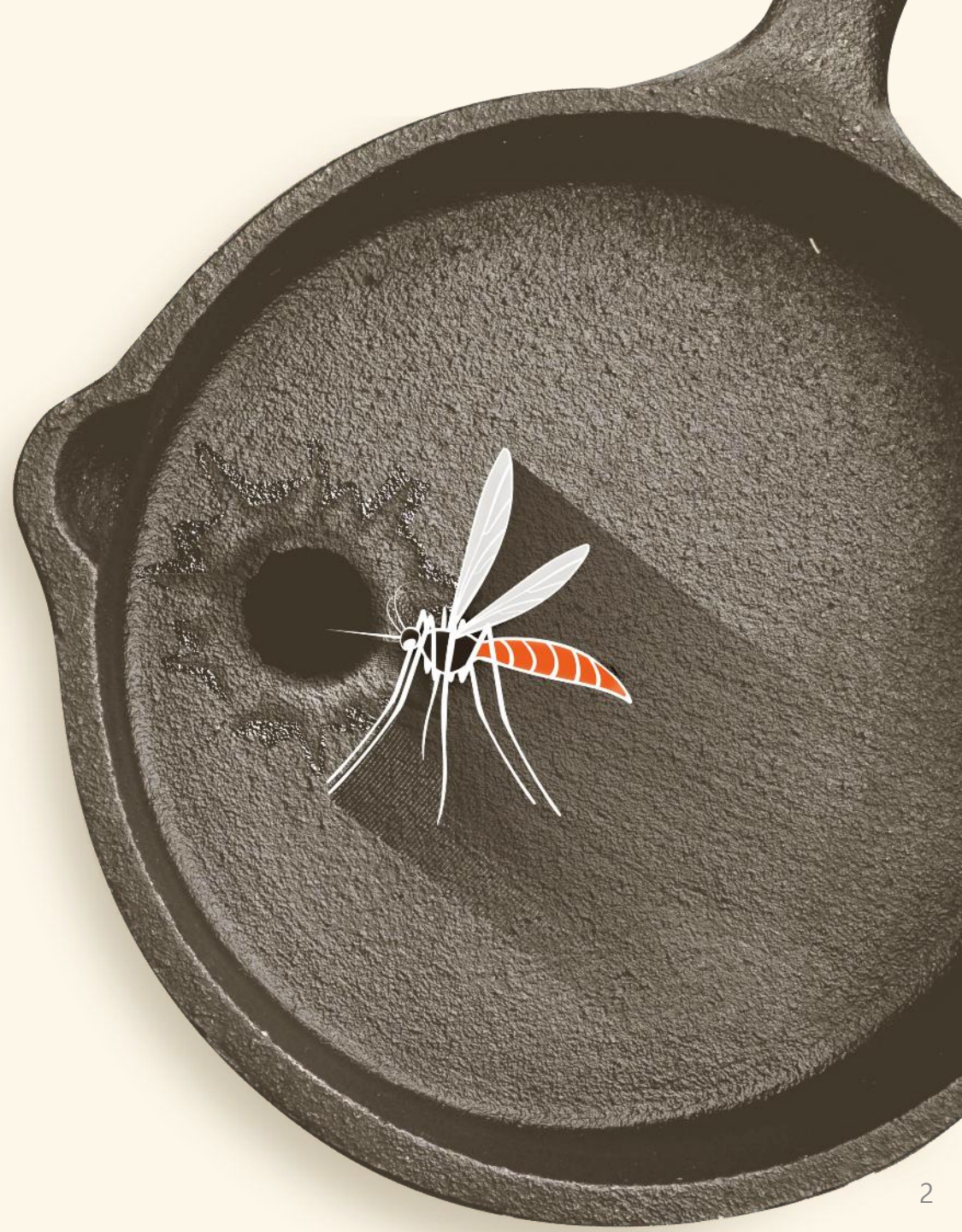
2024.04.15



“

모기도 굳센 의지를 가지고  
머리를 들이밀면  
무쇠도 능히 뚫으리라

- 서산대사



# Intro

신약성공률 vs. Risk

ONE Product Risk



항암제 vs. 반도체

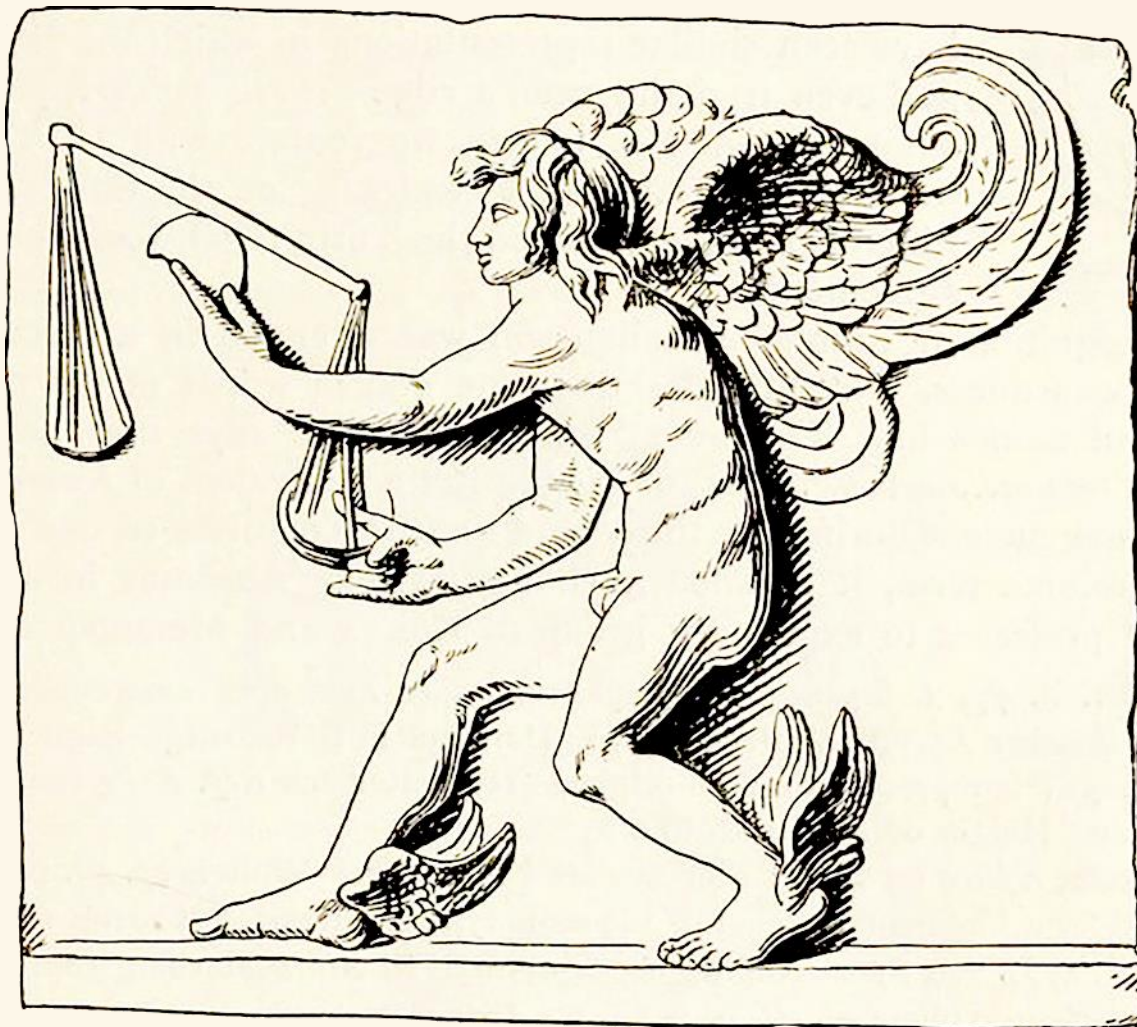
	2023	2027
항암제	300조	500조
반도체	700조	1,000조



HLB의 경우...

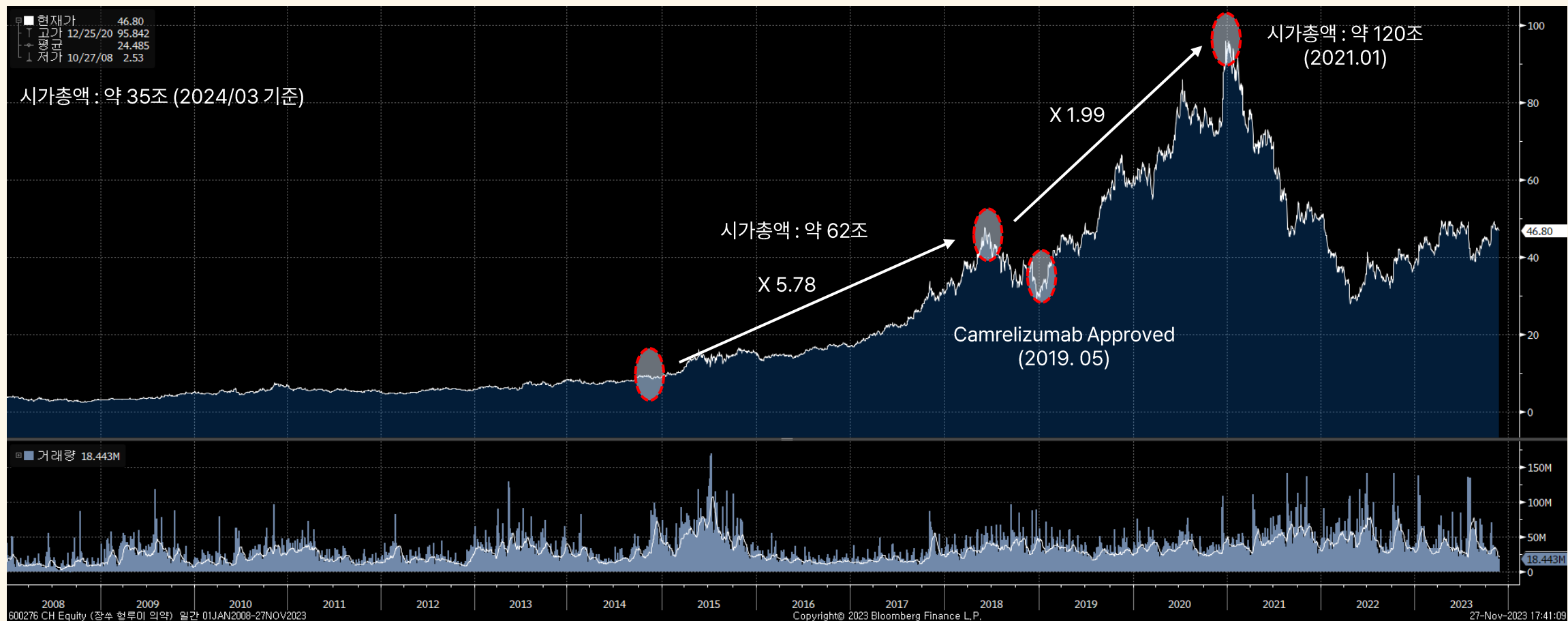
**UPSIDE >> RISK**



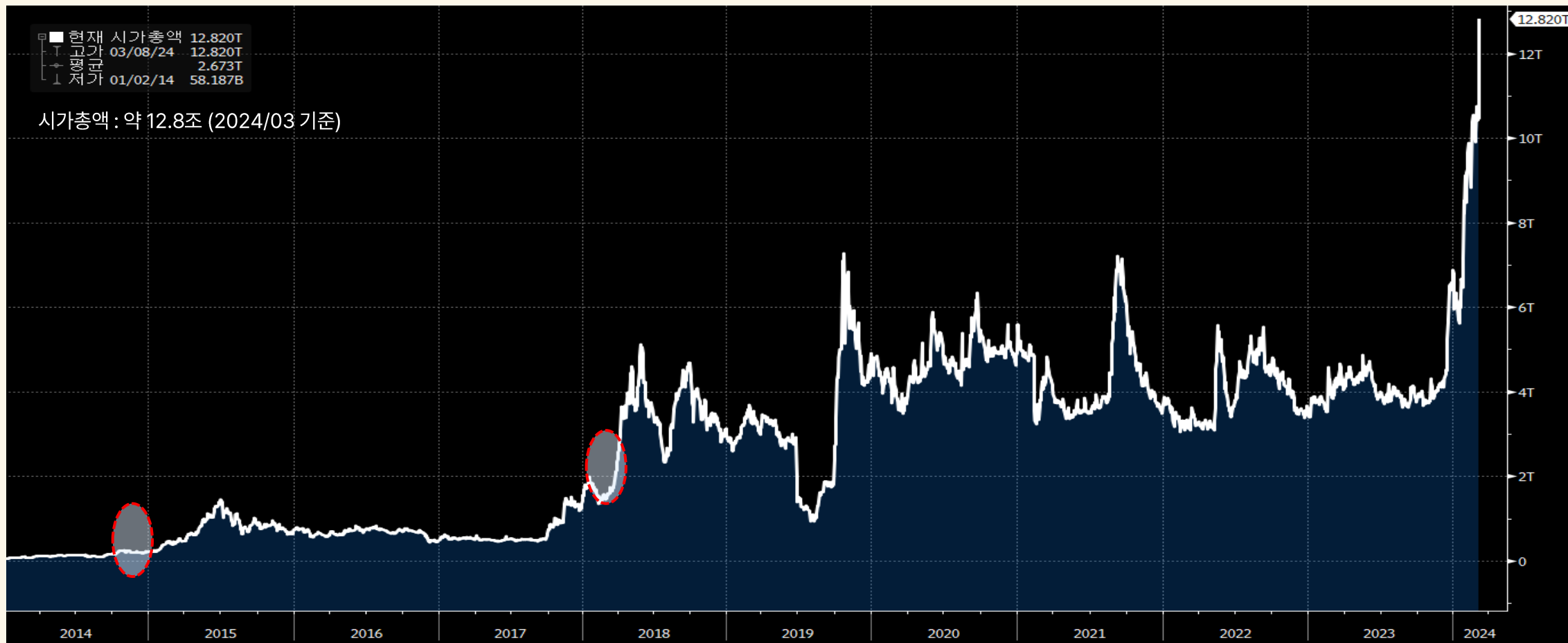


**Kairos**

# 항서제약 주가 차트



# HLB 주가 차트



# 진단에서 치료까지

## 합성신약

	Rivoceranib	항암
	Pyrotinib	
	Apealea	
	OKN-007	
	HP-P024	개량신약
	HP-P037	
	HP-P038	

## 바이오의약품

	RGN-259	펩타이드 의약품
	DD-S052	
	DD-A279	
	Lifeliver™	세포치료
	μMatricel-Hair	
	SynKIR-110	
	SynKIR-210	
	SynKIR-310	DNA 백신
	SynKIR-410	
	ITI-1000	
	ITI-1001	
	ITI-3000	

## 의료 기기

	Bleefix®	체내 이식 의료기기
	Hutrigel®	
	Multi-pen	의료기기
	Puncture needle	
	Syringe	
	Nasal Swab	

## 진단 키트

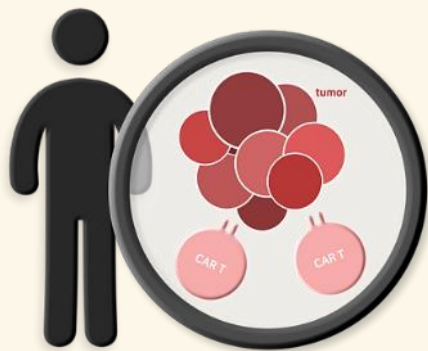
	Alzheimer diagnosis kit	질병진단
	PNAClamp™ PANAMutyper™	생체검사
	PANARealTyper™ PANAqPCR™	분자진단

# 주요 파이프라인

회사명	적응증	권리	단독/병용	임상진행 상황				
				전임상	1상	2상	3상	NDA
Elevor Therapeutics	간암 (HCC) 1차	글로벌 (중국제외)	Rivoceranib + Camrelizumab 병용	→				
	선낭암 (ACC) 1차		Rivoceranib 단독	→				
	위암 3/4차		Rivoceranib 단독	→				
	위암 2차		Paclitaxel 병용	→				
	대장암 3차		Lonsurf 병용	→				
Immunomic Therapeutics	교모세포종 (ITI-1000)	글로벌	Dendritic Cell vaccine	→				
	교모세포종 (ITI-1001)		DNA vaccine	→				
	메르켈세포암 (ITI-3000)		DNA vaccine	→				
Verismo Therapeutics	고형암 (SynKIR-110)	글로벌	CAR-T 치료제	→				
HLB Therapeutics	안구건조증	글로벌	RGN-259 단독	→				
	신경 영양성 각막염			→				



# HLB그룹의 미래형 파이프라인



CAR-T

장기

김리아 개발자 칼준 박사팀



Penn  
UNIVERSITY of PENNSYLVANIA

특허



자본

발  
서)

# 2023년 HLB 바이오포럼





**간암 1차 치료제**

**HepatoCellular Carcinoma**

**Rivoceranib + Camrelizumab**

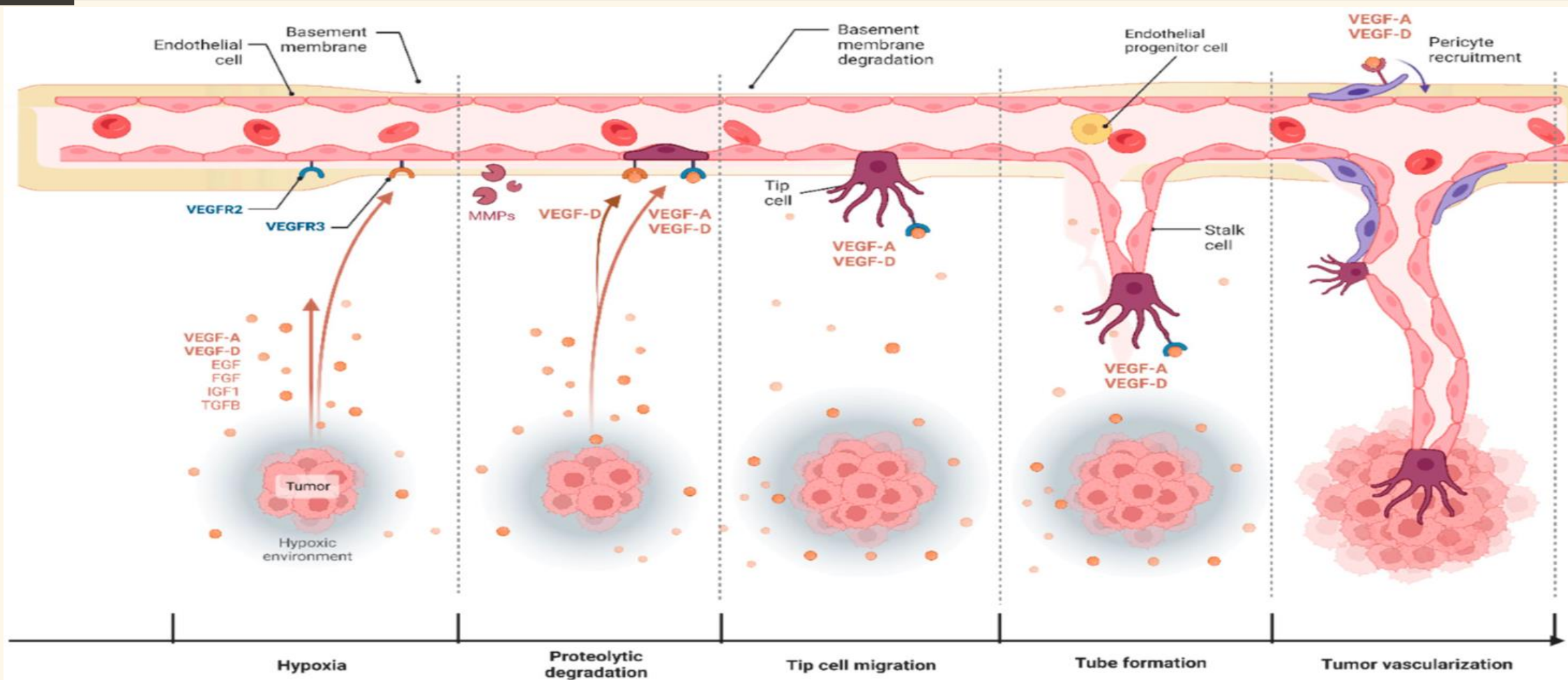
# 리보세라닙 VEGFR-2 작용기전 설명



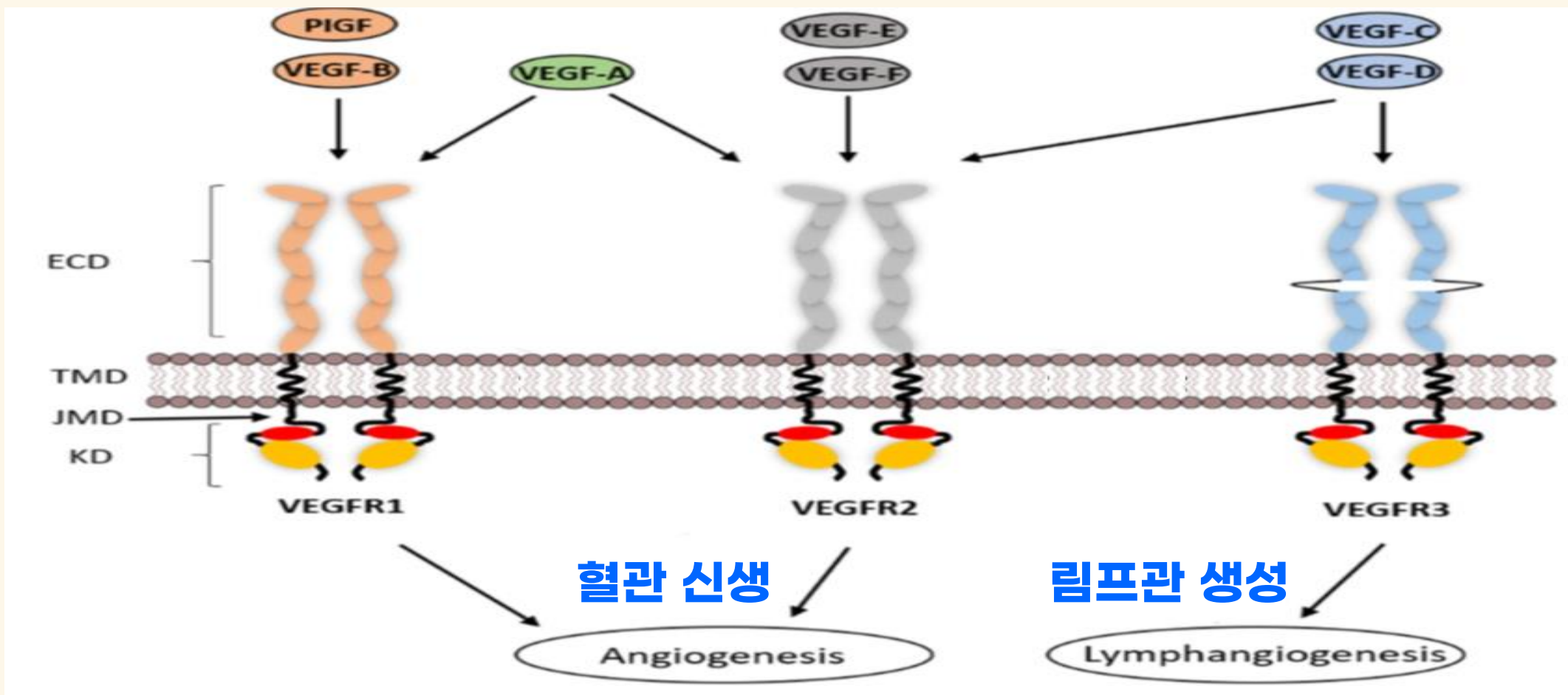
출처: <https://youtu.be/qycTqguJ5yM?si=HvU8eg8J2AaF1fap>



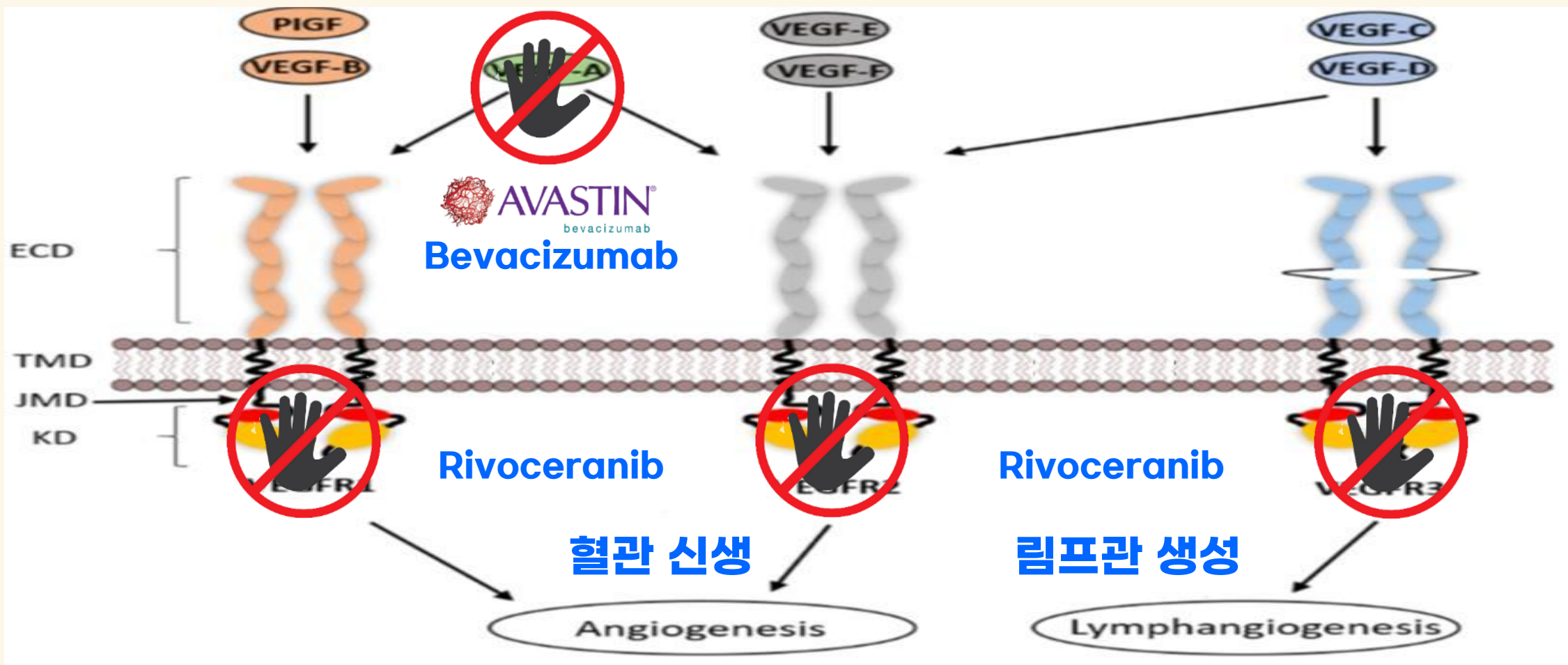
# 암과 혈관 신생 (Angiogenesis)



# 혈관 신생을 위한 신호전달



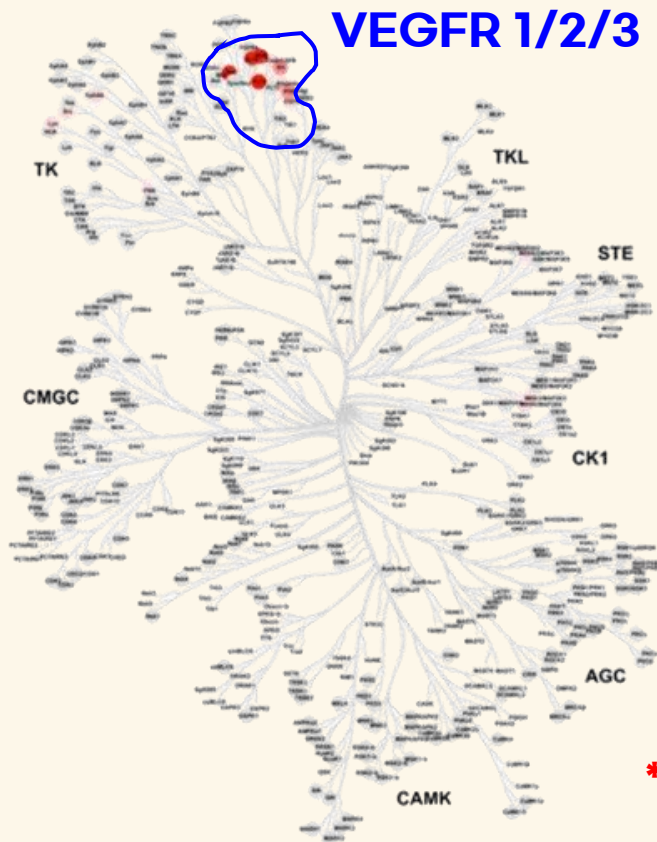
# 혈관 신생을 위한 신호전달



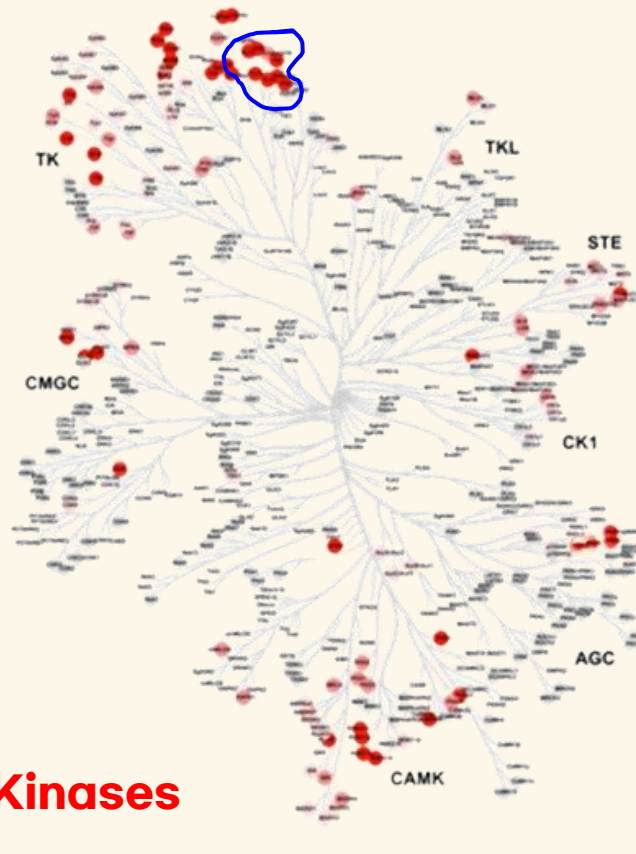


# 리보세라닙: 선택성이 탁월한 VEGFR 저해제

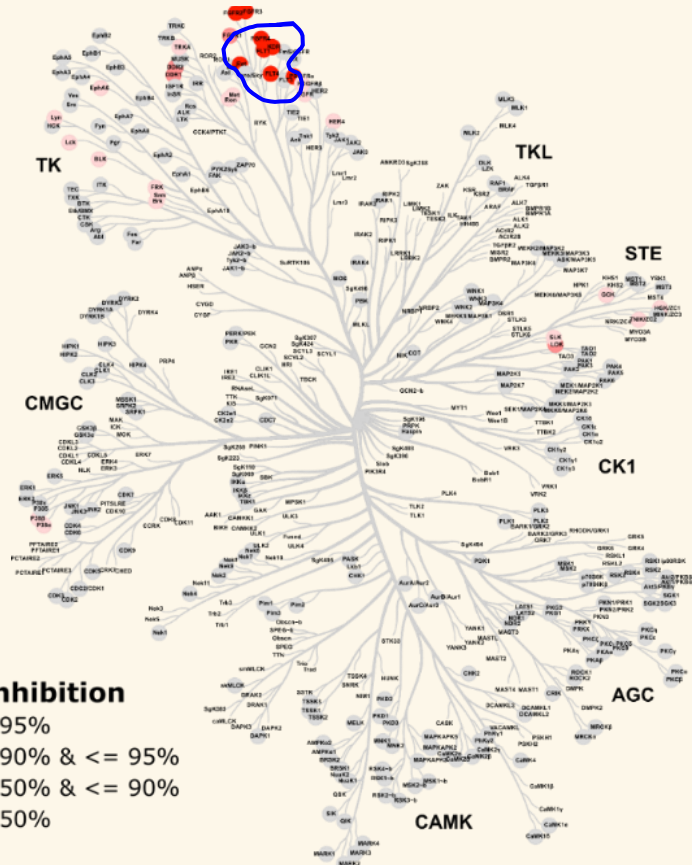
Rivoceranib



Sunitinib



Lenvatinib



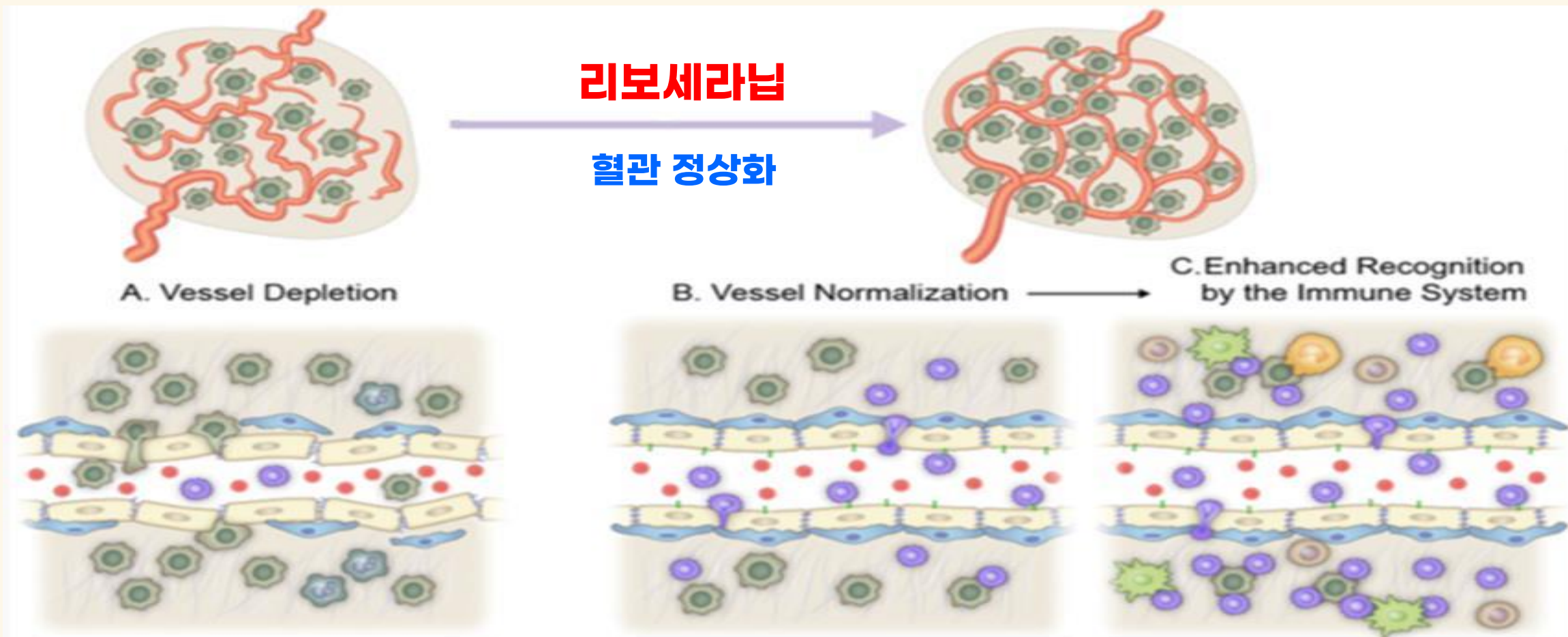
**% inhibition**

- > 95%
- > 90% & ≤ 95%
- > 50% & ≤ 90%
- < 50%

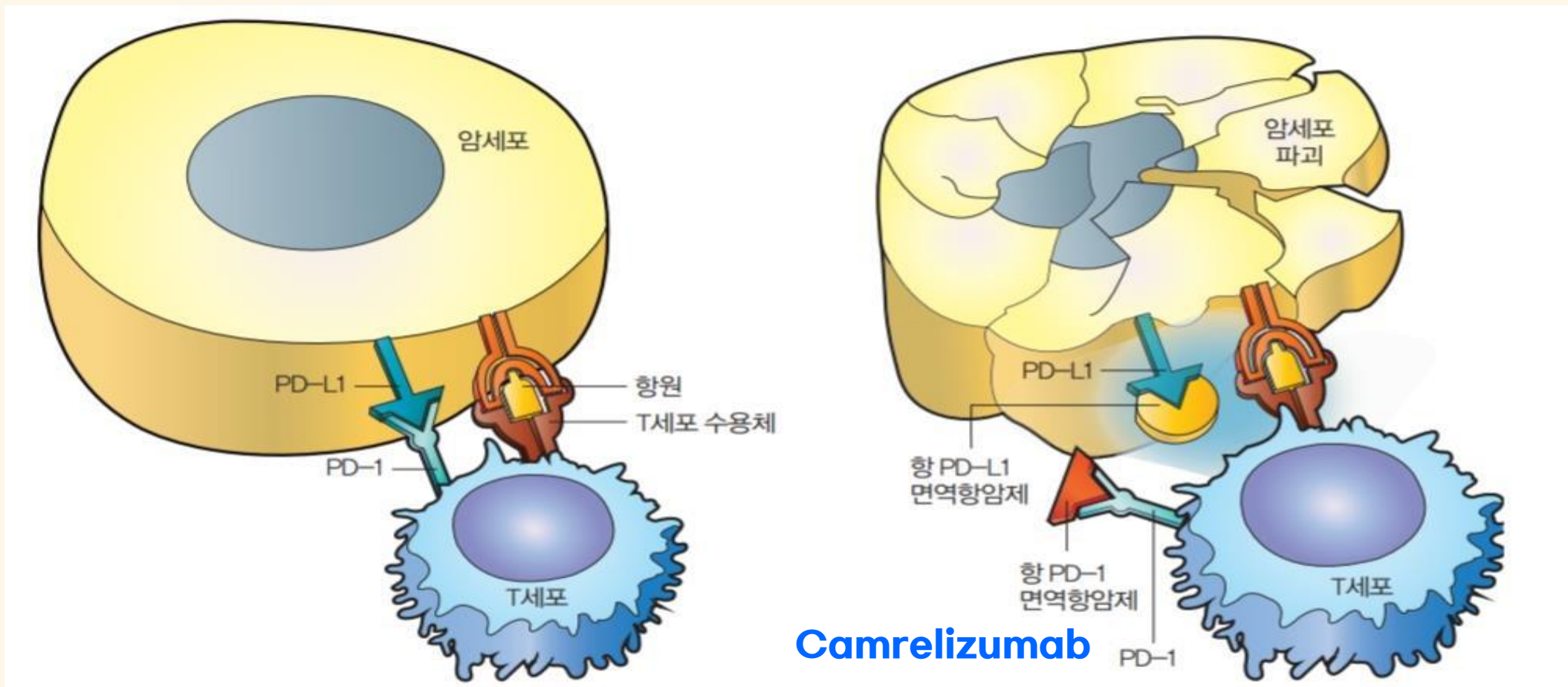
**\* 270 Kinases**



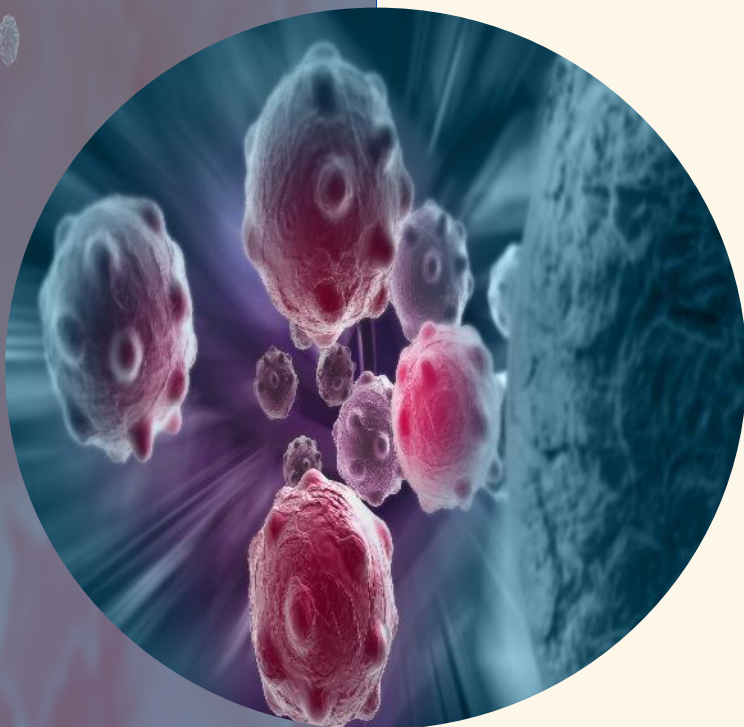
리보세라닙: 혈관 신생 억제 → 혈관 정상화 → T세포 침투력 증가 → 암 제압



# 캠렐리주맙 (면역항암제): T세포 활성화 → 암 제압



## 임상 3상 Overview (CARES-310)



Rivoceranib/Camrelizumab

272명

Sorafenib

271명

임상기간 : 2019 ~ 2022년

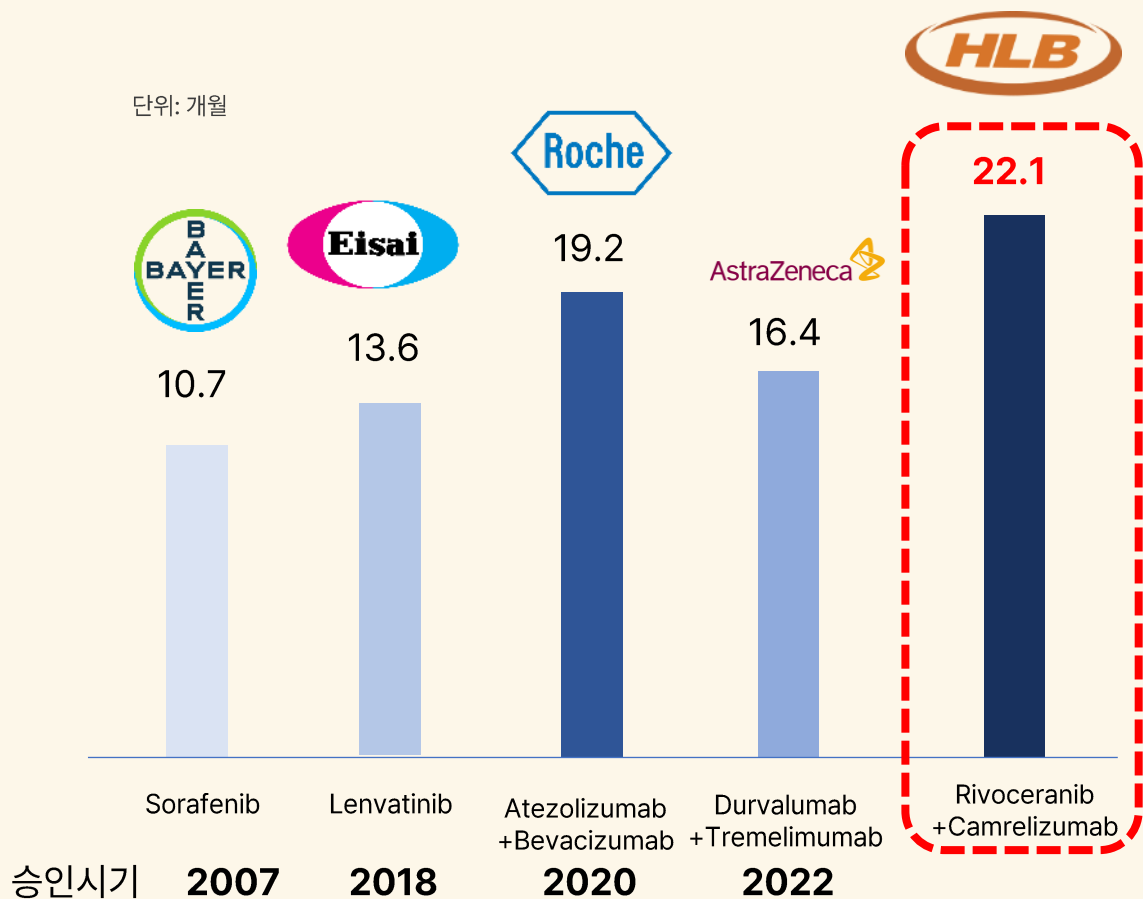
13개국 121개 병원 (글로벌 임상)

임상 환자수 : 543명

1차 평가지표 : 전체생존기간 mOS, 무진행 생존기간 mPFS

2차 평가지표 : 객관적 반응률 (ORR)

# 간암 1차 치료제 임상 3상 주요 결과 비교

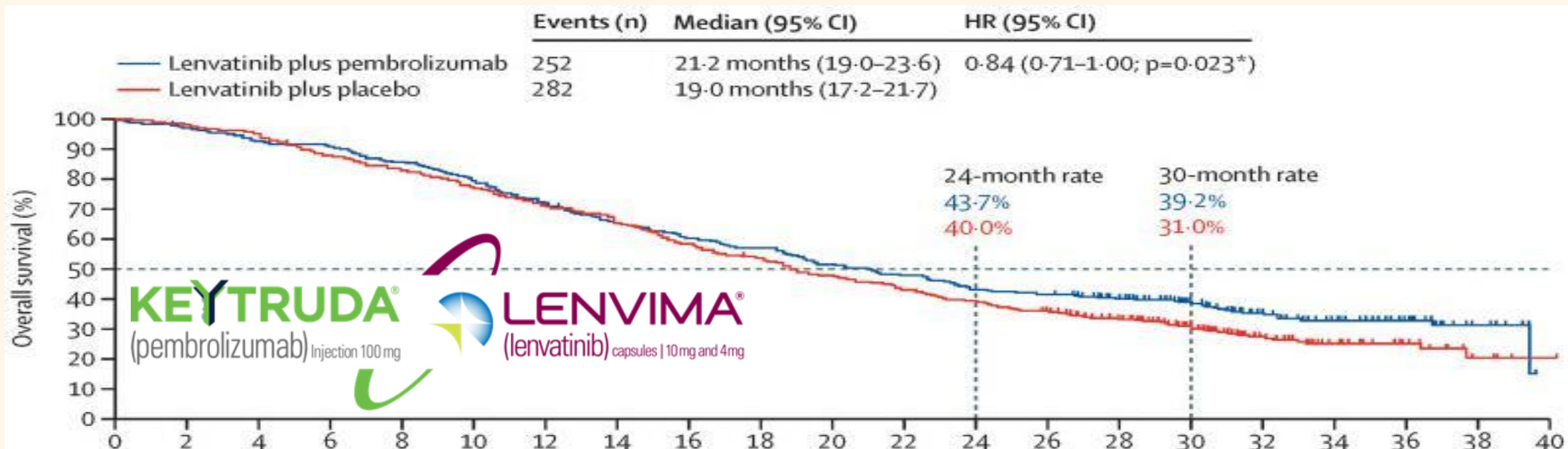


## HLB 임상 3상 주요 결과

주요 평가 지표	결과
전체 생존기간(mOS)	22.1 개월
무진행 생존기간(mPFS)	5.6개월
객관적 반응률(ORR)	33.1% (mRECIST)
질병 조절률(DCR)	78.3%
바이러스, 비바이러스 병인	29% 사망위험 감소

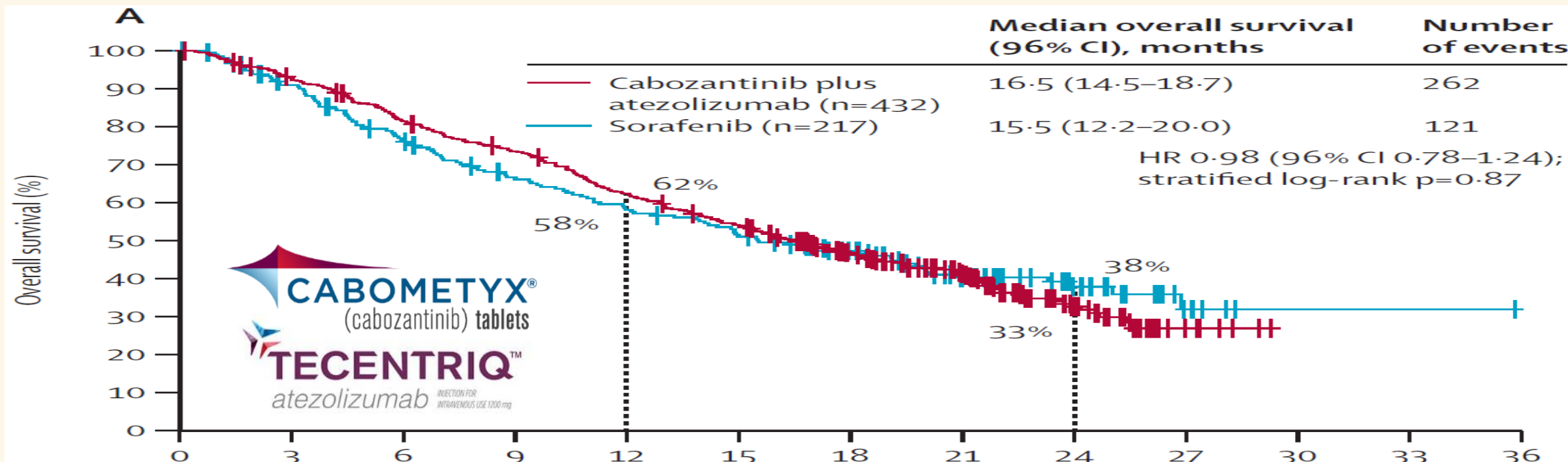


# 간암 1차 치료제 임상 3상 실패 사례



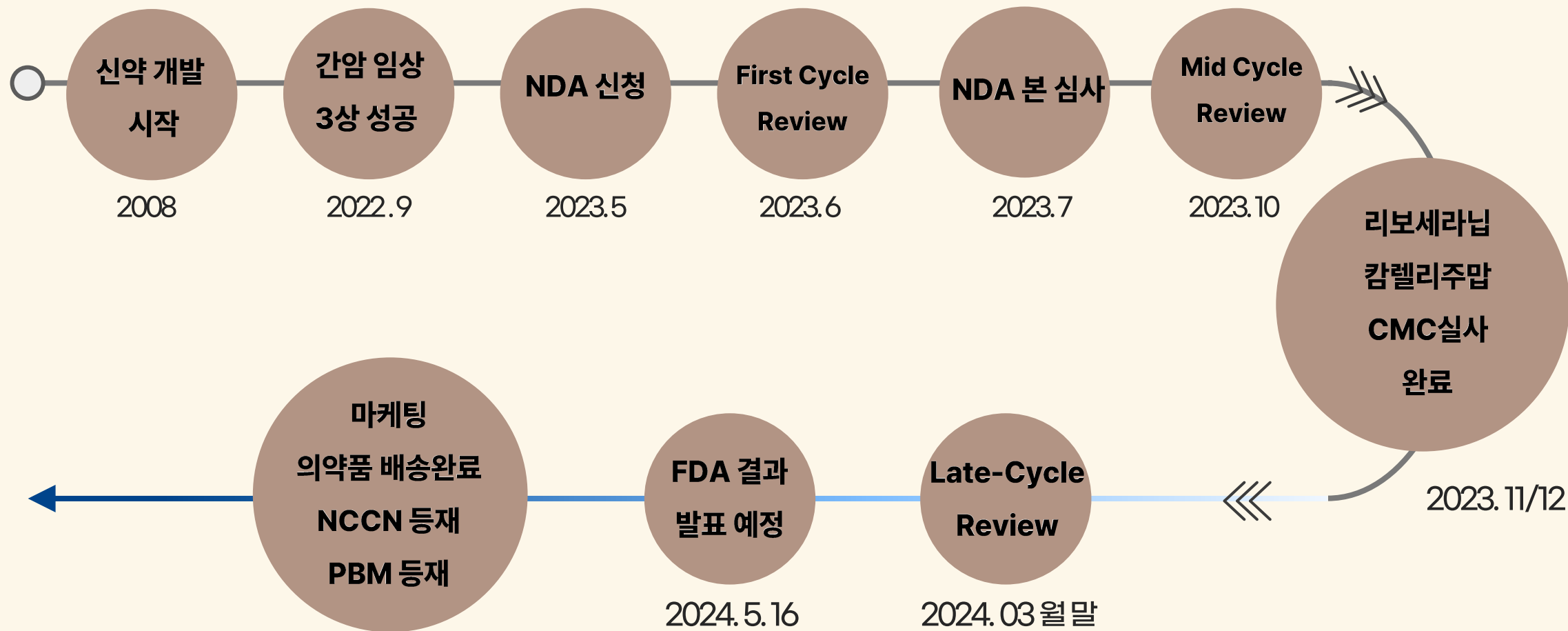
## [ESMO 2022] Merck의 키트루다와 Eisai의 렌비마 병용치료제 간암1차 치료제 임상 실패

# 간암 1차 치료제 임상 3상 실패 사례



## [THE LANCET 2024] ROCHE의 티센트릭과 Exelixis의 카보잔티닙 병용 간암1차 치료제 임상 실패

# 리보세라닙 NDA 진행 현황



# HLB의 달라질 미래

TECH

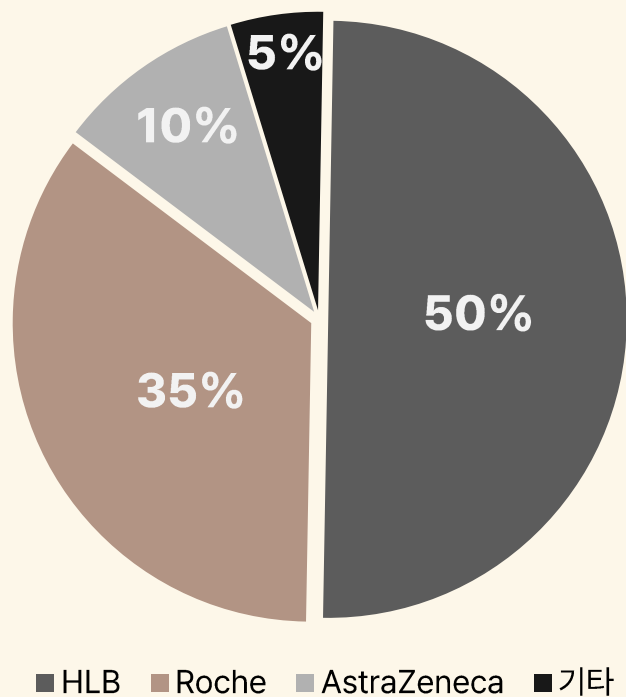


## 리보세라닙 간암 매출 기준 수익 구조

$$\text{매출} = f \left( \frac{\text{투약가능 환자수}}{\text{간암 환자수}} \times \text{투약기간} \times \text{약가} \times \text{시장점유율} \right)$$

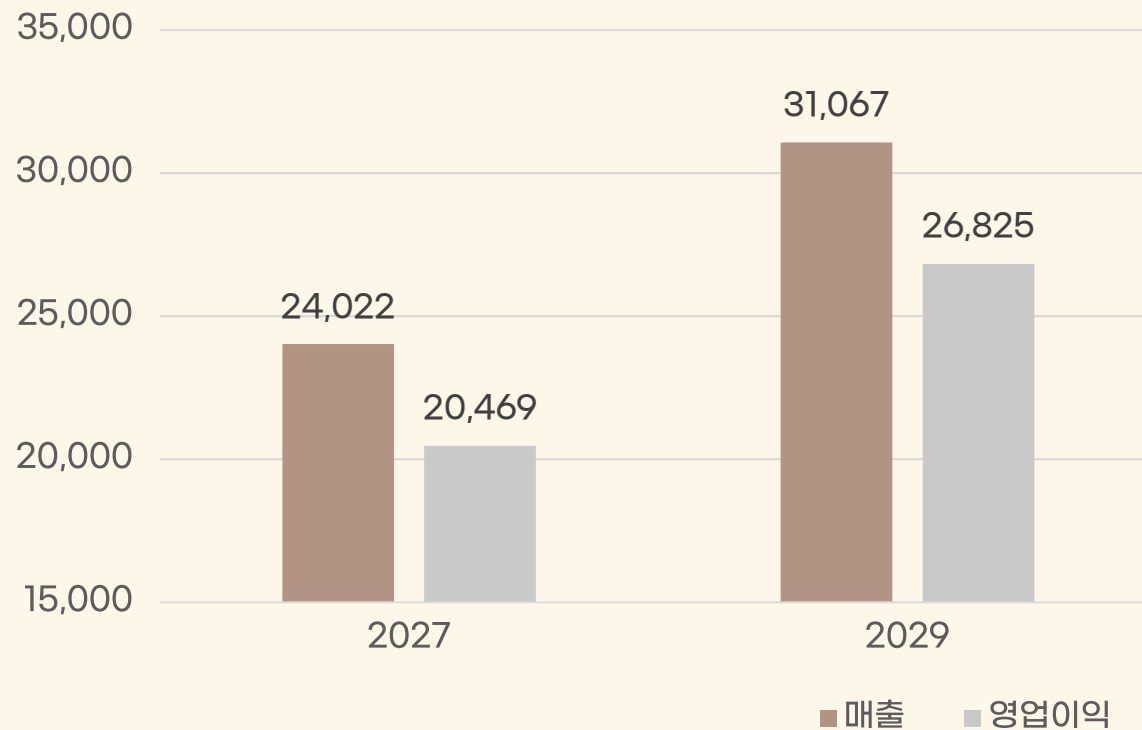
# 리보세라닙 간암 매출 기준 수익 구조

목표 점유율



목표 매출 및 영업이익

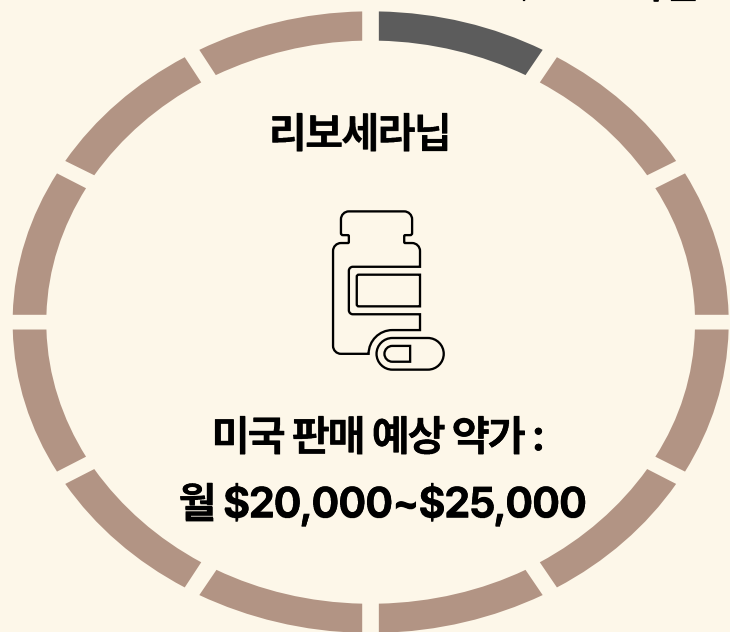
단위: 억원



\*2027년 발매3년차, 2029년 발매 5년차

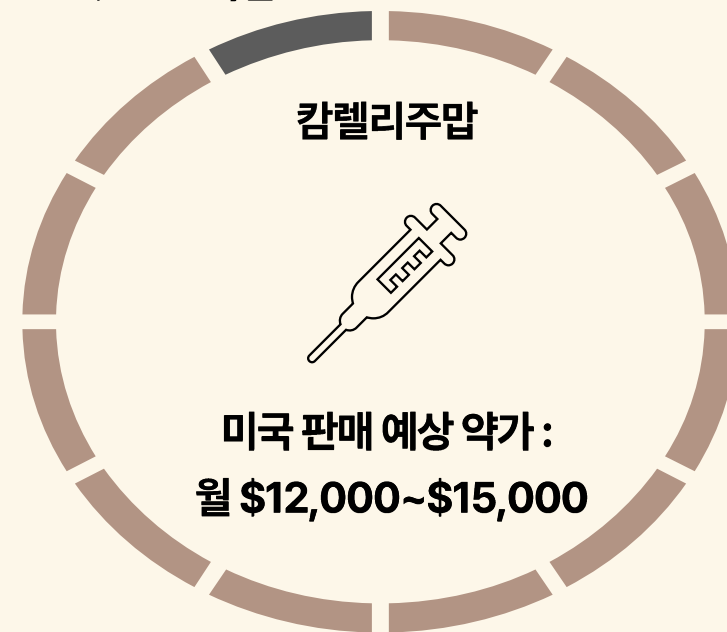
# 매출 이익률

매출 원가:  
\$144.84/월



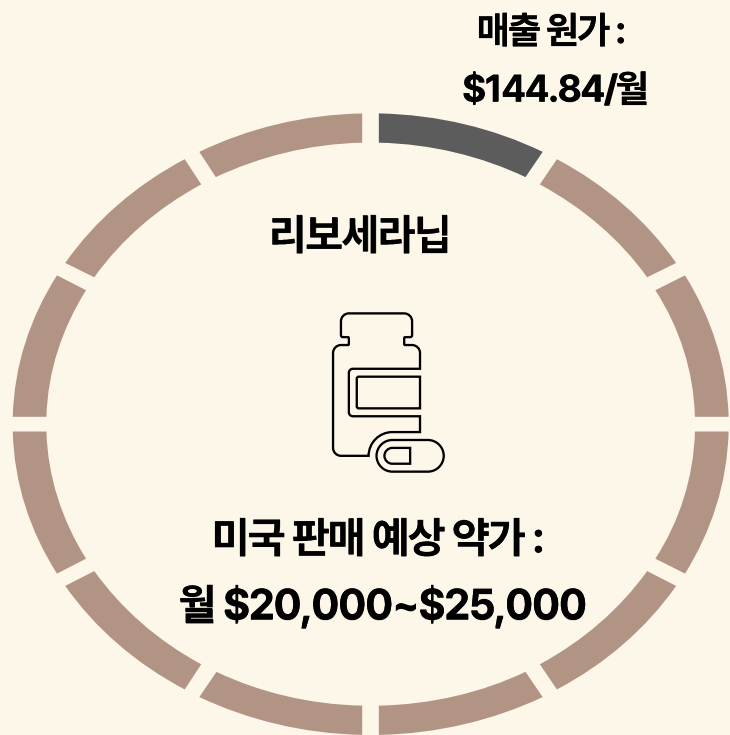
매출 총 이익률 99.28%

매출 원가:  
\$220.68/월

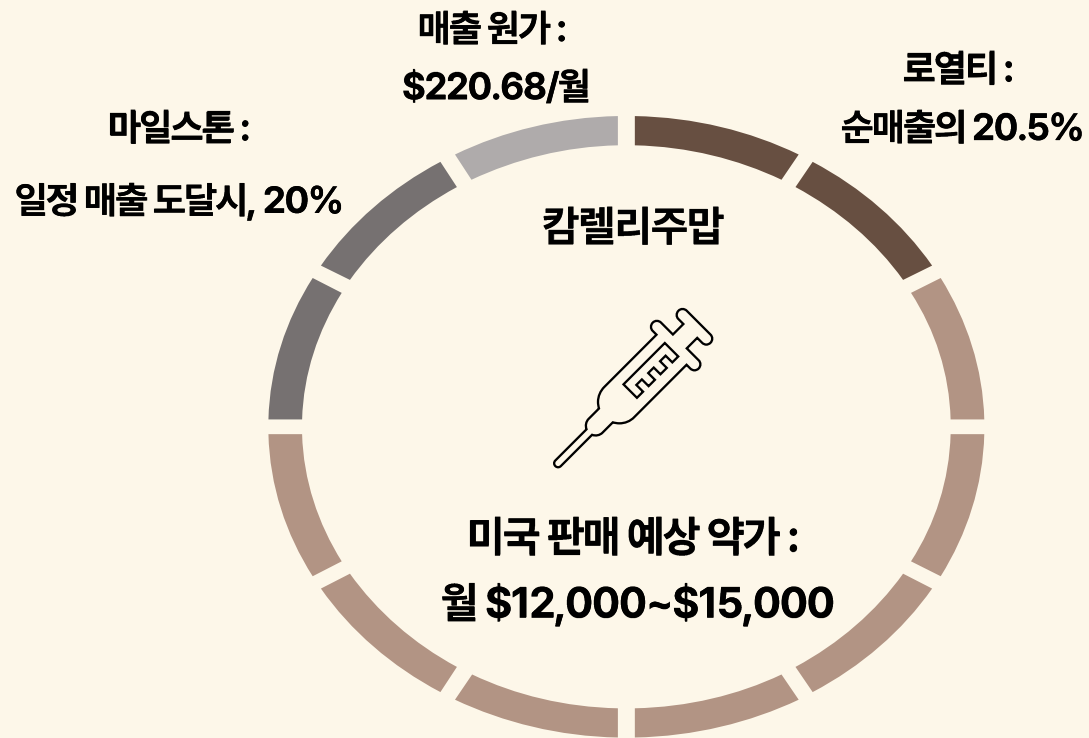


매출 총 이익률 98.16%

# 영업 이익률



영업 이익률 87.0%



영업 이익률 57.5%



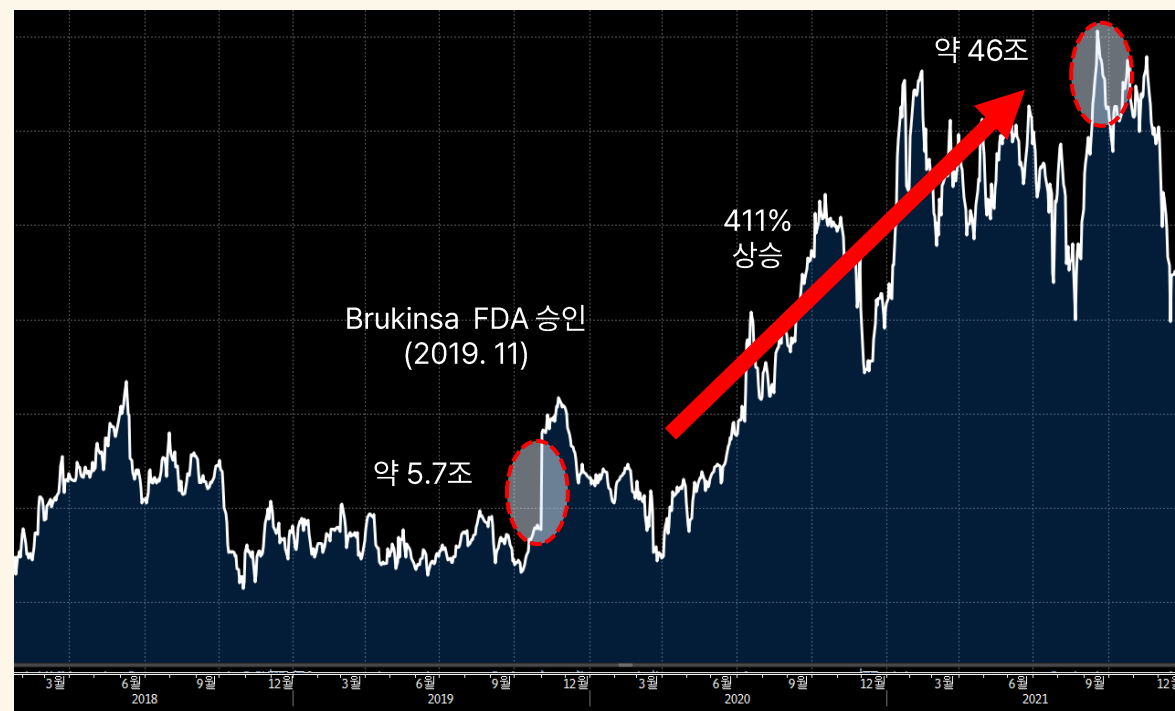
# 신약 승인 후 시가총액 변화

## Eisai 시가총액 변화 추이 (2014~2020)



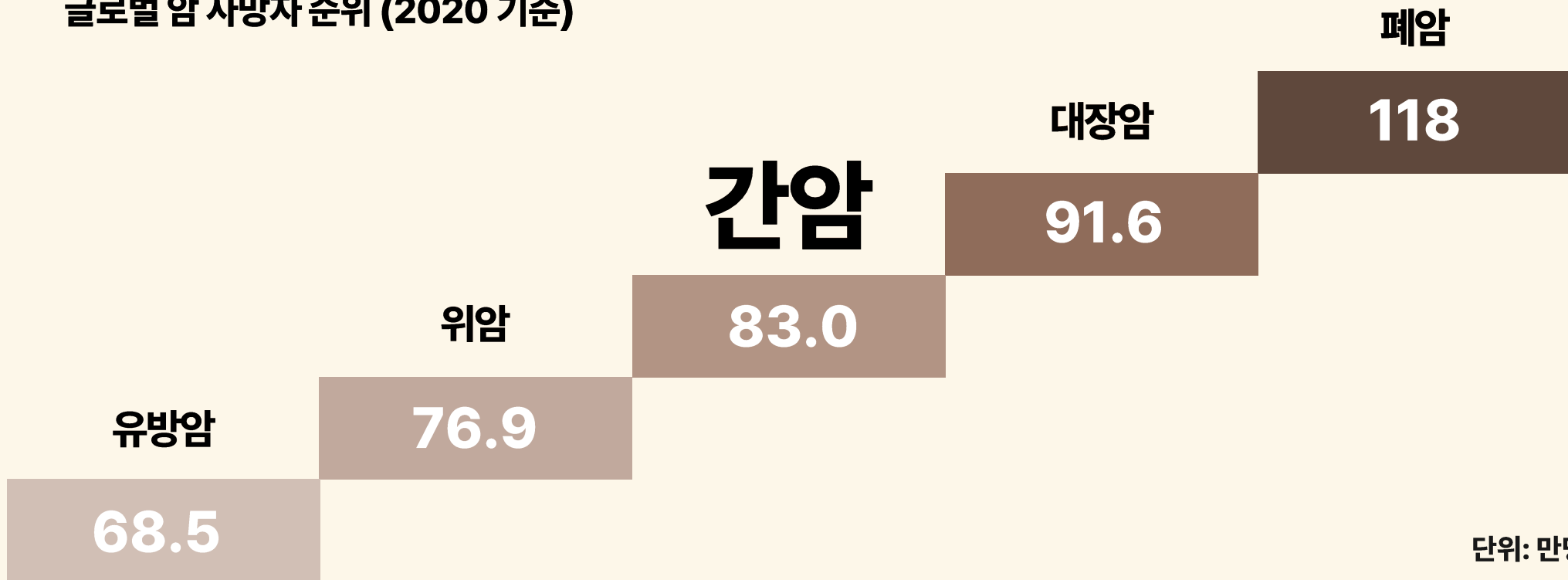
시가총액 : 약 35조 (2024/03 기준)

## Beigene 시가총액 변화 추이 (2018~2021)



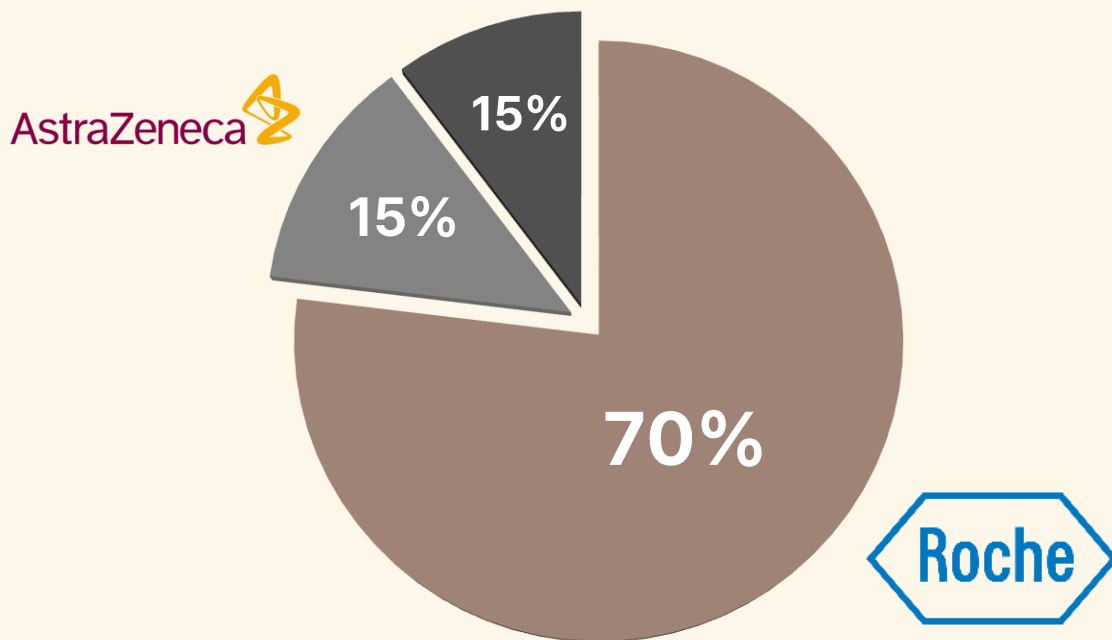
# 글로벌 간암 통계

글로벌 암 사망자 순위 (2020 기준)

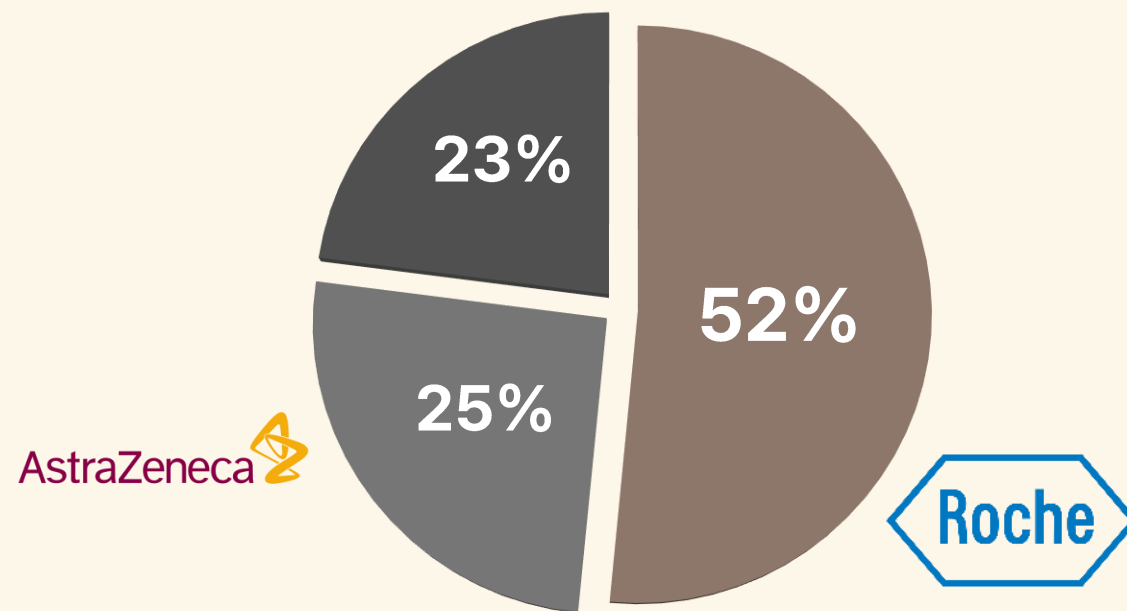


# 간암 1차 치료제 시장 점유율

23년 2월 말 기준



23년 11월 말 기준



로슈
  아스트라제네카
  기타

로슈
  아스트라제네카
  기타

## 마케팅 파워 요소



**생존기간 최대 연장  
22.1개월**

**우월한 유효성 확인  
(간기능 저하 환자)**



**출혈 고위험 환자군에게  
사용가능**

**발병 원인 무관한 치료효과**





## 마케팅 파워 요소 1: 최장 생존 기간

간암 치료제 중  
최장 환자 생존기간 **22.1**개월

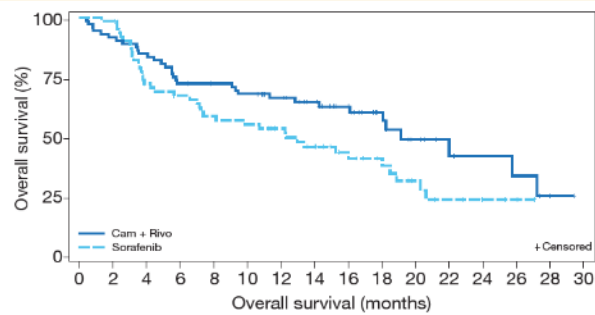
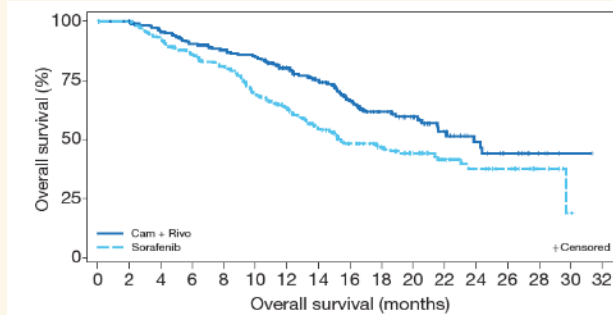


# 마케팅 파워 요소 2 : 우월한 유효성 입증

## CARES-310 (HLB & Elevar) Rivoceranib + Camrelizumab

### ALBI 1 Grade

### ALBI 2 Grade



Number of subjects at risk	
Cam + Rivo	200 199 189 179 174 168 149 131 91 63 47 28 20 14 4 1 0
Sorafenib	208 206 189 175 164 139 121 101 74 57 45 26 19 15 5 1 0

Number of subjects at risk	
Cam + Rivo	72 66 61 52 50 47 41 34 27 17 10 6 5 4 1 0
Sorafenib	63 62 43 39 34 32 28 23 17 13 8 5 3 2 1 0

ALBI Grade 1	Cam + Rivo (n=200)	Sorafenib (n=208)
OS events, n (%)	78 (39.0)	112 (53.8)
Median OS, <sup>a</sup> months (95% CI)	23.9 (20.3, NE)	15.4 (13.3, 21.6)
Hazard ratio <sup>b</sup> (95% CI)	0.62 (0.47, 0.83)	

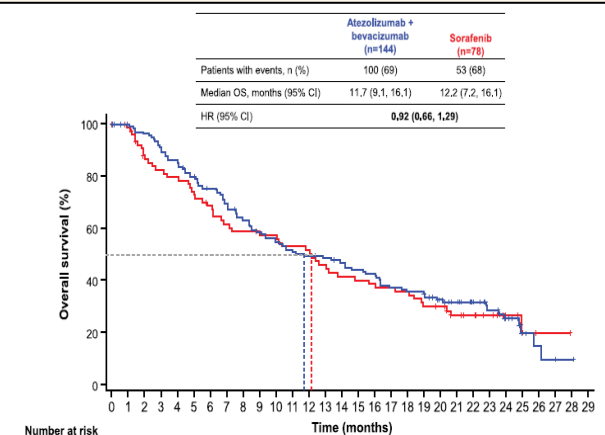
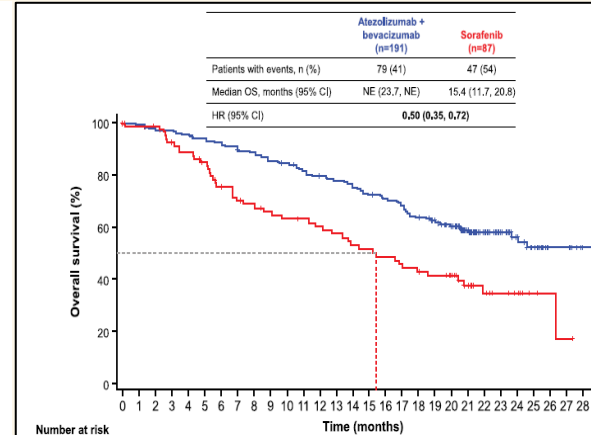
ALBI Grade 2	Cam + Rivo (n=72)	Sorafenib (n=63)
OS events, n (%)	33 (45.8)	39 (61.9)
Median OS, <sup>a</sup> months (95% CI)	19.1 (14.3, 27.2)	12.3 (7.1, 18.5)
Hazard ratio <sup>b</sup> (95% CI)	0.62 (0.4, 1.0)	

- ✓ ALBI 등급에 상관없이 모든 환자군에 약효가 좋으며 특히 Ate/Beva에서 약효가 없는 ALBI 2등급 환자들에게 우월한 약효를 나타냄
- ✓ ALBI G1 HR: 0.62 (0.47-0.83), ALBI G2 HR: **0.62** (0.4-1.0)

## Imbrave-150 (Roche) Atezolizumab (Tecentriq) + Bevacizumab (Avastin)

### ALBI 1 Grade

### ALBI 2 Grade



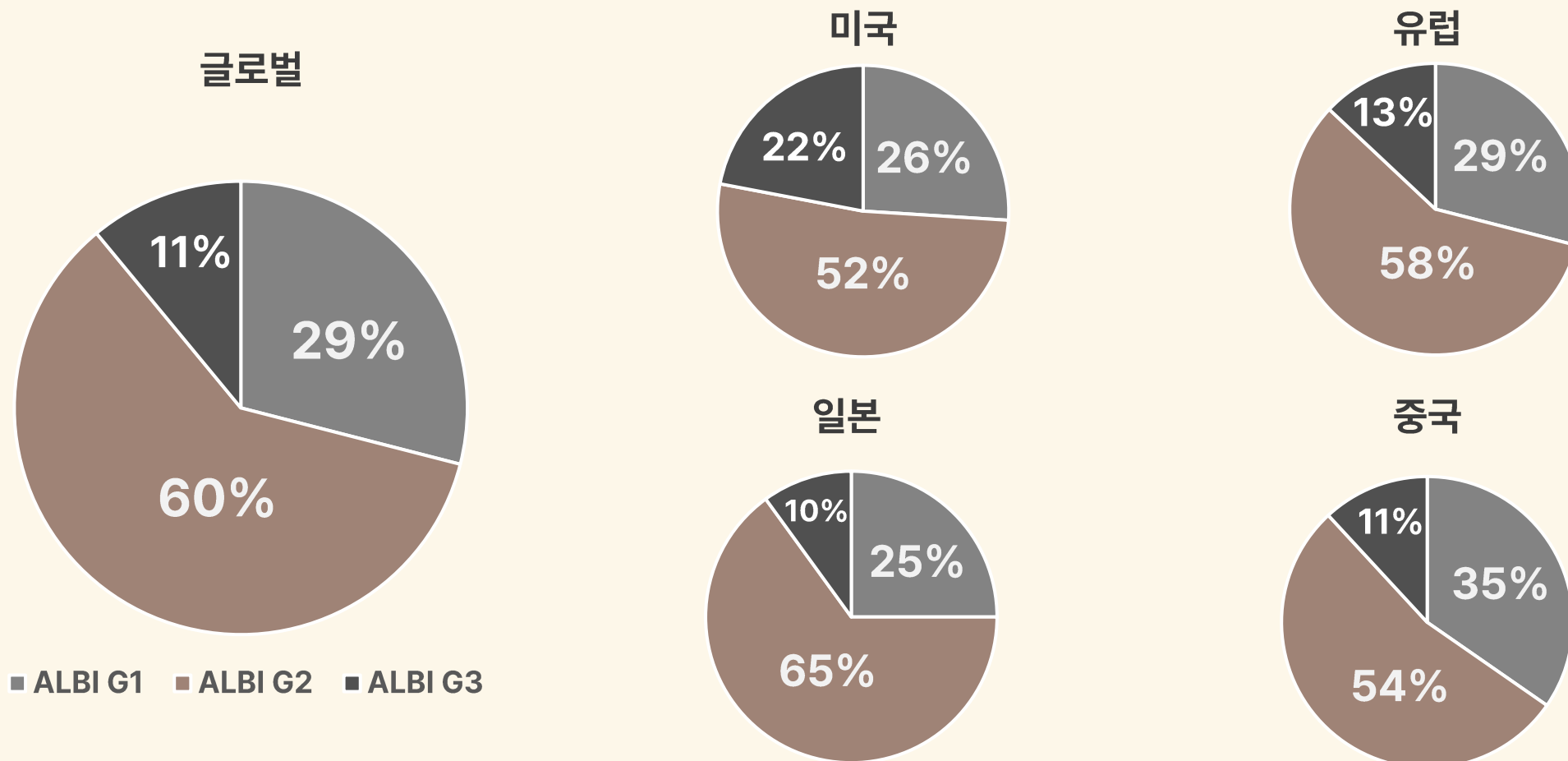
Number at risk	
Atezolizumab + bevacizumab	191 190 186 185 182 178 174 169 167 161 158 151 147 144 140 134 130 126 117 109 96 73 55 38 29 19 9 9 1 NE
Sorafenib	87 83 80 73 70 65 57 52 50 47 45 44 42 40 37 36 34 32 30 28 25 18 12 9 7 3 2 1 NE NE

Number at risk	
Atezolizumab + bevacizumab	144 139 134 127 120 110 102 94 85 79 75 70 67 65 62 58 56 49 47 38 32 25 19 13 5 3 2 1 NE
Sorafenib	78 75 64 60 58 54 49 44 42 41 40 37 36 32 29 28 27 26 25 21 19 14 12 9 5 4 1 1 NE NE

- ✓ ALBI 1등급 환자들에게만 약효가 좋으며 간기능이 안 좋은 환자들에게는 약효가 현저히 떨어짐
- ✓ ALBI G1 HR : 0.5 (0.35-0.72), ALBI G2 HR: **\*\*0.92** (0.66-1.29)

출처: Liver Cancer 2023, Supplementary appendix, Lancet 2023; published online July 24  
 \*ALBI 1/2 Grade는 간 기능의 저하 능력을 나타내는 지표이며 Grade 2가 Grade 1보다 간 기능이 더 저하된 환자군임  
 \*\*Hazard Ratio (HR)은 1에 가까울수록 약효가 없다는 뜻

# ALBI Grade 별 환자 수



# 마케팅 파워 요소 3 : 출혈 고위험 환자군 처방 가능

## Avastin 부작용 설명서

### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AVASTIN safely and effectively. See full prescribing information for AVASTIN.

**AVASTIN® (bevacizumab) injection, for intravenous use**

Initial U.S. Approval: 2004

#### RECENT MAJOR CHANGES

Indications and Usage, Hepatocellular Carcinoma (1.7)	05/2020
Dosage and Administration, Hepatocellular Carcinoma (2.8)	05/2020
Boxed Warning, Removed	06/2019
Warnings and Precautions (5.3, 5.9)	05/2020

#### 5.3 Hemorrhage

Avastin can result in two distinct patterns of bleeding: minor hemorrhage, which is most commonly Grade 1 epistaxis, and serious hemorrhage, which in some cases has been fatal. Severe or fatal hemorrhage, including hemoptysis, gastrointestinal bleeding, hematemesis, CNS hemorrhage, epistaxis, and vaginal bleeding, occurred up to 5-fold more frequently in patients receiving Avastin compared to patients receiving chemotherapy alone. Across clinical studies, the incidence of Grades 3-5 hemorrhagic events ranged from 0.4% to 7% in patients receiving Avastin [see Adverse Reactions (6.1)].

### 기존 치료제 대비 출혈 부작용 통제 가능



위장관 출혈 빈도가 적음



출혈 발생 시 빠른 대처 가능

혈중 반감기: Avastin 20일 vs. 리보세라닙 11시간

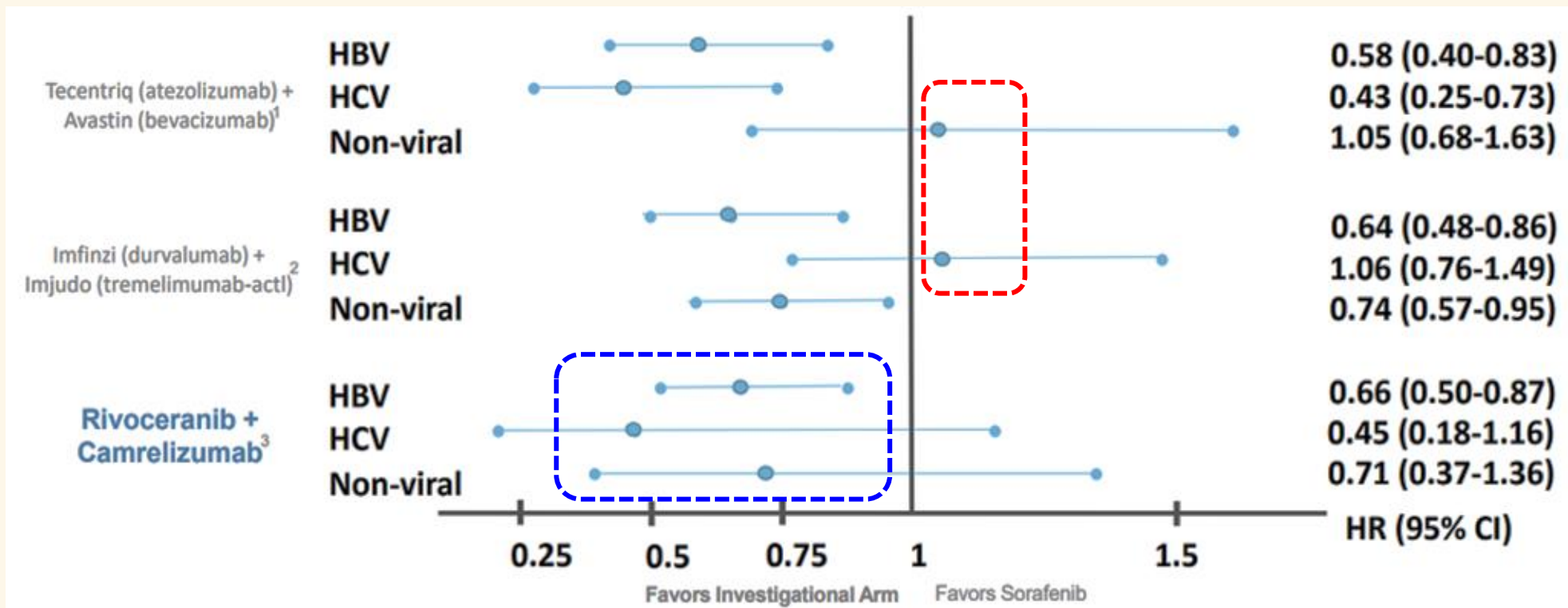


출혈 관련 고위험 환자군 처방 가능

An evaluation for the presence of varices is recommended within 6 months of initiation of Avastin in patients with HCC. There is lack of clinical data to support the safety of Avastin in patients with variceal bleeding within 6 months prior to treatment, untreated or incompletely treated varices with bleeding, or high risk of bleeding because these patients were excluded from clinical trials of Avastin in HCC [see Clinical Studies (14.10)].



# 마케팅 파워 요소 4 : 간암 발병 원인 무관한 치료 효과



✓ Rivoceranib + Camrelizumab 병용조합은 HCC의 발병 인자에 관계없이 모든 환자군에서 높은 약효 입증

# 세계 간암 KOL들의 평가와 찬사

“위험 대비 치료 이점이 높은 리보세라닙+캠렐리주맙 임상 결과는 사전 전신요법을 받지 않은 비절제성간암 환자들에게 **새로운 1차 치료옵션**이 될 수 있음을 뒷받침한다”



Shukui Qin 교수

“리보세라닙+캠렐리주맙 병용요법은 간암분야에서 **가장 긴 환자생존율**을 보였으며 1차 치료제의 새로운 옵션을 제시한다”



Ghassan K. Abou-Alfa 교수

“리보세라닙과 캠렐리주맙 병용요법은 간암 1차 치료제의 **높은 효능과 안전성**을 입증하였으며 진행성 간암 치료법을 변화시킬 수 있는 잠재력이 높다”



Stephen Chan 교수

# Lancet 논문 (발간일자: 07/24/2023)

## Camrelizumab plus rivoceranib versus sorafenib as first-line therapy for unresectable hepatocellular carcinoma (CARES-310): a randomised, open-label, international phase 3 study

Shukui Qin\*, Stephen L Chan\*, Shanzhi Gu, Yuxian Bai, Zhenggang Ren, Xiaoyan Lin, Zhendong Chen, Weidong Jia, Yongdong Jin, Yabing Guo, Xiaohua Hu, Zhiqiang Meng, Jun Liang, Ying Cheng, Jianping Xiong, Hong Ren, Fang Yang, Wei Li, Yajin Chen, Yong Zeng, Alexander Sultanbaev, Monika Pazgan-Simon, Margaryta Pisetska, Davide Melisi, Dmitriy Ponomarenko, Yurii Osypchuk, Ivan Sinielnikov, Tsai-Sheng Yang, Xiao Liang, Chunxia Chen, Linna Wang, Ann-Li Cheng†, Ahmed Kaseb†, Arndt Vogel†, for the CARES-310 Study Group‡

### Summary

**Background** Immunotherapy with immune checkpoint inhibitors combined with an anti-angiogenic tyrosine-kinase inhibitor (TKI) has been shown to improve overall survival versus anti-angiogenic therapy alone in advanced solid tumours, but not in hepatocellular carcinoma. Therefore, a clinical study was conducted to compare the efficacy and safety of the anti-PD-1 antibody camrelizumab plus the VEGFR2-targeted TKI rivoceranib (also known as apatinib) versus sorafenib as first-line treatment for unresectable hepatocellular carcinoma.

**Methods** This randomised, open-label, international phase 3 trial (CARES-310) was done at 95 study sites across 13 countries and regions worldwide. Patients with unresectable or metastatic hepatocellular carcinoma who had not previously received any systemic treatment were randomly assigned (1:1) to receive either camrelizumab 200 mg intravenously every 2 weeks plus rivoceranib 250 mg orally once daily or sorafenib 400 mg orally twice daily. Randomisation was done via a centralised interactive response system. The primary endpoints were progression-free survival, as assessed by the blinded independent review committee per Response Evaluation Criteria in Solid Tumours version 1.1, and overall survival in the intention-to-treat population. Safety was assessed in all patients who received at least one dose of the study drugs. We report the findings from the prespecified primary analysis for progression-free survival and interim analysis for overall survival. This study is registered with ClinicalTrials.gov (NCT03764293).

**Findings** Between June 28, 2019, and March 24, 2021, 543 patients were randomly assigned to the camrelizumab-rivoceranib (n=272) or sorafenib (n=271) group. At the primary analysis for progression-free survival (May 10, 2021), median follow-up was 7.8 months (IQR 4.1–10.6). Median progression-free survival was significantly improved with camrelizumab-rivoceranib versus sorafenib (5.6 months [95% CI 5.5–6.3] vs 3.7 months [2.8–3.7]; hazard ratio [HR] 0.52 [95% CI 0.41–0.65]; one-sided p<0.0001). At the interim analysis for overall survival (Feb 8, 2022), median follow-up was 14.5 months (IQR 9.1–18.7). Median overall survival was significantly extended with camrelizumab-rivoceranib versus sorafenib (22.1 months [95% CI 19.1–27.2] vs 15.2 months [13.0–18.5]; HR 0.62 [95% CI 0.49–0.80]; one-sided p<0.0001). The most common grade 3 or 4 treatment-related adverse events were hypertension (102 [38%] of 272 patients in the camrelizumab-rivoceranib group vs 40 [15%] of 269 patients in the sorafenib group), palmar-plantar erythrodysesthesia syndrome (33 [12%] vs 41 [15%]), increased aspartate aminotransferase (45 [17%] vs 14 [5%]), and increased alanine aminotransferase (35 [13%] vs eight [3%]). Treatment-related serious adverse events were reported in 66 (24%) patients in the camrelizumab-rivoceranib group and 16 (6%) in the sorafenib group. Treatment-related death occurred in two patients: one patient in the camrelizumab-rivoceranib group (ie, multiple organ dysfunction syndrome) and one patient in the sorafenib group (ie, respiratory failure and circulatory collapse).

**Interpretation** Camrelizumab plus rivoceranib showed a statistically significant and clinically meaningful benefit in progression-free survival and overall survival compared with sorafenib for patients with unresectable hepatocellular carcinoma, presenting as a new and effective first-line treatment option for this population.

**Funding** Jiangsu Hengrui Pharmaceuticals and Elevar Therapeutics.

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## 글로벌 간암 학계 KOL의 평가

- ✓ “리보세라닙+캠렐리주맵 병용요법은 간암분야에서 가장 긴 환자생존율을 보였으며 1차 치료제의 새로운 옵션을 제시한다”  
by Ghassan K. Abou-Alfa 교수  
(미국 Memorial Sloan Kettering Cancer Center)
- ✓ “리보세라닙과 캠렐리주맵 병용요법은 간암 1차 치료제의 높은 효능과 안전성을 입증하였으며 진행성 간암 치료법을 변화시킬 수 있는 잠재력이 높다”  
by Stephen Chan 교수 (홍콩중문대학교)
- ✓ “위험 대비 치료 이점이 높은 리보세라닙+캠렐리주맵 임상 결과는 사전 전신요법을 받지 않은 비절제성간암 환자들에게 새로운 1차 치료옵션이 될 수 있음을 뒷받침한다”  
by Shukui Qin 교수 (중국 난징의과대학교)

# Bayer와 Southwestern Texas대학교 논문 (발간일자: 09/12/2023)

## P-93 REAL-WORLD (RW) SYSTEMIC TREATMENT PATTERNS IN US PATIENTS (PTS) WITH HEPATOCELLULAR CARCINOMA (HCC): 2020

Amit G. Singal<sup>1</sup>, Kiran Choudhary<sup>2</sup>, Zdravko Vassilev<sup>3</sup>, Xiaoyun Pan<sup>3</sup>, Chi-Chang Chen<sup>4</sup>, Jasjit Multani<sup>5</sup>, and Lisa Zetterstrom<sup>7</sup>

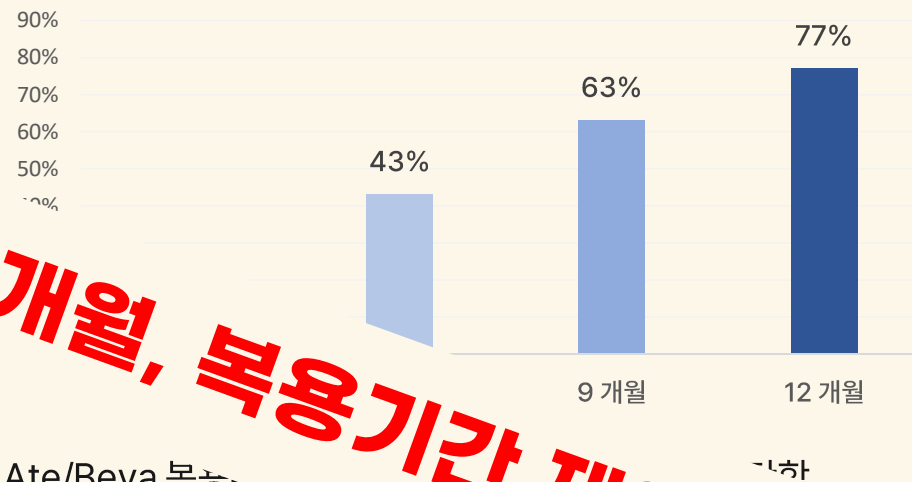
<sup>1</sup> Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX, USA; <sup>2</sup> Bayer Consumer and Healthcare, Whippany, NJ, USA; <sup>3</sup> Real World Evidence Solutions, IQVIA US, Falls Church, VA, USA; <sup>4</sup> Real World Evidence Solutions, IQVIA US, Falls Church, VA, USA; <sup>5</sup> Real World Evidence Solutions, IQVIA US, Falls Church, VA, USA; <sup>6</sup> Real World Evidence Solutions, IQVIA US, Falls Church, VA, USA; <sup>7</sup> Bayer AG, Berlin, Germany

**Introduction:** Treatment options for pts with advanced HCC include systemic agents, including atezolizumab plus bevacizumab (atezo+bev), which is standard of care for eligible pts. RW evidence for subsequent therapies following atezo+bev is no clear guidance on follow-up treatments for HCC. Therefore, this study examined treatment patterns in pts who received 1L atezo+bev for HCC in the USA.

**Methods:** Pts with HCC, aged ≥18 years, who initiated atezo+bev between June 1, 2020, and June 30, 2022, were identified in the IQVIA open-source medical claims and longitudinal prescription databases. Eligible pts had data available for ≥3 months before and ≥2 months after atezo+bev initiation (index date), no prior systemic HCC treatment, and no other prior primary cancers. Pts were followed from the index date until the date of last observation or the end of the study period. Endpoints included the proportion of pts discontinuing atezo+bev, time to atezo+bev discontinuation (TTD), the proportion of pts switching to other systemic treatments, treatment sequence, and time to next treatment (TTNT) in pts with at least 3, 6, 9, or 12 months' follow-up.

**Results:** Overall, 825 pts were included (median age 67 years [range, 18–85], 80% male) with a median follow-up period of 15.3 months (range, 0.3–28.4). Most pts had compensated liver disease, with a minority having ascites (25%), metastases (22%), esophageal varices (18%), encephalopathy (9%), and gastrointestinal hemorrhage (2%). Portal hypertension was observed in 18% of pts. Esophagogastroduodenoscopy was performed in 18% of pts >1-month post index date. At 3, 6, 9, and 12 months, the proportion of all pts discontinuing atezo+bev was 10%, 43%, 63%, and 77%, the mean TTD (SD) was 21 (0), 63 (31), 92 (53), and 117 (76) days, the proportion of pts switching to other systemic treatments was 4%, 11%, 16%, and 18%, and the mean TTNT (SD) was 62 (21), 104 (41), 138 (65), and 152 (80) days, respectively (Table). Targeted therapies were the most common subsequent therapy (Table); with lenvatinib (6%) and cabozantinib (4%) being the most frequent agents.

### Ate/Beva 복용기간 대비 치료 중단율



**평균 치료 중단 기간 5.1개월, 복용기간 제일 짧음**

- ✓ Ate/Beva 복용기간이 짧아 치료 중단율이 높음
- ✓ Ate/Beva의 평균 치료 중단 기간이 5.1개월로 짧음
- \*대표적인 부작용인 위/장간 출혈로 인한 특성으로 인해, 치료 중단된 환자에게 약효가 없어 다른 약으로 대체 됐을 거라 판단됨



# ESMO 2023 초록 by Eisai (발간일자: 10/23/2023)

1007P - Network meta-analysis of lenvatinib vs comparator in first-line unresectable hepatocellular carcinoma (uHCC)

Presentation Number 1007P  
 Speakers David Trueman (L  
 Onsite Poster display date ...

**Abstract**

**Background**  
 This research compared the relative efficacy of lenvatinib monotherapy (mono), a standard of care, with four comparators in first-line unresectable hepatocellular carcinoma (uHCC). We used a network meta-analysis (NMA) to compare lenvatinib mono with sorafenib, durvalumab + tremelimumab, durvalumab + tislelizumab, and durvalumab + tislelizumab + durvalumab 300 mg + durvalumab. We used inverse probability of treatment weighting (IPTW) and an NMA, updated evidence for lenvatinib mono from REFLECT and LEAP-002. We used aggregate data for confounding factors from REFLECT using IPTW. Weighted Cox regression including matching variables as covariates were used to derive hazard ratios (HRs) for OS and progression-free survival (PFS) comparing lenvatinib and sorafenib. The estimated HRs were included in fixed-effects Bayesian NMAs to compare lenvatinib and comparators. Scenario analyses explored alternative choices for IPTW estimators.

**Methods**  
 Randomized controlled trials (RCTs) were identified via systematic literature review. REFLECT and LEAP-002 investigated lenvatinib mono in uHCC, with similar or significantly improved OS and PFS when compared with other therapies. However, not all RCTs had a comparator arm of interest. To utilise all available lenvatinib data, the lenvatinib arm from LEAP-002 was adjusted for confounding factors using IPTW. Weighted Cox regression including matching variables as covariates were used to derive hazard ratios (HRs) for OS and progression-free survival (PFS) comparing lenvatinib and sorafenib. The estimated HRs were included in fixed-effects Bayesian NMAs to compare lenvatinib and comparators. Scenario analyses explored alternative choices for IPTW estimators.

**Results**  
 Eight RCTs (including REFLECT) and adjusted data from LEAP-002, were included in the NMA. Lenvatinib demonstrated a significant improvement in OS compared with sorafenib, and significant improvement in PFS compared with sorafenib, tremelimumab + durvalumab, tislelizumab and durvalumab (Table).

**Table: 1007P**

NMA results for OS and PFS – lenvatinib vs comparator

Comparator	OS; median HR (95% CrI)	PFS; median HR (95% CrI)
Sorafenib	0.75 (0.66, 0.86)	0.57 (0.49, 0.66)
Durvalumab + tremelimumab	0.88 (0.71, 1.08)	0.55 (0.45, 0.69)
Tislelizumab	0.88 (0.71, 1.11)	0.51 (0.41, 0.65)
Durvalumab 300 mg + durvalumab	0.97 (0.77, 1.20)	0.63 (0.51, 0.78)
Durvalumab + tislelizumab	1.14 (0.86, 1.51)	0.87 (0.67, 1.13)
Durvalumab + tislelizumab + durvalumab	1.21 (0.92, 1.60)	1.09 (0.82, 1.44)

Abbreviations: CrI, credible interval; HR, hazard ratio; OS, overall survival; PFS, progression-free survival

Legal entity responsible for the content: Eisai Inc.  
 Funding: Eisai Inc.

**리보세라닙+캄렐리주맙 최고의 약물 입증**

- ✓ 경쟁사인 Eisai가 ESMO 2023에서 발표한 OS/PFS HR에 관해 논문 발표
  - ✓ 시판중인 4개 약물 및 시판 예상되는 약물 (리보세라닙/캄렐리주맙)의 Lenvatinib 대비 효능 비교 분석
- \*주요 간암 1차 치료제 대비 HLB의 리보세라닙/캄렐리주맙이 OS/PFS HR Best in Class로 검증됨



# HLB의 지속 가능한 성장성

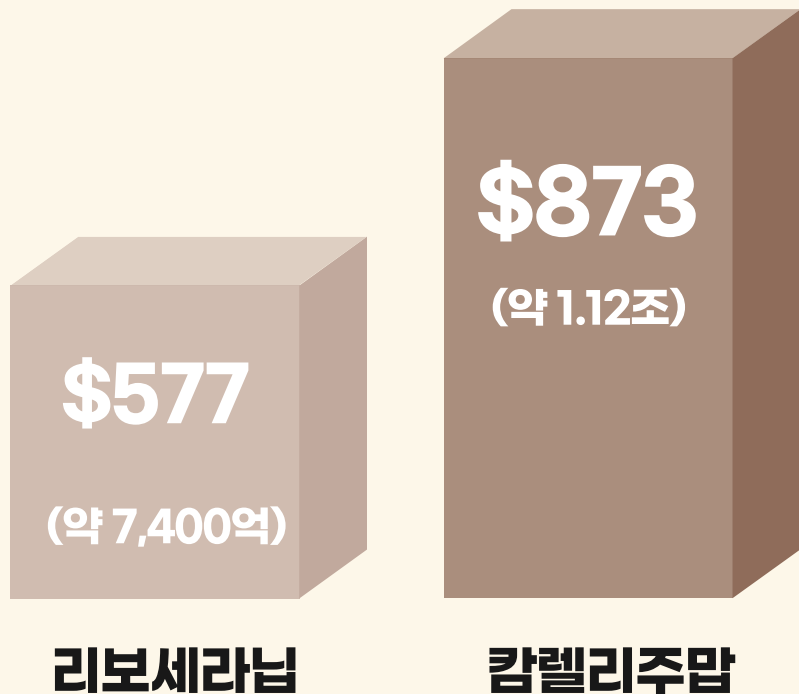
- I. Camrelizumab 판권 인수
- II. 항암제의 기본적 확장성
- III. HCC 임상을 따라 갈 다수의  
파이프라인



# 리보세라닙 적응증 확장성

## 리보세라닙/캄렐리주맙 중국 내 매출 (2023)

단위: USD Million



# 리보세라닙 적응증 확장성

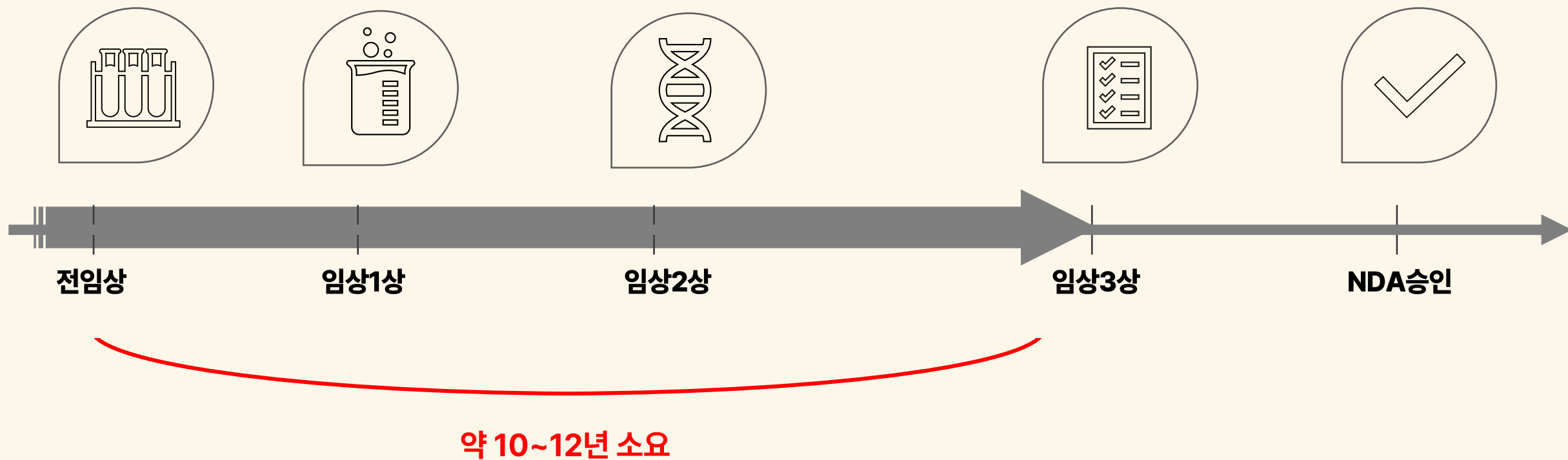
## 리보세라닙 단독/병용 완전 관해 사례

연도	적응증	임상자료
2018	전이성 대장암	3월 네이처 자매지
	혈액암, 비호지킨 림프종	중국 장저우 대학 발표
	혈액암	
	전이성 폐암	2018 ESMO (유럽종양학회)
	전이성/진행성 위암	
2019	말기 간암	국제학술지 (Digestive
	말기 위암	2019 ESMO (유럽종양학회)
	뇌종양	
2020	자궁경부암	2020 ASCO (미국임상종양학회)
	식도암	
	T세포 림프종	2020 ESMO (유럽종양학회)
	진행성 비소세포폐암	
	담낭암	중국 난징의과대학 제 1 부속병원
	비편평 비소세포폐암	상해 동제대학

연도	적응증	임상자료
2021	위암	2021 ASCO (미국임상종양학회)
	돌연변이 비소세포폐암	2021 IASLC (세계폐암학회)
	메르켈 세포암	SCI Frontier in Oncology
	재발 내성 난소암	'Ann Palliat Med' 학술지
	재발성 임신성 용모성종양	
	담관암	중국 장저우대 제1부속병원
	대장암	중국 허베이대학 부속병원
2022	흑색종	2022 ASCO (미국임상종양학회)
2023	비소세포폐암 3기	2023 ESMO (유럽종양학회)
	재발성전이성 비인두암	Journal of Clinical Oncology (국제 학술지)

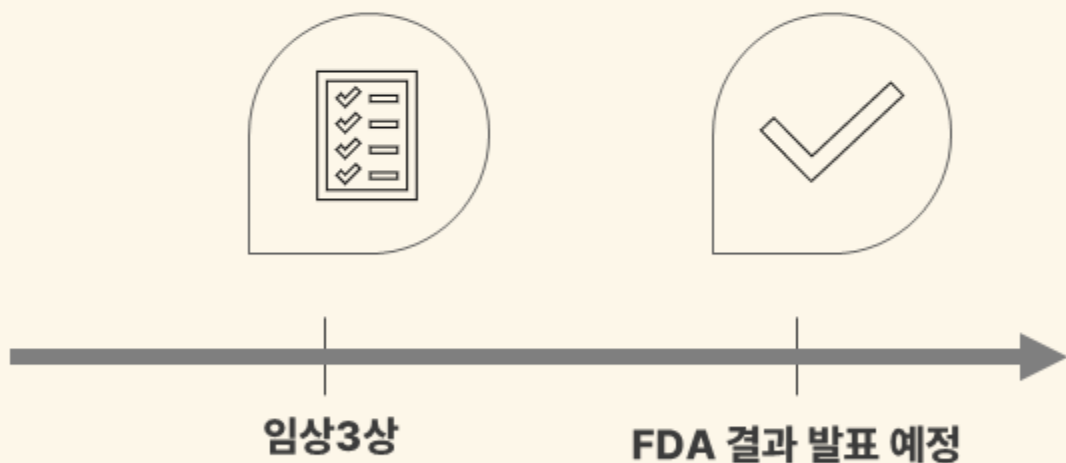
# 리보세라닙 적응증 확장성

## 임상 단계별 예상 비용 및 시간



# 리보세라닙 적응증 확장성

## 리보세라닙 임상3상 현황 (병용 포함)



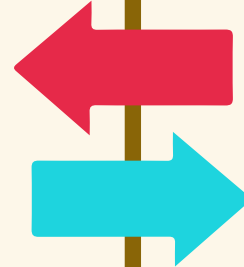
## 후속 적응증 시장 규모

적응증	시장 규모 (2022년 기준)
간암 수술 후 보조요법 (Adjuvant)	약 5조
간동맥 화학색전술	약 12조
위/식도암 1차	약 6조
난소암 2차	약 7조
유방암 2차	약 32조
전립선 1차	약 15조



# 리보세라닙 글로벌 시장 진출 본격화

24년 5월 품목허가  
판매/마케팅 준비중

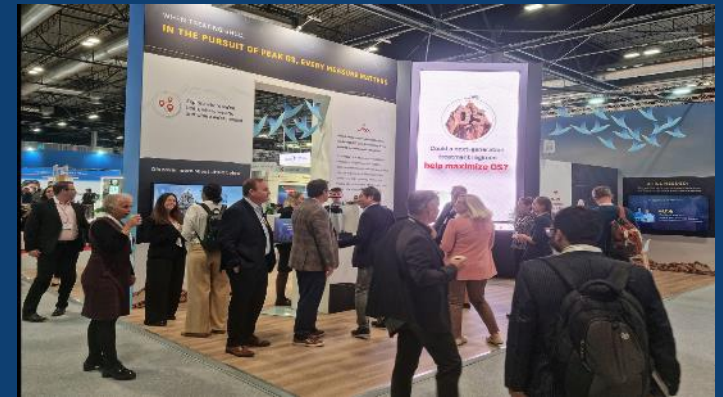


유럽 인허가 준비중  
마케팅 파트너 모색중

2023년 5월 ASCO Booth 개설 및 홍보



2023년 10월 ESMO 대형 Booth 개설 및 홍보



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# 제품 컨셉: "생존기간 연장에 따른 삶의 여유 "

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Introducing a novel PD-1/TKI combination to deliver more survival time with fewer trade-offs.

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When treating uHCC  
**IN THE PURSUIT OF PEAK OS  
EVERY MEASURE MATTERS**  
INCLUDING  
**ORR**

REFERENCE: LFNVMA Prescribing Information Eisai Inc. November 2021. TFCNTRIO Prescribing Information Genentech USA Inc. December 2021

Jennifer Florence and 36 others 4 reposts

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We loved engaging with the oncology community at ESMO 2023. Thank you **ESMO - European Society for Medical Oncology** for hosting such an important event that allows us to share the latest advancements in **#CancerCare**. ...see more

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Discover more about uHCC below

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In the pursuit of peak overall survival (OS) for patients with unresectable hepatocellular carcinoma (uHCC), every measure matters, including **QUALITY OF LIFE (QOL)**. ...see more

When treating uHCC  
**IN THE PURSUIT OF PEAK OS  
EVERY MEASURE MATTERS**  
INCLUDING  
**QUALITY OF LIFE**

REFERENCE: NCCN Practice Guidelines in Oncology: Hepatocellular Carcinoma, Version 2.2023

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When treating unresectable hepatocellular carcinoma (uHCC), oncologists do everything in their power to maximize overall survival (OS). In addition, other measures like **LIVER FUNCTION** need to be effectively addressed, too. ...see more

When treating uHCC  
**IN THE PURSUIT OF PEAK OS  
EVERY MEASURE MATTERS**  
INCLUDING  
**LIVER FUNCTION**

REFERENCE: NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma, version 2.2023. Accessed July 26, 2023.

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Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary  
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Join us for an industry expert theater presentation at ASCO GI:  
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**Natalia Raphael, PhD**  
Executive Director, Medical Affairs

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# 기업가치 상승의 핵심요소



1

리보세라닙의 탁월한 작용기전:  
최적의 병용약물



2

HCC가 가져올  
매출과 영업이익



3

3상 진입가능한  
여러 후속 파이프라인



4

항암제의 빠른 확장성



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Human Life Better