HLB

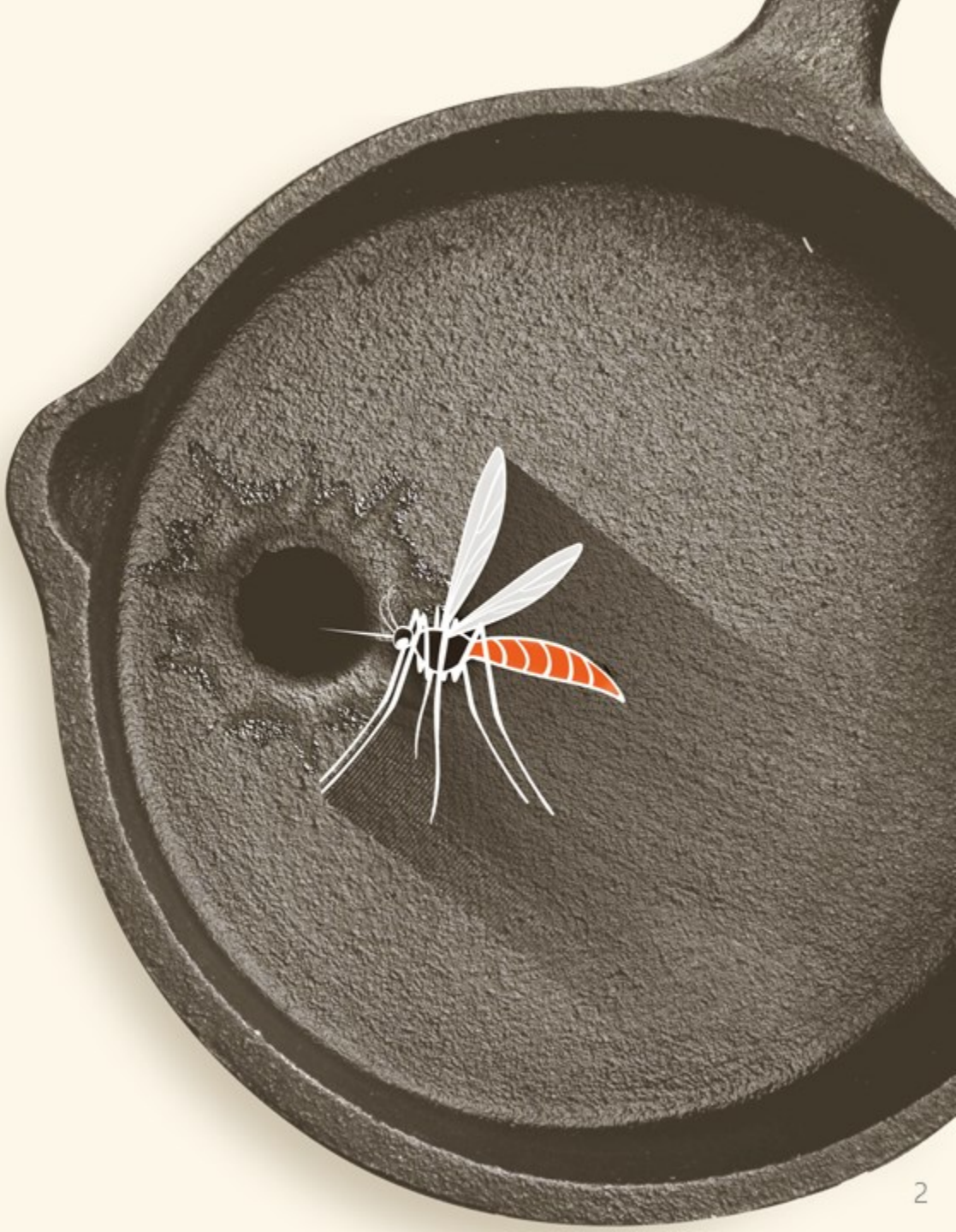
Human Life Better

2024. 03.

“

모기도 굳센 의지를 가지고
머리를 들이밀면
무쇠도 능히 뚫으리라

- 서산대사



Kairos

Intro

신약성공률 vs. Risk

ONE Product Risk

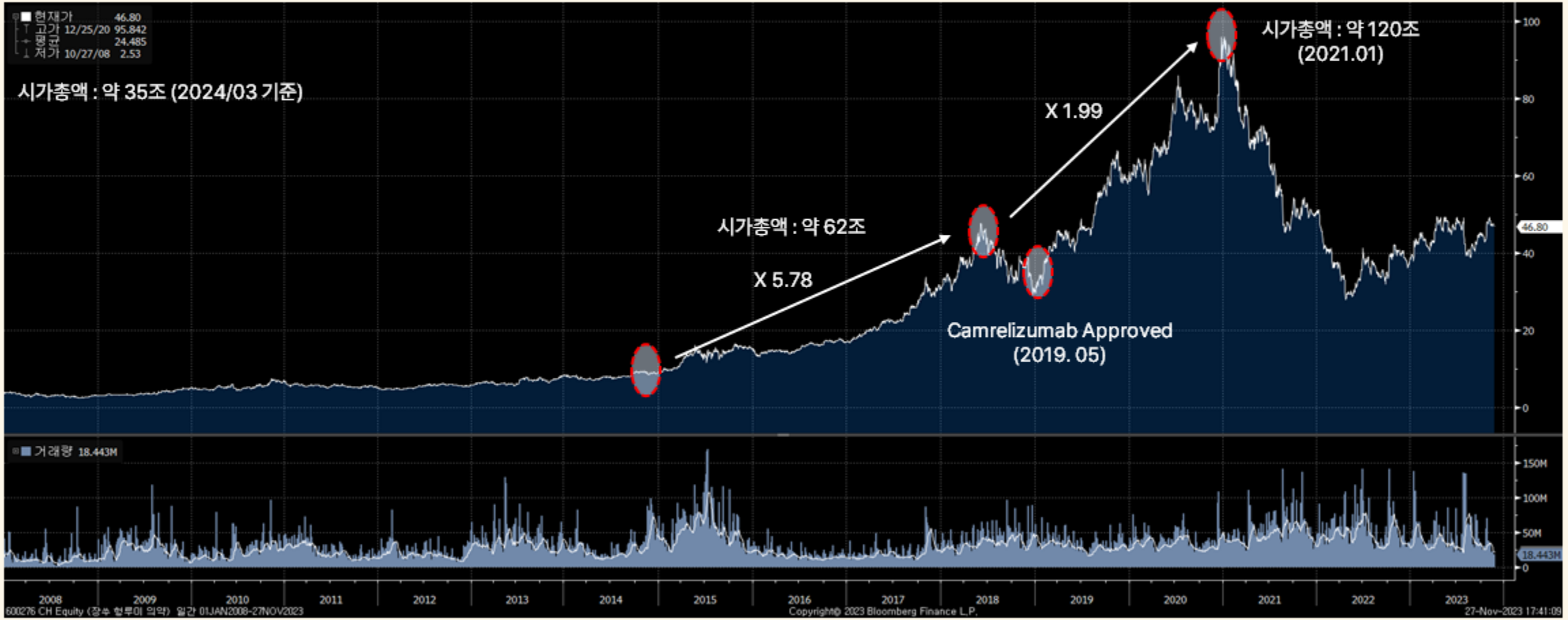
항암제 vs. 반도체

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

HLB의 경우...

UPSIDE >> RISK

항서제약 주가 차트


현재가 46.80
고가 12/25/20 95.842
평균 24.485
저가 10/27/08 2.53
시가총액 : 약 35조 (2024/03 기준)
시가총액 : 약 62조
X 5.78
X 1.99
시가총액 : 약 120조
(2021.01)
Camrelizumab Approved
(2019. 05)
거래량 18.443M
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
600276 CH Equity (장쑤 헝루이 의약) 일간 01JAN2008-27NOV2023
Copyright© 2023 Bloomberg Finance L.P.
27-Nov-2023 17:41:09

HLB 주가 차트


현재 시가총액 12.820T
고가 03/08/24 12.820T
평균 2.673T
저가 01/02/14 58.187B
시가총액 : 약 12.8조 (2024/03 기준)
12.820T
12T
10T
8T
6T
4T
2T
0
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024

진단에서 치료까지

합성신약

elevar therapeutics	Rivoceranib	항암
HLB 생명과학	Pyrotinib	
elevar therapeutics	Apealea	
HLB 테라퓨틱스	OKN-007	
HLB 제약	HP-P024	개량신약
	HP-P037	
	HP-P038	

바이오의약품

HLB 테라퓨틱스	RGN-259	펩타이드 의약품
HLB 사이언스	DD-S052	
	DD-A279	
HLB 셀	Lifeliver™	세포치료
	μMatricel-Hair	
Verismo THERAPEUTICS	SynKIR-110	
	SynKIR-210	
	SynKIR-310	
	SynKIR-410	
IMMUNOMIC THERAPEUTICS	ITI-1000	DNA 백신
	ITI-1001	
	ITI-3000	

의료 기기

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

진단 키트

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

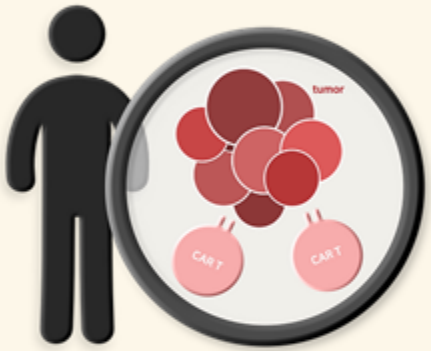
8

주요 파이프라인

회사명	적응증	권리	단독/병용	임상진행 상황
				전임상 / 1상 / 2상 / 3상 / NDA
Elevar 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			

출처: Global Liver Cancer Drugs Strategic Market Report to 2030 by Yahoo finance, Feb. 11, 2023

HLB그룹의 미래형 파이프라인



CAR-T

장기지속형 주사제

AI 딥러닝기반 신약 개발
(4,000억건의 빅데이터)

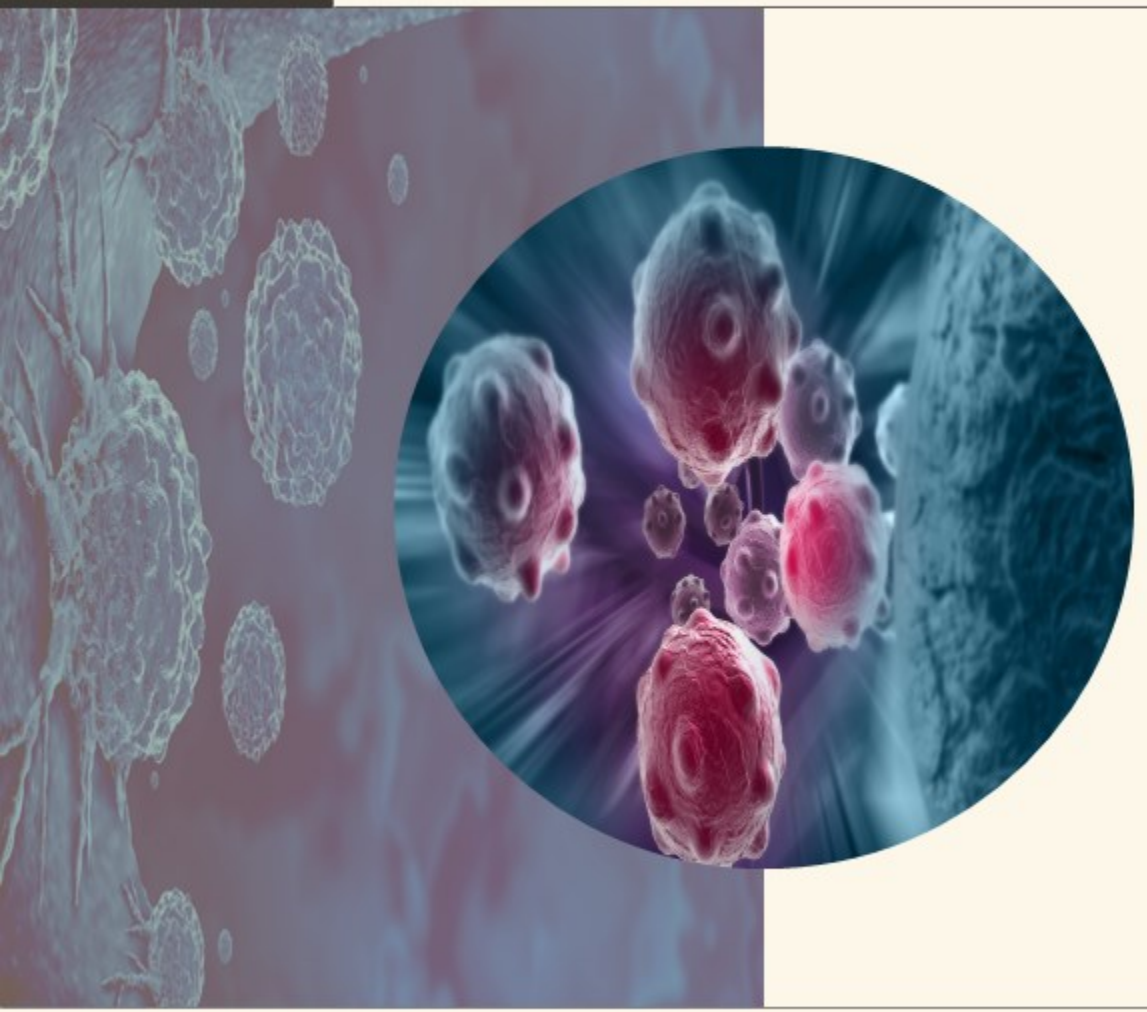
2023년 HLB 바이오포럼

간암 1차 치료제

HepatoCellular Carcinoma

Rivoceranib + Camrelizumab

임상 3상 Overview (CARES-310)



Rivoceranib/Camrelizumab	Sorafenib
272명	271명

임상기간 : 2019 ~ 2022년

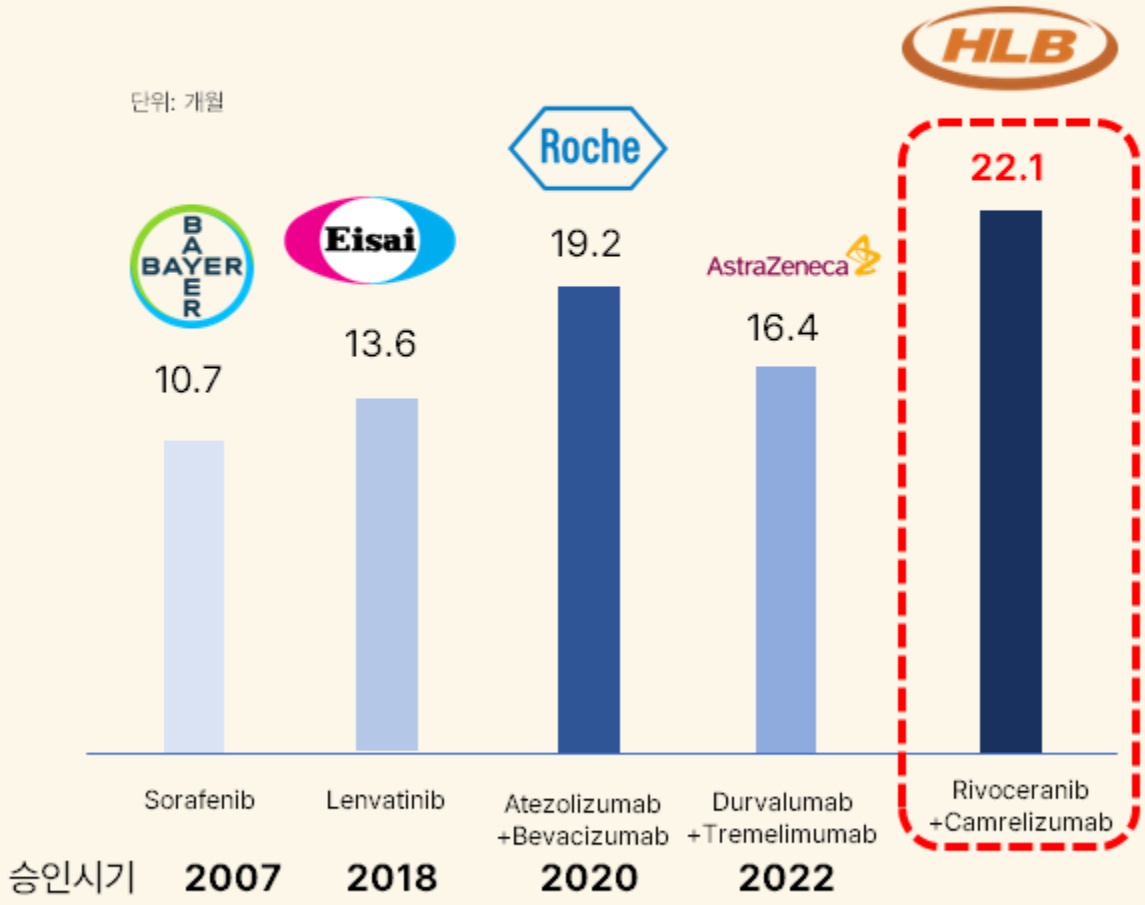
13개국 121개 병원 (글로벌 임상)

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

용어설명: OS (Overall Survival) = 생존 기간, HBV = B형간염, HCV = C형간염, Non-Viral = 비바이러스형

리보세라닙 NDA 진행 현황

PRE-NDA 2023.03

NDA 신청 2023.05

NDA 본 심사 2023.07

Mid-Cycle Review 2023.11

리보세라닙 실사 완료 2023.12

Last-Cycle Review 2024.03

FDA 결과 발표 예정 2024.05

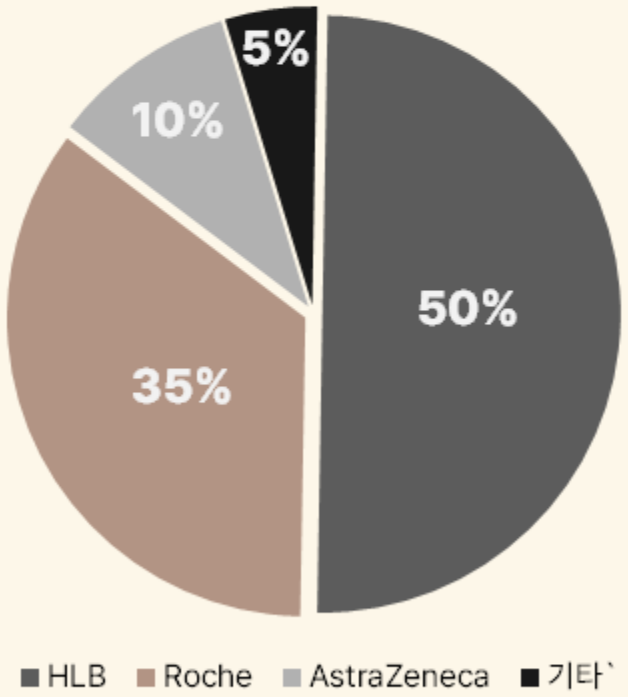
HLB의 달라질 미래

리보세라닙 간암 매출 기준 수익 구조

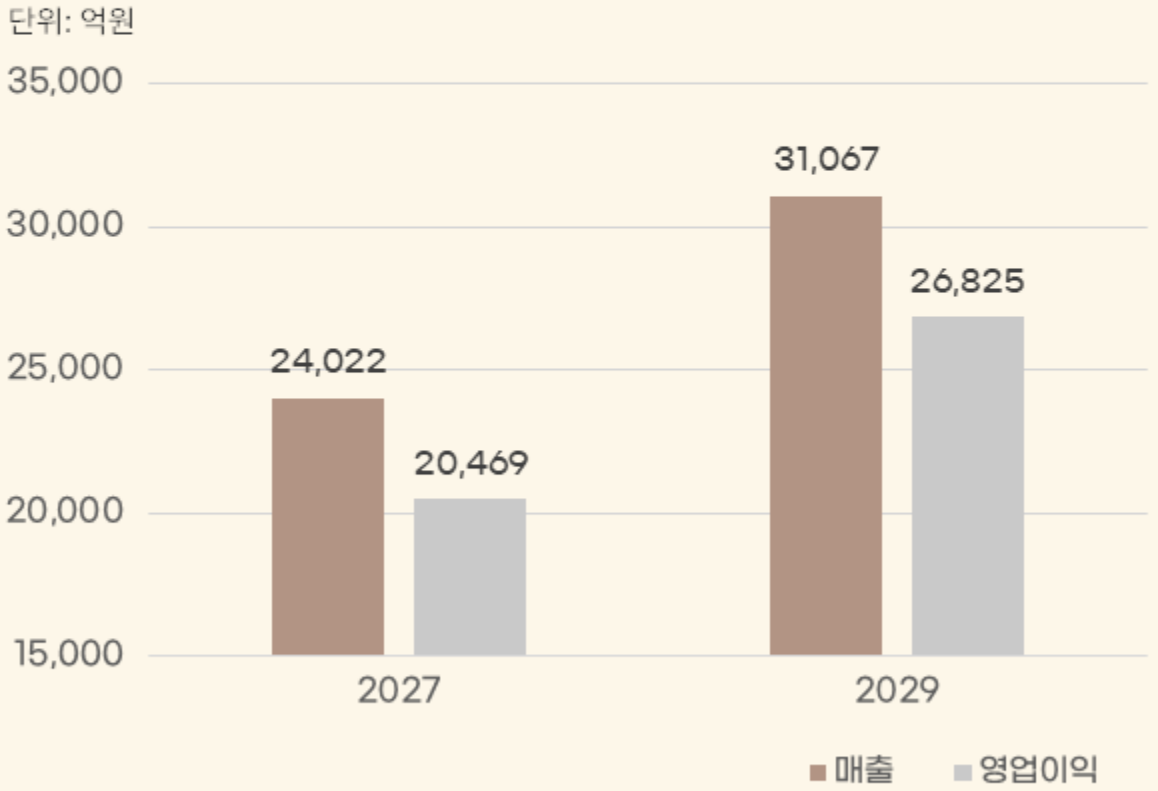
$$\text{매출} = f\left(\frac{\text{투약가능 환자수}}{\text{간암 환자수}} \times \text{투약기간} \times \text{약가} \times \text{시장점유율}\right)$$

리보세라닙 간암 매출 기준 수익 구조

목표 점유율



목표 매출 및 영업이익



*2027년 발매3년차, 2029년 발매 5년차

당사 자체적인 DCF모델링을 통한 예상 매출 및 영업이익이며 실제 매출 및 영업이익과 다를 수 있음을 명시합니다.

매출 이익률

매출 원가 :
$144.84/월

리보세라닙

미국 판매 예상 약가 :
월 $20,000~$25,000

매출 총 이익률 99.28%

매출 원가 :
$220.68/월

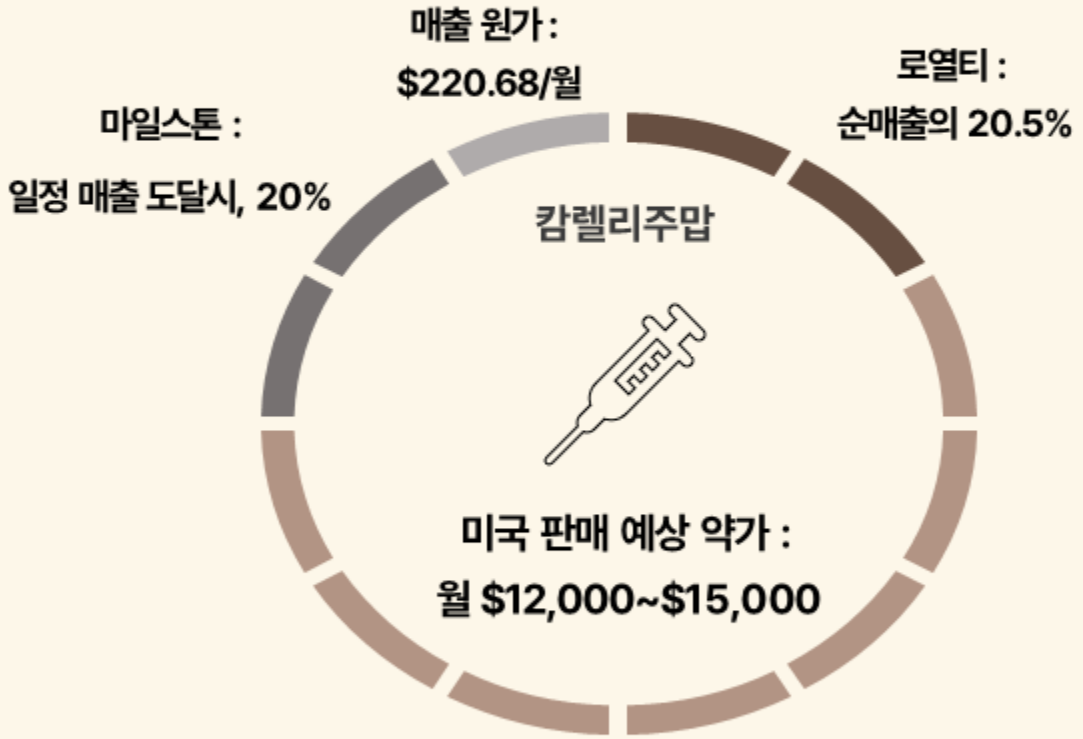
캄렐리주맙

미국 판매 예상 약가 :
월 $12,000~$15,000

매출 총 이익률 98.16%

영업 이익률

매출 총 이익률 99.28%



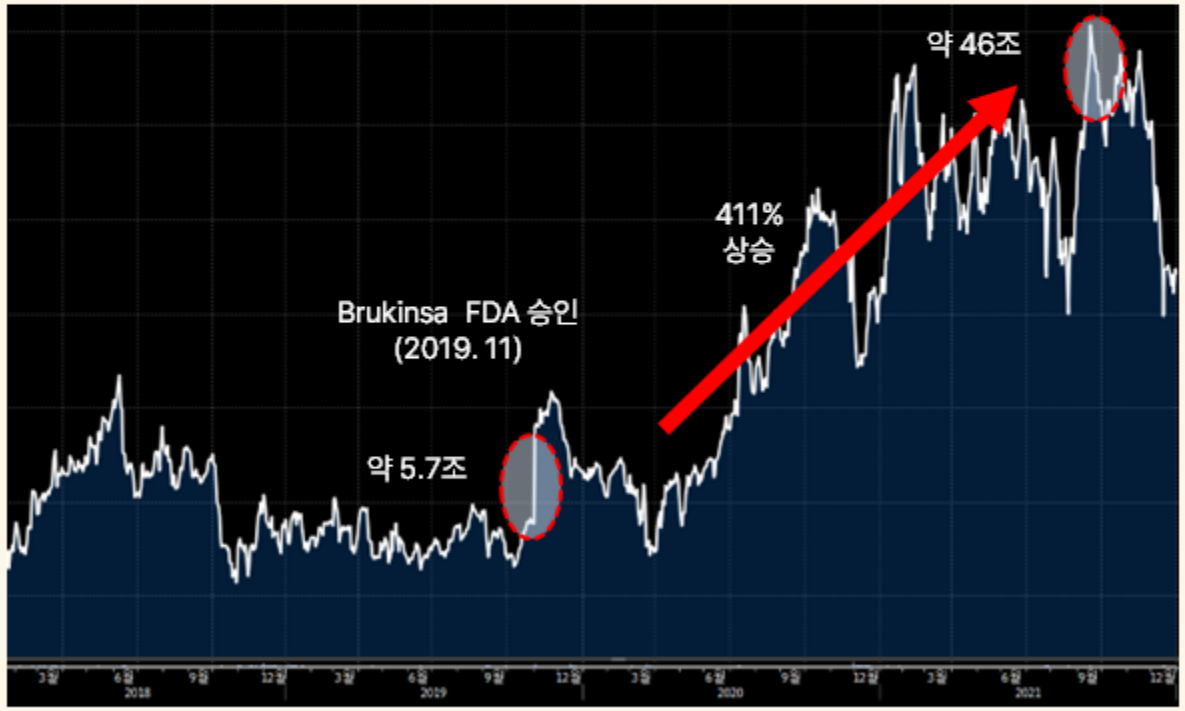
영업 이익률 57.5%

신약 승인 후 시가총액 변화

Eisai 시가총액 변화 추이 (2014~2020)

시가총액 : 약 35조 (2024/03 기준)

Beigene 시가총액 변화 추이 (2018~2021)



출처: 블룸버그

바이오텍 기업 비교 테이블

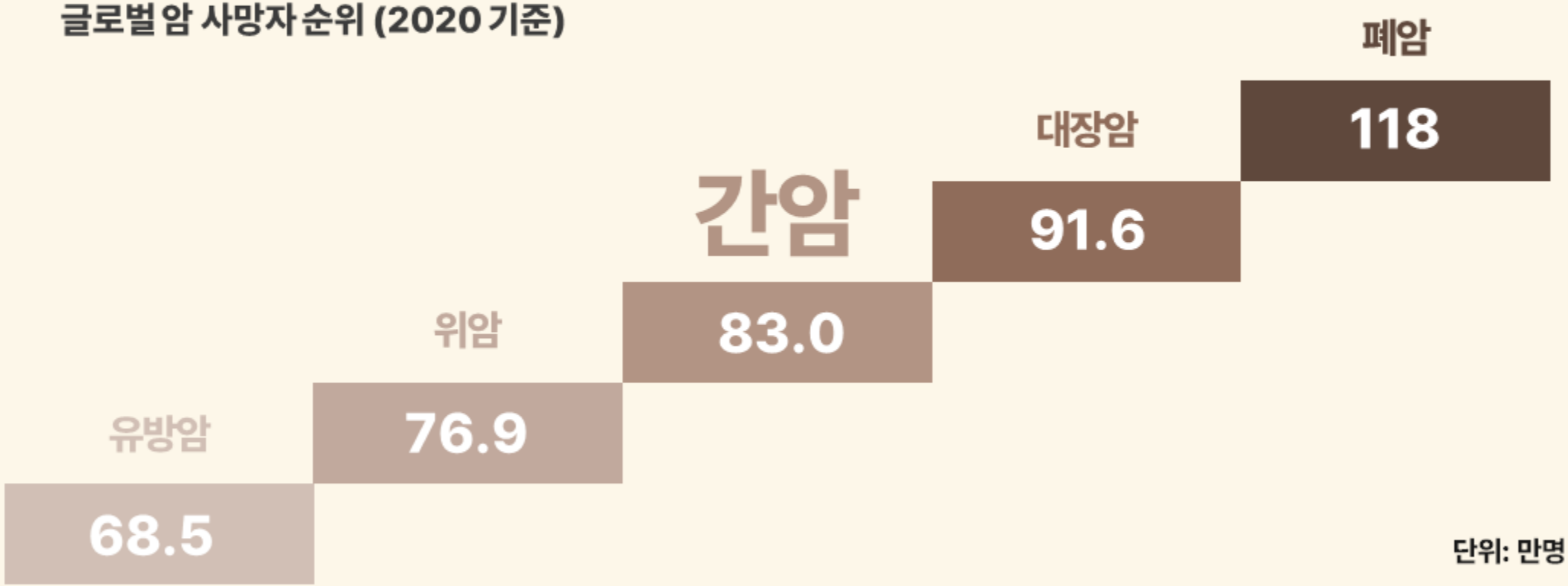
	HLB	BeiGene	Incyte	Eisai
설립일	10. 18, 1985	10. 28, 2010	04. 08, 1991	12.06, 1941
본사	서울, 한국	베이징, 중국 | 캠브릿지, 미국	윌밍턴, 미국	도쿄, 일본
IPO	KOSDAQ (KR)	NASDAQ (US), HKEX (HK), SSE (CH)	NASDAQ (US)	NiKKEI (Japan)
시가총액	12조 6,888억원	$18.2B (약 24조원)	$13.3B (약 17.5조 원)	$12.7B (약 16.7조 원)
주식 총 수	128,929,651	104,099,381	224,109,238	296,566,949
매출	223억원	$595.2mn	$954.6mn	3조7000억원
적응증	간암1차, 선낭암1차, 위암3차	외투세포림프종 (MCL) 월든스트롬 거시글로불혈증(WM)	골수섬유증, 다발성 경화증	갑상선암, 신장암, 간암, 자궁내막암, 유방암, 난소암, 쓸개관암, 알츠하이머, 불면증, 드라베 증후군
시장 규모	$13.3B	$10.05B	$3.0B	$27.2B

*매출, 주식총수 2023년 9월 말 기준, 시장 규모는 적응증 총합 규모, 시가총액 24년 3월13일 기준

출처: 2023년 9월 분기보고서, Investing.com, KRX정보시스템

글로벌 간암 통계

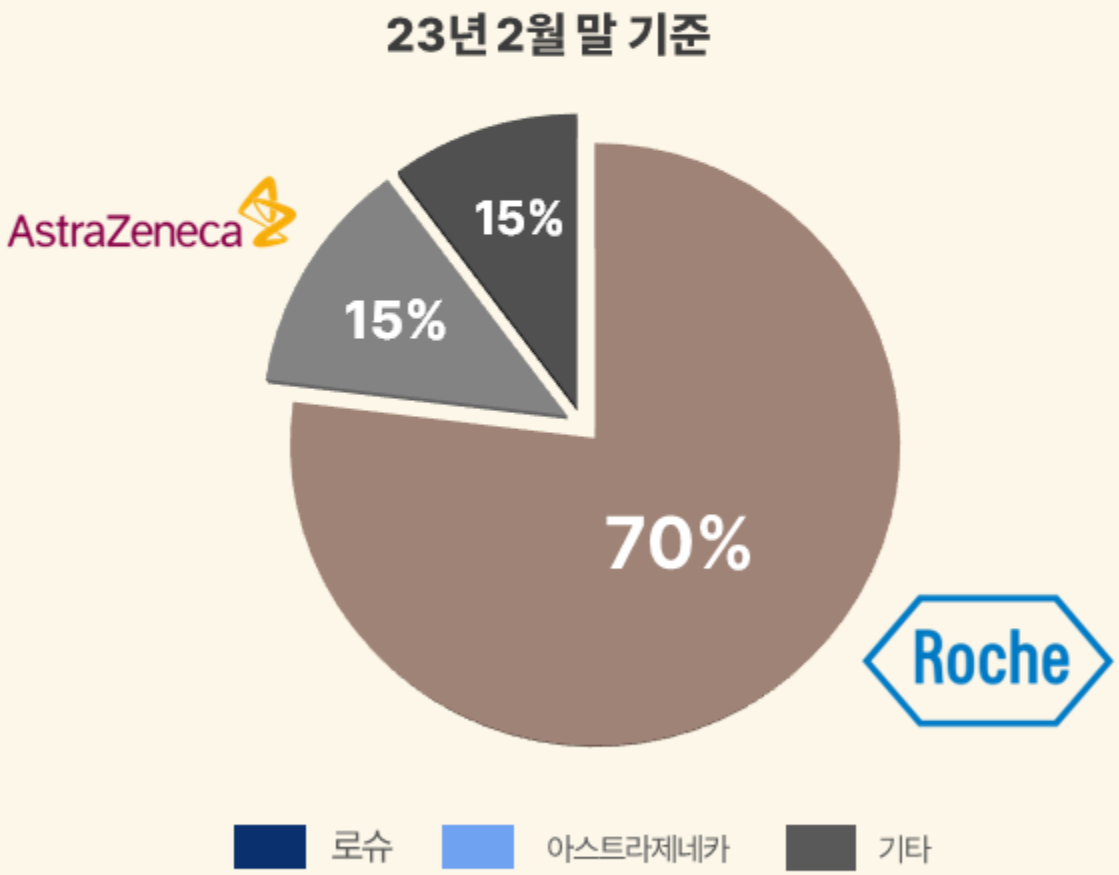
글로벌 암 사망자 순위 (2020 기준)

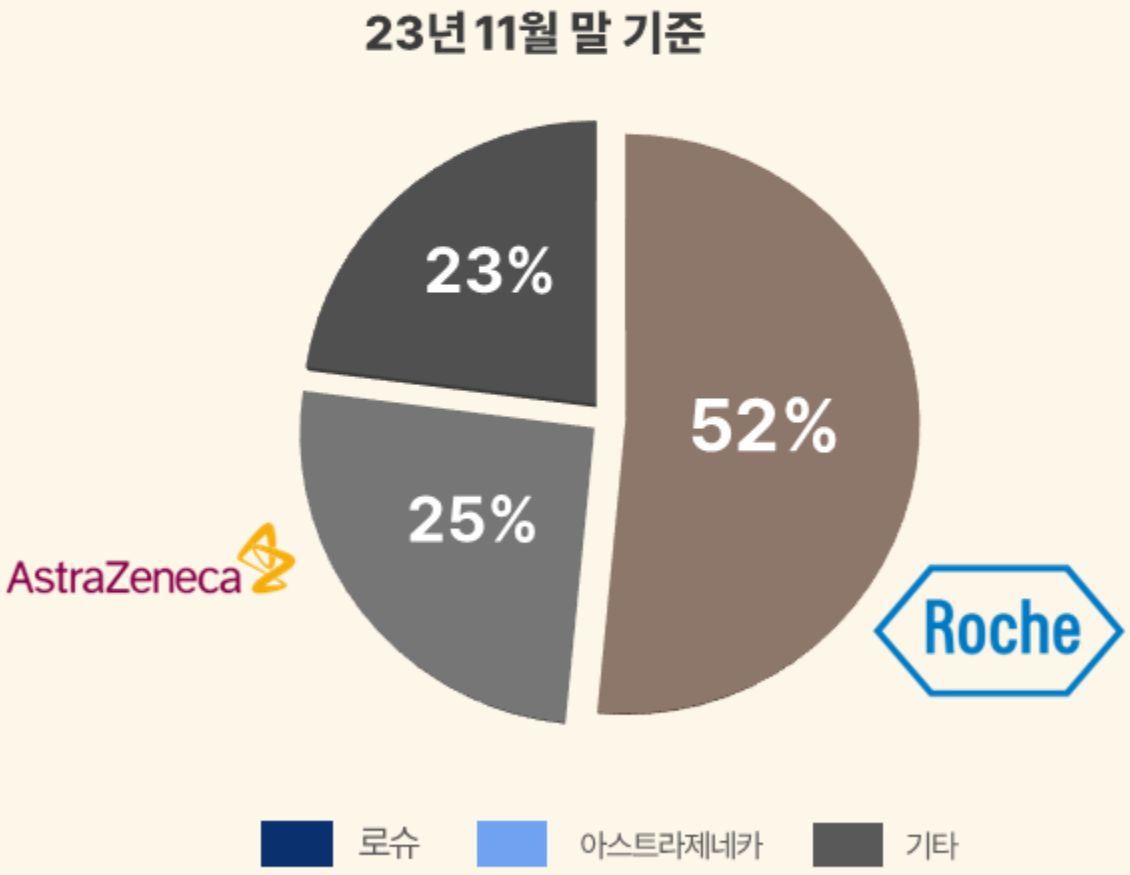


단위: 만명

출처: WHO Cancer Statistic

간암 1차 치료제 시장 점유율





출처: ElevarTx HCC Market Overview BrandImpact by IQVIA Oct, 2023

마케팅 파워 요소

생존기간 최대 연장
22.1개월

우월한 유효성 확인
(간기능 저하 환자)

출혈 고위험 환자군에게
사용가능

발병 원인 무관한 치료효과

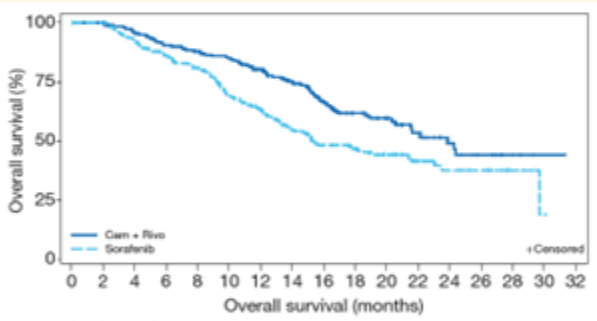
마케팅 파워 요소 1 : 최장 생존 기간

간암 치료제 중
최장 환자 생존기간 22.1개월

마케팅 파워 요소 2 : 우월한 유효성 입증

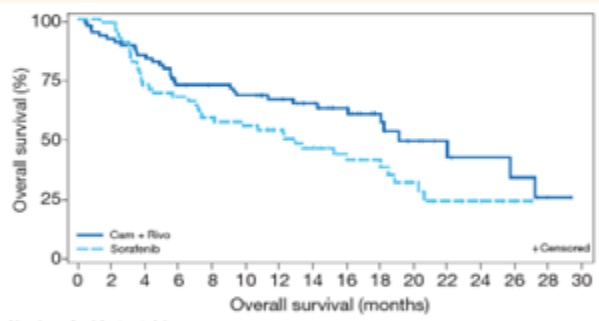
CARES-310 (HLB & Elevar)
Rivoceranib + Camrelizumab

ALBI 1 Grade



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

ALBI 2 Grade

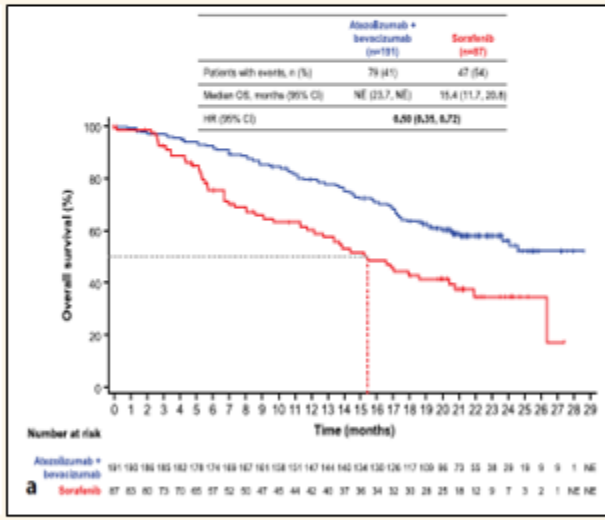


ALBI Grade 2	Cam + Rivo (n=72)	Sorafenib (n=63)
Median OS,* months (95% CI)	19.1 (14.3, 27.2)	12.3 (7.1, 18.5)
Hazard ratio* (95% CI)	0.62 (0.4, 1.0)	

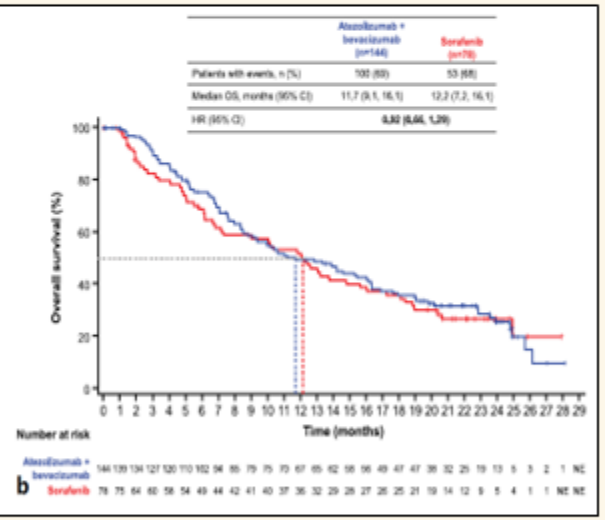
- ✓ ALBI 등급에 상관없이 모든 환자군에 약효가 좋으며 특히 Ate/Beva에서 약효가 없는 ALBI 2등급 환자들에게 우월한 약효를 나타냄
- ✓ ALBI G1 HR: 0.62 (0.47-0.83), ALBI G2 HR: 0.62 (0.4-1.0)

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

ALBI 1 Grade



ALBI 2 Grade

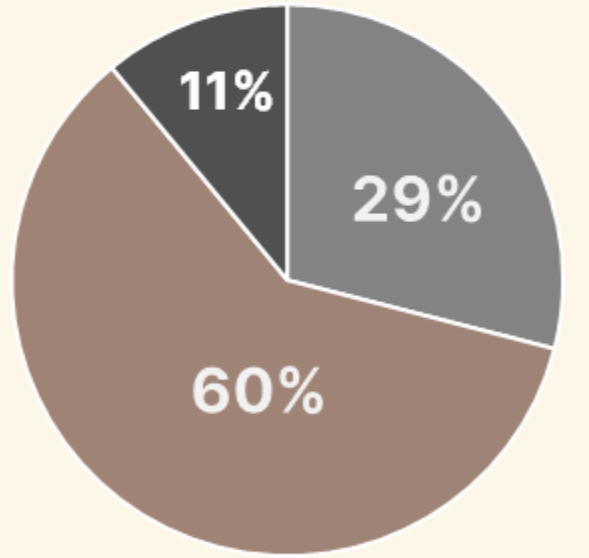


- ✓ ALBI 1등급 환자에게만 약효가 좋으며 간기능이 안 좋은 환자들에게는 약효가 현저히 떨어짐
- ✓ ALBI G1 HR : 0.5 (0.35-0.72), ALBI G2 HR: **0.92 (0.66-1.29)

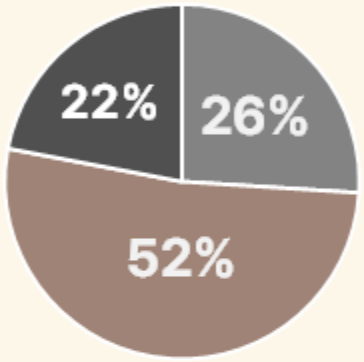
출처: Liver Cancer 2023, Supplementary appendix, Lancet 2023; published online July 24
*ALBI 1/2 Grade는 간 기능의 저하 능력을 나타내는 지표이며 Grade 2가 Grade 1보다 간 기능이 더 저하된 환자군임
**Hazard Ratio (HR)은 1에 가까울수록 약효가 없다는 뜻

ALBI Grade 별 환자 수

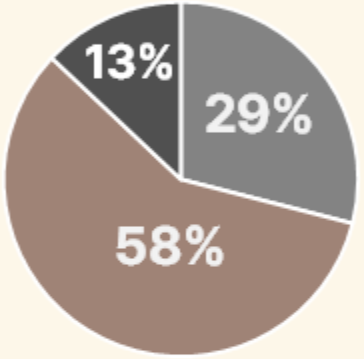
글로벌



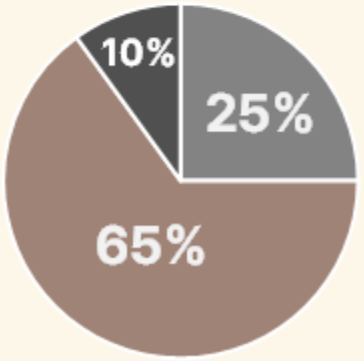
미국



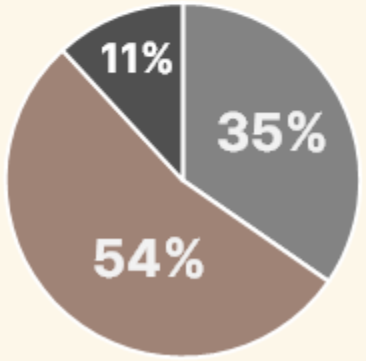
유럽



일본



중국



출처:Karger.com/Albumin-Bilirubin Grade Analyses of Atezolizumab plus Bevacizumab versus Sorafenib in Patients with Unresectable Hepatocellular Carcinoma: A Post Hoc Analysis of the Phase III IMbrave150 Study

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

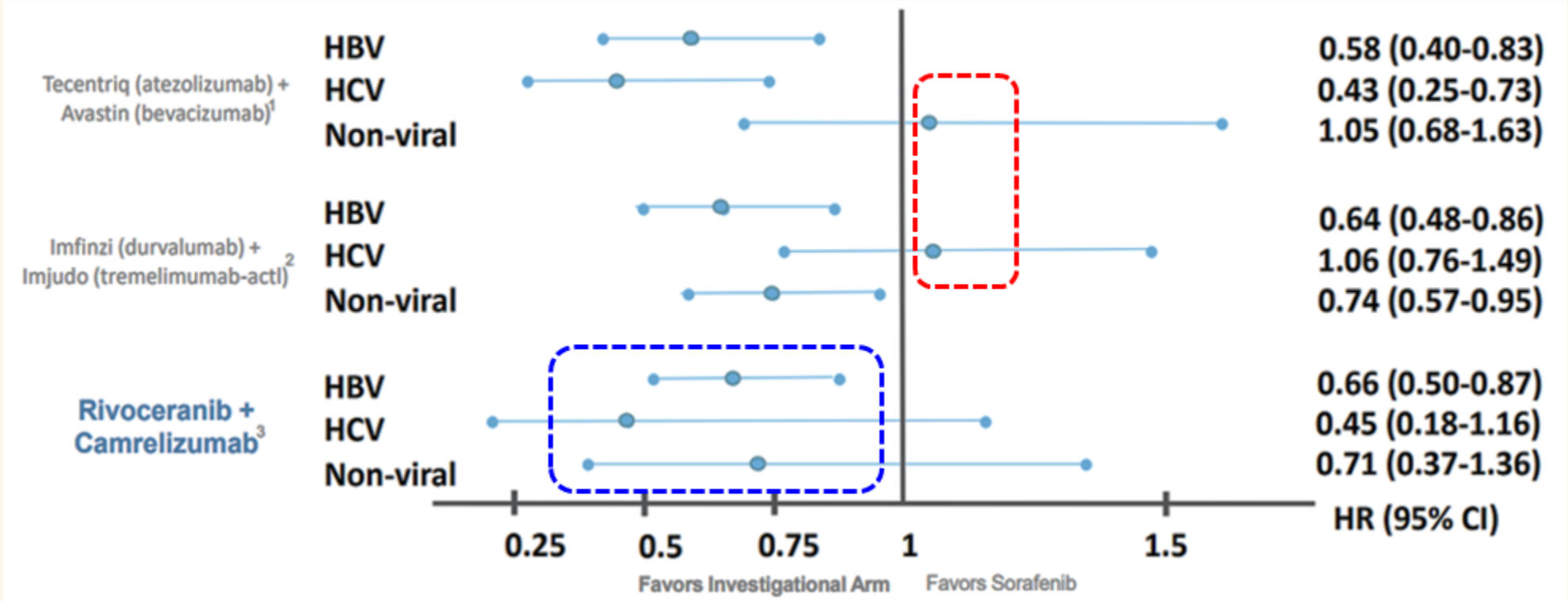
5.3 Hemorrhage

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)]*.

- ✓ FDA 의 Avastin 설명서에서 출혈위험이 있는 간암 환자의 사용에 대하여 경고함
- ✓ Avastin의 경우 반감기가 20일로 부작용에 대한 대처가 어려움
- ✓ 반면, 리보세라닙은 출혈이 거의 없으며 반감기 또한 11시간 수준임

※ 반감기: 약물의 혈중 농도가 절반으로 줄어드는데 걸리는 시간

마케팅 파워 요소 4 : 간암 발병 원인 무관한 치료 효과



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

세계 간암 KOL들의 평가와 찬사

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

Shukui Qin 교수

Ghassan K. Abou-Alfa 교수

"리보세라닙+캄렐리주맙 병용요법은 간암분야에서 **가장 긴 환자생존율**을 보였으며 1차 치료제의 새로운 옵션을 제시한다"

"리보세라닙과 캄렐리주맙 병용요법은 간암 1차 치료제의 **높은 효능과 안전성**을 입증하였으며 진행성 간암 치료법을 변화시킬 수 있는 잠재력이 높다"

Stephen Chan 교수

글로벌논문데이터

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-Lii 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 erythrodysaesthesia 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.

글로벌 간암 학계 KOL의 평가

- ✓ "리보세라닙+캄렐리주맙 병용요법은 간암분야에서 가장 긴 환자생존율을 보였으며 1차 치료제의 새로운 옵션을 제시한다"
  by Ghassan K. Abou-Alfa 교수
  (미국 Memorial Sloan Kettering Cnacer Center)

- ✓ "리보세라닙과 캄렐리주맙 병용요법은 간암 1차 치료제의 높은 효능과 안전성을 입증하였으며진행성 간암 치료법을 변화시킬 수 있는 잠재력이 높다"
  by Stephen Chan 교수 (홍콩중문대학교)

- ✓ "위험 대비 치료 이점이 높은 리보세라닙+캄렐리주맙 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 PATIE (PTS) WITH HEPATOCELLULAR CARCINOMA (HCC): 202(**

Amit G. Singal [1], Ki Zdravko Vassilev [3], Xiaoyun Pan [3], Chi-Chang Chen [4], Jasjit Multar

[1] Department of Int dical Center, Dallas, TX, USA; [2] Bayer Consumer C ticals, Whippany, NJ, USA; [4] Real World Evidence Vorld Evidence Solutions, IQVIA US, Falls Church, ing, PA, USA, [7] Bayer AG, Berlin, Germany

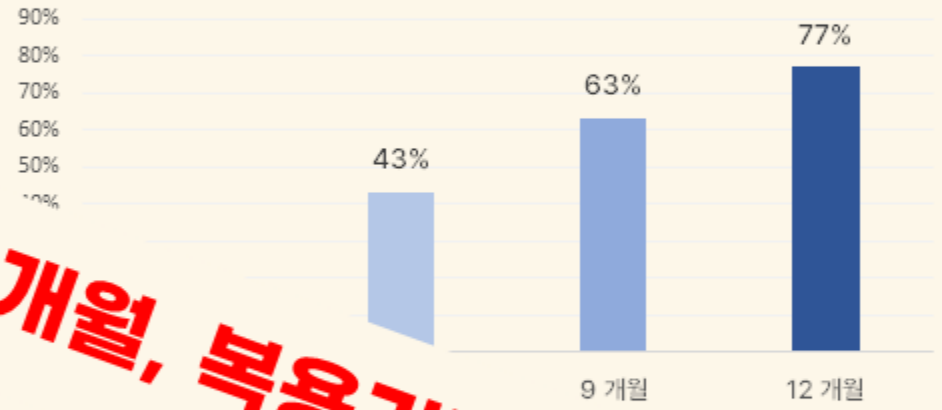
Introduction: Treatment options for pts with advance agents, including atezolizumab plus bevacizumab (atezo+bev), care for eligible pts. RW evidence for subsequent therapies follow is no clear guidance on follow-up treatments for HCC. Therefore, this stu patterns in pts who received 1L atezo+bev for HCC in the USA.

Methods: Pts with HCC, aged ≥18 years, who initiated atezo+bev between June 1, 2020, an 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.

평균 치료 중단 기간 5.1개월, 복용기간 제일 짧음

Ate/Beva 복용기간 대비 치료 중단율



- ✓ Ate/Beva 복용
- ✓ Ate/Beva의 평균 치료 중단

*대표적인 부작용인 위/장간 출혈로 인한 복

된 환자에게 약효가 없어 다른 약으로 대체 됐을 거라 판단됨

글로벌논문데이터

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

현 간암1차치료제 대비 리보/캄렐 Best In Class 입증

1007P - Network meta-a ...mparators in first-line unresectable hepatocellular carcinoma (uHCC)

Presentation Number 1007P
Speakers David Trueman
Onsite Poster display date Monday,

Abstract

Background

This research compared the relative efficacy of lenvatinib monotherapy (mono), a standard ... probability of treatment weighting (IPTW) and an NMA, updated evidence for lenvatinib mono from LEA... analyses.

Methods

Randomized controlled trials (RCTs) were identified via systematic literature review. REFLECT and LEAP-002 investigated lenvatinib mono in uHCC, with pa... available for each, however, only REFLECT had a comparator arm of interest. To utilise all available lenvatinib data, the lenvatinib arm from LEAP-002 was adjusted to ... 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.

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).

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	0.88 (0.71, 1.08)	0.55 (0.45, 0.69)
...umab	0.88 (0.71, 1.11)	0.51 (0.41, 0.65)
...00 mg + durvalumab	0.97 (0.77, 1.20)	0.63 (0.51, 0.78)
...	1.14 (0.86, 1.51)	0.87 (0.67, 1.13)
...	1.21 (0.92, 1.60)	1.09 (0.82, 1.44)

...interval; HR, hazard ratio; OS, overall survival; PFS, progression-free survival

These ... significantly improved OS and PFS when compared with other therapies.

Legal entity responsible ...

Eisai Inc.

Funding

Eisai Inc.

- ✓ 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

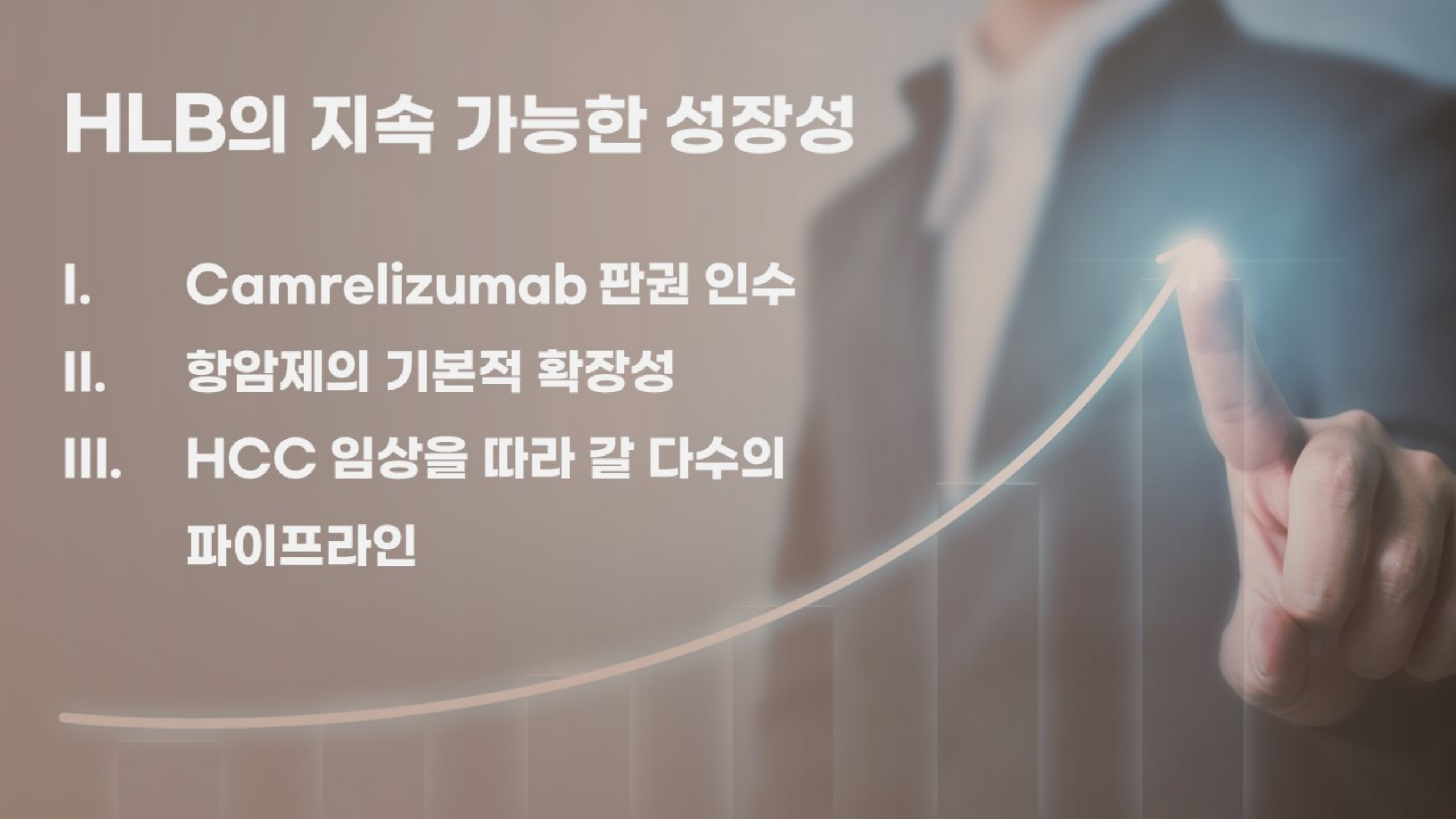
*주요 간암 1차 치료제 대비 HLB의 리보세라닙/캄렐리주맙이 OS/PFS HR Best in Class로 검증됨

HLB의 지속 가능한 성장성

I. Camrelizumab 판권 인수

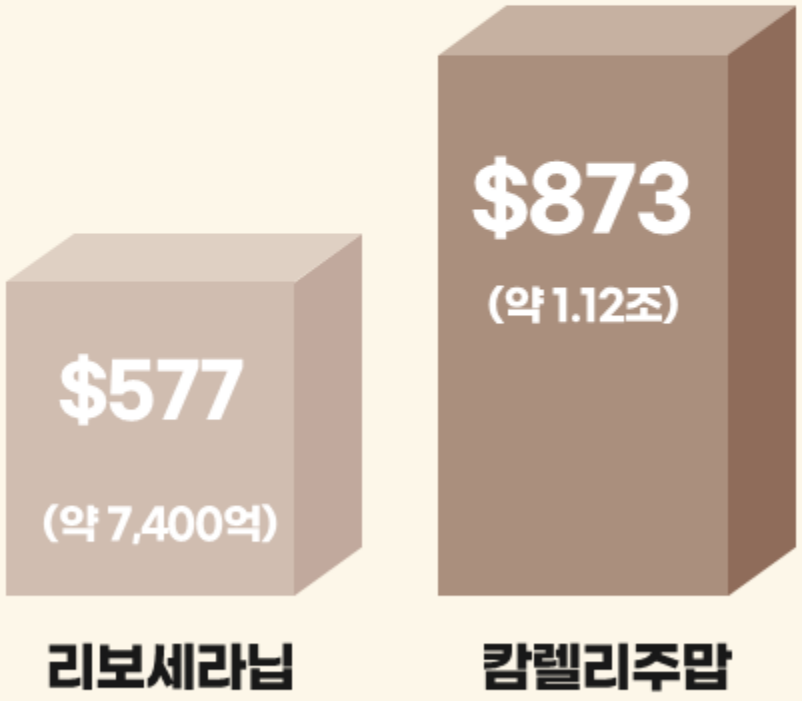
II. 항암제의 기본적 확장성

III. HCC 임상을 따라 갈 다수의 파이프라인



리보세라닙 적응증 확장성

리보세라닙/캄렐리주맙 중국 내 매출 (2023)



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	2018 ESMO (유럽종양학회)
	전이성 폐암	
	전이성/진행성 위암	
2019	말기 간암	국제학술지 (Digestive
	말기 위암	2019 ESMO (유럽중앙학회)
	뇌종양	
2020	자궁경부암	2020 ASCO (미국임상종양학회)
	식도암	2020 ESMO (유럽종양학회)
	T세포 림프종	
	진행성 비소세포폐암	
	담낭암	중국 난징의과대학 제 1 부속병원
	비편평 비소세포폐암	상해 동제대학

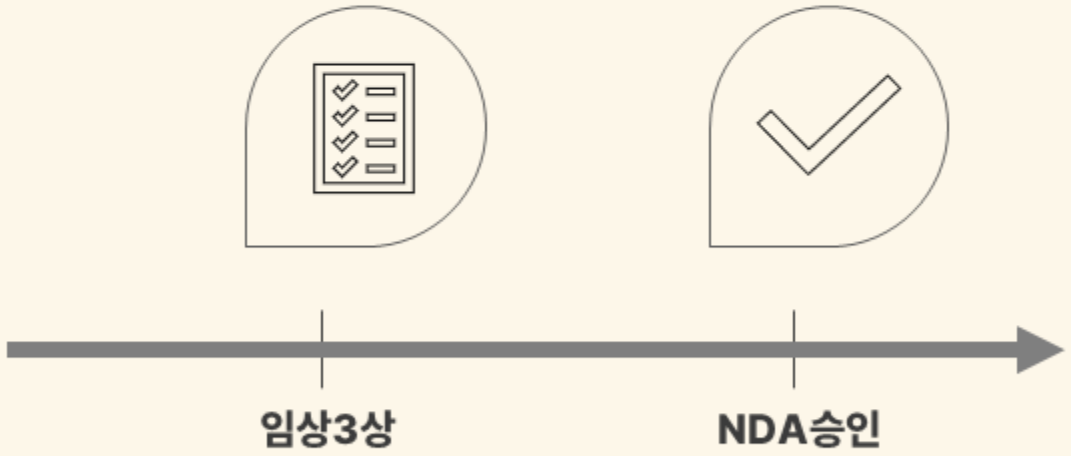
연도	적응증	임상자료
2021	위암	2021 ASCO (미국임상종양학회)
	돌연변이 비소세포폐암	2021 IASLC (세계폐암학회)
	메르켈 세포암	SCI Frontier in Oncology
	재발 내성 난소암	'Ann Palliat Med' 학술지
	재발성 임신성 융모성종양	
	담관암	중국 장저우대 제1부속병원
	대장암	중국 허베이대학 부속병원
2022	흑색종	2022 ASCO (미국임상종양학회)
2023	비소세포폐암 3기	2023 ESMO (유럽종양학회)
	재발성전이성 비인두암	Journal of Clinical Oncology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

감사합니다

HLB

Human Life Better