HLB

Human

Life

Better

"모기도 굳센 의지를 가지고 머리를 들이밀면
무쇠도 능히 뚫으리라"

Kairos

신약성공률 vs. Risk

ONE Product Risk

항암제 vs. 반도체

	2024	2027
항암제	300조	500조
반도체	700조	1,000조

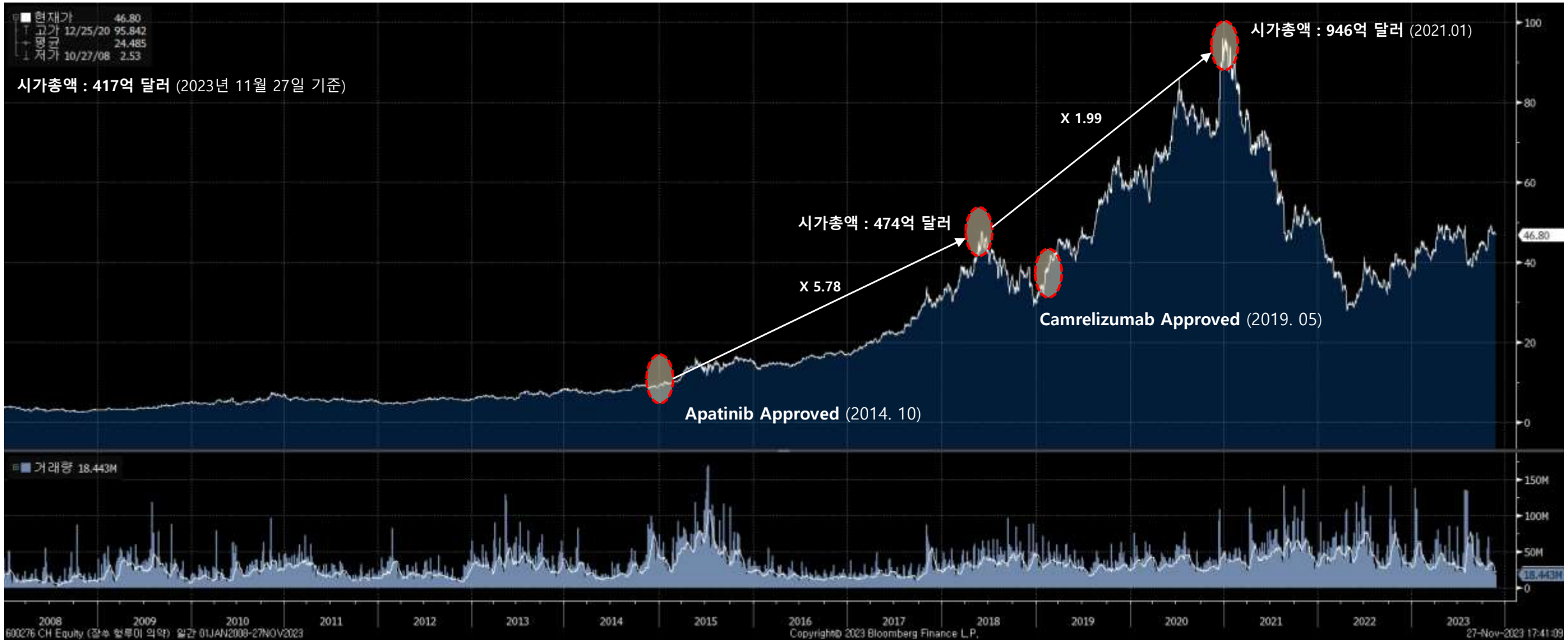
HLB

HLB의 경우...

UPSIDE >> RISK

Rivoceranib (Apatinib: Aitan)

항서제약(Jiangsu Hengrui Pharmaceuticals)




2014-04-21
HLB (028300), 주간
2023-11-20
일본식차트(주간) MA_종가,5 MA_종가,20 MA_종가,60 MA_종가,120 MA_종가,200
최고가 : 85,144 (2019/10/25)
권리락(-9.04%)
권리락(-49.94%)
권리락(-2.07%)
권리락(-4.62%)
최저가 : 1,467 (2014/08/01)
30,700
-0.32%
거래량 MA_거래량,5 MA_거래량,20 MA_거래량,60
*1000
3,999
0.17%
2014/04
2015
2016
2017
2018
2019
2020
2021
2022
2023
Daishin Securities Co. Ltd.

HLB Group Bio Business Structure

Founded (2)
Acquisition (13)

Business Category	HLB Group							
비임상 연구						HLB바이오스텝 (2021)		
연구개발 (신약)	Elevar Therapeutics (2005)	HLB생명과학 (2015)	HLB사이언스 (2018)	Immunomic Therapeutics (2020)	Verismo Therapeutics (2021)	HLB테라퓨틱스 (2021)	HLB생명과학 R&D (2022)	
의약품		신화어드밴스 (2016)		HLB제약 (2020)				
의료기기	HLB셀 (2009)		화진메디칼 (2018)					
진단						HLB 헬스케어 사업본부 (2021)	HLB 생명과학 메디케어사업부 (2022)	HLB파나진 (2023)

01

진단부터 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	
SynKIR-410	
ITI-1000	
ITI-1001	DNA 백신
ITI-3000	

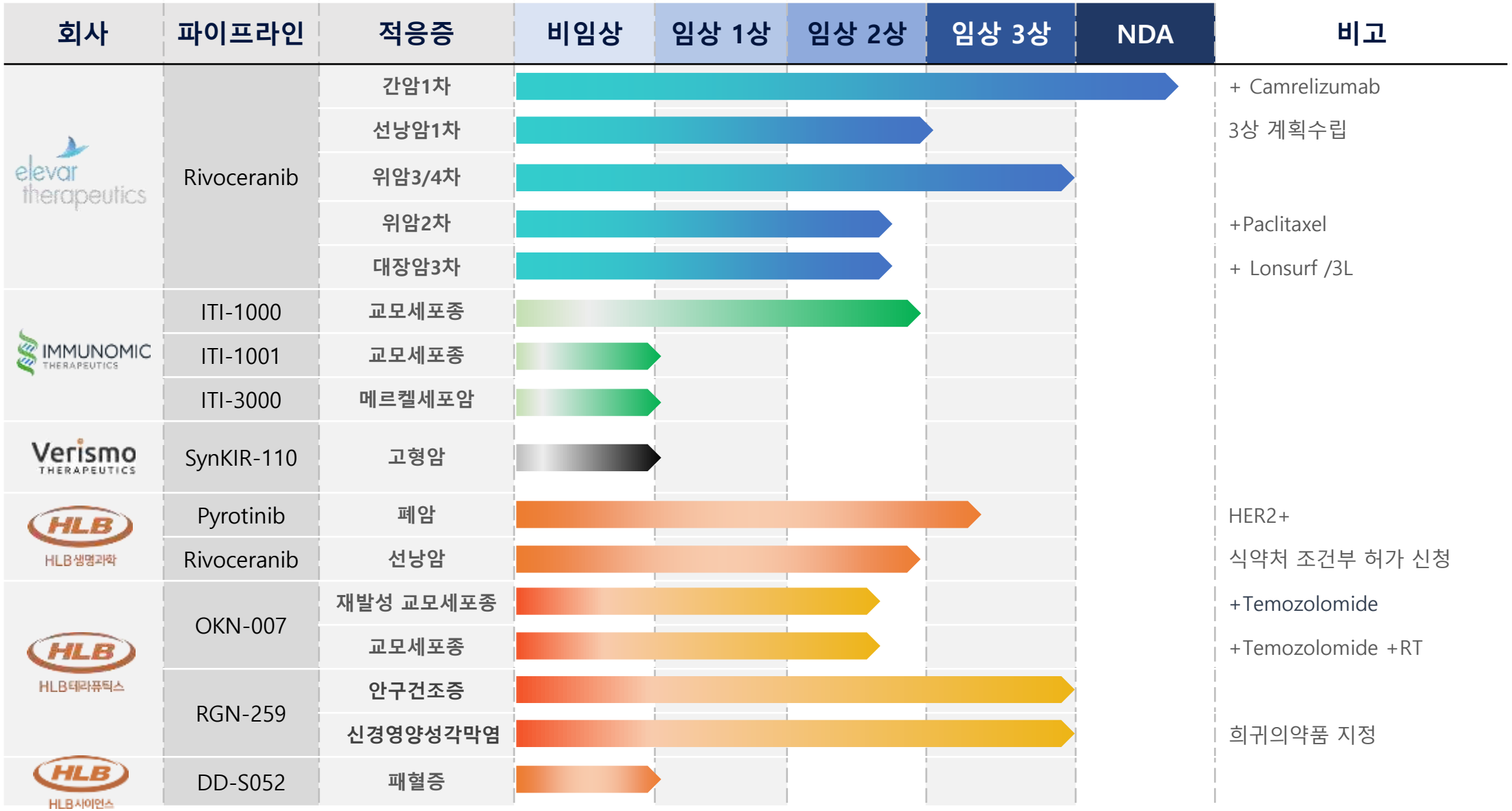
의료 기기

Bleefix®	체내 이식 의료기기
Hutrigel®	
Multi-pen	의료기기
puncture needle	
syringe	
Nasal Swab	

진단 키트

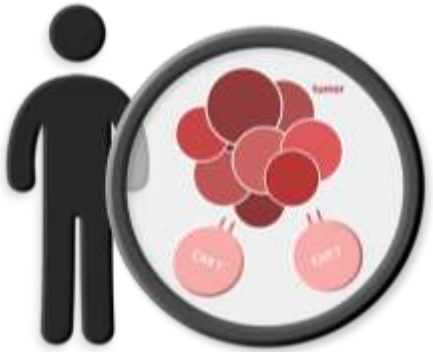
Alzheimer diagnosis kit	질병진단
PNAClamp™ PANAMutyper™	생체검사
PANARealTyper™ PANAqPCR™	분자진단

HLB그룹내 주요 신약 파이프라인



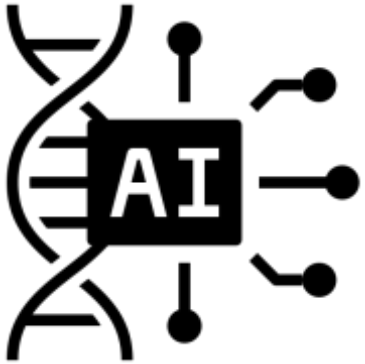
회사	파이프라인	적응증	비임상	임상 1상	임상 2상	임상 3상	NDA	비고
elevar therapeutics	Rivoceranib	간암1차						+ Camrelizumab
		선낭암1차						3상 계획수립
		위암3/4차						
		위암2차						+Paclitaxel
		대장암3차						+ Lonsurf /3L
IMMUNOMIC THERAPEUTICS	ITI-1000	교모세포종						
	ITI-1001	교모세포종						
	ITI-3000	메르켈세포암						
Verismo THERAPEUTICS	SynKIR-110	고형암						
HLB HLB생명과학	Pyrotinib	폐암						HER2+
	Rivoceranib	선낭암						식약처 조건부 허가 신청
HLB HLB테라퓨틱스	OKN-007	재발성 교모세포종						+Temozolomide
		교모세포종						+Temozolomide +RT
	RGN-259	안구건조증						
		신경영양성각막염						희귀의약품 지정
HLB HLB사이언스	DD-S052	패혈증						

HLB그룹의 미래형 파이프라인



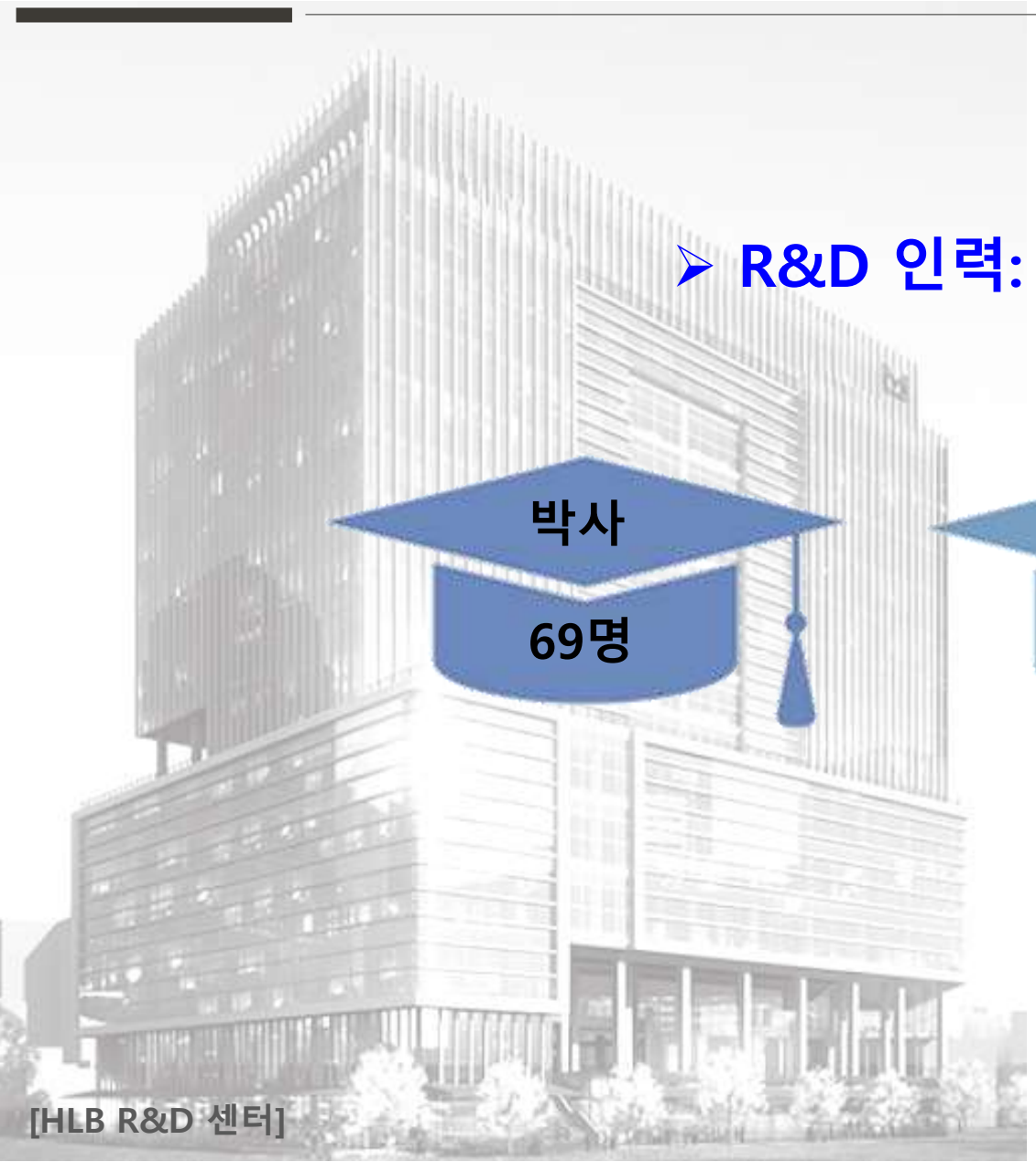
CAR-T

장기지속형 주사제



AI 딥러닝기반 신약 개발
(4,000억건의 빅데이터)

HLB그룹내 바이오 전문인력 현황



[HLB R&D 센터]

➢ **R&D 인력: 총 207명** (‘23년 11월말 기준)

HLB 바이오포럼 (2023년4월)

Rivoceranib + Camrelizumab

1차 치료제
간암 (HCC: Hepatocellular carcinoma)

간암치료제 임상 3상 시험 개요 (CARES-310 Study)

❖ 임상기간: 2019년 - 2022년

❖ 13개국 121개 병원

❖ 543명 시험대상자

Rivoceranib + Camrelizumab

272명

Sorafenib

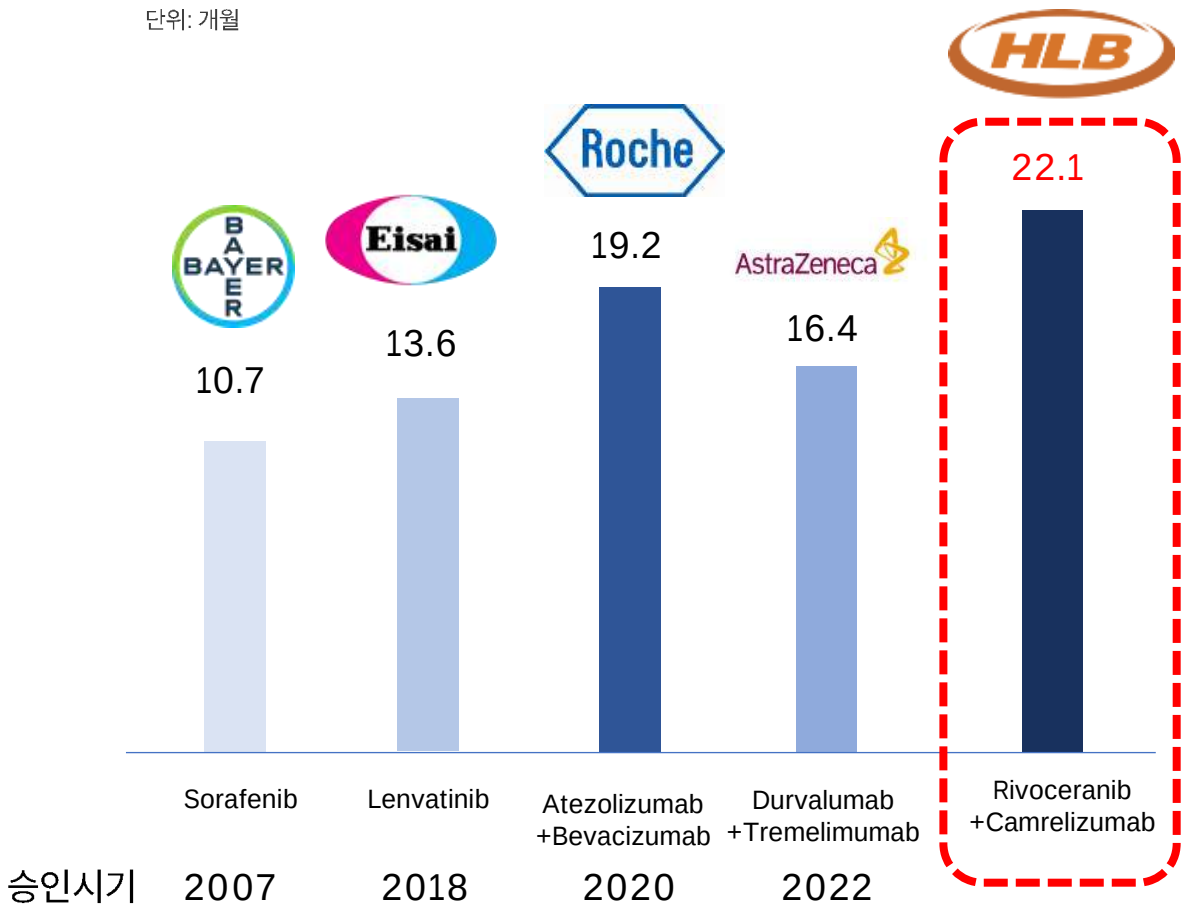
271명

✓ 1차 평가지표: 전체생존기간(mOS), 무진행 생존기간(mPFS)

✓ 2차 평가지표: 객관적 반응률 (ORR)

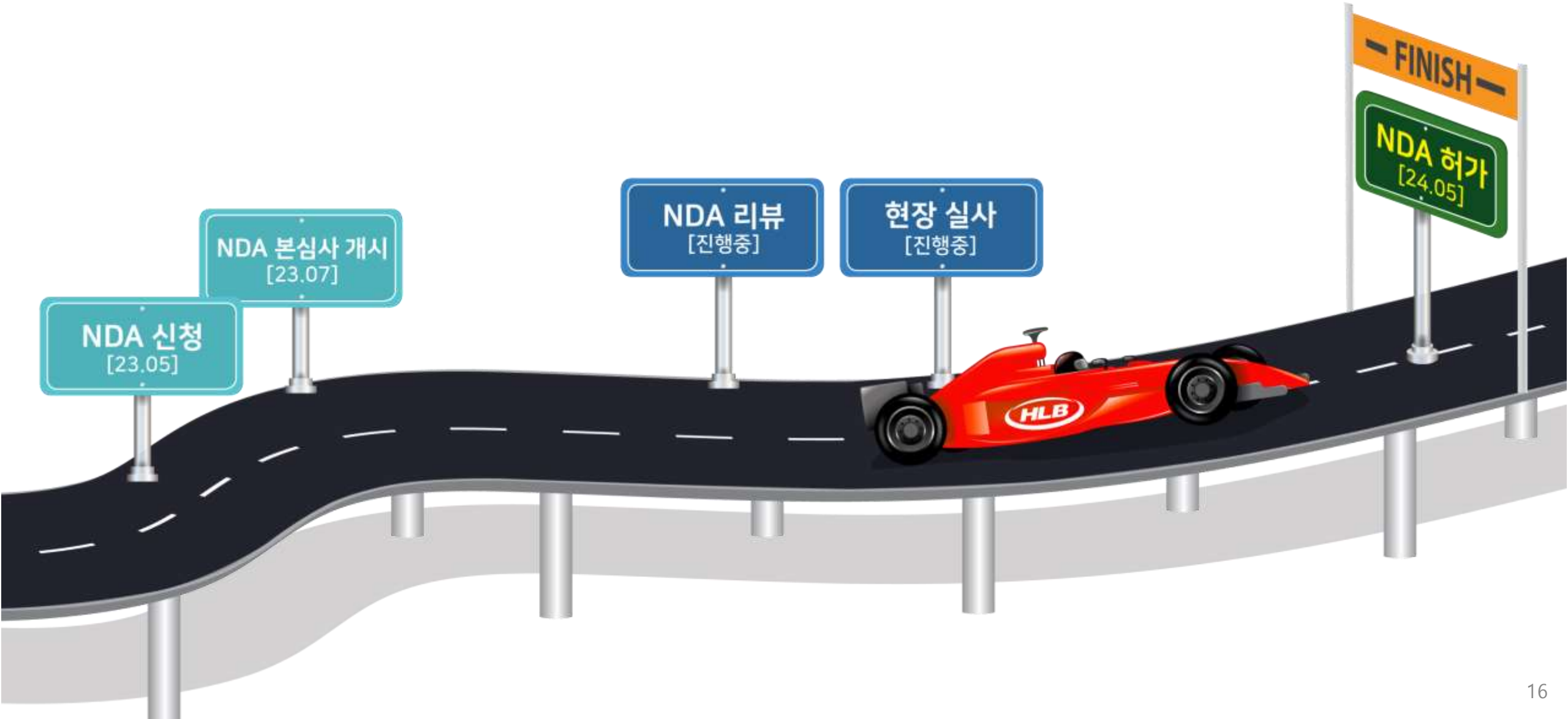
간암치료제 임상 3상 주요 결과 (CARES-310 Study)

➢ 간암 1차 치료제들의 전체 생존기간 비교



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

NDA 승인까지 남은 과정



“ HLB의 달라질 미래 ”

1. 매출, 수익구조

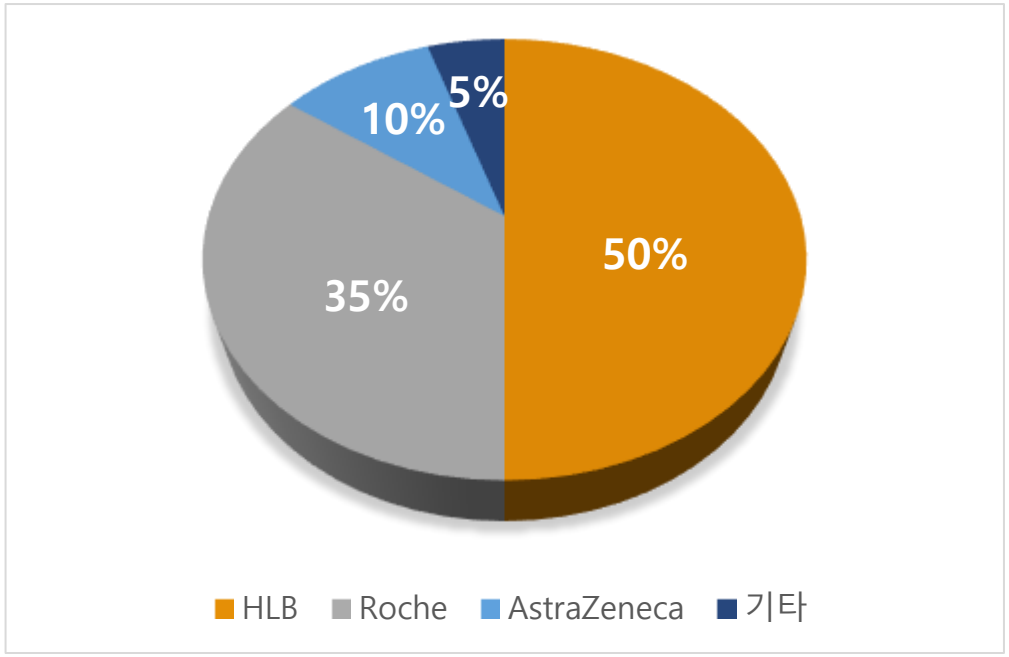
2. 시가 총액

매출 및 수익구조의 변화 (리보세라닙 간암매출 기준)

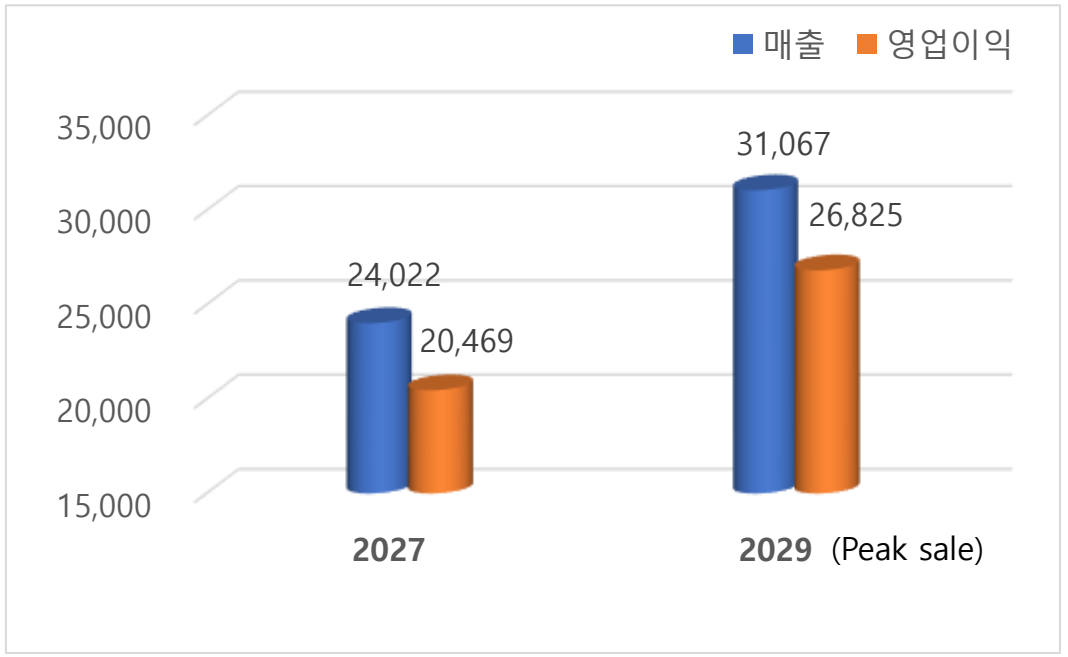
$$\text{매출} = f\left(\frac{\text{투약가능 환자수}}{\text{간암 환자수}} \times \text{투약기간} \times \text{약가} \times \textbf{시장점유율}\right)$$

매출 및 수익구조의 변화 (리보세라닙 간암치료제매출 기준)

목표 점유율



목표 매출 및 영업 이익



*2027년 발매3년차, 2029년 발매 5년차

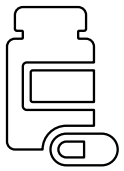
✓ 당사 예상 NPV(순현재가치) 약 17조원

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

리보세라닙/캄렐리주맙 판매 약가 전략

매출 원가 :
$144.84/월

리보세라닙



미국 판매 예상 약가 :
월 $20,000~$25,000

99.28% 매출 총 이익률

매출 원가 :
$220.68/월

캄렐리주맙

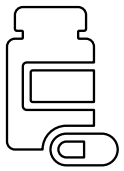
미국 판매 예상 약가 :
월 $12,000~$15,000

98.16% 매출 총 이익률

리보세라닙/캄렐리주맙 판매 약가 전략

매출 원가 :
$144.84/월

리보세라닙



미국 판매 예상 약가 :
월 $20,000~$25,000

99.28% 매출 총 이익률

매출 원가 :
$220.68/월

로열티 :
순매출의 20.5%

마일스톤 :
일정 매출 도달시, 20%

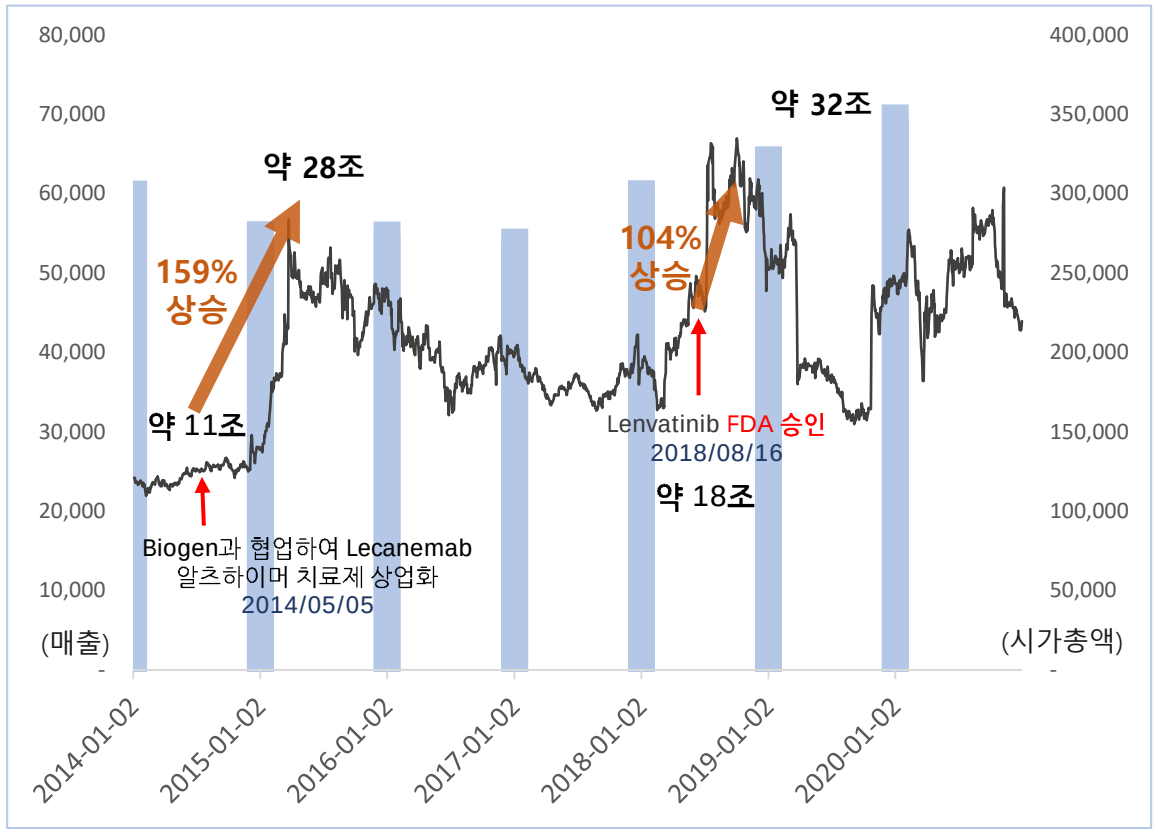
캄렐리주맙

미국 판매 예상 약가 :
월 $12,000~$15,000

57.5% 영업이익률

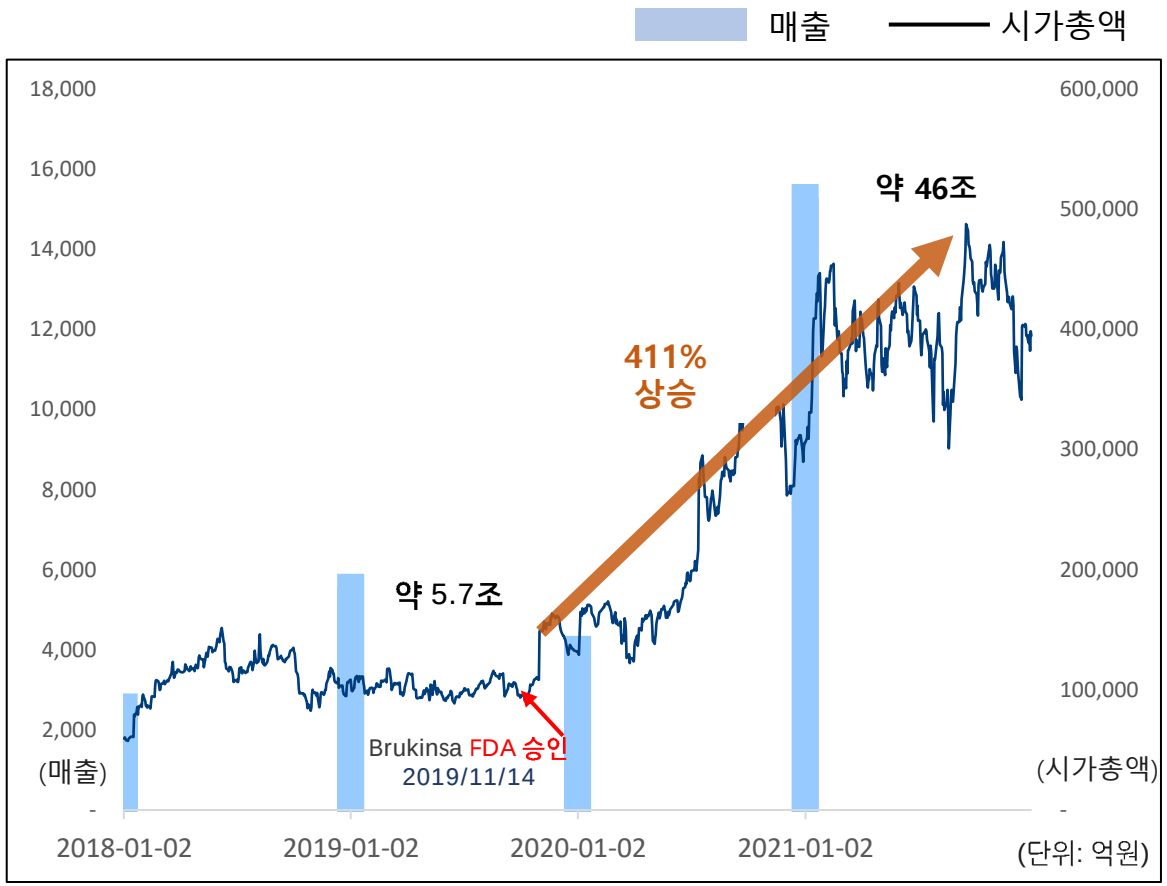
시가총액의 변화

Eisai 시가총액 및 매출 추이 (2014~2020)



[출처] 블룸버그

BeiGene 시가총액 및 매출 추이 (2018~2021)



02

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	6조 3,870억원	$19.9B (약 26조원)	$13.9B (약 18조원)	$14.2B (약 18조원)
주식 총 수	128,989,387	104,099,381	224,109,238	296,566,949
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	약 17조	약 13조	약 3조 9천억	약 35조 7700억

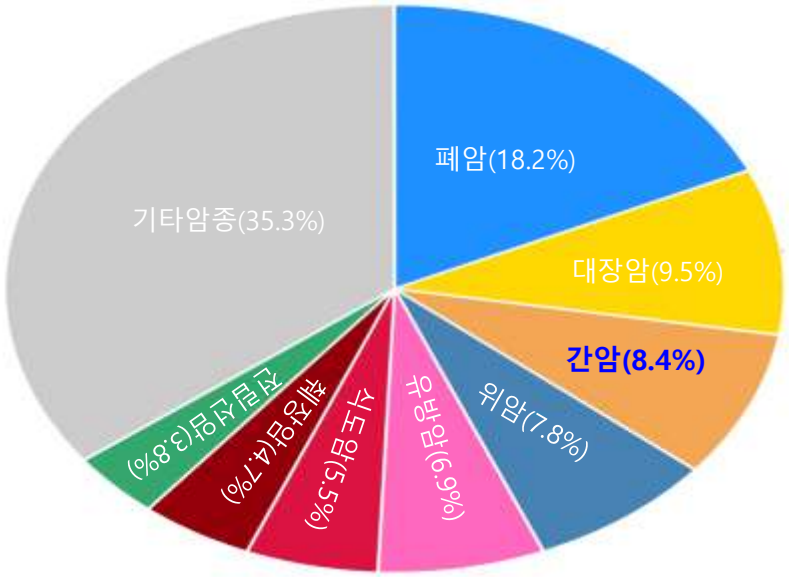
*매출, 주식총수 2023년 9월 말 기준, 시가총액 2024년 1월3일 기준, 시장 규모는 적응증 총합 규모

출처: 2023년 9월 분기보고서, Investing.com, Yahoo Finance

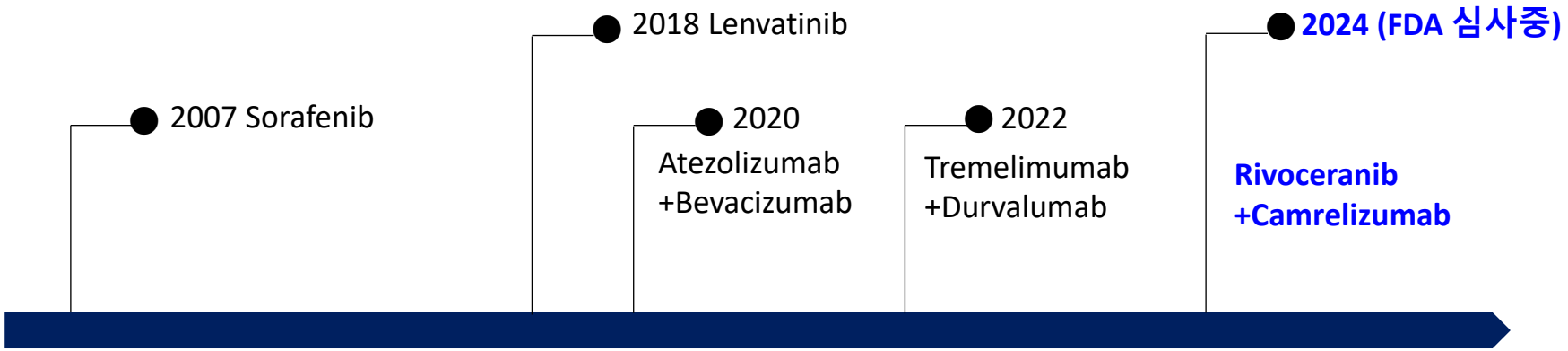
간암 및 간암 1차 치료제 현황

➢ 전세계 암 사망률 통계

(WHO 2020년도 기준)

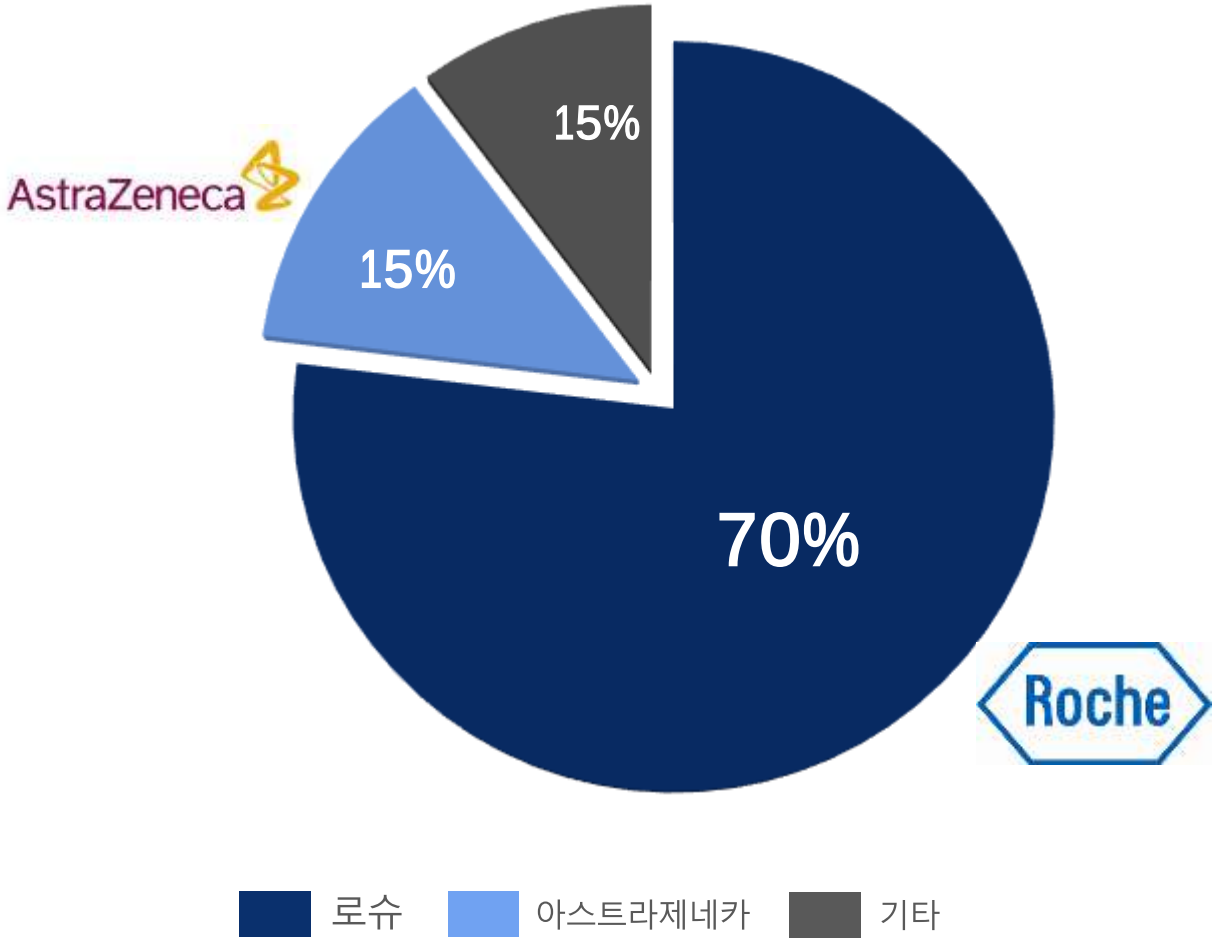


➢ 간암 1차치료제 승인 약물

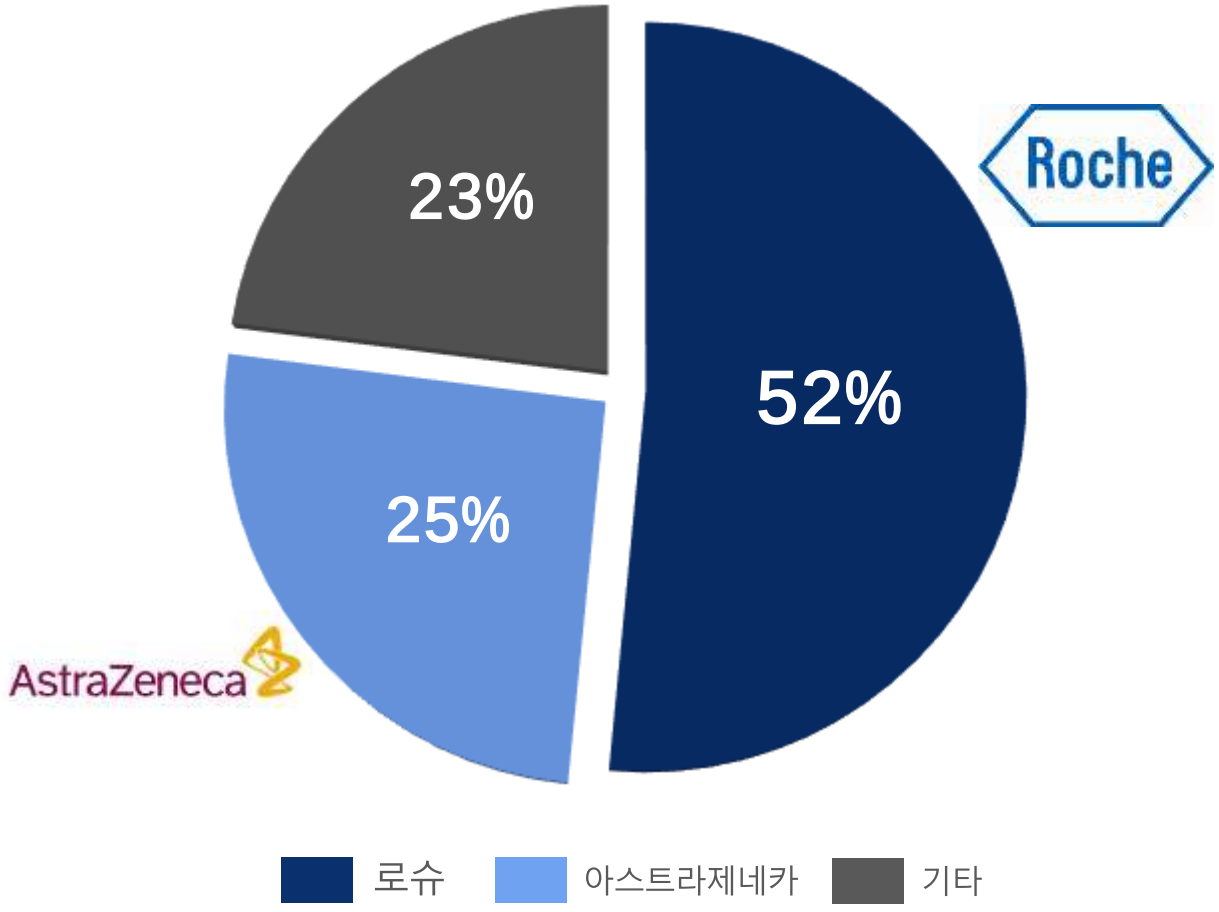


간암 1차 치료제 시장 점유율

23년 2월 말 기준



23년 11월 말 기준



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

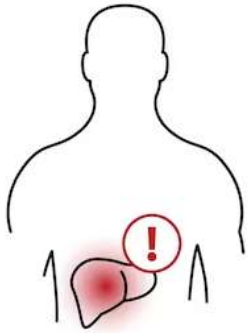
25

마케팅 파워 1. Data - Best-in-Class in HCC

1

환자 생존기간 최대 연장

2



간기능 저하 환자에서 우월한 유효성 확인

3

출혈 고위험 환자에 사용 가능

4

발병 원인 무관한 치료효과

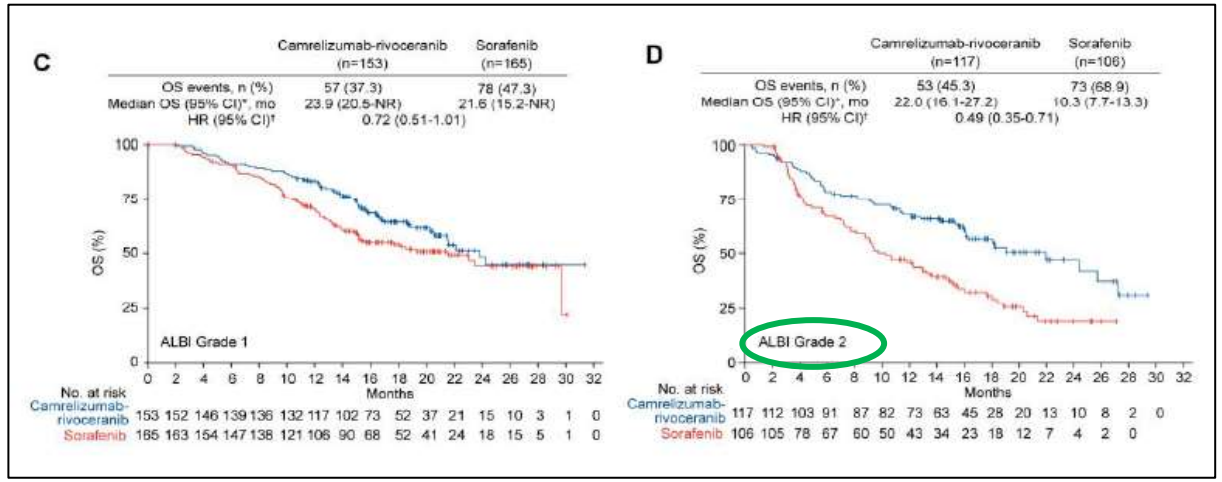
간암 임상에서 최장 생존기간 확인

Sorafenib	Lenvatinib	Durvalumab + Tremelumumab	Atezolizumab + Bevacizumab	Rivoceranib + Camrelizumab
10.7 개월	13.6 개월	16.4 개월	19.2 개월	22.1 개월

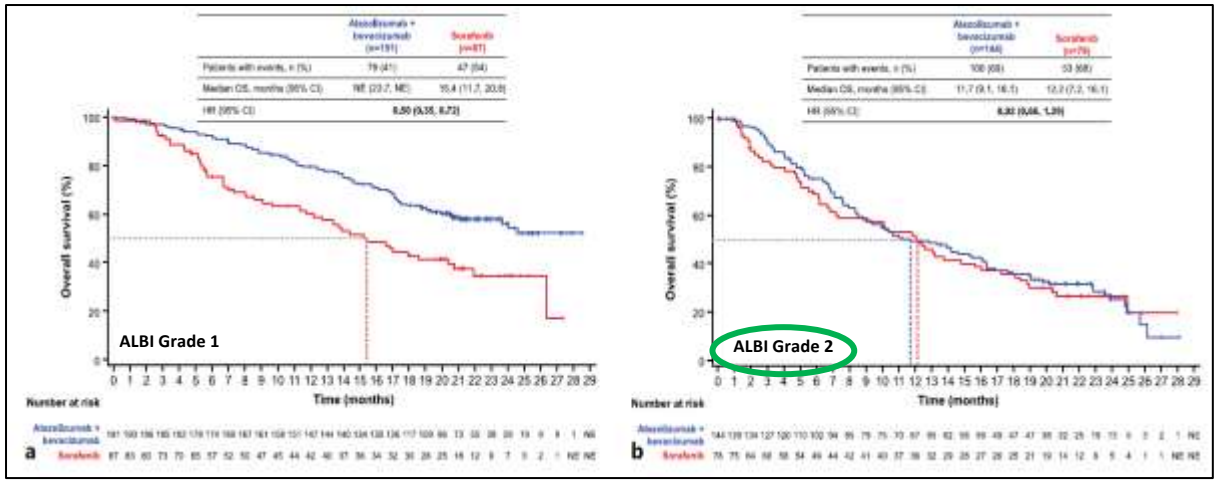
➢ 간암 치료제 중 최장 환자 생존기간 22.1개월

간기능 저하 환자에서의 치료 효과 확인

CARES-310 Rivoceranib + Camrelizumab



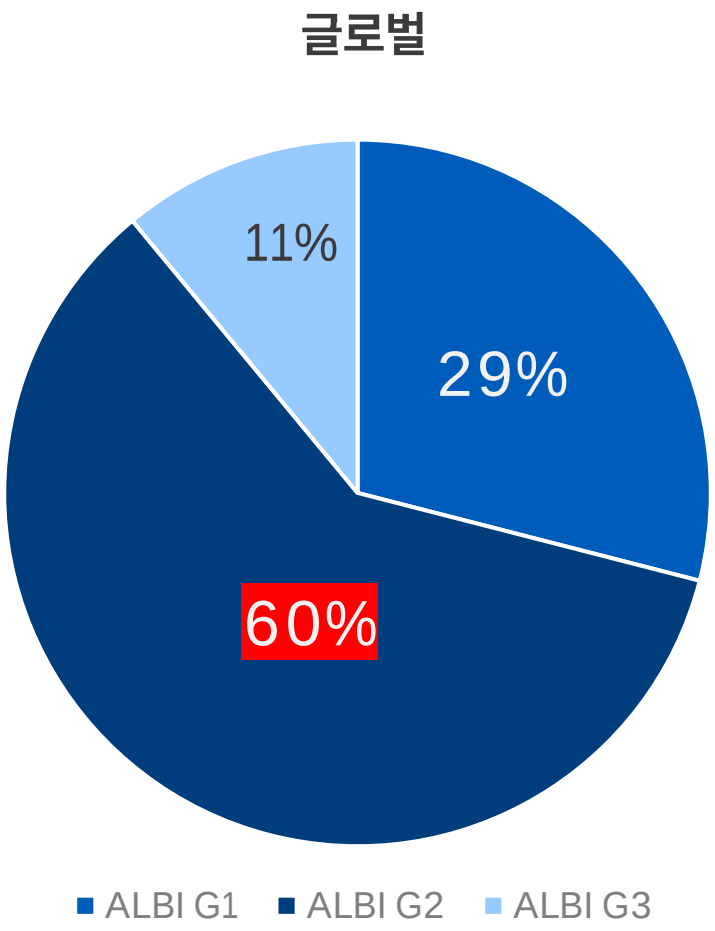
IMbrave 150 Atezolizumab + Bevacizumab

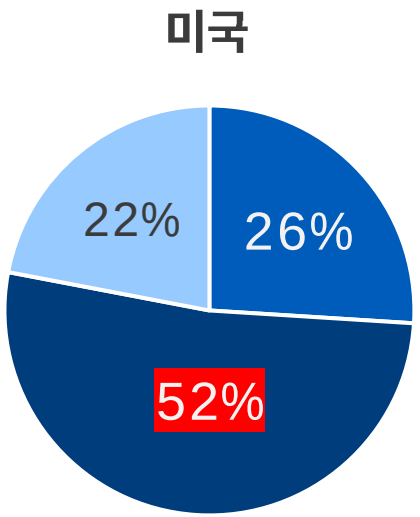


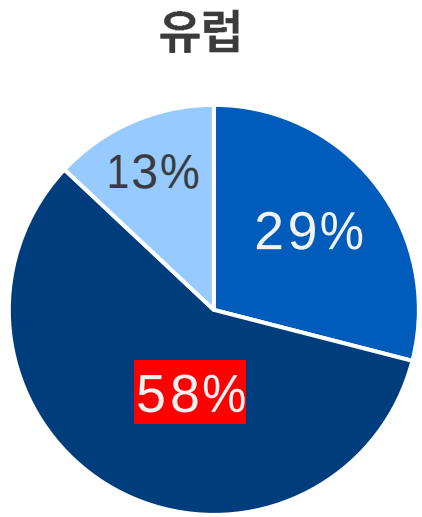
- ✓ **ALBI (Albumin-Bilirubin)** : 빌리루빈과 알부민 수치를 계산하여 간세포 암 환자의 **간기능을 평가**하기 위한 점수. 간기능이 저하될수록 grade가 높아짐
- ✓ 리보세라닙은 간암이 많이 진행되어 간기능이 저하된 환자에서도 우월하게 작용함

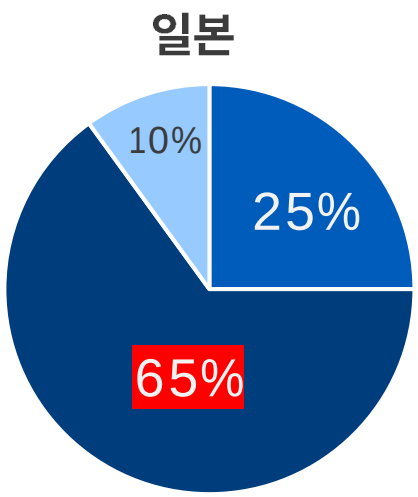
Ref. supplementary appendix
Lancet 2023; published online July 24. https://doi.org/10.1016/S0140-6736(23)00961-3

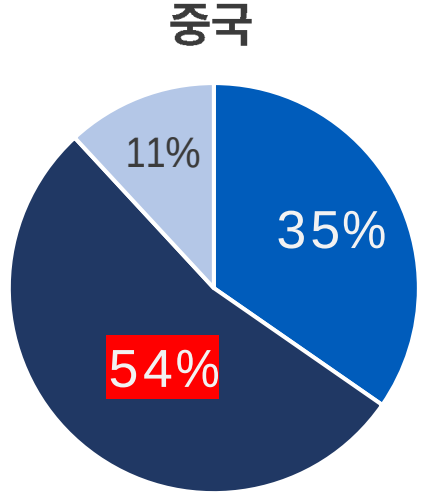
ALBI Grade 별 환자 구성표











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

기존 간암 치료제의 위장관 출혈 문제

❖ FDA 의 아바스틴 설명서 중 부작용 경고문

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

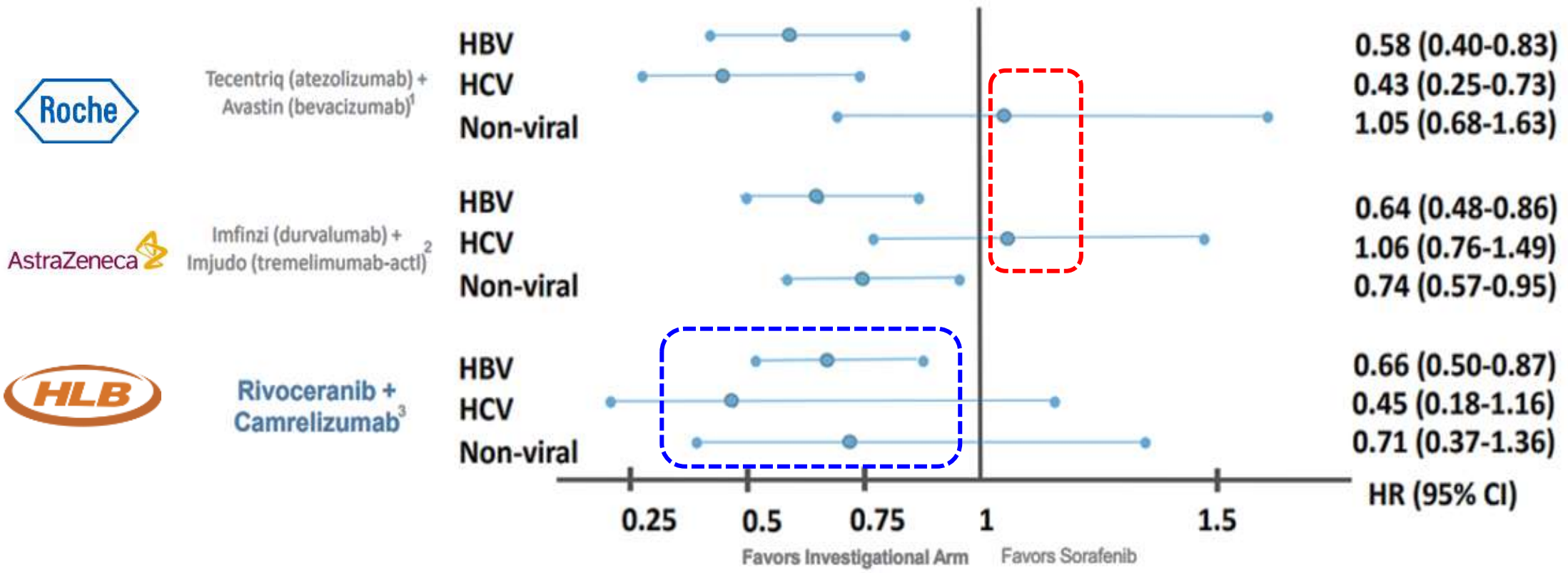
5.3 Hemorrhage

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 **아바스틴** 설명서에서 **출혈위험**이 있는 간암 환자의 사용에 대하여 **경고**함
- ✓ **아바스틴**의 경우 반감기가 **20일**로 부작용에 대한 대처가 어려움
- ✓ 반면, **리보세라닙**은 출혈이 거의 없으며 반감기 또한 **11시간** 수준임

※ 반감기: 약물의 혈중 농도가 절반으로 줄어드는데 걸리는 시간

간암 1차 치료제의 병인별 약효 비교



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

마케팅 파워 2: 세계 석학들의 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

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

Ghassan K. Abou-Alfa 교수

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

Stephen Chan 교수

마케팅 파워 3. 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)

마케팅 파워 4. Bayer와 Southwestern Texas대 논문 09/12/2023

P-93 **REAL-WORLD (RW) SYSTEMIC TREATMENT PATTERNS IN US PATIENTS (PTS) WITH HEPATOCELLULAR CARCINOMA (HCC): 2020–2022**

Amit G. Singal [1], Kirhan Özgürdal [2], Xiaozhou Fan [3], Zdravko Vassilev [3], Xiaoyun Pan [3], Chi-Chang Chen [4], Jasjit Multani [5], Zifan Zhou [4], Jing He [6], Federica Pisa [7]

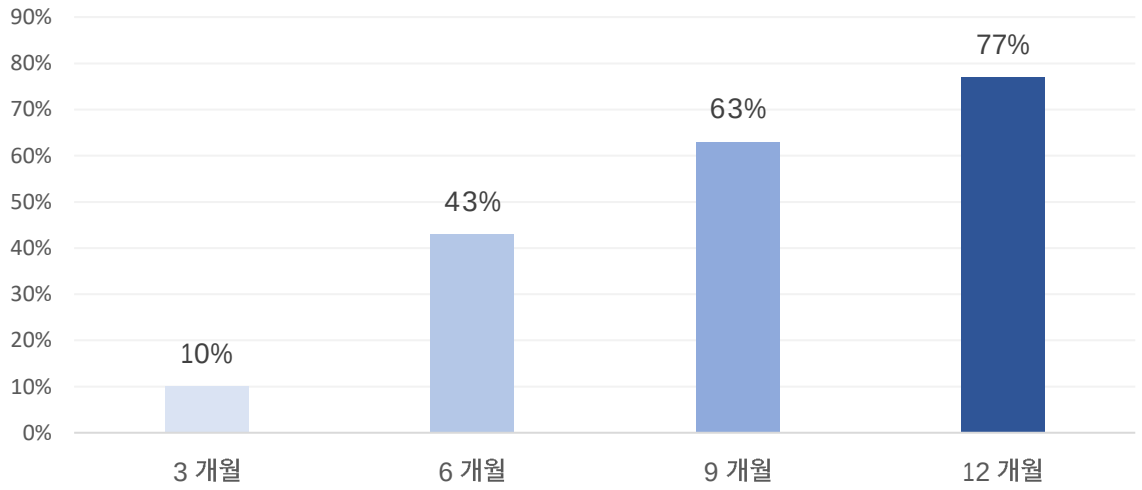
[1] Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX, USA; [2] Bayer Consumer Care AG, Basel, Switzerland; [3] Bayer HealthCare Pharmaceuticals, Whippany, NJ, USA; [4] Real World Evidence Solutions, IQVIA US, Plymouth Meeting, PA, USA; [5] Real World Evidence Solutions, IQVIA US, Falls Church, VA, USA; [6] Advanced Analytics, IQVIA US, Plymouth Meeting, PA, USA, [7] Bayer AG, Berlin, Germany

Introduction: Treatment options for pts with advanced HCC have expanded with the approval of new agents, including atezolizumab plus bevacizumab (atezo+bev), which is the first-line (1L) standard of care for eligible pts. RW evidence for subsequent therapies following atezo+bev is needed as there is no clear guidance on follow-up treatments for HCC. Therefore, this study describes RW 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



- ✓ Ate/Beva 복용환자 77%가 12개월 이내 치료를 중단함
- ✓ Ate/Beva의 평균 치료 중단 기간은 5.1개월로 나타남

*대표적인 부작용인 위/장간 출혈로 인한 복용 중단 및 간기능이 악화된 환자에게 약효가 없어 다른 약으로 대체 됐을 거라 판단됨

마케팅 파워 5. ESMO 2023 초록 by Eisai (10/23/2023)

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

Presentation Number 1007P
Speakers David Trueman (London, United Kingdom)
Onsite Poster display date Monday, 23 October 2023

Abstract

Background

This research compared the relative efficacy of lenvatinib monotherapy (mono), a standard of care for treatment of uHCC, versus approved / anticipated comparators. Using inverse probability of treatment weighting (IPTW) and an NMA, updated evidence for lenvatinib mono from LEAP-002, in addition to evidence from REFLECT, were included in the analyses.

Methods

Randomized controlled trials (RCTs) were identified via systematic literature review. REFLECT and LEAP-002 investigated lenvatinib mono in uHCC, with patient-level data 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 match 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)
Tislelizumab	0.88 (0.71, 1.11)	0.51 (0.41, 0.65)
Tremelimumab 300 mg + durvalumab	0.97 (0.77, 1.20)	0.63 (0.51, 0.78)
Atezolizumab + bevacizumab	1.14 (0.86, 1.51)	0.87 (0.67, 1.13)
Camrelizumab + apatinib	1.21 (0.92, 1.60)	1.09 (0.82, 1.44)

Bold = significant resultAbbreviations: CrI, credible interval; HR, hazard ratio; OS, overall survival; PFS, progression-free survival

Conclusions

These results suggest that patients with uHCC treated with lenvatinib mono have similar or significantly improved OS and PFS when compared with other therapies.

Legal entity responsible for the study

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**

특히 주목할 내용(지속 가능한 성장)

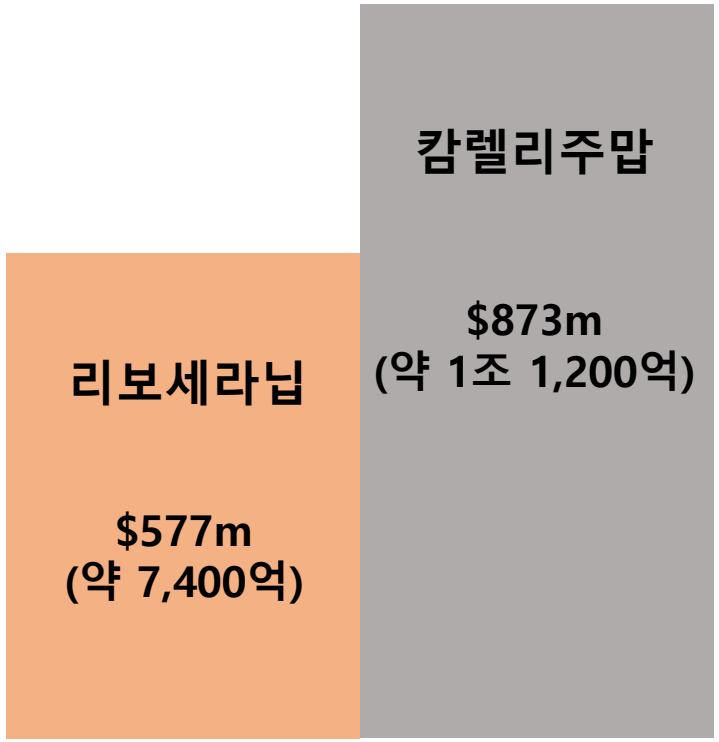
1. Camrelizumab 상업적 권리(판권) 인수(2023.10)

2. 항암제의 기본적 확장성

3. HCC 임상 경로를 따라 갈 다수의 파이프라인

리보세라닙 적응증 확장성

리보세라닙/캄렐리주맙 중국 내 매출 (2023년 기준)



리보세라닙	캄렐리주맙
위암 3차	간암 (1/2차)
간암 1차	비소세포폐암 1차
간암 2차	위/식도암 1차
	호치킨 림프종 3차
	비인두암 2차

출처: PharmExec.com, Bloomberg

리보세라닙 적응증 확장성

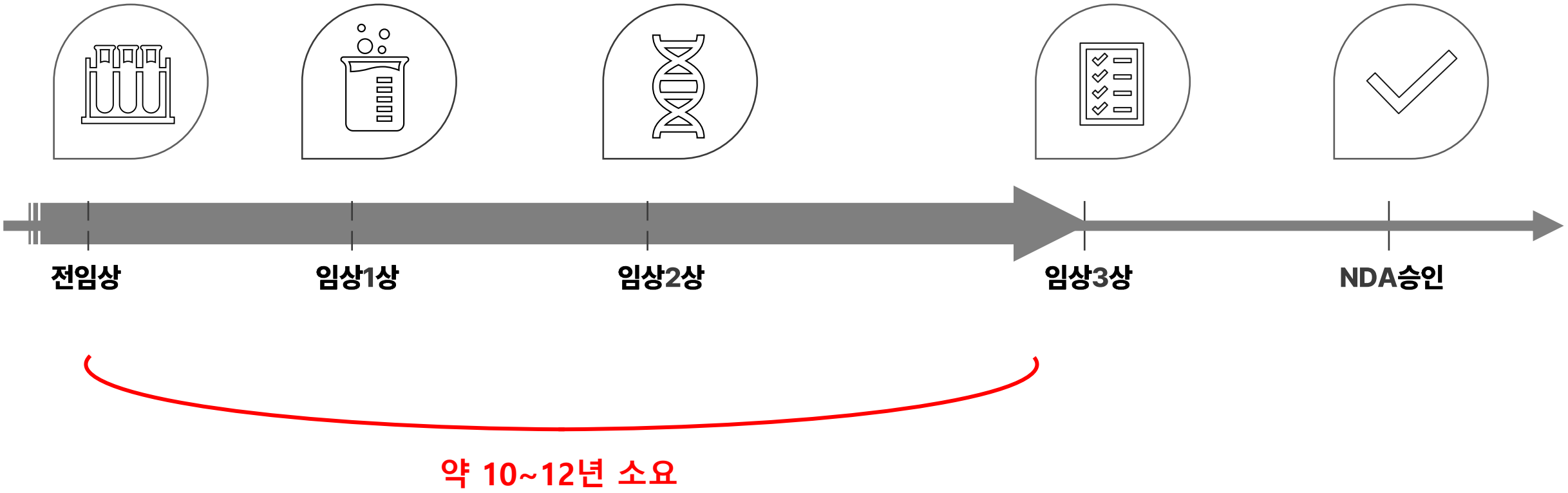
리보세라닙 단독/병용 완전 관해 사례

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)

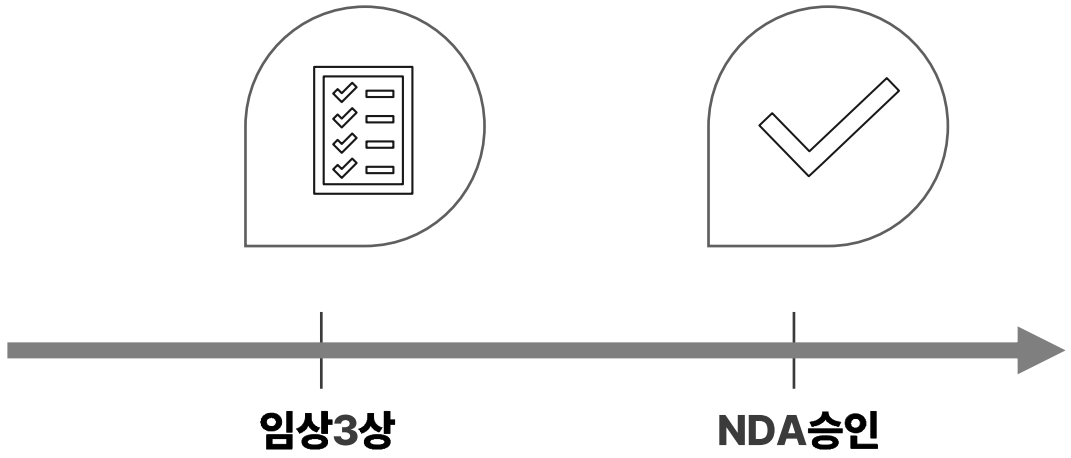
리보세라닙 적응증 확장성

임상 단계별 예상 비용 및 시간



리보세라닙 적응증 확장성

리보세라닙 임상3상 현황 (병용 포함)



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

출처: Precedence Research, Pharmanews Intelligence, Market Research Future, Yahoo Finance

HLB

Human

Life

Better