



2023

HLB

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2023년 12월 21일

HLB 글로벌투자전략팀

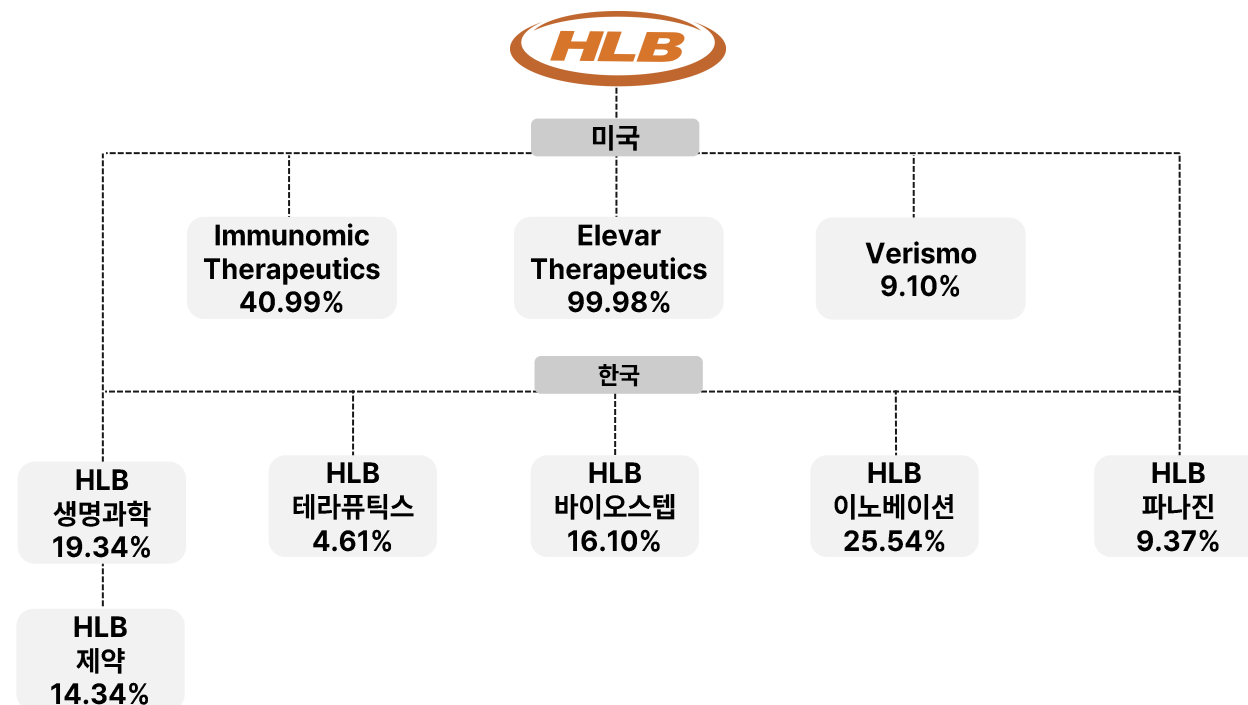


회사 개요

회사 요약

대표이사	진양곤, 백윤기
R&D 인력	205명
사업내용	바이오 · 헬스케어
본점소재지	세종특별자치시
자본금 (2023 3Q)	645 억원
자산 (2023 3Q)	1조 1,100 억원
부채 (2023 3Q)	726 억원
부채비율 (2023 3Q)	6.5%
시가총액 (2023.12.20)	6조 3,870억원

HLB 계열사 구조



“진단에서 치료까지, 2~3세대 항암제에서 차세대 CAR-T치료제까지 ”

주요 파이프라인

회사명	적응증	권리	단독/병용	임상진행 상황				
				전임상	1상	2상	3상	NDA
Elever Therapeutics	간암 (HCC) 1차	글로벌 (중국제외)	Rivoceranib + Camrelizumab 병용	[Progress bar from Pre-clinical to NDA]				
	선낭암 (ACC) 1차		Rivoceranib 단독	[Progress bar from Pre-clinical to Phase 2]				
	위암 3/4차		Rivoceranib 단독	[Progress bar from Pre-clinical to Phase 3]				
	위암 2차		Paclitaxel 병용	[Progress bar from Pre-clinical to Phase 2]				
	대장암 3차		Lonsurf 병용	[Progress bar from Pre-clinical to Phase 2]				
Immunomic Therapeutics	교모세포종 (ITI-1000)	글로벌	Dendritic Cell vaccine	[Progress bar from Pre-clinical to Phase 2]				
	교모세포종 (ITI-1001)		DNA vaccine	[Progress bar from Pre-clinical to Phase 1]				
	메르켈세포암 (ITI-3000)		DNA vaccine	[Progress bar from Pre-clinical to Phase 1]				
Verismo Therapeutics	고형암 (SynKIR-110)	글로벌	CAR-T 치료제	[Progress bar from Pre-clinical to Phase 1]				

간암1차 치료제 임상데이터 비교



약물	Rivoceranib + Camrelizumab	Atezolizumab + Bevacizumab	Tremelimumab + Durvalumab	Lenvatinib	Sorafenib
환자 수	543명	501명	782명	954명	602명
대조군	Sorafenib	Sorafenib	Sorafenib	Sorafenib (비열등성)	Placebo
OS	22.1 vs. 15.2 HR 0.62	19.2 vs 13.4 HR 0.66	16.4 vs 13.8 HR 0.78	13.6 vs 12.3 HR: 0.92	10.7 vs 7.9 HR: 0.69
PFS	5.6 vs. 3.7 HR 0.52	6.8 vs 4.3 HR 0.59	3.8 vs 4.1 HR 0.9	7.4 vs 3.7 HR: 0.66	5.5 vs 2.8
ORR	25.4% vs. 5.9%	27.3% vs 11.9%	20.1% vs 5.1%	18.8% vs 6.5%	2% vs 1%
DCR	78.3% vs. 53.9%		73.6% vs. 55.3%		43% vs 32%
시장 점유율	50% 목표	52%	25%		
비고	*NDA 심사중	2020년 승인	2022년 승인	2018년 승인	2007년 승인

리보세라닙/캠렐리주맙 주요 현황

Drug	Combination	Indications	Approval date	Line
Rivoceranib	camrelizumab	1st-line unresectable or metastatic hepatocellular carcinoma	2023.02	1 st
		Advanced hepatocellular carcinoma	2020.12	2 nd
		Gastric adenocarcinoma or gastroesophageal junction adenocarcinoma	2014.12	3 rd
Camrelizumab	Rivoceranib	1st-line unresectable or metastatic hepatocellular carcinoma	2023.02	1 st
	cisplatin+paclitaxel	1st-line unresectable locally advanced/relapsed or metastatic esophageal squamous cell carcinoma	2021.12	1 st
	cisplatin+gemcitabine	1st-line locally relapsed or metastatic nasopharyngeal carcinoma	2021.06	1 st
		Relapsed and refractory classical Hodgkin lymphoma after at least two systematic therapies	2021.06	3 rd
		Advanced nasopharyngeal carcinoma progressed after or intolerable to 2nd-line+ chemotherapy	2021.04	2 nd
	carboplatin+paclitaxel	1st-line locally advanced/metastatic sq-NSCLC	2020.06	1 st
		Locally advanced or metastatic esophageal adenocarcinoma progressed after or intolerable to 1st-line treatment	2020.06	1 st
	pemetrexed+carboplatin	Unresectable locally advanced or metastatic EGFR-mut ALK-negative NSCLC	2020.06	1 st
	Advanced hepatocellular carcinoma after sorafenib and/or oxaliplatin-containing chemotherapy treatments	2020.03	2 nd	

리보세라닙 NDA 진행 현황



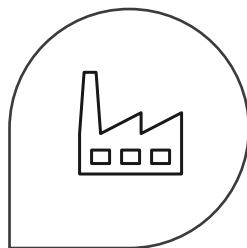
2023. 05

- NDA 신청



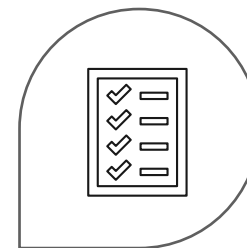
2023.07

- NDA 본 심사개시



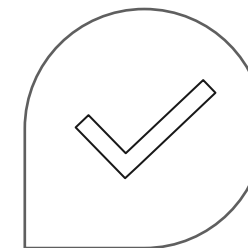
2023. 11/12

- FDA Mid-Cycle Review 이슈 없이 **완료**
- 리보세라닙 현장 실사 **완료**



2024. 03

- Final Review 예정



2024. 05

- FDA NDA 승인 결과 발표

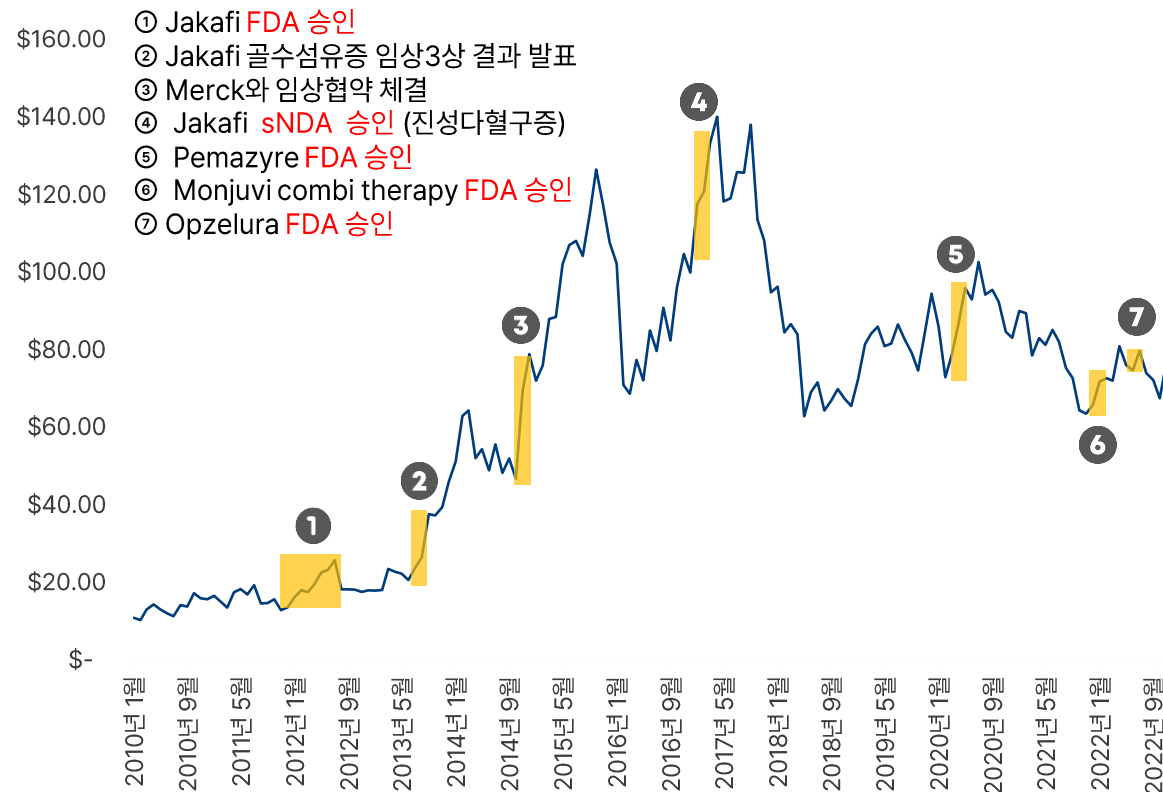
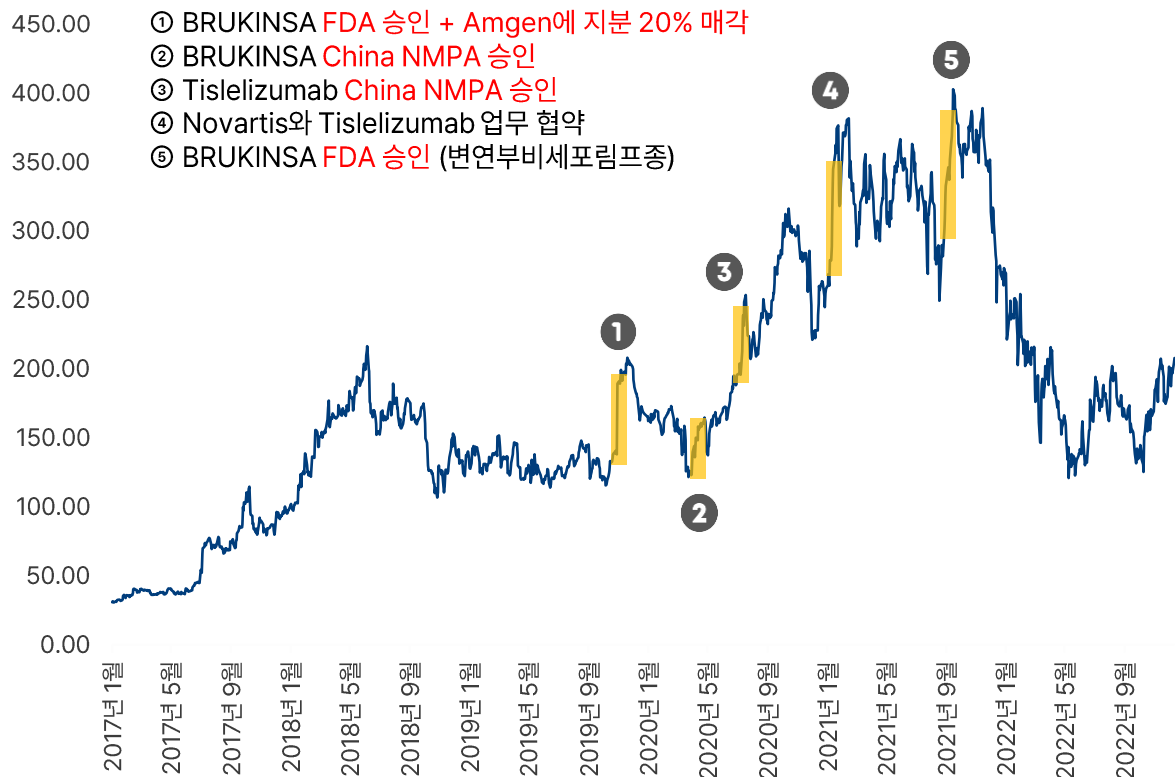
바이오텍 기업 비교 테이블



	HLB	BeiGene	Incyte	Eisai
설립일	10. 18, 1985	10. 28, 2010	04. 08, 1991	12.06, 1941
본사	서울, 한국	베이징, 중국 캠브릿지, 미국	월명턴, 미국	도쿄, 일본
IPO	KOSDAQ (KR)	NASDAQ (US), HKEX (HK), SSE (CH)	NASDAQ (US)	NIKKI (Japan)
시가총액	6조 3,870억원	\$19.9B (약 26조원)	\$13.9B (약 18조원)	\$14.2B (약 18조원)
주식 총 수	128,929,651	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	\$13.3B	\$10.05B	\$3.0B	\$27.2B

*매출, 시가총액, 주식총수 2023년 6월 말 기준, 시장 규모는 적응증 총합 규모

주요 이벤트 타임라인 및 주가 추이



간암1차 치료제 NDA승인이후 매출 추이



(in Thousands USD)

(in Thousands USD)

	BRUKINSA	Tislelizumab	Total
2017	-	-	\$238,387
2018	-	-	\$198,220
2019	\$1,039	-	\$428,212
2020	\$41,702	\$163,358	\$308,874
2021	\$217,987	\$255,119	\$1,176,283
2022	\$564,651	\$422,885	\$1,254,612

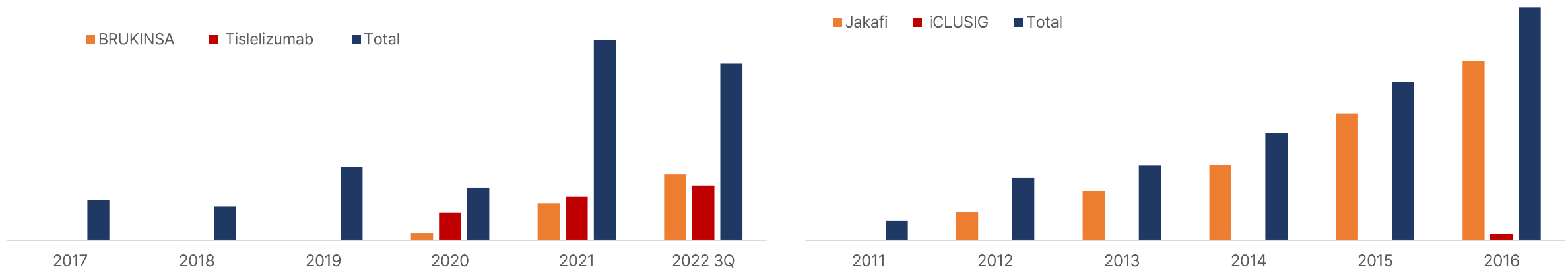
	Jakafi	iCLUSIG	Total
2011	\$2,012	-	\$94,455
2012	\$136,001	-	\$297,059
2013	\$235,443	-	\$354,947
2014	\$357,562	-	\$511,495
2015	\$601,015	-	\$753,751
2016	\$852,800	\$29,600	\$1,105,719

BRUKINSA
FDA Approval
Tislelizumab
NMPA Approval

Jakafi
FDA Approval

BRUKINSA Tislelizumab Total

Jakafi iCLUSIG Total



Eisai의 성장



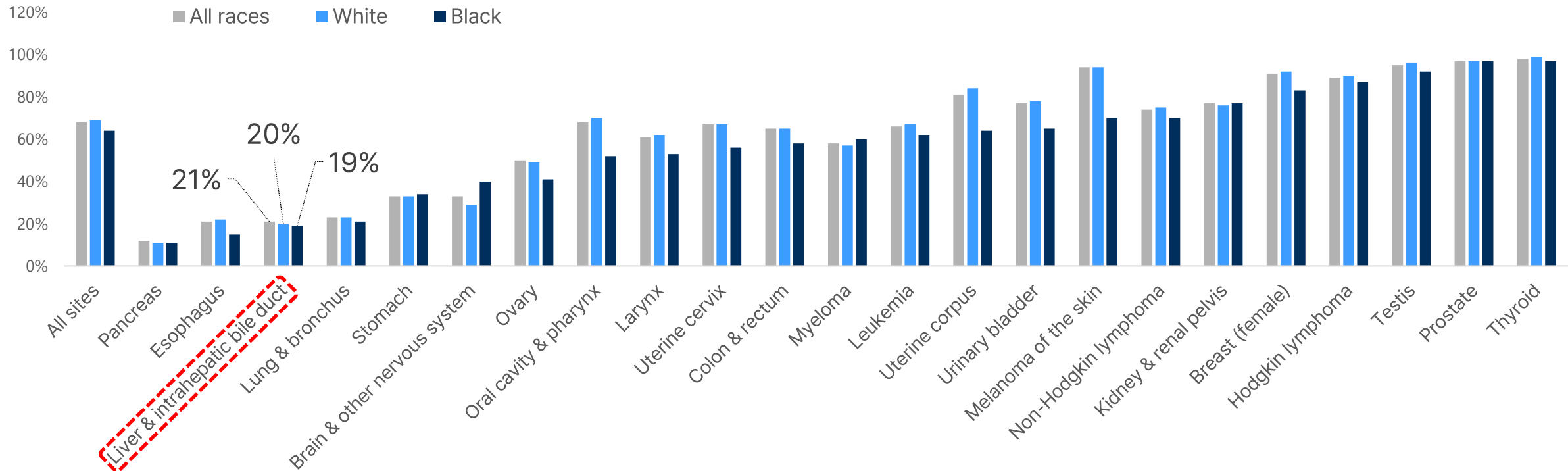
주요 파이프라인

약물명	치료 분야	FDA 승인 시기	매출
Lenvima	갑상선암	Feb. 2015	1조 3,248억원
	신장암	May, 2016	
	간암	Aug, 2018	
	자궁내막암 (병용)	Sep, 2019	
	신장암 (병용)	Aug, 2021	
Dayvigo	신경계	Dec, 2019	1,696억원
Halaven	지방육종	Jan. 2016	1,644억원
Fycompa	신경계	Oct. 2012	1,189억원
Leqembi	신경계	Jan, 2023	*35억원

2023년 3월 Annual Report 기준, 병용요법은 모두 머크의 키트루다와 함께 쓰임
 *Leqembi 매출은 23년 1월 FDA 승인 이후, 4월~9월달까지의 매출을 나타냄

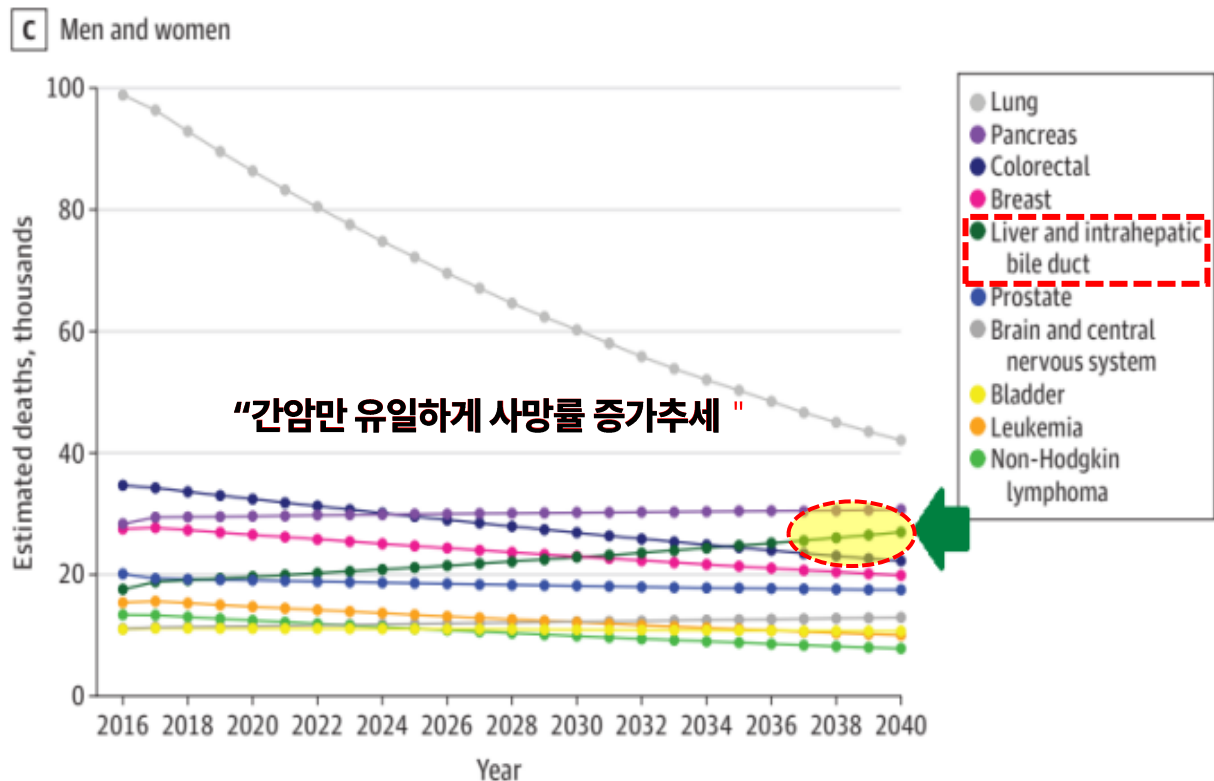
간암1차치료제 시장 성장성

미국 암 질환 별 생존율 비교

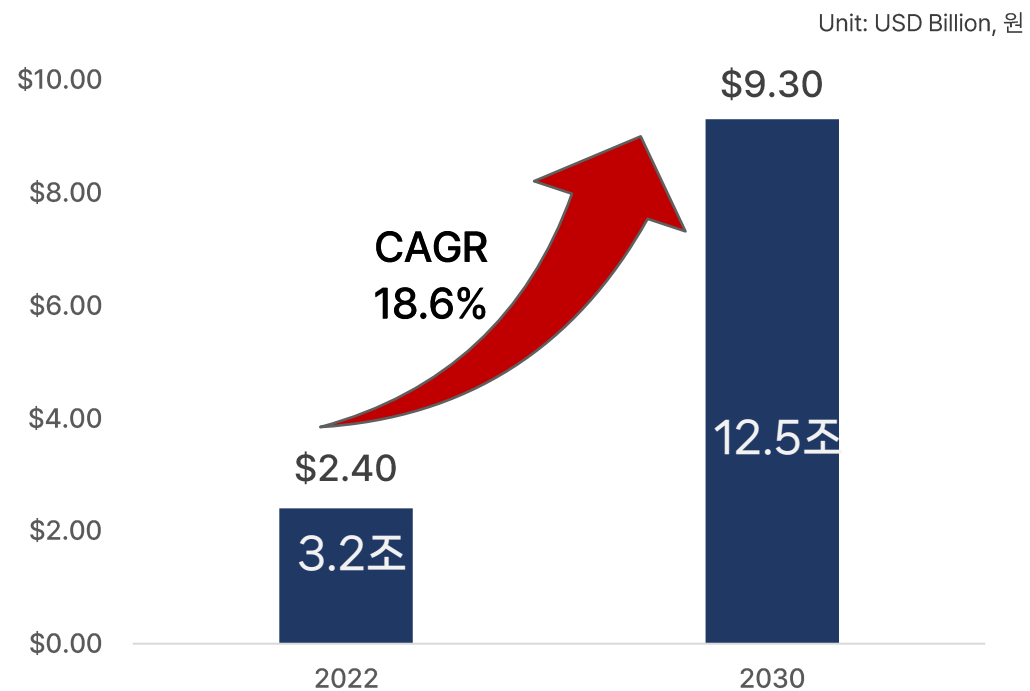


간암1차치료제 시장 성장성

암 종별 사망률 추이

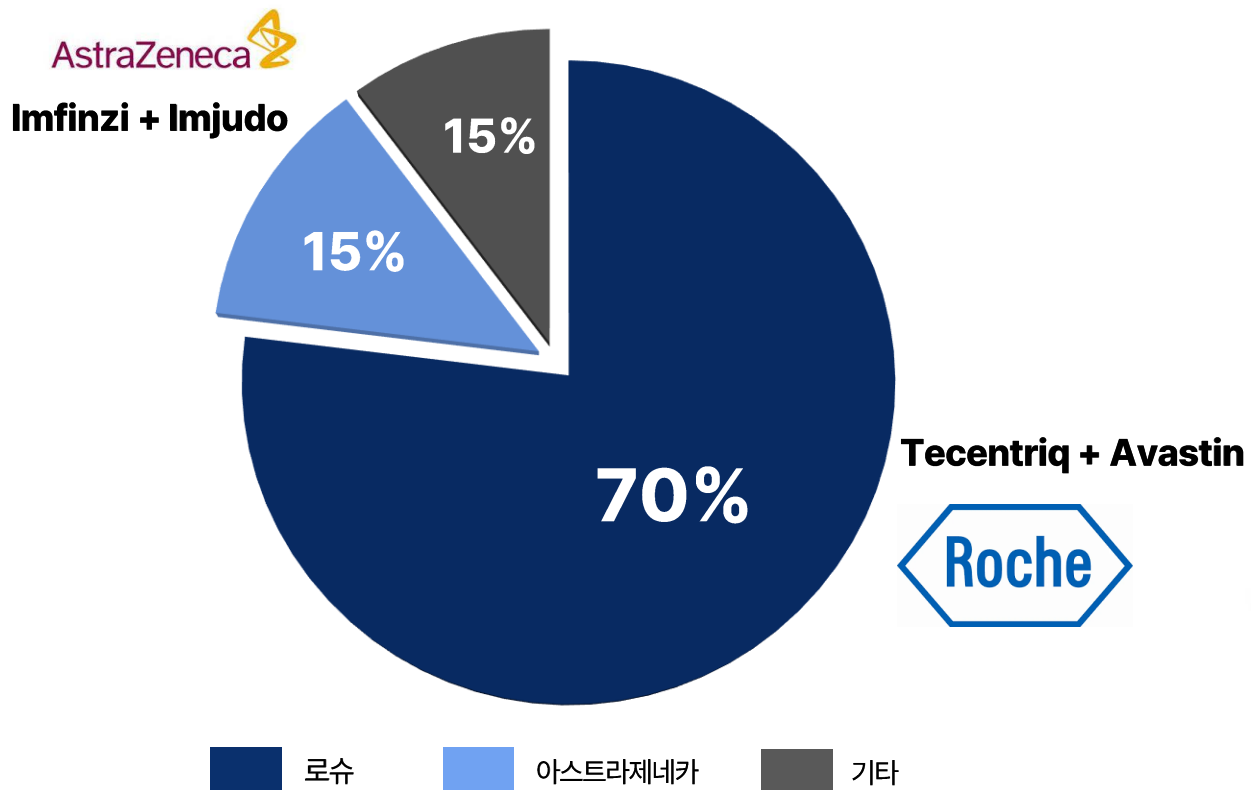


글로벌 간암 치료제 시장 규모

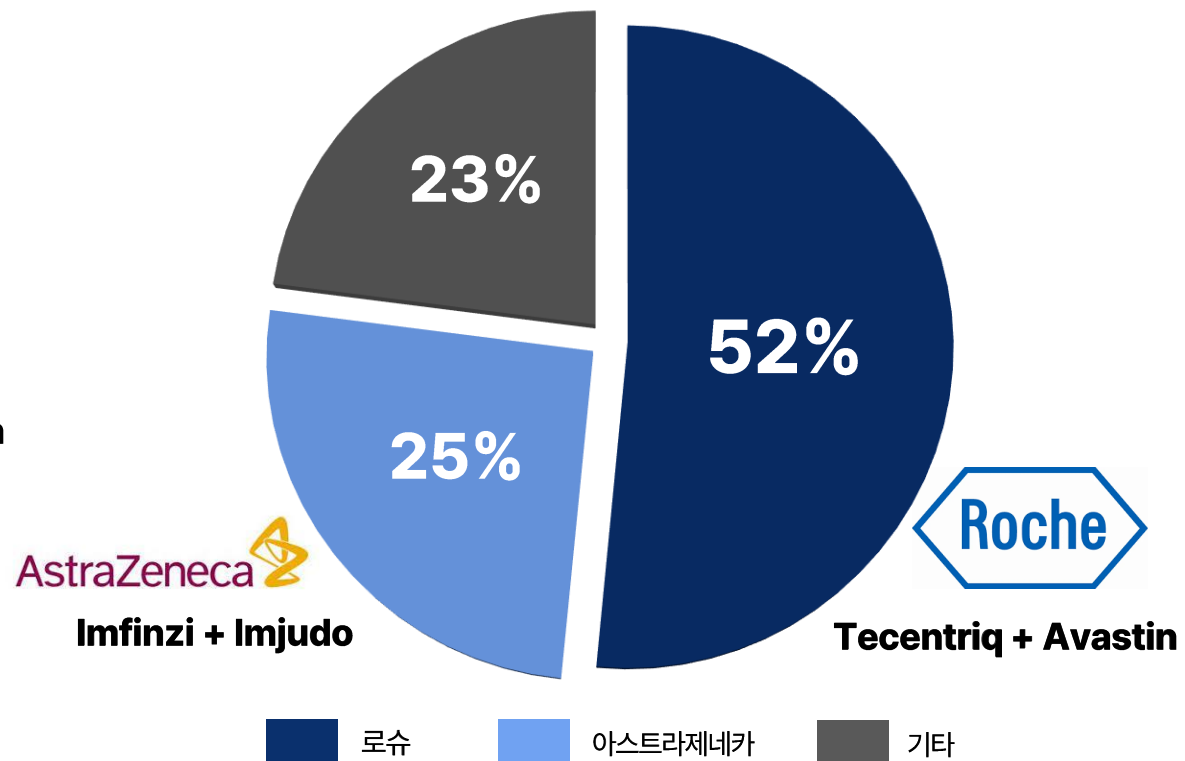


간암1차 시장 경쟁사 점유율

23년 2월 말 기준



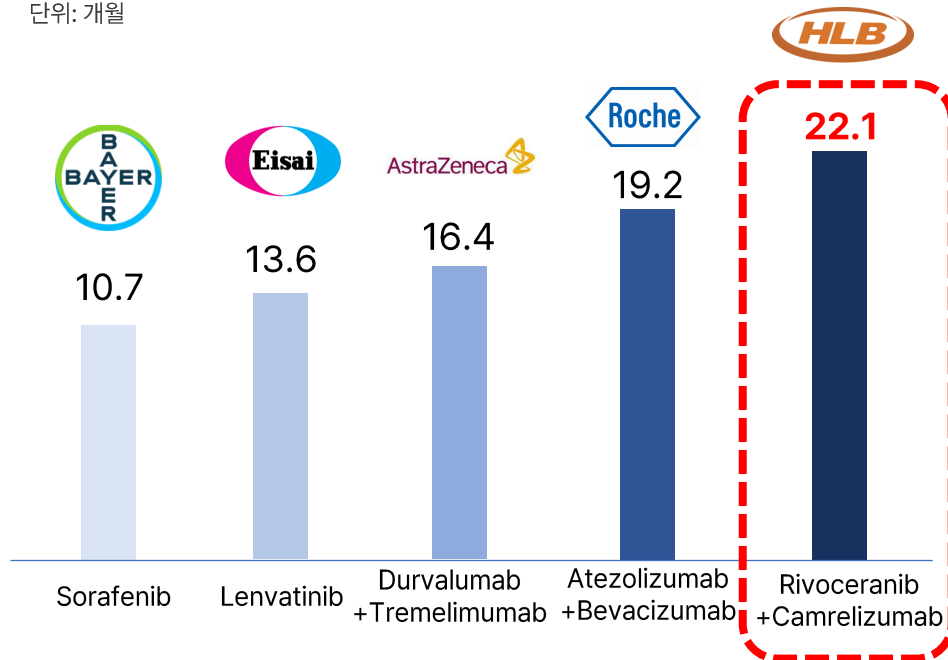
23년 11월 말 기준



Best-in-Class 임상데이터

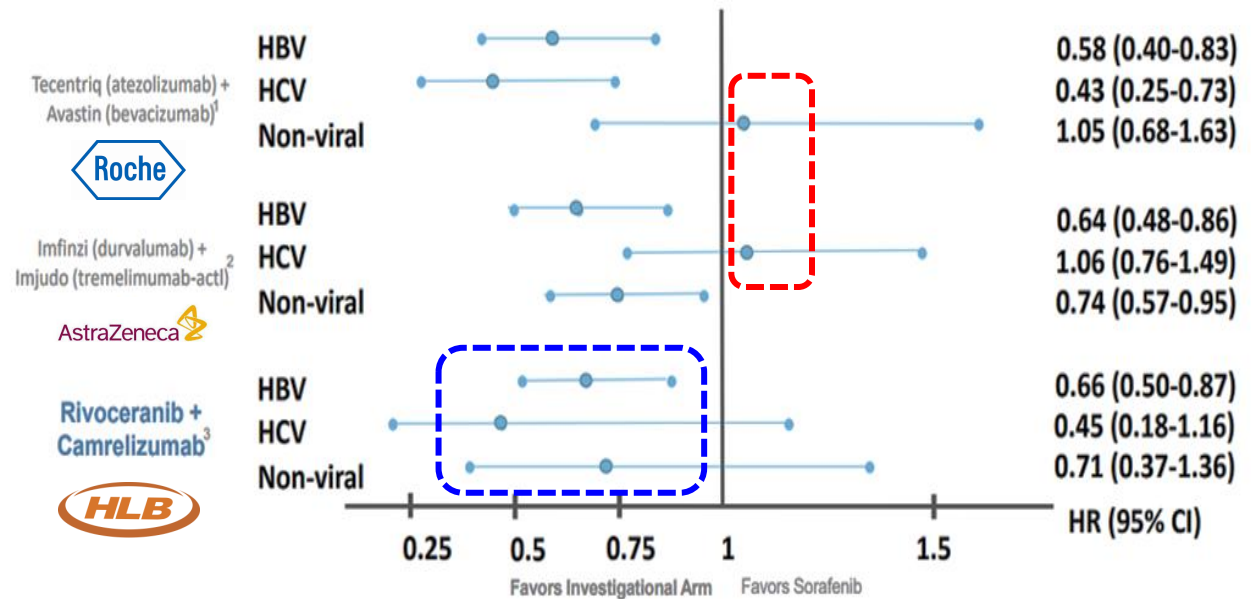
간암 1차치료제 OS (생존 기간) 비교

단위: 개월



- ✓ 리보세라닙/캠렐리주맙, 현 간암1차치료제 중 역대 최장 생존기간 (OS) 22.1개월을 기록

간암 발병 인자 종류별 약효 비교

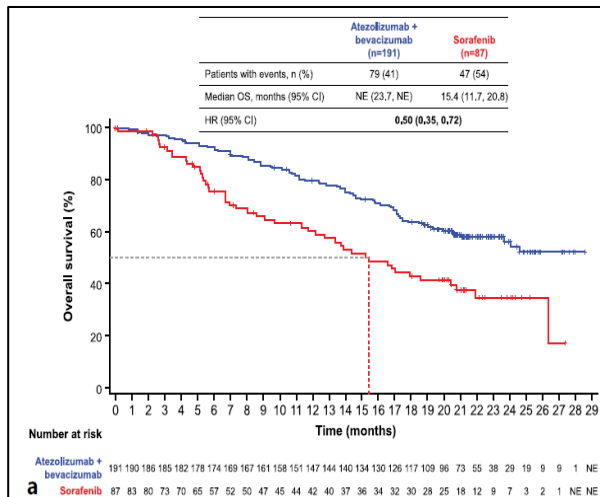


- ✓ 현 간암1차치료제 중 리보세라닙/캠렐리주맙이 유일하게 모든 발병원인 환자 군에게 높은 약효가 입증됨

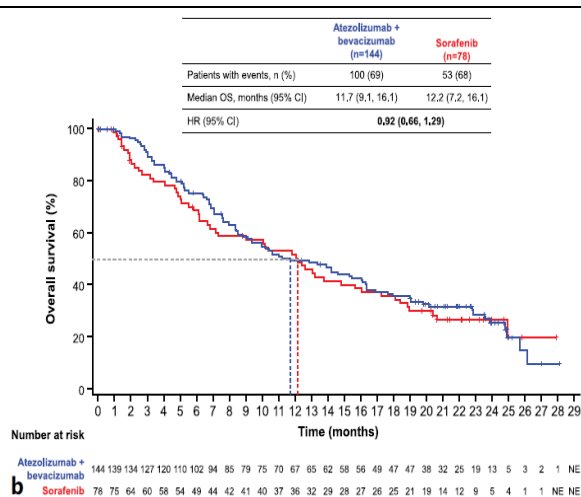
Best-in-Class 임상데이터

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

ALBI 1 Grade



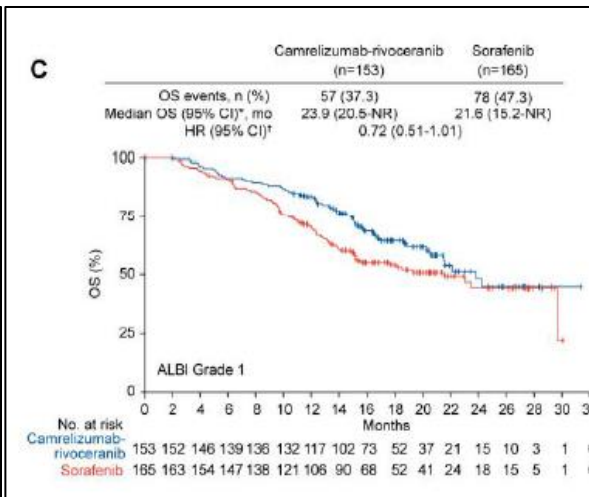
ALBI 2 Grade



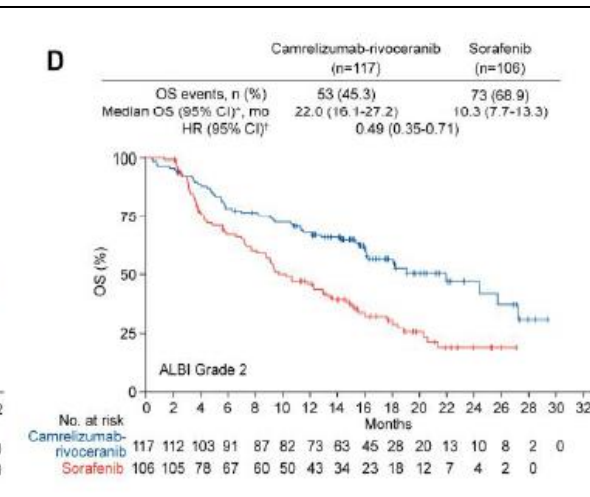
- ✓ ALBI 1등급 환자에게만 약효가 좋으며 간기능이 안 좋은 환자들에게는 약효가 현저히 떨어짐
- ✓ ALBI G1 HR : 0.5 (0.35-0.72), ALBI G2 HR: ****0.92 (0.66-1.29)**

CARES-310 (HLB & Elevar) Rivoceranib + Camrelizumab

ALBI 1 Grade



ALBI 2 Grade

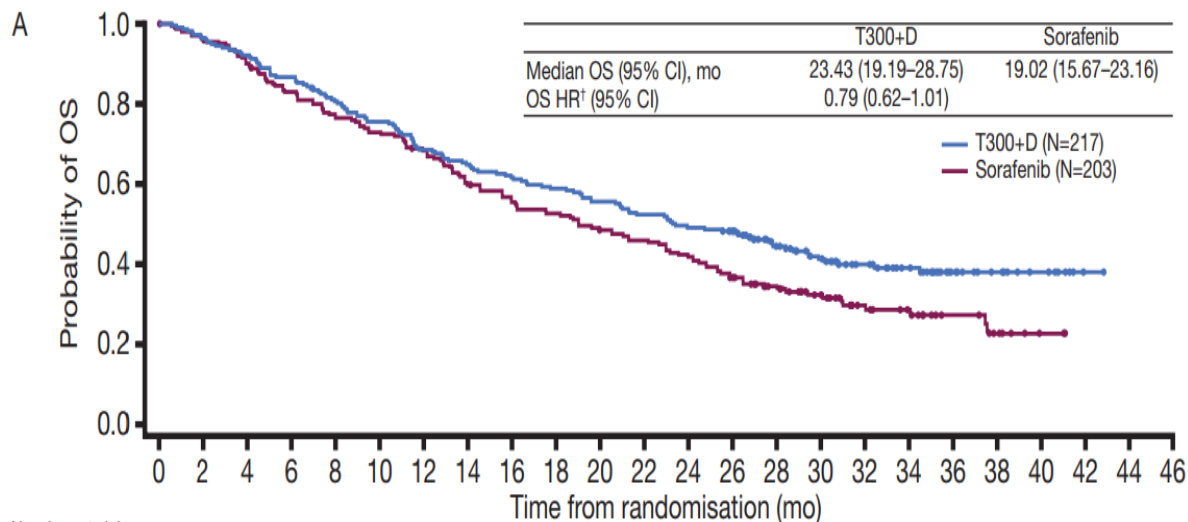


- ✓ ALBI 등급에 상관없이 모든 환자군에 약효가 좋으며 특히 Ate/Beva에서 약효가 없는 ALBI 2등급 환자들에게 우월한 약효를 나타냄
- ✓ ALBI G1 HR: 0.72 (0.51-1.01), ALBI G2 HR: **0.49 (0.35-0.71)**

Best-in-Class 임상데이터

HIMALAYA (AstraZeneca) Tremelimumab (Imjudo) + Durvalumab (Imfinzi)

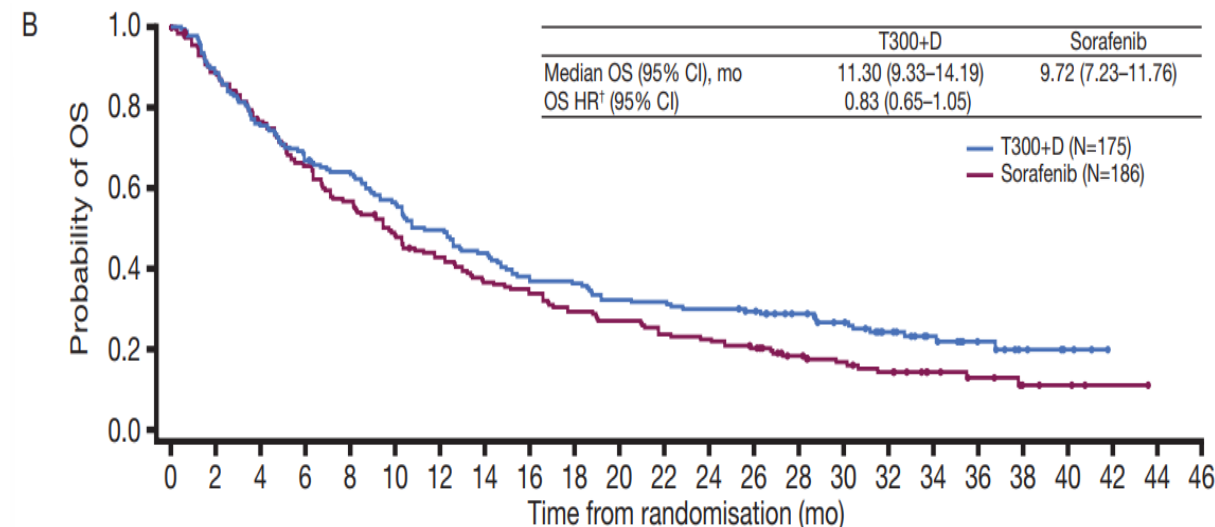
ALBI 1 Grade



Number at risk

Time (mo)	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
T300+D:	217	209	200	188	174	163	148	140	133	127	120	113	106	101	77	63	50	38	21	13	8	1	0	0
Sorafenib:	203	193	180	165	153	144	135	118	110	103	94	89	81	70	53	41	27	21	13	8	2	0	0	0

ALBI 2 Grade

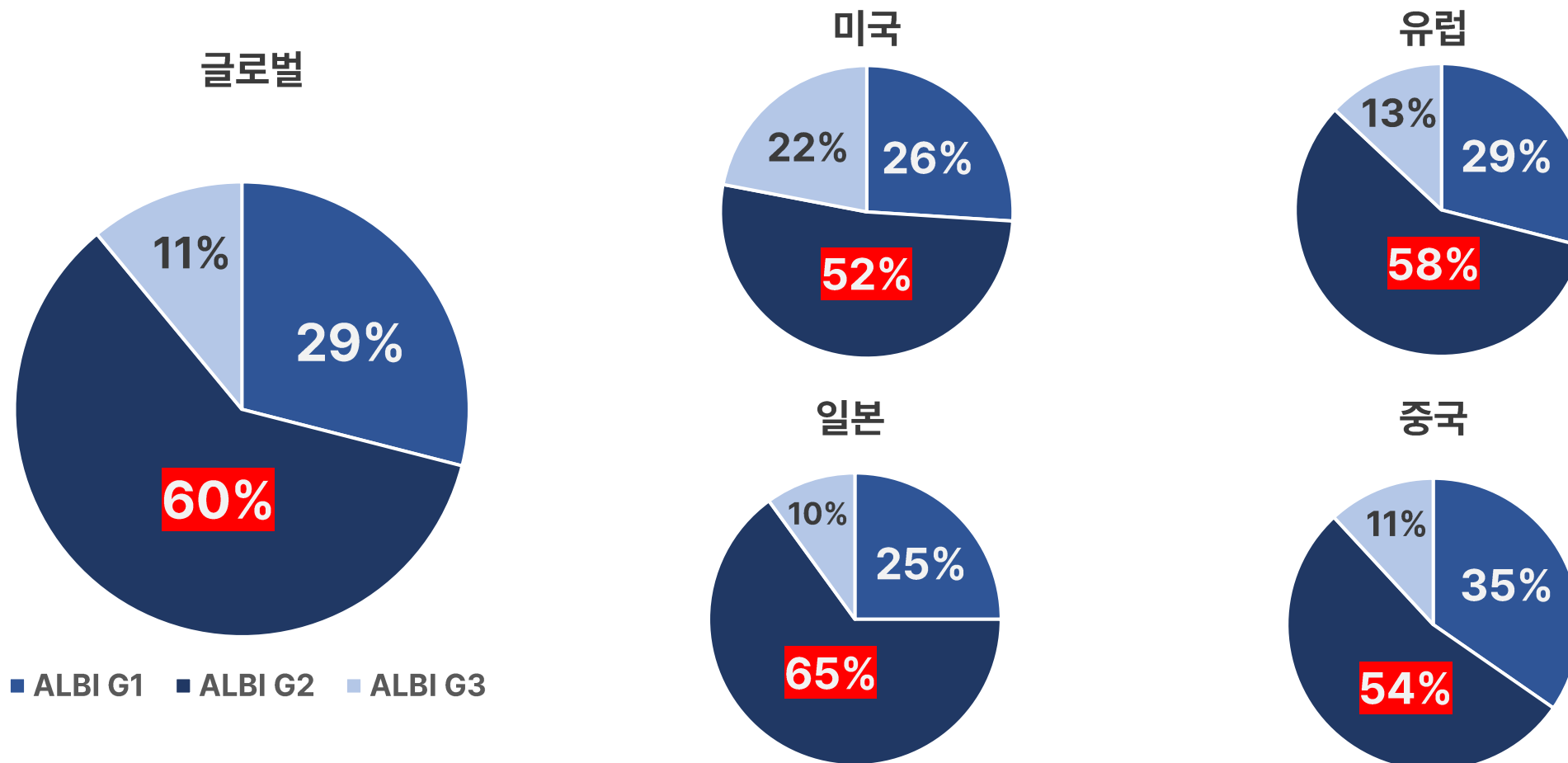


Number at risk

Time (mo)	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46
T300+D:	175	155	132	119	110	98	86	76	64	63	56	55	52	49	42	35	25	17	11	6	3	0	0	0
Sorafenib:	186	163	139	118	102	87	76	65	60	52	48	42	40	36	26	21	17	11	8	4	3	1	0	0

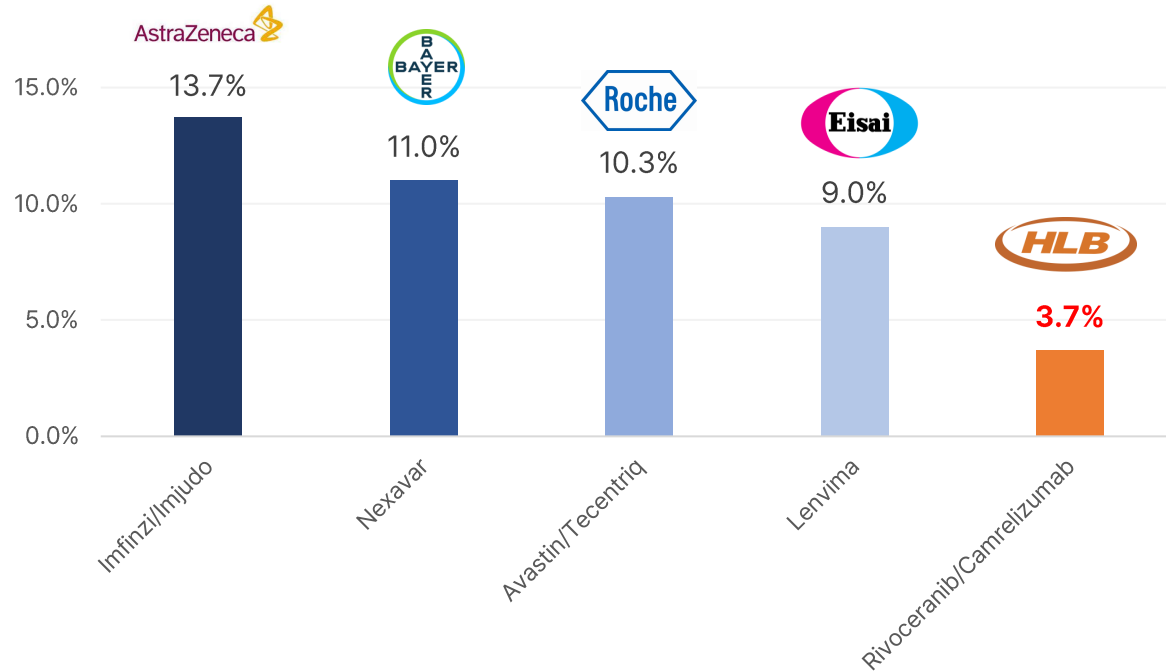
✓ 아스트라제네카의 치료제는 ALBI Grade 2 환자에게 약효가 있지만, 당사의 치료제보다 OS가 약 **5.7개월** 낮아 경쟁력이 낮음

ALBI Grade 별 환자 수



Best-in-Class 임상데이터

간암 1차 치료제 임상 중단율



✓ 로슈의 Ate./Beva 임상 중단율 10.3%

*Ate/Beva의 부작용인 위/장관 출혈로 인한 중단 일 것으로 추측됨

✓ HLB의 리보세라닙/캠렐리주맙 3.7% (최저)

간암1차 치료제 Half-Life 비교

치료제	약물 Half-Life
Sorafenib	25-48 hours
Lenvatinib	48 hours
Atezolizumab+Bevacizumab	20 days
Tremelimumab+Druvalumab	22 days
Rivoceranib+Camrelizumab	11 hours

✓ 현존 하는 간암1차치료제 중 리보세라닙/캠렐리주맙이 가장 낮은 약물 반감기를 가지고 있음

✓ 다른 약물과 달리 부작용 리스크가 적으며 약물 컨트롤이 용이 함

Best-in-Class 임상데이터

향후 간암1차치료제 시장에서의 리보세라닙/캄렐리주맙 후행 약물

회사명	약물명	임상 NCT #	임상 단계	임상 종료 기간
Junshi Biosciences	Toripalimab	NCT04523493	3상	09.01.2026
AstraZeneca	Durvalumab	NCT03847428	3상	08.31.2025
BMS	Nivolumab+Relatlimab	NCT05337137	1/2상	12.15.2026
BMS	Nivolumab	NCT04039607	3상	06.30.2025
Merck	Pembrolizumab	NCT03867084	3상	08.31.2029
LG Chem+AstraZeneca	Tivozanib+Durvalumab	NCT03970616	1/2상	04.04.2023

- ✓ 향후 5년이내, 간암1차 치료제를 목표로 임상 중에 있는 약물 중 5년 내로 상업화가 될 가능성이 있는 약물은 없음
*리보/캄렐의 특허기간은 2038년 + 5년으로 2043년까지 특허 유효
- ✓ 이 기간 동안 리보세라닙/캄렐리주맙의 매출을 극대화할 수 있으며 안정적인 시장점유율을 확보 할 수 있음

Best-in-Class 임상데이터

- ✓ 현재 리보세라닙/캄렐리주맙, 간암1차치료제 중 가장 높은 OS (Overall Survival) 생존기간 22.1개월 보유함
- ✓ 리보세라닙/캄렐리주맙은 타 경쟁사 치료제와 달리 간암 발병 인자와 상관없이 모든 환자군에 높은 약효가 입증 됨
- ✓ 간암1차치료제 시장에서 시장점유율이 가장 높은 Ate/Beva 치료제는 기저 ALBI 1등급 환자에게만 약효가 좋은 반면, 리보세라닙/캄렐리주맙은 기저 ALBI 1,2 등급 환자에게 모두 약효가 나타나며 특히, 경쟁사인 Ate/Beva에서 약효가 없는 ALBI 2등급 환자에게 월등히 좋은 약효가 나타남
- ✓ 리보세라닙/캄렐리주맙, 간암1차 치료제 임상 중 임상중단율이 타 경쟁사 대비 현저히 낮았으며 (객관적 논문으로 재차 입증, 9페이지 참조) 부작용으로 인한 치료 중단 가능성이 매우 낮음
- ✓ 리보세라닙/캄렐리주맙, 약물 반감기가 타 경쟁사 대비 매우 짧은 약 11시간으로, 부작용 발생 시 약물 중단과 부작용 관리가 용이하며, 다른 치료제에 비해 부작용 리스크가 현저히 낮음

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, Yuriy 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+캠렐리주맙 병용요법은 간암분야에서 가장 긴 환자생존율을 보였으며 1차 치료제의 새로운 옵션을 제시한다”
by Ghassan K. Abou-Alfa 교수
(미국 Memorial Sloan Kettering Cancer Center)
- ✓ “리보세라닙과 캠렐리주맙 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+캠렐리주맙 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): 2020–2022

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

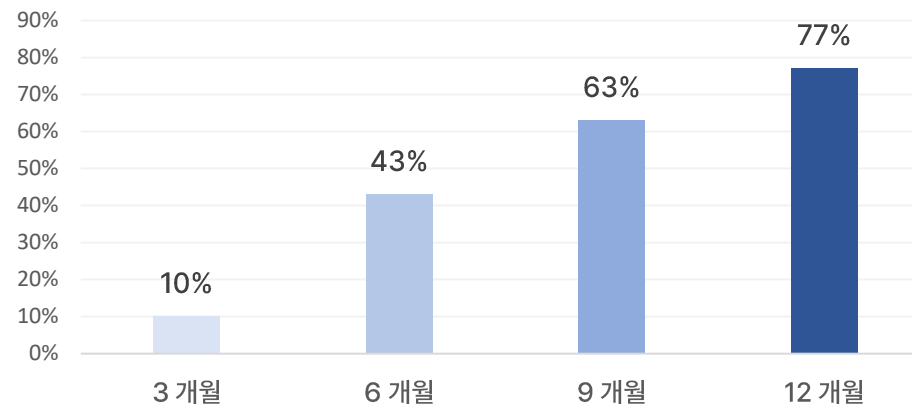
¹ Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas, TX, USA; ² Bayer Consumer Care AG, Basel, Switzerland; ³ Bayer HealthCare Pharmaceuticals, Whippany, NJ, USA; ⁴ Real World Evidence Solutions, IQVIA US, Plymouth Meeting, PA, USA; ⁵ Real World Evidence Solutions, 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

ESMO 2023 초록 by Eisai (발간일자: 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 result Abbreviations: 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.

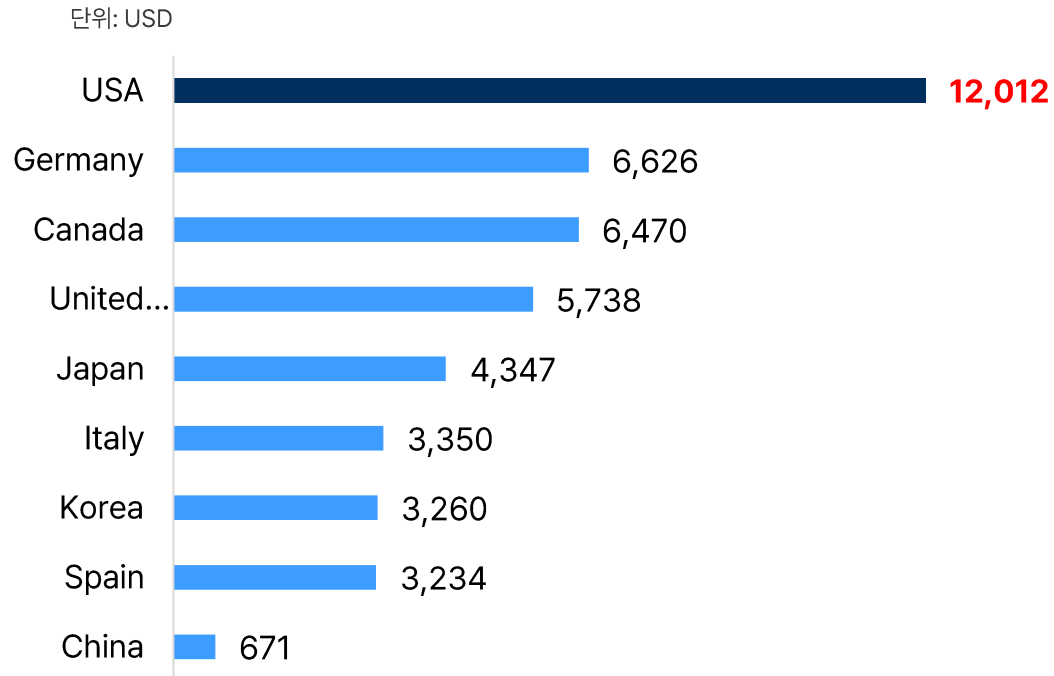
- ✓ 경쟁사인 Eisai가 ESMO 2023에서 발표한 OS/PFS HR에 관해 논문 발표
- ✓ 시판중인 4개 약물 및 시판 예상되는 약물 (리보세라닙/캠렐리주맙)의 Lenvatinib 대비 효능 비교 분석

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

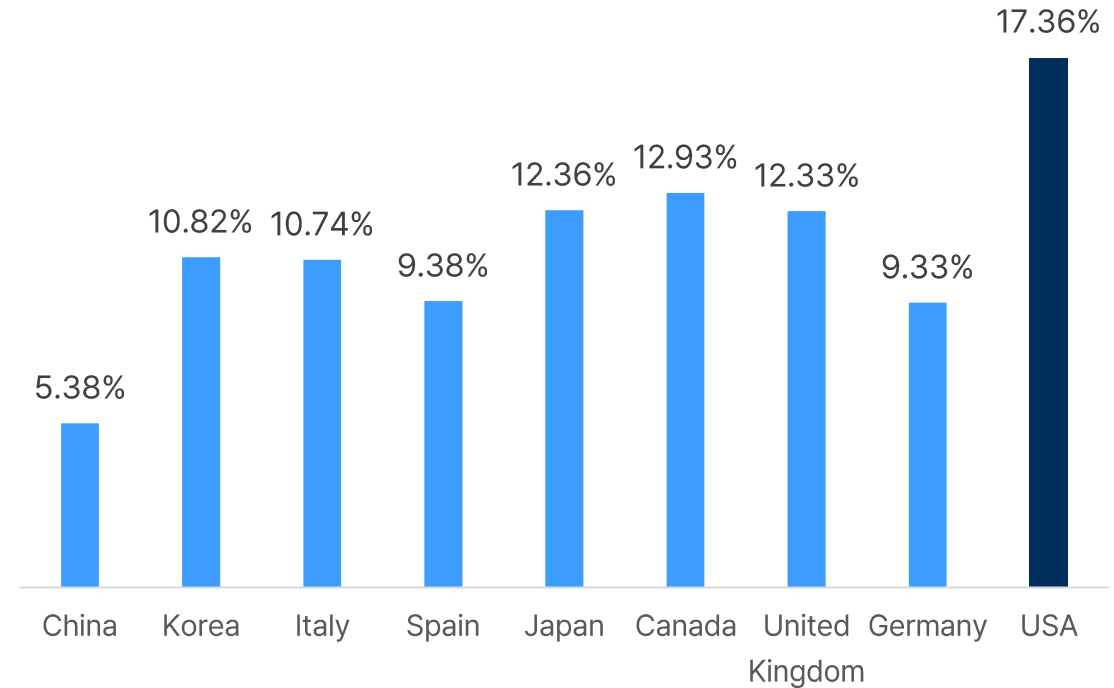
APPENDIX

주요 국가별 의료비 지출 비교

1 인당 의료비 지출 비용



GDP 대비 의료비 비중





감사합니다

HLB 글로벌투자전략팀