Breakfast with the Investigators: Hepatobiliary Cancers

A CME Symposium Held in Conjunction with the 2023 ASCO® Annual Meeting

Saturday, June 3, 2023

6:45 AM – 7:45 AM CT

Faculty

Anthony El-Khoueiry, MD

Robin K (Katie) Kelley, MD

Prof Arndt Vogel, MD

Moderator

Neil Love, MD

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Faculty

Anthony El-Khoueiry, MD
Associate Professor of Medicine
Associate Director for Clinical Research
Phase I Program Director
USC Norris Comprehensive Cancer Center
Los Angeles, California

Professor Arndt Vogel, MD
Managing Senior Consultant
Department of Gastroenterology, Hepatology and Endocrinology
Hannover Medical School
Hannover, Germany

Robin K (Katie) Kelley, MD
Professor of Clinical Medicine, Division of Hematology/Oncology
Helen Diller Family Comprehensive Cancer Center
University of California, San Francisco (UCSF)
San Francisco, California

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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TO PRACTICE

Dr El-Khoueiry — Disclosures

Advisory Committee and Consulting Agreements	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Exelixis Inc, Genentech, a member of the Roche Group, Merck, Qurient, Senti Bio, Tallac Therapeutics
Contracted Research	Astex Pharmaceuticals, AstraZeneca Pharmaceuticals LP, Auransa Inc, Fulgent

Dr Kelley — Disclosures

Advisory Committee (Payments to Institution)	Agios Pharmaceuticals Inc, AstraZeneca Pharmaceuticals LP, Exelixis Inc, Ipsen Biopharmaceuticals Inc, Merck
Consulting Agreements	Compass Therapeutics, Exact Sciences Corporation, Kinnate Biopharma, Regeneron Pharmaceuticals Inc, Tyra Biosciences
Contracted Research	Agios Pharmaceuticals Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Bristol Myers Squibb, EMD Serono Inc, Exelixis Inc, Genentech, a member of the Roche Group, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Novartis, Partner Therapeutics, QED Therapeutics, Relay Therapeutics, Surface Oncology, Taiho Oncology Inc
Data and Safety Monitoring Board/Committee (Uncompensated)	Genentech, a member of the Roche Group, Merck
Travel Support	AstraZeneca Pharmaceuticals LP, Merck

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Prof Vogel — Disclosures

Consulting Agreements	Amgen Inc, AstraZeneca Pharmaceuticals LP, BeiGene Ltd, Boehringer Mannheim, Bristol Myers Squibb, BTG, Daiichi Sankyo Inc, Eisai Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Merck Sharp & Dohme LLC, Pierre Fabre, Roche Laboratories Inc, Servier Pharmaceuticals LLC, Sirtex Medical Ltd, Taiho Oncology Inc, Terumo Medical Corporation
Speaker	Advanced Accelerator Applications, Amgen Inc, AstraZeneca Pharmaceuticals LP, BeiGene Ltd, Boehringer Mannheim, Bristol Myers Squibb, BTG, Daiichi Sankyo Inc, Eisai Inc, GSK, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Jiangsu Hengrui Medicine Co Ltd, Merck Sharp & Dohme LLC, Pierre Fabre, Roche Laboratories Inc, Servier Pharmaceuticals LLC, Sirtex Medical Ltd, Taiho Oncology Inc, Terumo Medical Corporation

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Eisai Inc, Exelixis Inc, Incyte Corporation, Jazz Pharmaceuticals Inc, Merck, Seagen Inc, and Servier Pharmaceuticals LLC.

Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Friday June 2	**Gastroesophageal Cancers** 11:45 AM – 12:45 PM CT (12:45 PM – 1:45 PM ET)
	Non-Small Cell Lung Cancer 6:30 PM – 9:00 PM CT (7:30 PM – 10:00 PM ET)
Saturday June 3	**Hepatobiliary Cancers** 6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)
	Prostate Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Sunday June 4	**Ovarian Cancer** 6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)
	Lymphoma, Chronic Lymphocytic Leukemia and Multiple Myeloma 7:00 PM – 9:30 PM CT (8:00 PM – 10:30 PM ET)
Monday June 5	**Urothelial Bladder Cancer** 6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)
	Breast Cancer 7:00 PM – 9:30 PM CT (8:00 PM – 10:30 PM ET)
Tuesday June 6	**Renal Cell Carcinoma (Webinar)** 7:00 AM – 8:00 AM CT (8:00 AM – 9:00 AM ET)

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Exciting CME Events in Chicago You Do Not Want to Miss

A CME Hybrid Symposium Series Held in Conjunction with the 2023 ASCO® Annual Meeting

Gastroesophageal Cancers

Friday, June 2, 2023

11:45 AM – 12:45 PM CT (12:45 PM – 1:45 PM ET)

Faculty

Yelena Y Janjigian, MD
Manish A Shah, MD
Harry H Yoon, MD, MHS

Hepatobiliary Cancers

Saturday, June 3, 2023

6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)

Faculty

Anthony El-Khoueiry, MD
Robin K (Katie) Kelley, MD
Professor Arndt Vogel, MD

Non-Small Cell Lung Cancer

Friday, June 2, 2023

6:30 PM – 9:00 PM CT (7:30 PM – 10:00 PM ET)

Faculty

Edward B Garon, MD, MS
John V Heymach, MD, PhD
Corey J Langer, MD
Ticiana Leal, MD
David R Spigel, MD
Helena Yu, MD

Prostate Cancer

Saturday, June 3, 2023

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Emmanuel S Antonarakis, MD
Prof Karim Fizazi, MD, PhD
Rana R McKay, MD
Alicia K Morgans, MD, MPH
A Oliver Sartor, MD

Exciting CME Events in Chicago You Do Not Want to Miss

A CME Hybrid Symposium Series Held in Conjunction with the 2023 ASCO® Annual Meeting

Ovarian Cancer

Sunday, June 4, 2023
6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)

Faculty
Philipp Harter, MD, PhD
David M O'Malley, MD
Shannon N Westin, MD, MPH

Urothelial Bladder Cancer

Monday, June 5, 2023
6:45 AM – 7:45 AM CT (7:45 AM – 8:45 AM ET)

Faculty
Matthew D Galsky, MD
Andrea Necchi, MD
Scott T Tagawa, MD, MS

Lymphoma, Chronic Lymphocytic Leukemia and Multiple Myeloma

Sunday, June 4, 2023
7:00 PM – 9:30 PM CT (8:00 PM – 10:30 PM ET)

Faculty
John N Allan, MD
Shaji K Kumar, MD
Ann S LaCasce, MD, MMSc
Sagar Lonial, MD
Loretta J Nastoupil, MD
Susan O'Brien, MD

Breast Cancer

Monday, June 5, 2023
7:00 PM – 9:30 PM CT (8:00 PM – 10:30 PM ET)

Faculty
Komal Jhaveri, MD
Kevin Kalinsky, MD, MS
Ian E Krop, MD, PhD
Joyce O'Shaughnessy, MD
Hope S Rugo, MD
Professor Peter Schmid, FRCP, MD, PhD

Exciting CME Events in Chicago You Do Not Want to Miss

A CME Hybrid Symposium Series Held in Conjunction with the 2023 ASCO® Annual Meeting

Renal Cell Carcinoma Webinar

Tuesday, June 6, 2023

7:00 AM – 8:00 AM CT (8:00 AM – 9:00 AM ET)

Faculty

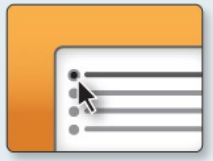
David F McDermott, MD

Sumanta Kumar Pal, MD

Clinicians in the Meeting Room

Networked iPads are available.

Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.



Answer Survey Questions: Complete the pre- and postmeeting surveys.

Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

Complete Your Evaluation: Tap the CME Evaluation button to complete your evaluation electronically to receive credit for your participation.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

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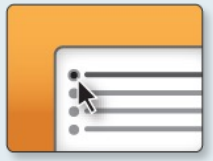
Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.



Answer Survey Questions: Complete the pre- and postmeeting surveys.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get CME Credit: A CME credit link will be provided in the chat room at the conclusion of the program.

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PREMEETING SURVEY – Available Now

Clinicians in Attendance: If you have not already done so, please take a moment to complete the premeeting survey on the iPads for attendees in the room and on Zoom for those attending virtually. Your input on this survey will be integral to the program today.

A postmeeting survey will be posted toward the end of the session.

Thank you for your input.

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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
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Neil Love, MD

RTP RESEARCH TO PRACTICE

Agenda

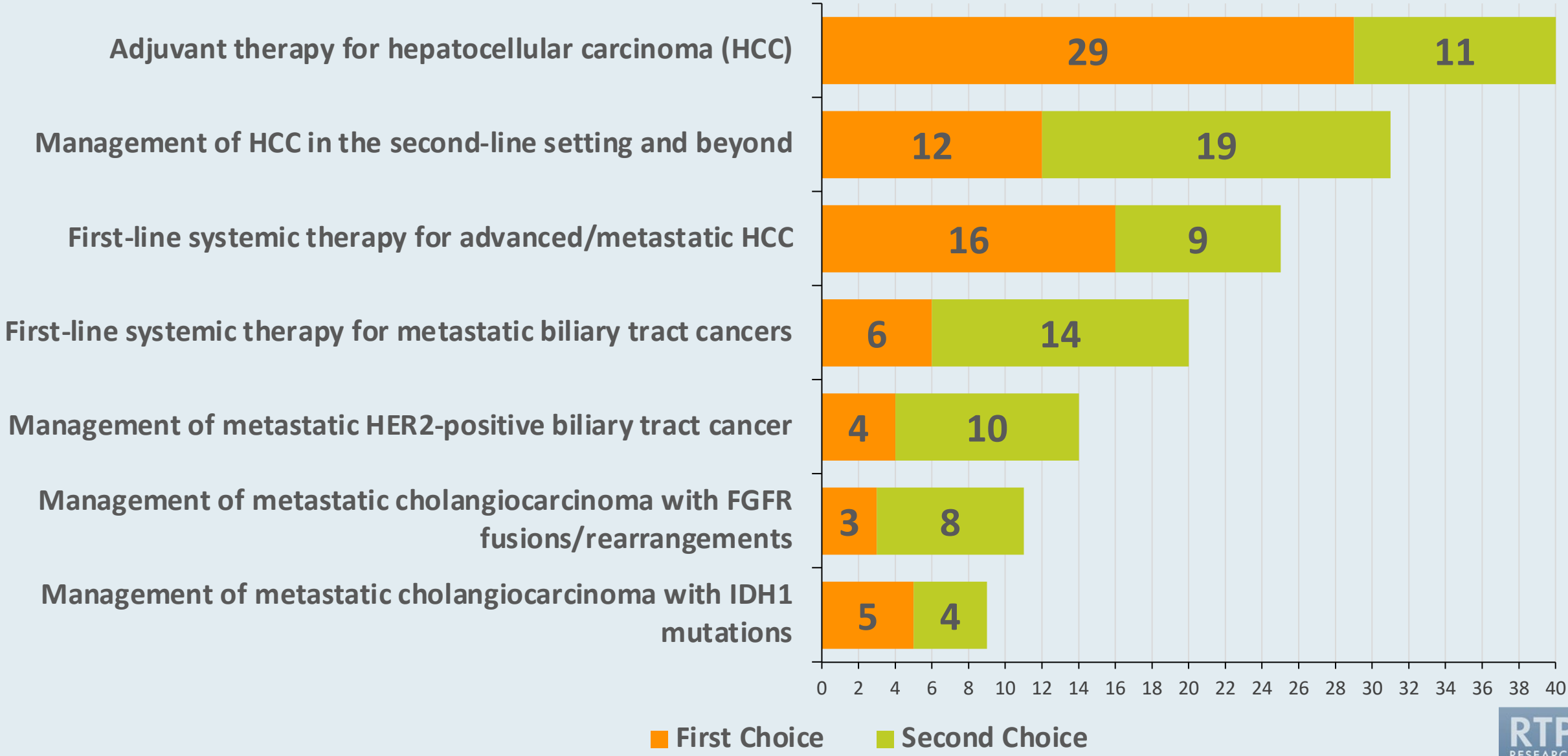
Module 1: **Hepatocellular Carcinoma (HCC)**

- Adjuvant therapy for HCC
- First-line systemic therapy for advanced/metastatic HCC
- Management of HCC in the second-line setting and beyond

Module 2: **Biliary Tract Cancers (BTCs)**

- First-line systemic therapy for metastatic BTCs
- Management of metastatic cholangiocarcinoma with FGFR fusions/rearrangements
- Management of metastatic cholangiocarcinoma with IDH1 mutations
- Management of metastatic HER2-positive BTC

Topics of Interest for Future CME Programs



Survey of US-based general medical oncologists, May 2023. N = 75

Agenda

Module 1: **Hepatocellular Carcinoma (HCC)**

- Adjuvant therapy for HCC
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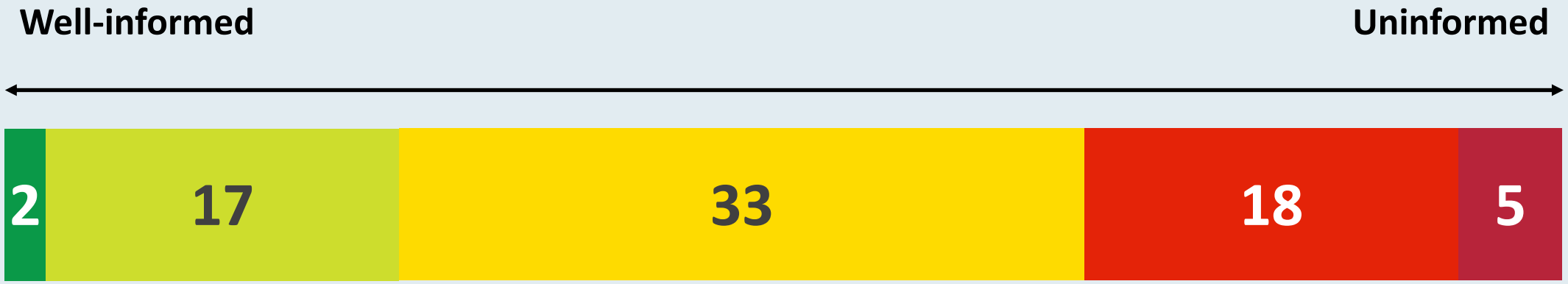
- Management of metastatic HER2-positive BTC

How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to adjuvant therapy for HCC?



25% feel well informed

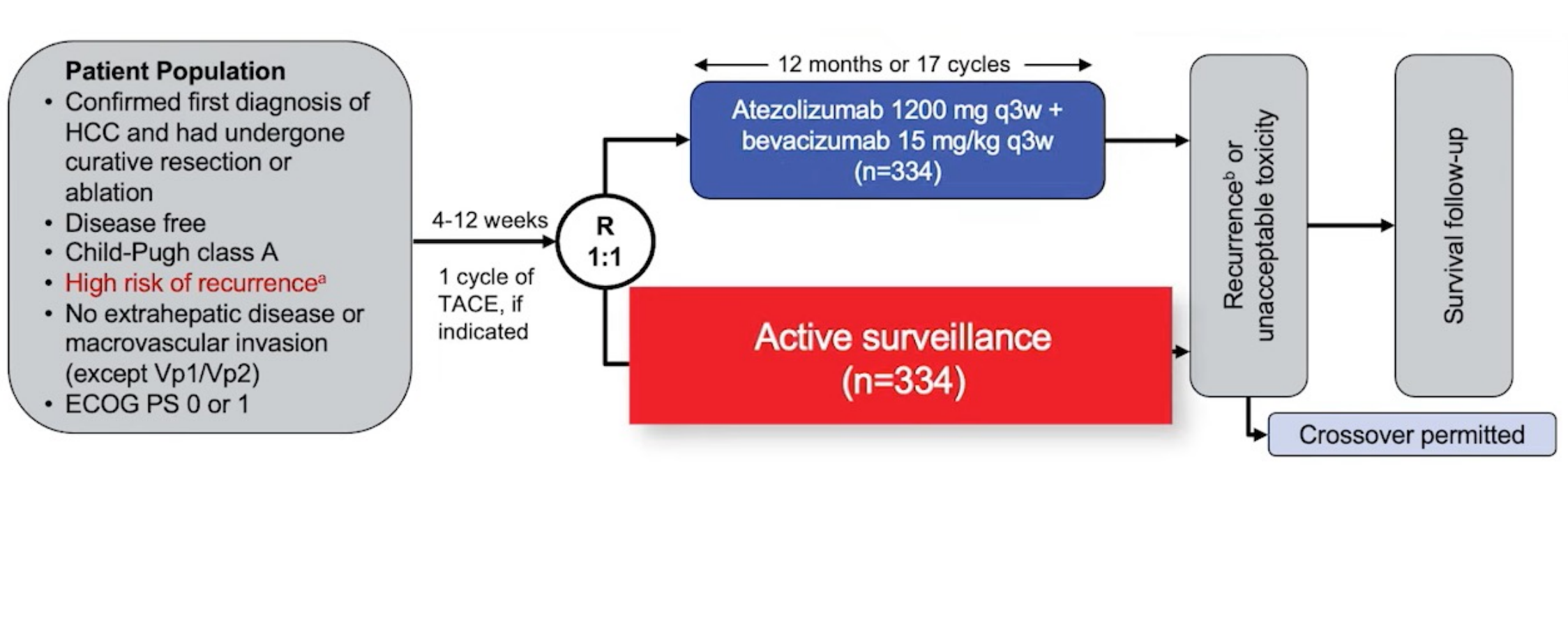
Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

Adjuvant therapy for HCC

- Chow P et al. **IMbrave050: Phase 3 study of adjuvant atezolizumab + bevacizumab versus active surveillance in patients with hepatocellular carcinoma (HCC) at high risk of disease recurrence following resection or ablation.** AACR 2023;Abstract CT003.
- Kudo M et al. **Efficacy, safety and patient reported outcomes (PROs) from the Phase III IMbrave050 trial of adjuvant atezolizumab (atezo) + bevacizumab (bev) vs active surveillance in patients with hepatocellular carcinoma (HCC) at high risk of disease recurrence following resection or ablation.** ASCO 2023;Abstract 4002.

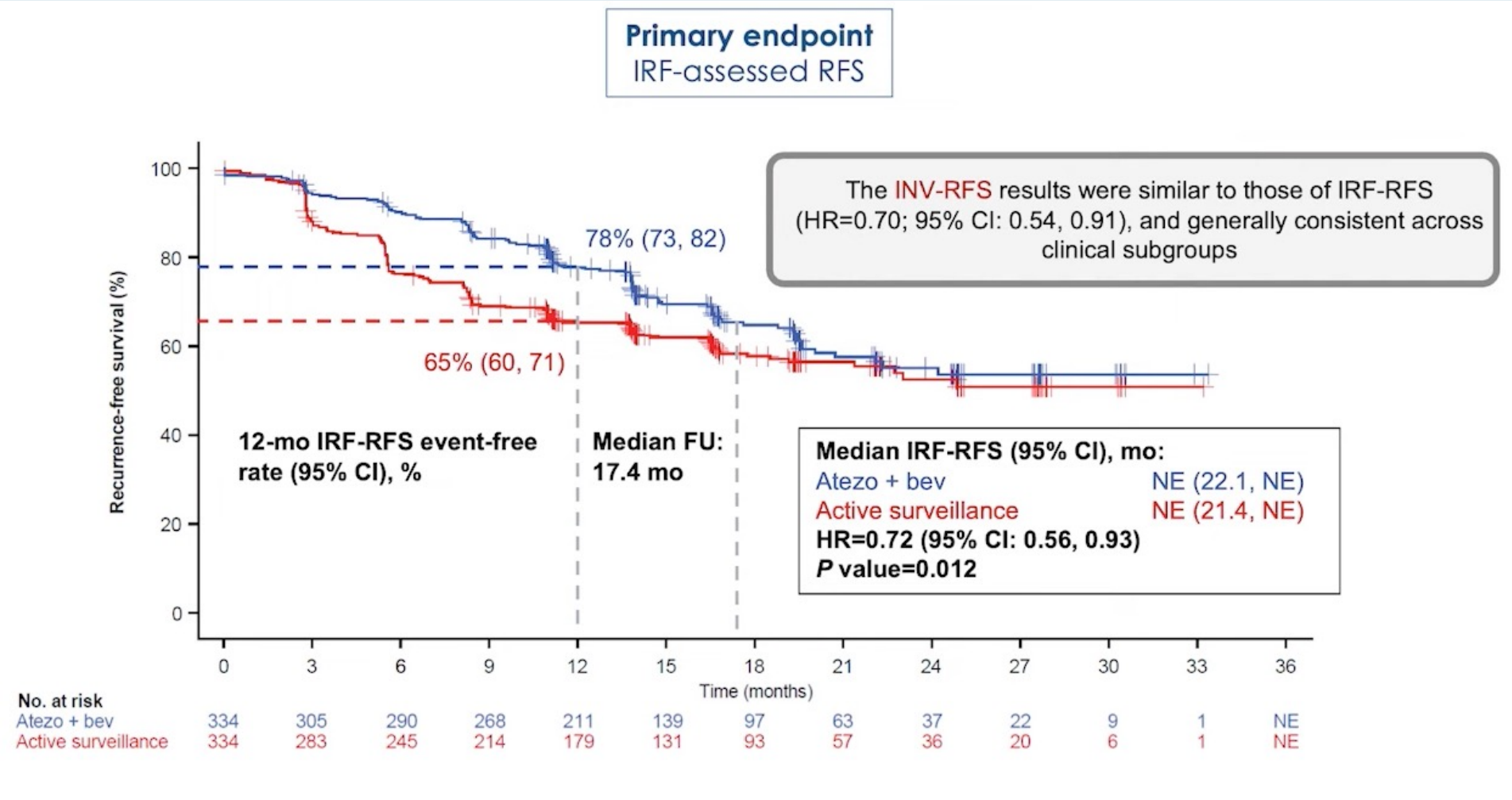
IMbrave050: Phase III Trial Design



TACE = transarterial chemoembolization

Chow P et al. AACR 2023;Abstract CT003.

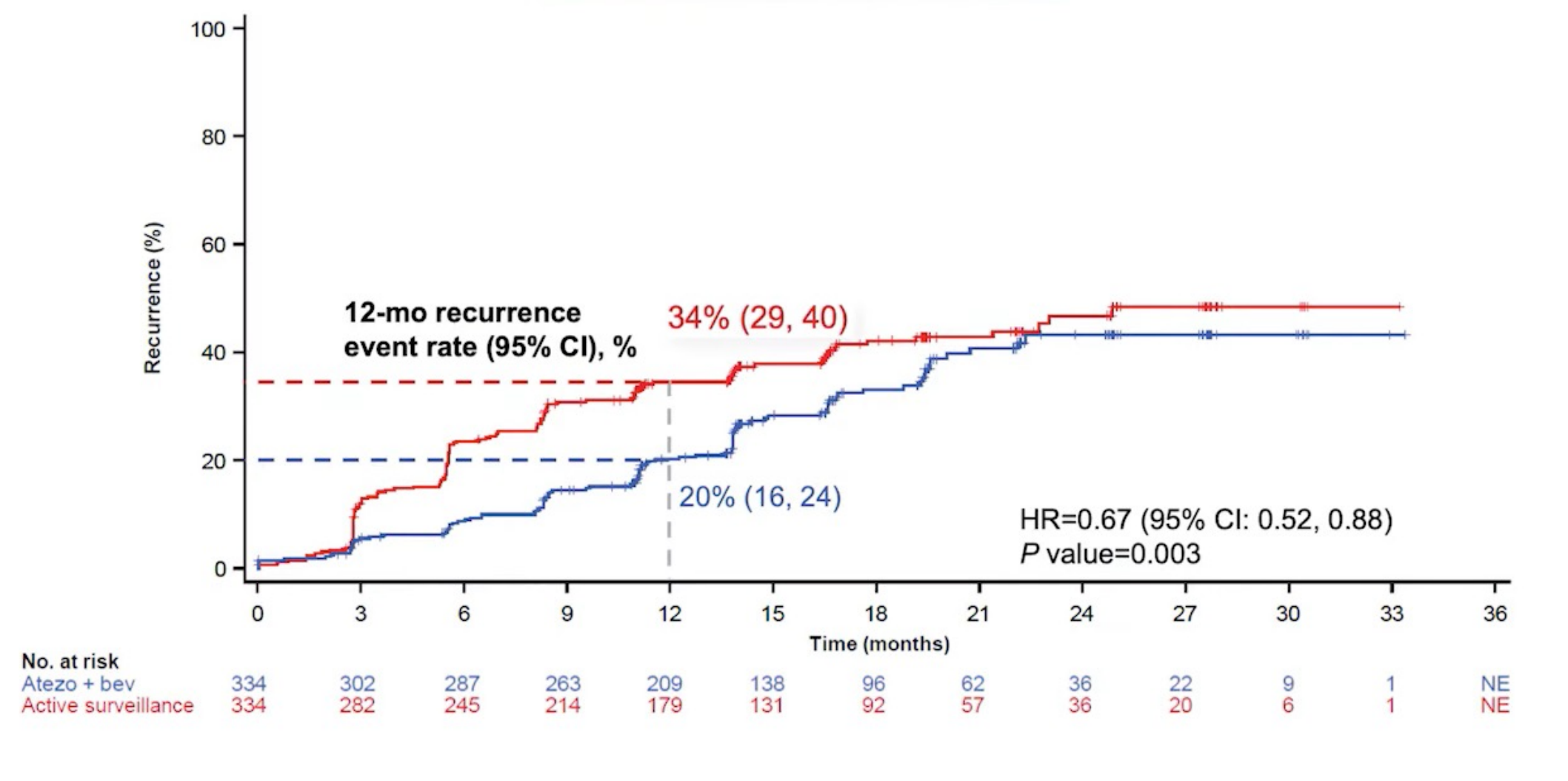
IMbrave050 Primary Endpoint: Independent Review Faculty (IRF)-Assessed Recurrence-Free Survival (RFS)



Atezo = atezolizumab; bev = bevacizumab

Chow P et al. AACR 2023;Abstract CT003.

IMbrave050: IRF-Assessed Disease Recurrence



IRF = independent review faculty; atezo = atezolizumab; bev = bevacizumab

Chow P et al. AACR 2023;Abstract CT003.

IMbrave050: Recurrence-Free Survival Subgroup Analysis

Baseline risk factors	No. of patients	Unstratified HR (95% CI)
All patients	668	0.74 (0.57, 0.95)
<65 years old	427	0.80 (0.58, 1.08)
≥65 years old	241	0.64 (0.41, 1.00)
Male	555	0.74 (0.56, 0.98)
Female	113	0.73 (0.38, 1.40)
Asian	545	0.75 (0.56, 0.99)
White	78	0.59 (0.28, 1.25)
Other race	45	0.91 (0.36, 2.29)
ECOG PS 0	527	0.65 (0.48, 0.87)
ECOG PS 1	141	1.13 (0.67, 1.91)
PD-L1 ≥1%	294	0.82 (0.55, 1.20)
PD-L1 <1%	270	0.62 (0.43, 0.91)
Unknown PD-L1	104	0.82 (0.39, 1.71)
1 high-risk feature[a]	311	0.74 (0.48, 1.14)
≥2 high-risk features[a]	274	0.77 (0.55, 1.08)
BCLC 0/A	569	0.78 (0.59, 1.04)
BCLC B	57	0.44 (0.18, 1.08)
BCLC C	42	0.73 (0.31, 1.73)

Baseline risk factors	No. of patients	Unstratified HR (95% CI)
Hepatitis B etiology	416	0.87 (0.63, 1.20)
Hepatitis C etiology	72	0.65 (0.30, 1.40)
Non-viral etiology	83	0.70 (0.34, 1.42)
Unknown etiology	97	0.45 (0.23, 0.89)
Resection	585	0.75 (0.58, 0.98)
Ablation	83	0.61 (0.26, 1.41)
In patients who underwent resection		
1 tumor	526	0.77 (0.58, 1.03)
>1 tumors	59	0.60 (0.28, 1.27)
Tumor size >5 cm	327	0.66 (0.48, 0.91)
Tumor size ≤5 cm	258	1.06 (0.65, 1.74)
mVI present	354	0.79 (0.56, 1.10)
mVI absent	231	0.69 (0.45, 1.06)
Poor tumor differentiation	245	0.76 (0.51, 1.12)
No poor tumor differentiation	340	0.74 (0.52, 1.07)
Received TACE	66	1.21 (0.57, 2.59)
Did not receive TACE	519	0.71 (0.53, 0.94)

Atezo = atezolizumab; bev = bevacizumab

Chow P et al. AACR 2023;Abstract CT003.

Questions from General Medical Oncologists

- **Adjuvant immunotherapy. Is it prime time?**
- **If adjuvant immunotherapy is approved, how long after resected HCC would it still be reasonable to offer immunotherapy?**
- **42 yo with history of HBV presents with locally advanced HCC. He is not a candidate for up-front resection/transplant due to vascular invasion. Pt had a good response with rTACe and atezo/bev and undergoes resection. Would you proceed with adjuvant therapy in this case?**
- **I have a 76-year-old man who just had HCC resection. Stage I but vascular invasion was seen. Anything we can do to reduce the risk of recurrence? What is the role of ctDNA to predict recurrence?**

Survey of US-based general medical oncologists, May 2023. N = 75

Agenda

Module 1: Hepatocellular Carcinoma (HCC)

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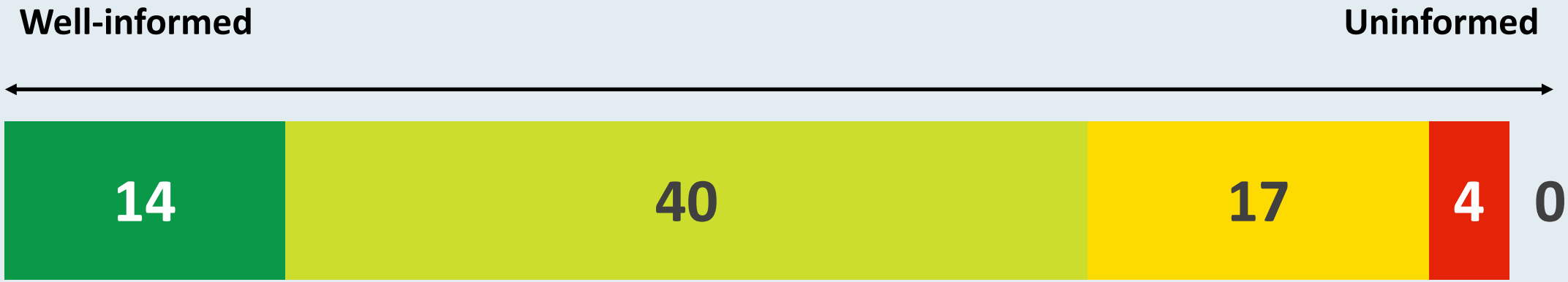
- Management of metastatic cholangiocarcinoma with IDH1 mutations
- Management of metastatic HER2-positive BTC

How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to first-line systemic therapy for advanced/metastatic HCC?



72% feel well informed

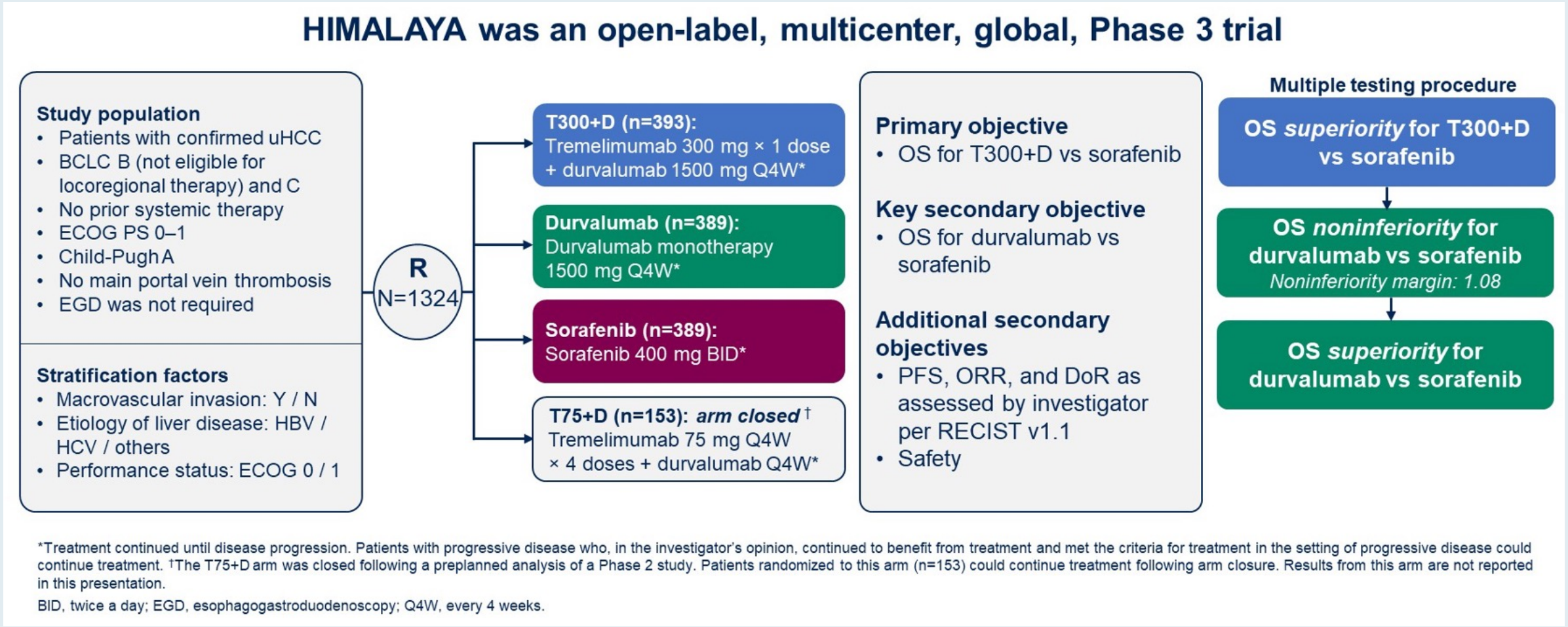
Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

First-line systemic therapy for advanced/metastatic HCC

- Cheng A-L et al. **Updated efficacy and safety data from IMbrave150: Atezolizumab plus bevacizumab vs sorafenib for unresectable hepatocellular carcinoma**. *J Hepatol* 2022;76(4):862-73.
- Abou-Alfa G et al. **Tremelimumab plus durvalumab in unresectable hepatocellular carcinoma.** *NEJM Evid* 2022;1(8).
- Lau G et al. **Outcomes by occurrence of immune-mediated adverse events (imAEs) with tremelimumab (T) plus durvalumab (D) in the Phase 3 HIMALAYA study in unresectable hepatocellular carcinoma (uHCC).** ASCO 2023;Abstract 4004.
- Rimini M et al. **Atezolizumab plus bevacizumab versus lenvatinib or sorafenib in non-viral unresectable hepatocellular carcinoma: An international propensity score matching analysis.** *ESMO Open* 2022;7(6):100591.

HIMALAYA Phase III Trial Schema

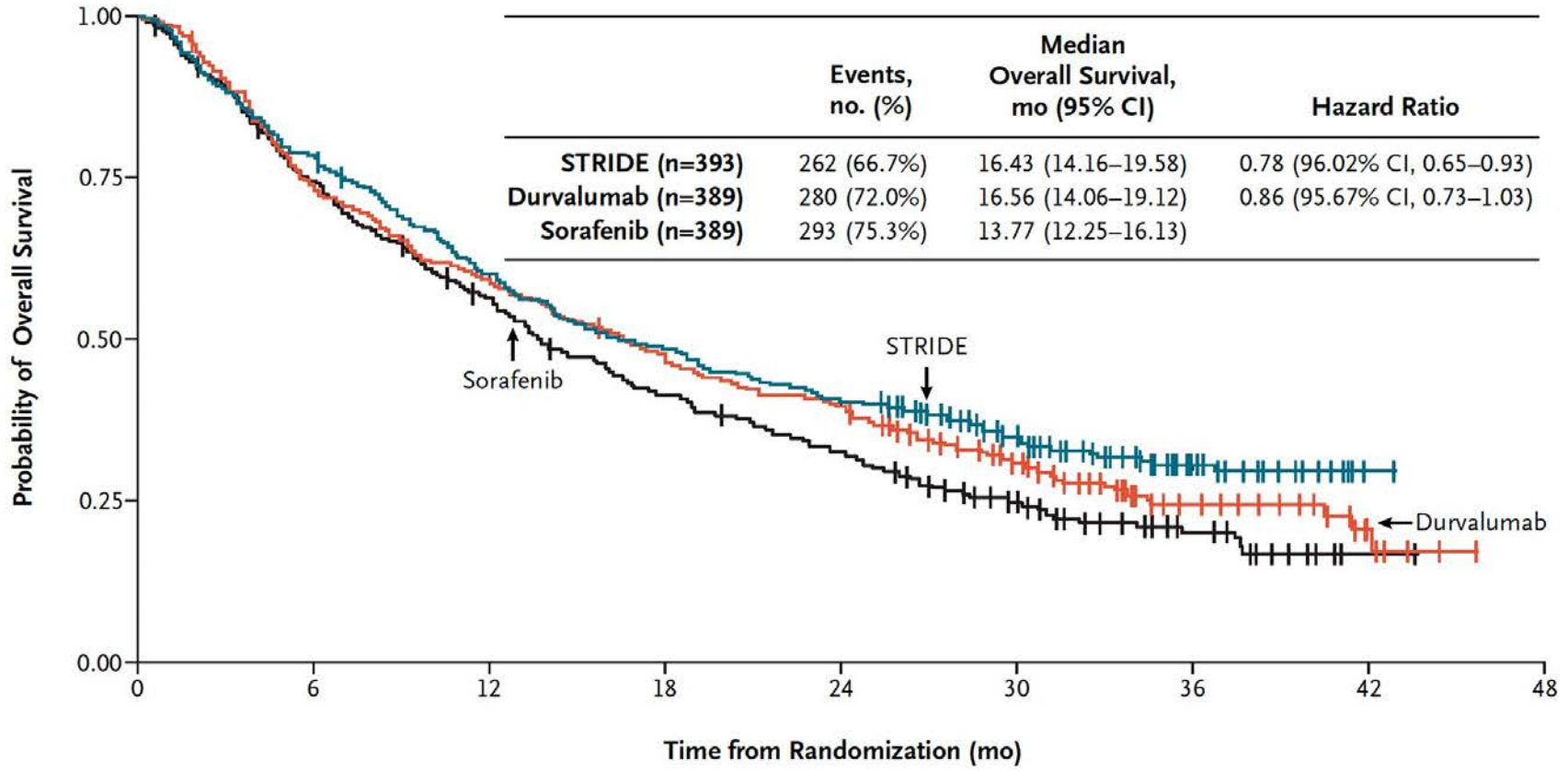


*Treatment continued until disease progression. Patients with progressive disease who, in the investigator's opinion, continued to benefit from treatment and met the criteria for treatment in the setting of progressive disease could continue treatment. †The T75+D arm was closed following a preplanned analysis of a Phase 2 study. Patients randomized to this arm (n=153) could continue treatment following arm closure. Results from this arm are not reported in this presentation.

BID, twice a day; EGD, esophagogastroduodenoscopy; Q4W, every 4 weeks.

Abou-Alfa GK et al. Gastrointestinal Cancers Symposium 2022;Abstract 379.

HIMALAYA: Overall Survival

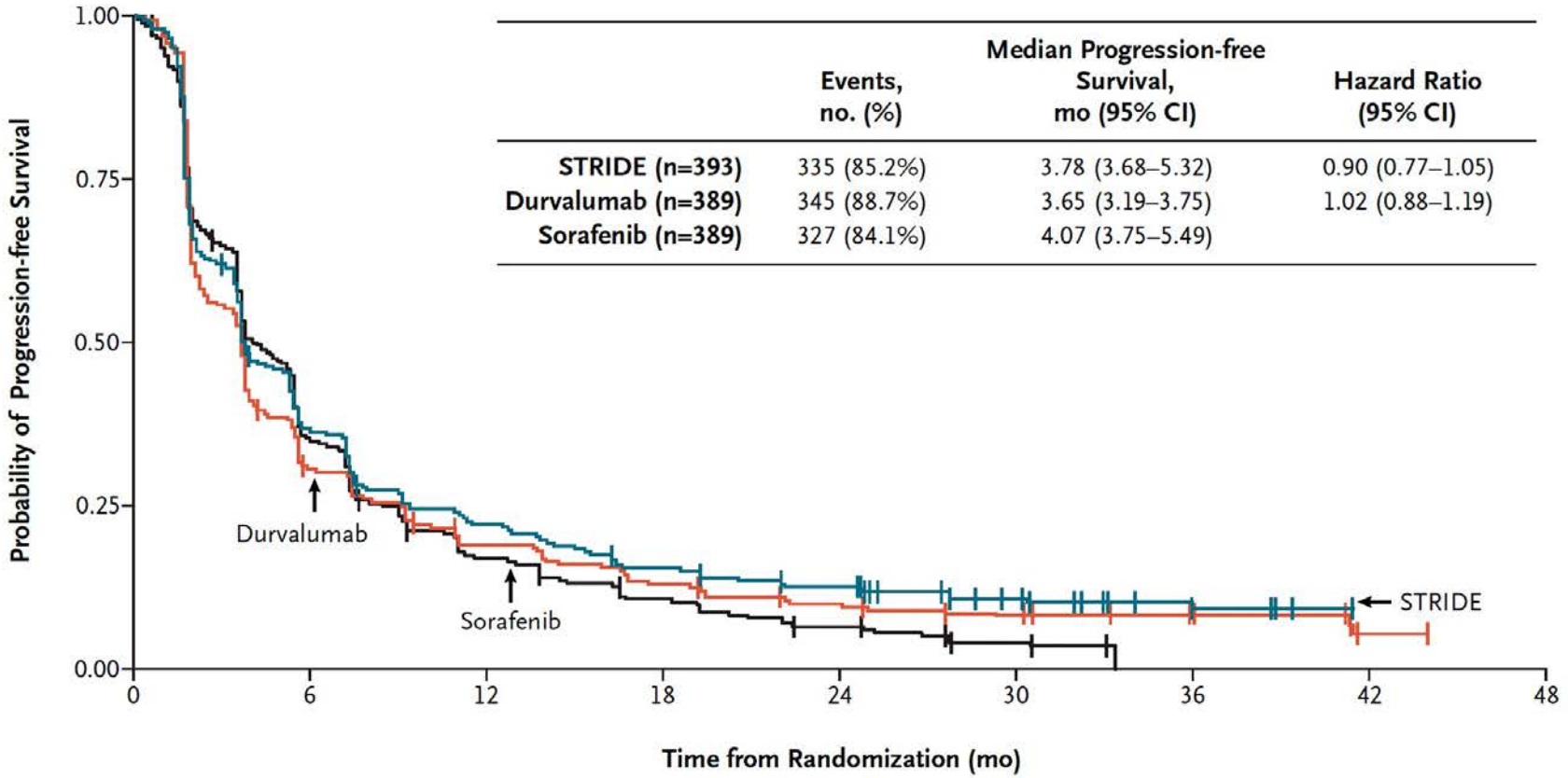


	Events, no. (%)	Median Overall Survival, mo (95% CI)	Hazard Ratio
STRIDE (n=393)	262 (66.7%)	16.43 (14.16–19.58)	0.78 (96.02% CI, 0.65–0.93)
Durvalumab (n=389)	280 (72.0%)	16.56 (14.06–19.12)	0.86 (95.67% CI, 0.73–1.03)
Sorafenib (n=389)	293 (75.3%)	13.77 (12.25–16.13)	

No. at Risk									
STRIDE	393	308	235	190	158	98	32	1	0
Durvalumab	389	286	230	183	153	87	27	6	0
Sorafenib	389	283	211	155	121	62	21	1	0

Abou-Alfa G et al. *NEJM Evid* 2022;1(8).

HIMALAYA: Progression-Free Survival



	Events, no. (%)	Median Progression-free Survival, mo (95% CI)	Hazard Ratio (95% CI)
STRIDE (n=393)	335 (85.2%)	3.78 (3.68–5.32)	0.90 (0.77–1.05)
Durvalumab (n=389)	345 (88.7%)	3.65 (3.19–3.75)	1.02 (0.88–1.19)
Sorafenib (n=389)	327 (84.1%)	4.07 (3.75–5.49)	

No. at Risk									
STRIDE	393	135	81	55	43	26	7	0	0
Durvalumab	389	115	68	47	34	20	6	1	0
Sorafenib	389	118	53	31	18	6	0	0	0

Abou-Alfa G et al. *NEJM Evid* 2022;1(8).

HIMALAYA: Treatment Emergent Adverse Events (Safety Population)

Event	STRIDE (n=388)	Durvalumab (n=388)	Sorafenib (n=374)	T75+D (n=152)
Treatment-emergent adverse events of any cause				
Any	378 (97.4)	345 (88.9)	357 (95.5)	145 (95.4)
Any serious	157 (40.5)	115 (29.6)	111 (29.7)	52 (34.2)
Any grade 3 or 4	196 (50.5)	144 (37.1)	196 (52.4)	60 (39.5)
Leading to discontinuation	53 (13.7)	32 (8.2)	63 (16.8)	23 (15.1)
Leading to dose delay	134 (34.5)	95 (24.5)	178 (47.6)	58 (38.2)
Leading to death	30 (7.7)	26 (6.7)	27 (7.2)	12 (7.9)
Immune-mediated requiring high-dose steroids	78 (20.1)	37 (9.5)	7 (1.9)	29 (19.1)
Any grade 3 or 4 immune-mediated	49 (12.6)	25 (6.4)	9 (2.4)	19 (12.5)
Immune-mediated leading to death	6 (1.5)	0	0	0
Any grade 3 or 4 hepatic SMQ	54 (13.9)	54 (13.9)	39 (10.4)	26 (17.1)

Abou-Alfa G et al. *NEJM Evid* 2022;1(8).

ESMO Open 2022 December;7(6):100591.

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO OPEN SCIENCE FOR OPTIMAL CANCER CARE

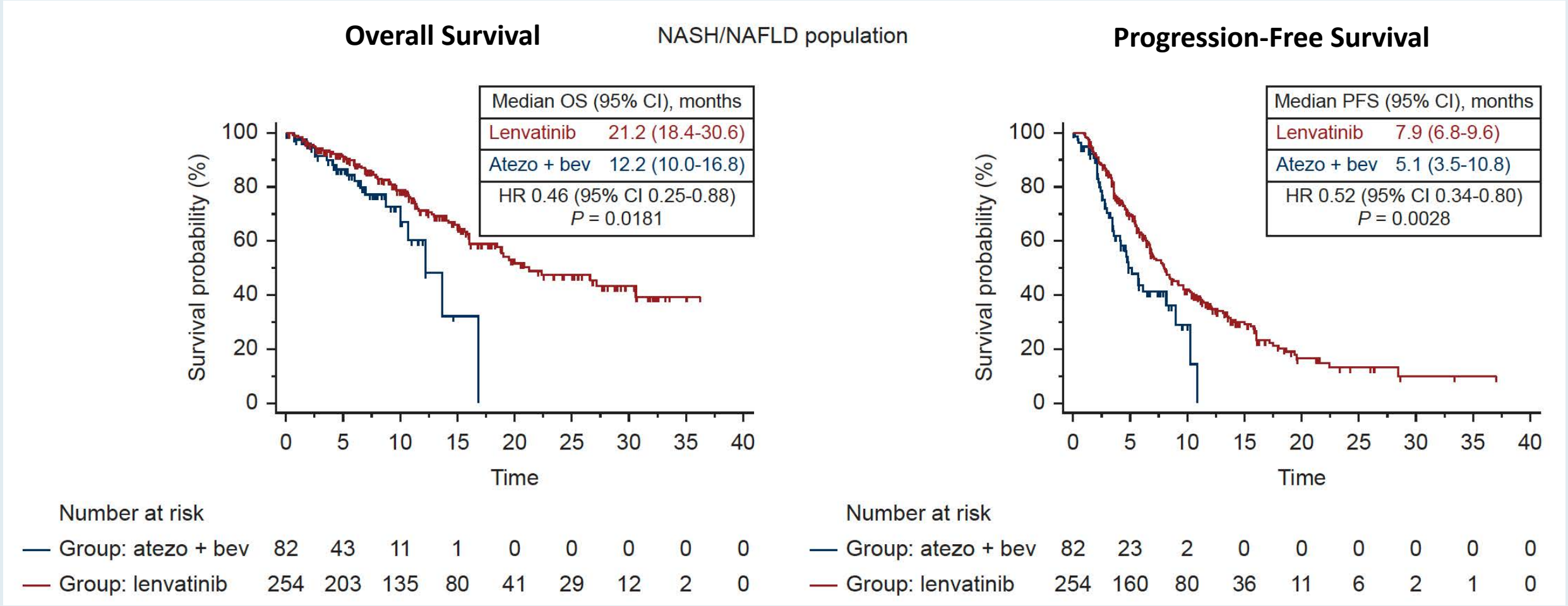
ORIGINAL RESEARCH

Atezolizumab plus bevacizumab versus lenvatinib or sorafenib in non-viral unresectable hepatocellular carcinoma: an international propensity score matching analysis

M. Rimini[1†], L. Rimassa[2,3†], K. Ueshima[4], V. Burgio[1], S. Shigeo[5], T. Tada[6], G. Suda[7,8], C. Yoo[9], J. Cheon[10], D. J. Pinato[11,12], S. Lonardi[13], M. Scartozzi[14], M. Iavarone[15], G. G. Di Costanzo[16], F. Marra[17], C. Soldà[18], E. Tamburini[19], F. Piscaglia[20], G. Masi[21,22], G. Cabibbo[23], F. G. Foschi[24], M. Silletta[25], T. Pressiani[3], N. Nishida[4], H. Iwamoto[5], N. Sakamoto[7,8], B.-Y. Ryoo[9], H. J. Chon[10], F. Claudia[11,12], T. Niizeki[5], T. Sho[7,8], B. Kang[10], A. D'Alessio[11,12], T. Kumada[26], A. Hiraoka[27], M. Hirooka[28], K. Kariyama[29], J. Tani[30], M. Atsukawa[31], K. Takaguchi[32], E. Itobayashi[33], S. Fukunishi[34], K. Tsuji[35], T. Ishikawa[36], K. Tajiri[37], H. Ochi[38], S. Yasuda[39], H. Toyoda[39], C. Ogawa[40], T. Nishimur[41], T. Hatanaka[42], S. Kakizaki[43], N. Shimada[44], K. Kawata[45], T. Tanaka[27], H. Ohama[34], K. Nouso[29], A. Morishita[30], A. Tsutsui[32], T. Nagano[32], N. Itokawa[31], T. Okubo[31], T. Arai[31], M. Imai[36], A. Naganuma[46], Y. Koizumi[28], S. Nakamura[6], K. Joko[38], H. Iijima[41], Y. Hiasa[28], F. Pedica[47], F. De Cobelli[48], F. Ratti[49], L. Aldrighetti[49], M. Kudo[4], S. Cascinu[50] & A. Casadei-Gardini[50*]

RTP RESEARCH TO PRACTICE

Atezolizumab/Bevacizumab versus Lenvatinib for Nonviral Unresectable Hepatocellular Carcinoma: NASH/NAFLD Population



NASH = nonalcoholic steatohepatitis; NAFLD = nonalcoholic fatty liver disease

Rimini M et al. *ESMO Open* 2022 December;7(6):100591.

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists

- **When to use tremelimumab plus durvalumab over bevacizumab plus atezolizumab**
- **What are the options for Child-Pugh C patients but who are in relatively good health?**
- **My biggest struggle is sequencing between liver-directed therapy and systemic therapy. IR folks push toward Y-90 even if larger tumor as first-line option. Is there a tumor size cutoff where these therapies would not be first option and preference would be for systemic therapy?**
- **The best regimen that can provide RAPID response in patients with metastatic disease, severe pain in the bone mets (HCC proven) eligible for ALL classes of drugs, age 65**

Survey of US-based general medical oncologists, May 2023. N = 75

Questions from General Medical Oncologists (Continued)

- **If someone is started on bevacizumab and atezolizumab with response and then has a Grade 3 or 4 immunotherapy toxicity, would you continue single-agent bevacizumab until progression or intolerance?**
- **Would you give systemic therapy in a patient with diffuse involvement of the liver with HCC and no extrahepatic disease, or is liver-directed therapy adequate?**
- **Do antibodies to atezolizumab impact PFS and OS in HCC? Should they be measured? How reliable are the testing results?**

Survey of US-based general medical oncologists, May 2023. N = 75

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- First-line systemic therapy for metastatic BTCs
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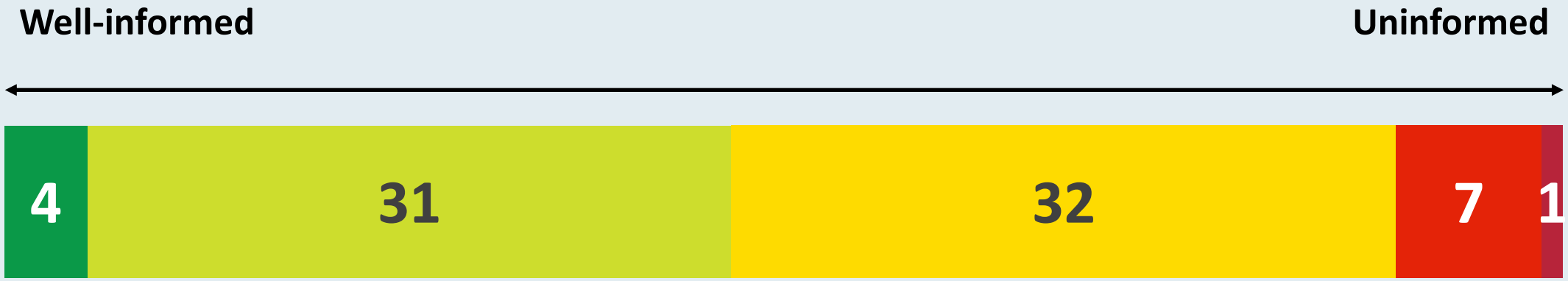
- Management of metastatic cholangiocarcinoma with IDH1 mutations
- Management of metastatic HER2-positive BTC

How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to management of HCC in the second-line setting and beyond?



47% feel well informed

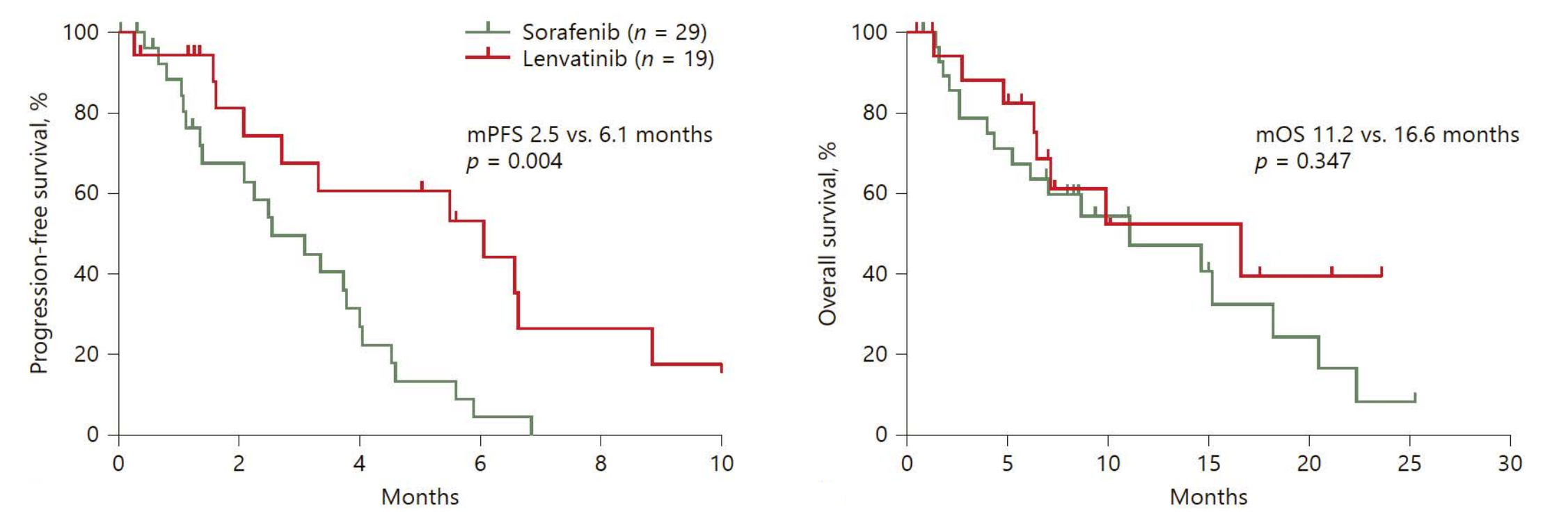
Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

Management of HCC in the second-line setting and beyond

- Yoo C et al. **Clinical outcomes with multikinase inhibitors after progression on first-line atezolizumab plus bevacizumab in patients with advanced hepatocellular carcinoma: A Multinational Multicenter retrospective study.** *Liver Cancer* 2021;10(2):107-14.
- El-Khoueiry AB et al. **Safety and efficacy of cabozantinib for patients with advanced hepatocellular carcinoma who advanced to Child-Pugh B liver function at study week 8: A retrospective analysis of the CELESTIAL randomised controlled trial.** *BMC Cancer* 2022;22(1):377.
- Qin S et al. **Pembrolizumab versus placebo as second-line therapy in patients from Asia with advanced hepatocellular carcinoma: A randomized, double-blind, Phase III trial.** *J Clin Oncol* 2023;41(7):1434-43.
- Melero I et al. **Nivolumab (NIVO) plus ipilimumab (IPI) combination therapy in patients with advanced hepatocellular carcinoma (aHCC): 5-year results from CheckMate 040.** ESMO World Congress on Gastrointestinal Cancer 2022;Abstract SO-12.

Retrospective Analysis of Sorafenib and Lenvatinib for Patients with Advanced HCC That Progressed on First-Line Atezolizumab with Bevacizumab – PFS and OS



Yoo C et al. *Liver Cancer* 2021;10:107-14.

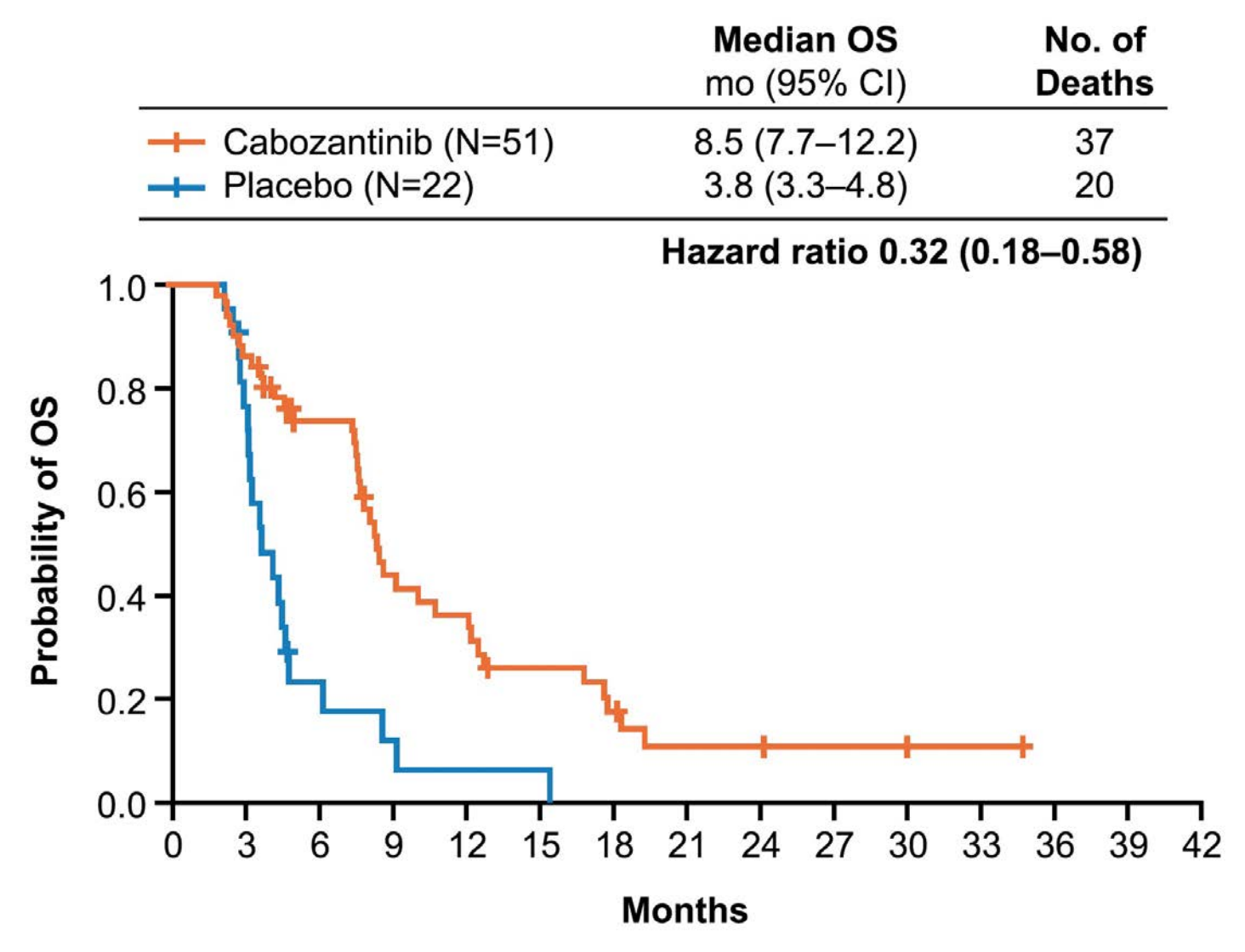
Retrospective Analysis of Sorafenib and Lenvatinib for Patients with Advanced HCC That Progressed on First-Line Atezolizumab with Bevacizumab – Best Response

	Total ($n = 49$)[a]	Sorafenib ($n = 29$)	Lenvatinib ($n = 19$)	p value
PR	3 (6.1)	0 (0)	3 (15.8)	
SD	28 (57.1)	18 (62.1)	9 (47.4)	
PD	14 (28.6)	8 (27.6)	6 (31.6)	
NE[b]	4 (8.2)	3 (10.3)	1 (5.3)	
ORR	3 (6.1)	0 (0)	3 (15.8)	0.062
DCR	31 (63.3)	18 (62.1)	12 (63.2)	1.000

Values denote n (%). PR, partial response; SD, stable disease; PD, progressive disease; NE, not evaluable; ORR, objective response rate; DCR, disease control rate; MKI, multikinase inhibitor. [a] One patient treated with cabozantinib achieved stable disease. [b] NE: not evaluable d/t loss to follow-up ($n = 3$) and too short duration of follow-up to evaluate response ($n = 1$).

Yoo C et al. *Liver Cancer* 2021;10:107-14.

Cabozantinib for Patients with Advanced HCC and Child-Pugh B Liver Function in CELESTIAL: Overall Survival



El-Khoueiry AB et al. *BMC Cancer* 2022;22(1):377.

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists

- **What is the best TKI to start with?**
- **What is your dosing approach with cabozantinib? Do you start at a lower or higher dose?**
- **Any good options for Child-Pugh B or higher in second line?**
- **Do patients with paraneoplastic features of HCC such as erythrocytosis affect responses to targeted, angiogenesis inhibition or checkpoint inhibitors?**
- **Conversation re: dosing of lenvatinib; I have some experience, but more advice would help**

Survey of US-based general medical oncologists, May 2023. N = 75

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- First-line systemic therapy for metastatic BTCs
- Management of metastatic cholangiocarcinoma with FGFR fusions/rearrangements
- Management of metastatic cholangiocarcinoma with IDH1 mutations
- Management of metastatic HER2-positive BTC

How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to first-line systemic therapy for metastatic biliary tract cancers?

60% feel well informed

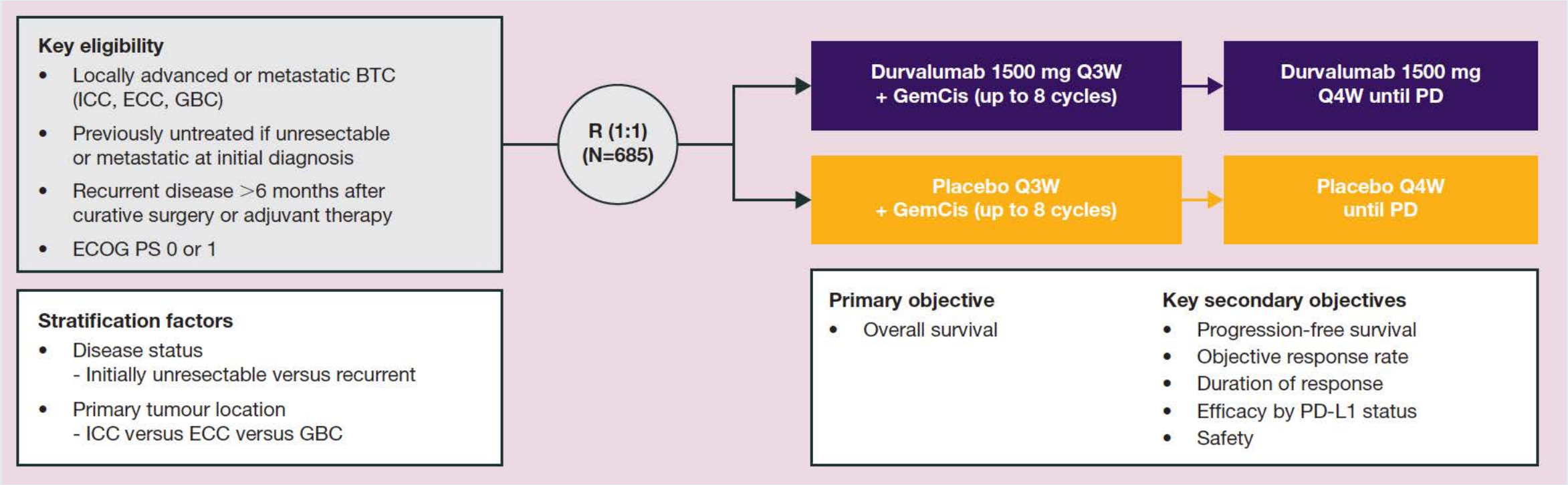
Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

First-line systemic therapy for metastatic BTCs

- Oh D-Y et al. **Updated overall survival (OS) from the phase III TOPAZ-1 study of durvalumab (D) or placebo (PBO) plus gemcitabine and cisplatin (+ GC) in patients (pts) with advanced biliary tract cancer (BTC).** ESMO 2022;Abstract 56P.
- Kelley RK et al. **Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet* 2023;[Online ahead of print].
- Yoo C et al. **Health-related quality of life (HRQoL) in the Phase 3 KEYNOTE-966 study of pembrolizumab (pembro) plus gemcitabine and cisplatin (gem/cis) versus placebo plus gem/cis for advanced biliary tract cancer (BTC).** ASCO 2023;Abstract 4003.

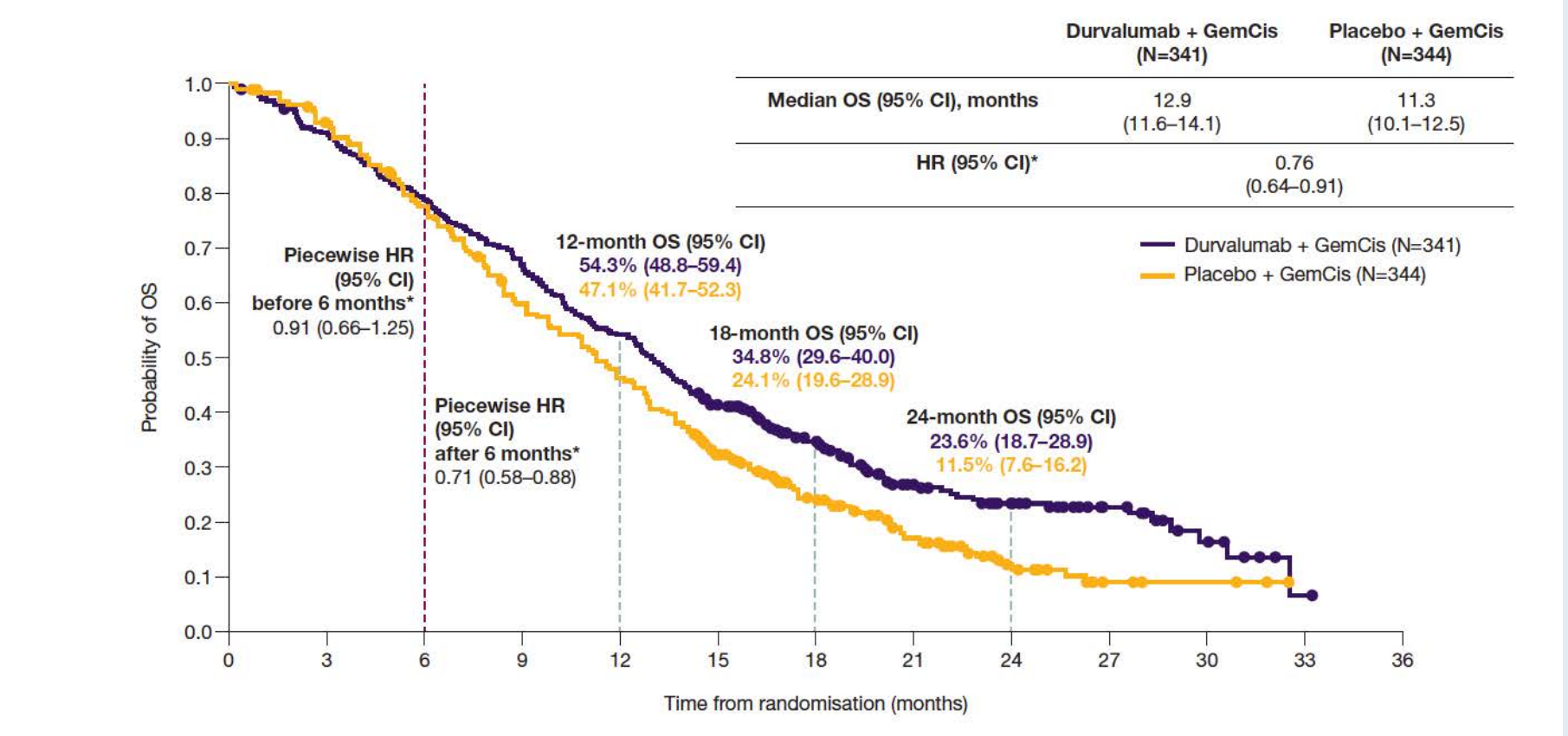
TOPAZ-1 Phase III Trial Schema



BTC = biliary tract cancer

Oh D-Y et al. ESMO 2022;Abstract 56P.

TOPAZ-1: Results Summary with Durvalumab and Gemcitabine/Cisplatin for Advanced Biliary Tract Cancer



- Grade 3/4 treatment-related adverse events (TRAEs) occurred in 60.9% of patients receiving durvalumab and 63.5% of patients receiving placebo.
- TRAEs leading to discontinuation of any study medication occurred in 8.9% and 11.4% of patients receiving durvalumab and placebo, respectively.

Oh D-Y et al. ESMO 2022;Abstract 56P.

RTP RESEARCH TO PRACTICE

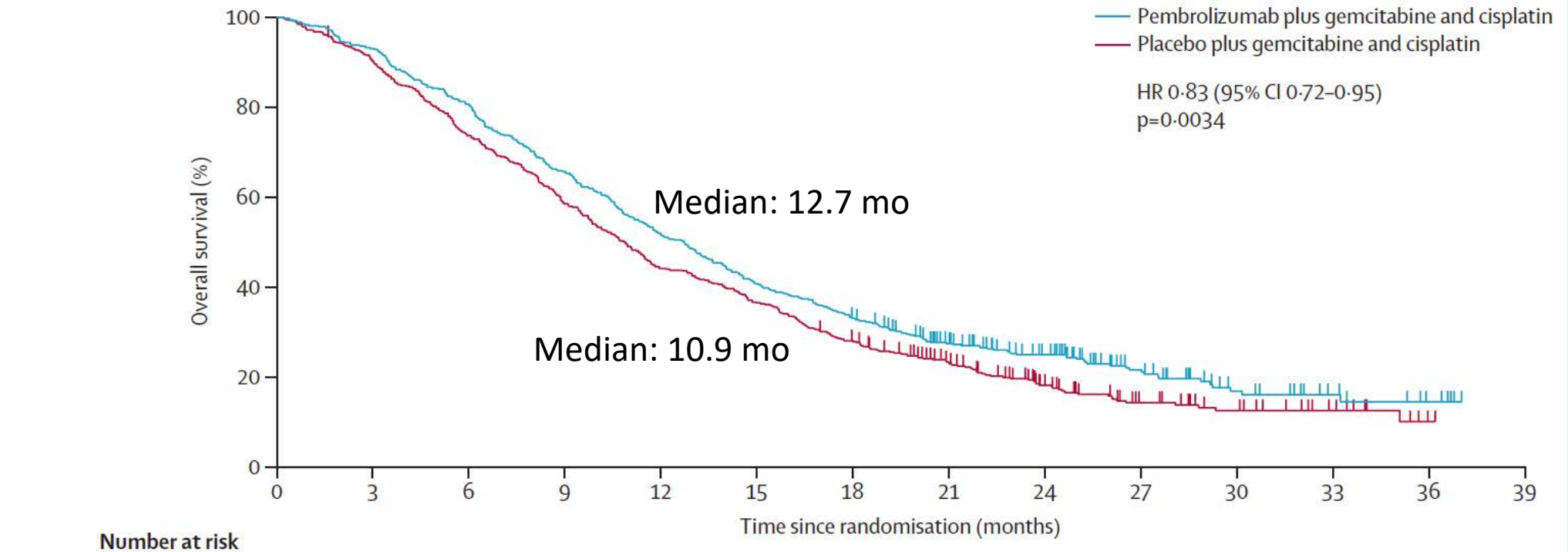
Lancet 2023 April 14;[Online ahead of print].

Articles

Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial

Robin Kate Kelley, Makoto Ueno*, Changhoon Yoo, Richard S Finn, Junji Furuse, Zhenggang Ren, Thomas Yau, Heinz-Josef Klümpen, Stephen L Chan, Masato Ozaka, Chris Verslype, Mohamed Bouattour, Joon Oh Park, Olga Barajas, Uwe Pelzer, Juan W Valle, Li Yu, Usha Malhotra, Abby B Siegel, Julien Edeline, Arndt Vogel*, on behalf of the KEYNOTE-966 Investigators†*

KEYNOTE-966 Primary Endpoint: Overall Survival (Final Analysis)



Number at risk (number censored)														
Pembrolizumab plus gemcitabine and cisplatin	533 (0)	496 (0)	430 (0)	350 (0)	275 (0)	217 (0)	175 (1)	122 (26)	88 (50)	46 (83)	21 (100)	11 (109)	5 (114)	0 (119)
Placebo plus gemcitabine and cisplatin	536 (0)	483 (1)	394 (1)	313 (1)	236 (1)	195 (1)	148 (3)	97 (30)	59 (49)	32 (65)	20 (74)	10 (84)	1 (92)	0 (93)

The efficacy boundary for a statistically significant overall survival benefit for the pembrolizumab group was met (significance threshold, $p = 0.0200$).

Kelley RK et al. *Lancet* 2023 April 14;[Online ahead of print].

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists

- **What is the best platform for checking NGS?**
- **How do you incorporate KEYNOTE-966 data with TOPAZ-1 data?**
- **I usually use the TOPAZ regimen. But I wonder when should we use cisplatin/gem/paclitaxel? When can we not give cisplatin first line?**
- **What is preferred first line in patients with pre-existing renal insufficiency?**
- **Any studies looking at durva w/ other chemo combinations? Cisplatin is not well tolerated by all, and there is now a national shortage of carbo and soon to be cisplatin shortage, we are told!**
- **For metastatic disease TMB-H, would you use gem/cis/durva or ipi/nivo as 1L therapy?**

Survey of US-based general medical oncologists, May 2023. N = 75

Questions from General Medical Oncologists (Continued)

- **In a patient with NTRK mutation, should NTRK-targeting agents be used first, or should this be reserved for after progression on chemoimmunotherapy?**
- **How to treat oligomets**

Survey of US-based general medical oncologists, May 2023. N = 75

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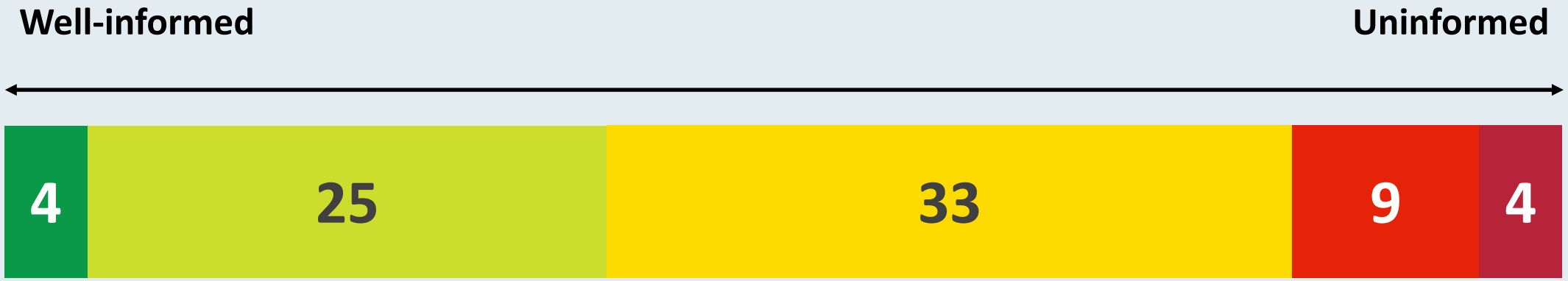
- Management of metastatic HER2-positive BTC

How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to management of metastatic cholangiocarcinoma with FGFR fusions/rearrangements?



39% feel well informed

Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

Management of metastatic cholangiocarcinoma with FGFR fusions/ rearrangements

- Vogel A et al. **Pemigatinib for previously treated locally advanced or metastatic cholangiocarcinoma: Final results from FIGHT-202.** ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.
- Goyal L et al. **Futibatinib for FGFR2-rearranged intrahepatic cholangiocarcinoma.** *N Engl J Med* 2023;388(3):228-39.

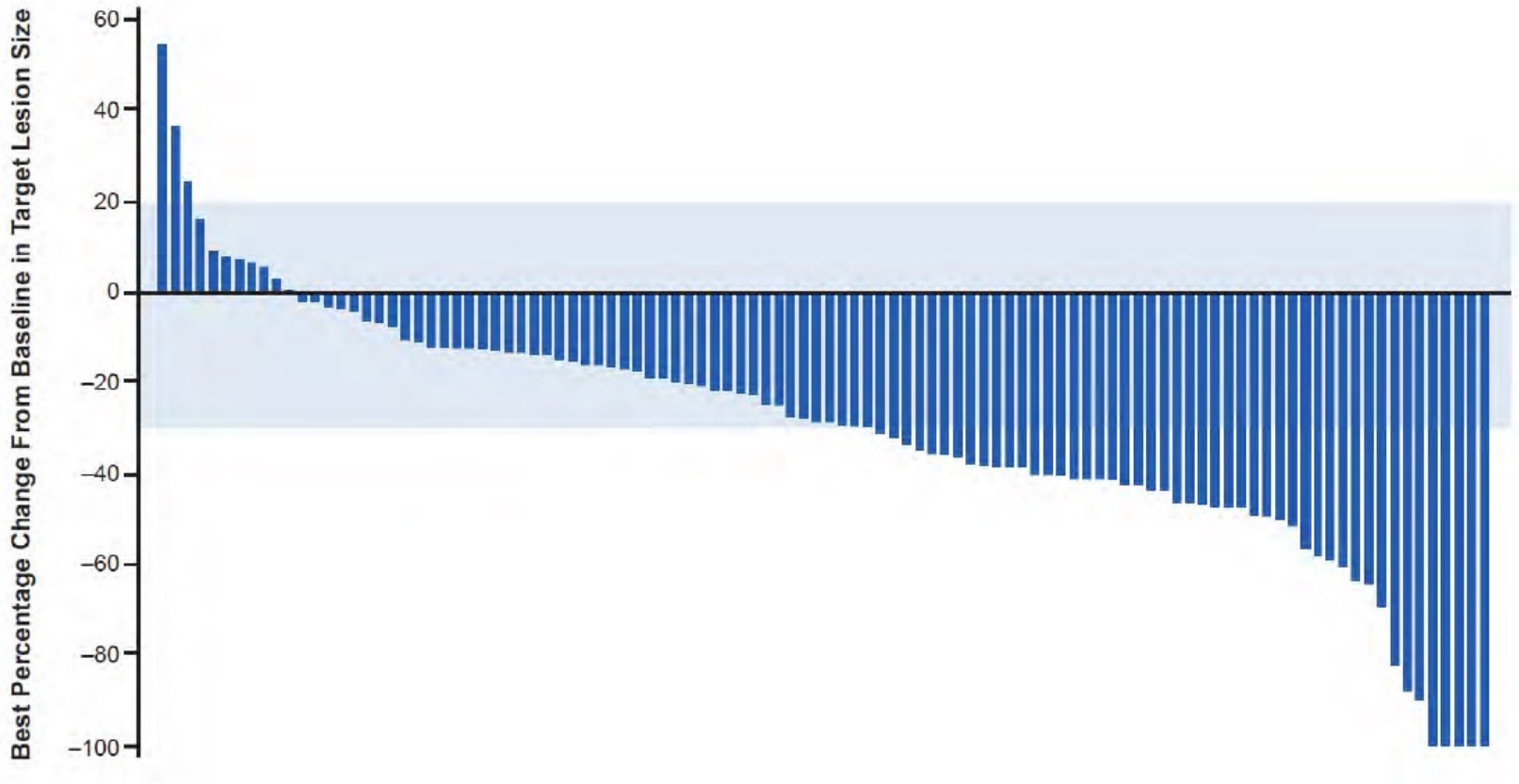
Efficacy of FDA-Approved FGFR Inhibitors for FGFR2 Fusion-Positive Cholangiocarcinoma

	Pemigatinib (N = 107)	Futibatinib (N = 67)
ORR	37.0%	42.0%
Disease control rate	82.0%	83.0%
Median progression-free survival	7.0 mo	9.0 mo
Median overall survival	17.5 mo	21.7 mo
Toxicities	Hyperphosphatemia, alopecia, diarrhea	Hyperphosphatemia, diarrhea, dry mouth

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2; Goyal L et al. *N Engl J Med* 2023;388:228-39.

FIGHT-202 Final Results: Best Change from Baseline in Target Lesion Size in Cohort A

- Among 104 evaluable patients, median best percentage change from baseline in the sum of target lesion diameters was –28.4% (range, –100% to +55%)

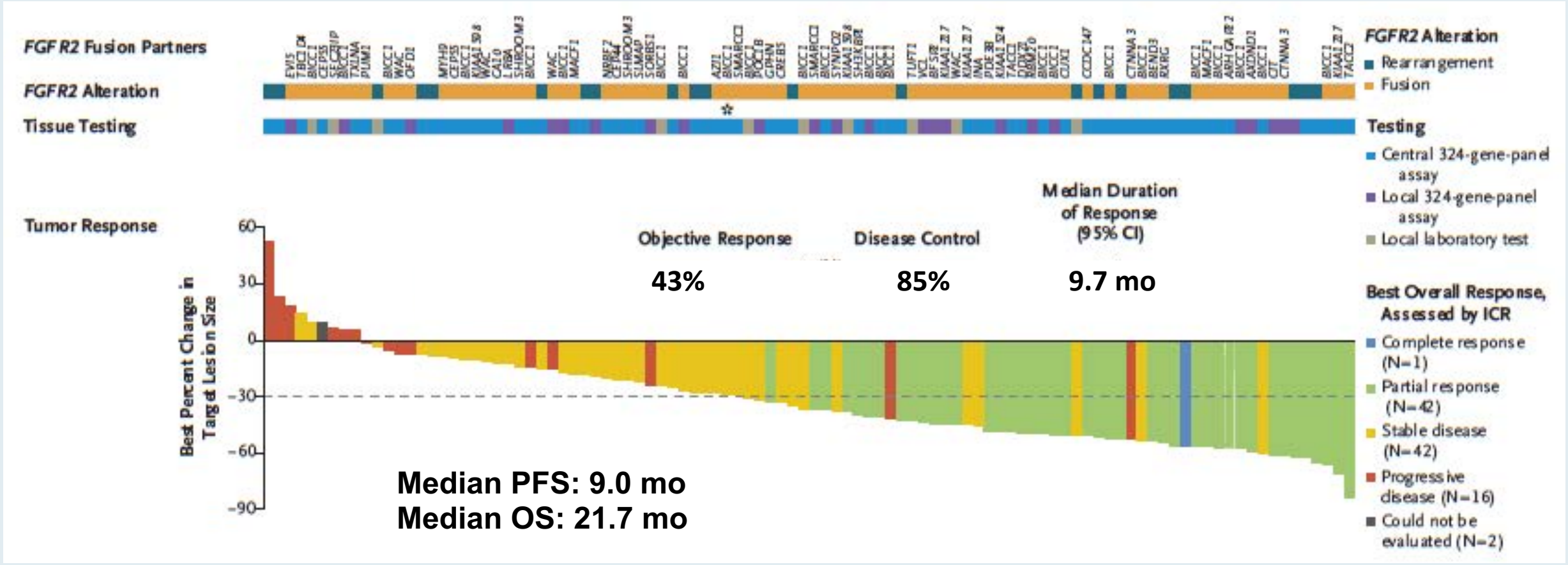


Lower limit of blue shading indicates criterion for partial response (≥30% decrease in sum of target lesion diameters).

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.

RTP RESEARCH TO PRACTICE

FOENIX-CCA2: A Phase II Study of Futibatinib for Intrahepatic Cholangiocarcinoma with FGFR2 Fusions or Rearrangements



PFS = progression-free survival; OS = overall survival

Goyal L et al. *N Engl J Med* 2023;388:228-39.

Questions from General Medical Oncologists

- **Which NGS testing is most useful for accurate detection of FGFR2 fusions?**
- **Can you use targeted therapy first, or always start with gem cis durvalumab?**
- **A 72 yo with metastatic biliary tract cancer has progressed on two chemotherapy regimens. NGS shows both an IDH1 and FGFR fusion mutation. What would be your preferred therapy?**
- **A patient has metastatic FGFR fusion and is about to be started on targeted therapy. What drug would you use, and what practical advice would you give about any dosing, prophylactic support, monitoring?**

Survey of US-based general medical oncologists, May 2023. N = 75

Questions from General Medical Oncologists (Continued)

- **I am treating a patient with cholangiocarcinoma with pemigatinib. This individual developed hyperphosphatemia and nail toxicity. Would you be able to provide "pearls" for someone who doesn’t use the drug very often?**
- **How often are you checking phosphorus levels?**
- **What are the differences between reversible and irreversible FGFR inhibitors both in activity and side-effect profiles? Can they be used if progression on an FGFR inhibitor?**

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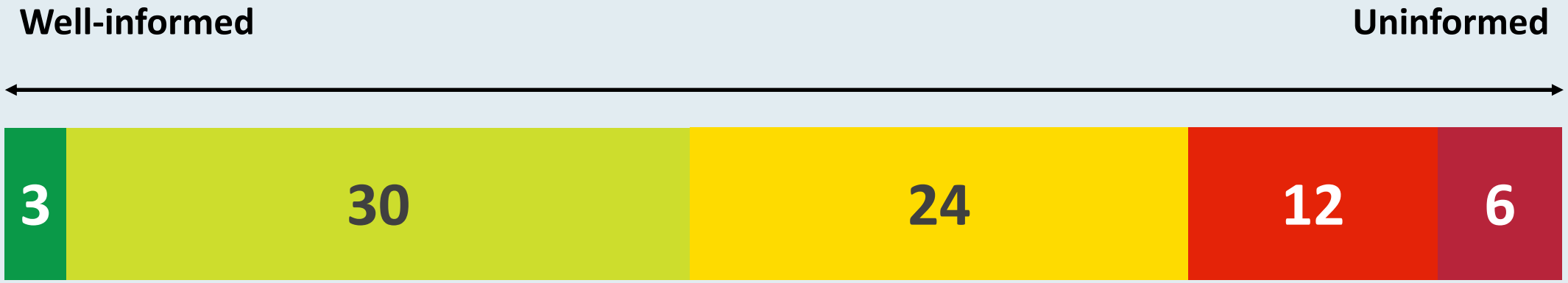
How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to management of metastatic cholangiocarcinoma with IDH1 mutations?



44% feel well informed

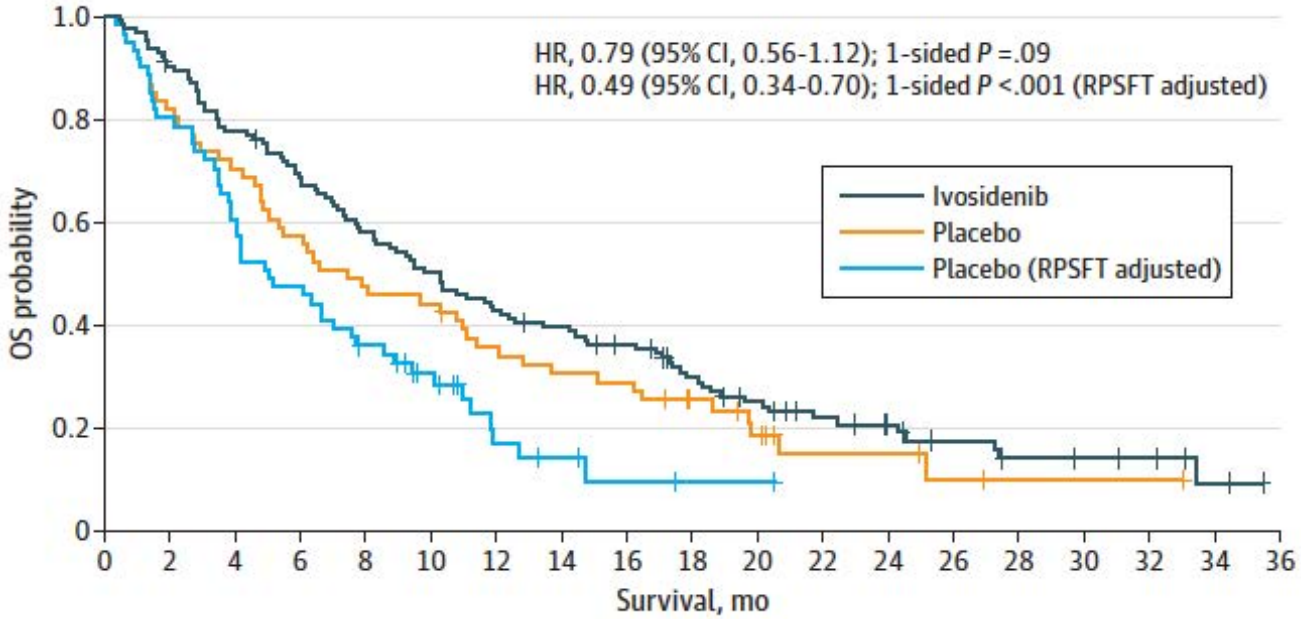
Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

Management of metastatic cholangiocarcinoma with IDH1 mutations

- Zhu AX et al. **Final overall survival efficacy results of ivosidenib for patients with advanced cholangiocarcinoma with IDH1 mutation: The Phase 3 randomized clinical ClarIDHy trial.** *JAMA Oncol* 2021;7(11):1669-77.

ClarIDHy: Final Overall Survival (OS) with Ivosidenib for Patients with Advanced Cholangiocarcinoma with IDH1 Mutations



No. at risk

Ivosidenib	126	113	97	85	72	62	53	48	42	32	25	18	14	10	7	6	5	2
Placebo	61	50	43	35	29	27	21	18	17	12	8	4	4	2	1	1	1	
Placebo (RPSFT adjusted)	61	49	37	29	21	14	6	4	2	1	1							

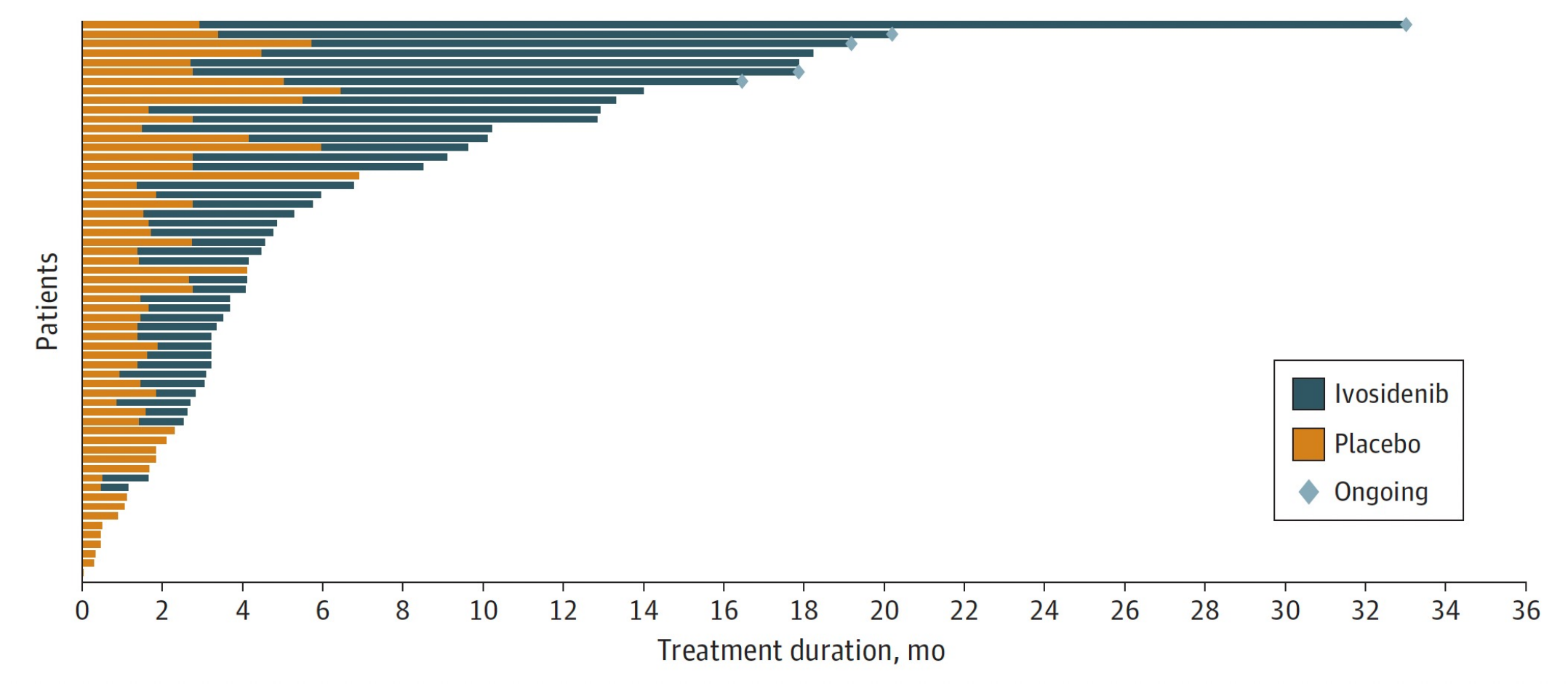
Treatment group	Events/patients, No.	OS, median (95% CI), mo
Ivosidenib	100/126	10.3 (7.8-12.4)
Placebo	50/61	7.5 (4.8-11.1)
Placebo adjusted by RPSFT	49/61	5.1 (3.8-7.6)

RPSFT = rank-preserving structural failure time

Zhu AX et al. *JAMA Oncol* 2021;7(11):1669-77.

RTP RESEARCH TO PRACTICE

ClarIDHy: Treatment Duration for All Patients Who Received Placebo, Including Those Who Crossed Over to Ivosidenib



Zhu AX et al. *JAMA Oncol* 2021;7(11):1669-77.

RTP RESEARCH TO PRACTICE

Questions from General Medical Oncologists

- **How often have you seen differentiation syndrome, and how are you managing it?**
- **What are the common adverse effects associated with IDH inhibitors, and recommendations regarding optimal management of such?**
- **A pt in her 70s failed first TOPAZ regimen. She has IDH 1 mutation. I planned ivosidenib. Pt went to MD Anderson for a second opinion. Surprisingly, the recommendation was FOLFIRI. The reason was low response rate of ivosidenib. Pt rapidly progressed with chemo.**

Survey of US-based general medical oncologists, May 2023. N = 75

Questions from General Medical Oncologists (Continued)

- **I have a 66-year-old male with metastatic cholangiocarcinoma whom I treated with durvalumab plus gemcitabine plus cisplatin, and he responded well for 11 months. He has now progressed and has an IDH 1 mutation. Do I re-challenge him with durvalumab plus gemcitabine plus cisplatin or give him IDH 1-targeted treatment? His ECOG is 1 and he has no comorbidities.**

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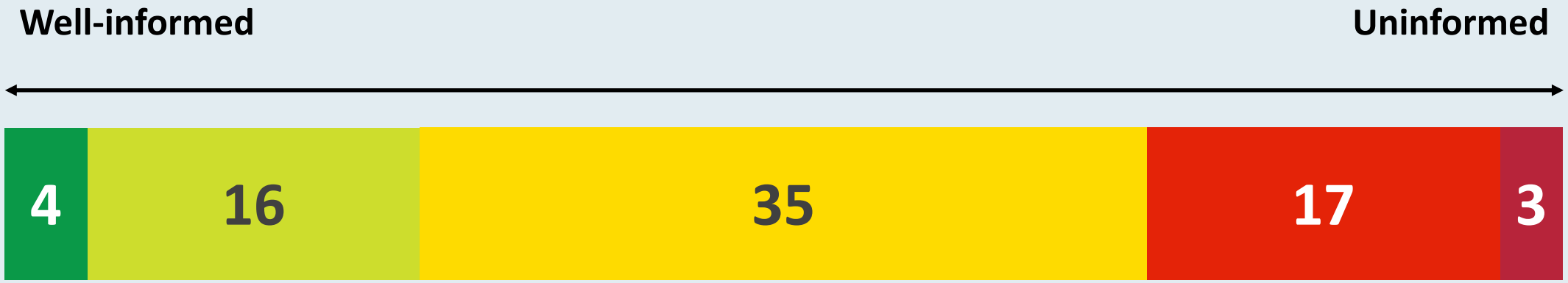
How comfortable/familiar are you with the published data sets, available guidelines, investigator perspectives and ongoing research studies pertaining to management of metastatic HER2-positive biliary tract cancer?



27% feel well informed

Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

Management of metastatic HER2-positive BTC

- Pant S et al. **Results from the pivotal phase (Ph) 2b HERIZON-BTC-01 study: Zanidatamab in previously-treated HER2-amplified biliary tract cancer (BTC).** ASCO 2023;Abstract 4008.
- Nakamura Y et al. **Tucatinib and trastuzumab for previously treated HER2-positive metastatic biliary tract cancer (SGNTUC-019): A phase 2 basket study.** ASCO 2023;Abstract 4007.
- Ohba A et al. **Trastuzumab deruxtecan (T-DXd; DS-8201) in patients (pts) with HER2-expressing unresectable or recurrent biliary tract cancer (BTC): An investigator-initiated multicenter phase 2 study (HERB trial).** ASCO 2022;Abstract 4006.
- Meric-Bernstam F et al. **Efficacy and safety of trastuzumab deruxtecan (T-DXd) in patients (pts) with HER2-expressing solid tumors: DESTINY-PanTumor02 (DP-02) interim results.** ASCO 2022;Abstract LBA3000 .

Pant S et al. ASCO 2023;Abstract 4008.

2023 ASCO ANNUAL MEETING

Results from the Pivotal Phase 2b HERIZON-BTC-01 Study: Zanidatamab in Previously-treated HER2-amplified Biliary Tract Cancer (BTC)

Shubham Pant, MD[1]; Jia Fan, MD, PhD[2]; Do-Youn Oh, MD, PhD[3]; Hye Jin Choi, MD, PhD[4]; Jin Won Kim, MD, PhD[5]; Heung-Moon Chang, MD, PhD[6]; Lequn Bao, MD[7]; Sun Huichuan, MD, PhD[2]; Teresa Macarulla, MD, PhD[8]; Feng Xie, MD[9]; Jean-Philippe Metges, MD[10]; Jie'er Ying, MD[11]; John A Bridgewater, MD, PhD[12]; Myung-Ah Lee, MD, PhD[13]; Mohamedtaki A Tejani, MD[14]; Emerson Y Chen, MD, MCR[15]; Dong Uk Kim, MD[16]; Harpreet Wasan, MD, FRCP[17]; Michel Ducreux, MD, PhD[18]; Yuanyuan Bao, MS[19]; Lin Yang, PhD[20]; JiaFang Ma, MD[19]; Phillip M Garfin, MD[20]; James J Harding, MD[21]

[1]MD Anderson Cancer Center, Houston, Texas, US; [2]Affiliated Zhongsha
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Seongnam, Korea; [6]Asan Medical Center, University of Ulsan College of
Vall d'Hebrón Institute of Oncology, Barcelona, Spain; [9]The Third Affiliate
Hopital Morvan, ARPEGO Network, Brest, France; [11]Zhejiang Cancer Ho
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Full Publication – *The Lancet Oncology*

Articles

Zanidatamab for *HER2*-amplified, unresectable, locally advanced or metastatic biliary tract cancer (HERIZON-BTC-01): a multicentre, single-arm, phase 2b study

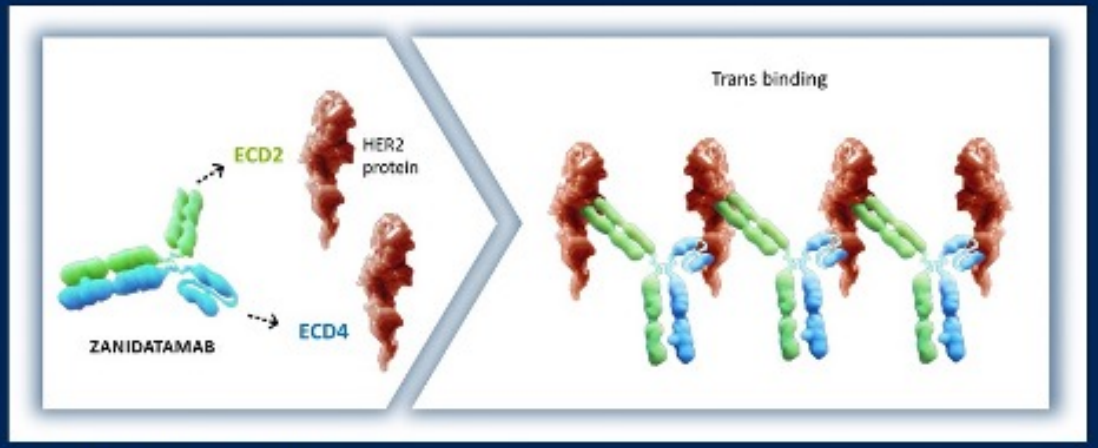
James J Harding, Jia Fan*, Do-Youn Oh, Hye Jin Choi, Jin Won Kim, Heung-Moon Chang, Lequn Bao, Hui-Chuan Sun, Teresa Macarulla, Feng Xie, Jean-Philippe Metges, Jie'er Ying, John Bridgewater, Myung-Ah Lee, Mohamedtaki A Tejani, Emerson Y Chen, Dong Uk Kim, Harpreet Wasan, Michel Ducreux, Yuanyuan Bao, Lisa Boyken, Jiafang Ma, Phillip Garfin, Shubham Pant, on behalf of the HERIZON-BTC-01 study group†*

- www.thelancet.com/oncology
- **Published online June 2, 2023 https://doi.org/10.1016/S1470-2045(23)00242-5**

RTP RESEARCH TO PRACTICE

Zanidatamab is a HER2-targeted Bispecific Antibody with a Unique Mechanism of Action (MOA)

- Zanidatamab simultaneously binds 2 separate HER2 molecules in *trans*[1]
- Unique binding properties of zanidatamab to HER2 result in multiple MOAs[1]
- Preclinical studies demonstrate greater activity than trastuzumab ± pertuzumab[1]
- Zanidatamab has shown a manageable safety profile and encouraging antitumor activity in patients with HER2-expressing BTC in a Phase 1 trial[2]



ECD = extracellular domain

[1] Weisser NE, et al. Nature Commun 2023;14:1394. [2] Meric-Bernstam F, et al. Lancet Oncol 2022;23:1558–1570.

Pant S et al. ASCO 2023;Abstract 4008.

Disease Response in Patients with HER2-positive BTC (Cohort 1)

- 16 patients had ongoing responses at the time of data cutoff

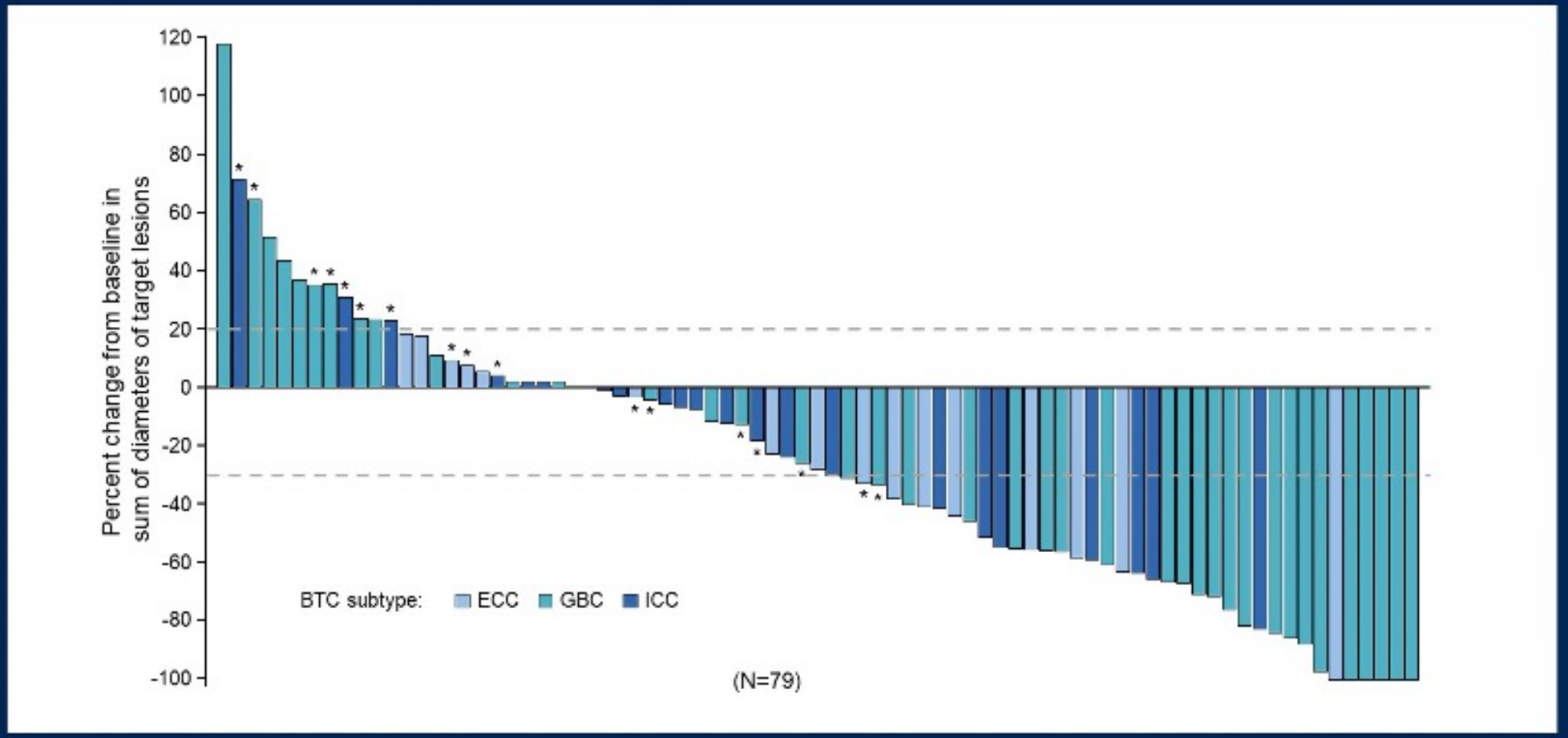
		By ICR Assessment (N = 80)	By Investigator Assessment (N = 80)
cORR, % (95% CI)		41.3 (30.4, 52.8)	41.3 (30.4, 52.8)
Confirmed BOR, n (%)	CR	1 (1.3)	4 (5.0)
	PR	32 (40.0)	29 (36.3)
	SD	22 (27.5)	21 (26.3)
	PD	24 (30.0)	25 (31.3)
	NE[1]	1 (1.3)	1 (1.3)
DCR [CR + PR + SD], % (95% CI)		68.8 (57.4, 78.7)	67.5 (56.1, 77.6)
CBR [CR + PR + (SD ≥ 6 months)], % (95% CI)		47.5 (36.2, 59.0)	47.5 (36.2, 59.0)

CBR = clinical benefit rate; CI = confidence interval; CR = complete response; DCR = disease control rate; NE = not evaluable; PD = progressive disease; PR = partial response; SD = stable disease.

[1] NE = one patient died prior to first post-baseline tumor assessment.

Pant S et al. ASCO 2023;Abstract 4008.

Majority of evaluable patients (68.4%) had a decrease in target lesions (Cohort 1)



* Indicates patients with IHC 2+ status; all other patients had IHC status of 3+.
Dotted lines indicate 20% increase and 30% decrease in sum of diameters of target tumors.

Pant S et al. ASCO 2023;Abstract 4008.

Adverse Events

	Cohort 1 (N = 80)		Total (N = 87)	
	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Any TEAE, n (%)	78 (97.5)	46 (57.5)	84 (96.6)	52 (59.8)
Any TRAE, n (%)	61 (76.3)	15 (18.8)	63 (72.4)	16 (18.4)
Serious TRAE, n (%)	7 (8.8)	7 (8.8)	7 (8.0)	7 (8.0)
TRAEs leading to treatment discontinuation, n (%)	2 (2.5)	1 (1.3)	2 (2.3)	1 (1.1)
TRAEs leading to death, n (%)	0	0	0	0
TRAEs, any Grade occurring in ≥ 10% of patients or Grade ≥ 3 in ≥ 2 patients, n (%)				
Diarrhea	32 (40.0)	4 (5.0)	32 (36.8)	4 (4.6)
IRR	28 (35.0)	1 (1.3)	29 (33.3)	1 (1.1)
Ejection fraction decreased	8 (10.0)	3 (3.8)	8 (9.2)	3 (3.4)
Nausea	8 (10.0)	1 (1.3)	8 (9.2)	1 (1.1)
Anemia	4 (5.0)	2 (2.5)	4 (4.6)	2 (2.3)

TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event.

- 2 TRAEs led to zanidatamab discontinuation:
  - 1 Grade 2 ejection fraction decreased
  - 1 Grade 3 pneumonitis
- 3 patients had TRAES that led to dose reductions:
  - 1 Grade 3 diarrhea
  - 1 Grade 3 diarrhea and Grade 3 nausea
  - 1 Grade 2 weight decreased
- No serious TRAEs occurred in more than 1 patient
- No Grade 4 TRAES; no treatment-related deaths

Pant S et al. ASCO 2023;Abstract 4008.

2023 ASCO ANNUAL MEETING

Abstract 4007

Tucatinib and Trastuzumab for Previously Treated HER2-Positive Metastatic Biliary Tract Cancer (SGNTUC-019): A Phase 2 Basket Study

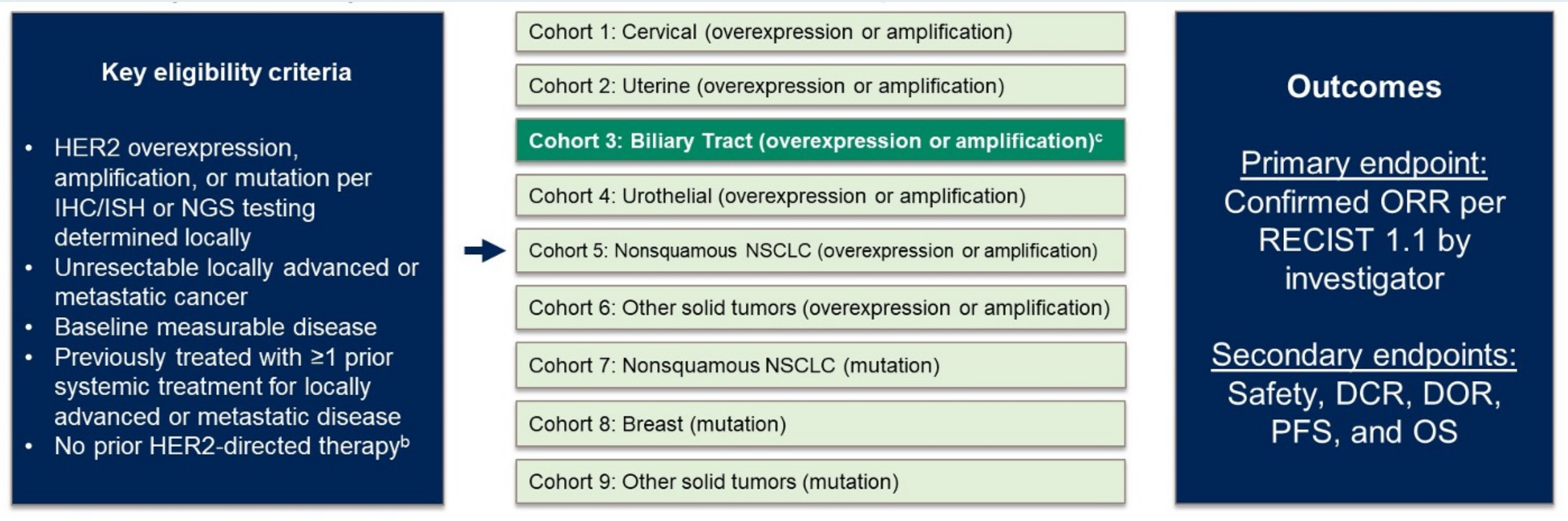
Yoshiaki Nakamura

National Cancer Center Hospital East, Kashiwa, Japan

Nobumasa Mizuno, Yu Sunakawa, Erika P. Hamilton, Hidetoshi Hayashi, Seung Tae Kim, Keun-Wook Lee, Bradley J. Monk, Danny Nguyen, Alicia Okines, David M. O'Malley, Paula R. Pohlmann, Martin Reck, Evan Y. Yu, Roman Groisberg, Jorge Ramos, Sherry Tan, Thomas E. Stinchcombe, Tanios S. Bekaii-Saab

RTP RESEARCH TO PRACTICE

SGNTUC-019: Phase II Trial Schema



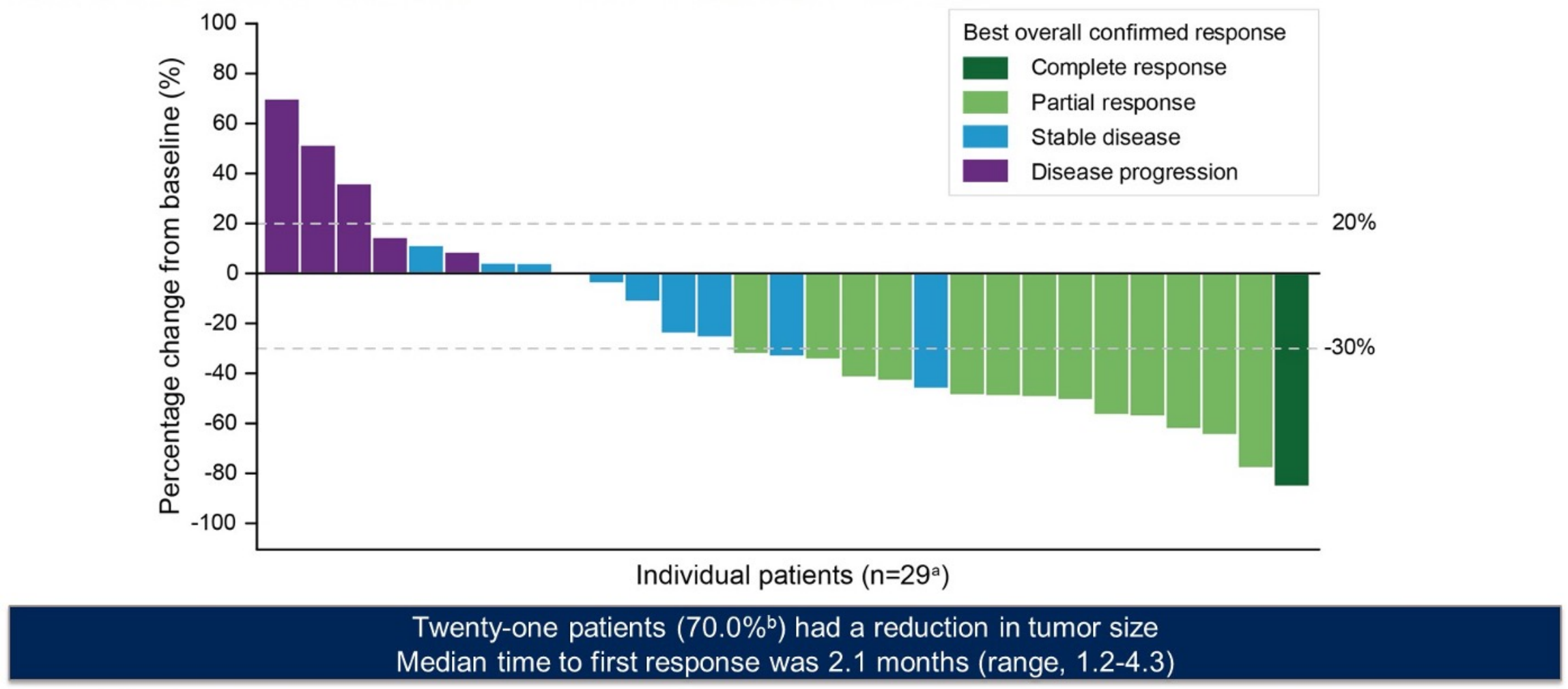
Nakamura Y et al. ASCO 2023;Abstract 4007.

SGNTUC-019: Response to Tucatinib and Trastuzumab

		Total (N=30)
Best overall response, n (%)	CR	1 (3.3)
	PR	13 (43.3)
	SD	9 (30.0)
	PD	6 (20.0)
	Not available	1 (3.3)[a]
cORR, % (90% CI)		**46.7 (30.8-63.0)**
Median DOR, months (90% CI)		6.0 (5.5-6.9)
DCR, n (%)		23 (76.7)

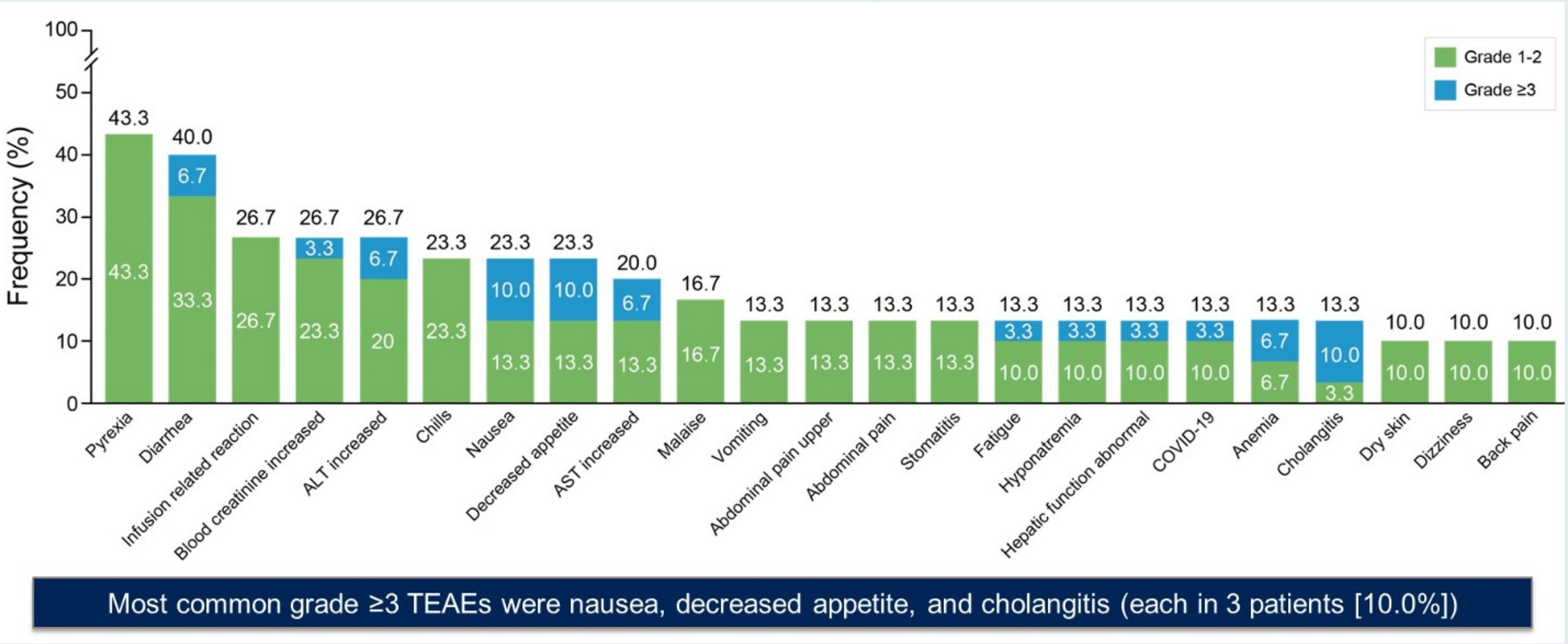
Nakamura Y et al. ASCO 2023;Abstract 4007.

SGNTUC-019: Best Percent Change from Baseline with Tucatinib and Trastuzumab



Nakamura Y et al. ASCO 2023;Abstract 4007.

SGNTUC-019: Most Common TEAEs



Nakamura Y et al. ASCO 2023;Abstract 4007.

HERB Primary Endpoint: Confirmed Objective Response Rate (ORR) by Blinded Independent Central Review

- Tumor response

*: P =0.01

	HER2-positive (n=22)	HER2-low-expressing (n=8)	All pts (n=30)
Confirmed ORR (90% CI) (95% CI)	**36.4% (19.6-56.1)*** (17.2–59.3)	12.5% – (0.3–52.7)	30.0% – (14.7–49.4)
Confirmed DCR (95% CI)	81.8% (59.7–94.8)	75.0% (34.9–96.8)	80.0% (61.4–92.3)
Confirmed best response, n (%)			
CR	2 (9.1)	0 (0)	2 (6.7)
PR	6 (27.3)	1 (12.5)	7 (23.3)
SD	10 (45.5)	5 (62.5)	15 (50.0)
PD	3 (13.6)	1 (12.5)	4 (13.3)
NE	1 (4.5)	1 (12.5)	2 (6.7)

- Best percentage change

Ohba A et al. ASCO 2022;Abstract 4006.

HERB: Interstitial Lung Disease/Pneumonitis with Trastuzumab Deruxtecan for Biliary Tract Cancer

	ILDs (n=8)*
Grade, n (%) 1 2 3 5	 3 (37.5) 1 (12.5) 2 (25.0) 2 (25.0)
Median time to onset (range), days	124 (35–247)**
Median Age (range), years	73 (51–75)
Sex, female, n (%)	3 (37.5)
Number of prior regimens, n (%) 1 ≥ 2	 4 (50.0) 4 (50.0)
HER2 status of IHC/ISH, n (%) 3+/+ 2+/+	 5 (62.5) 3 (37.5)
Lung metastasis, n (%)	3 (37.5)
Smoking history, n (%)	3 (37.5)
Biliary drainage, n (%)	4 (50.0)

Ohba A et al. ASCO 2022;Abstract 4006.

Trastuzumab Deruxtecan Meets Prespecified Criteria of Objective Response Rate and Duration of Response in the Phase II DESTINY-PanTumor02 Trial

Press Release – March 6, 2023

"Positive high-level results from an analysis of the ongoing DESTINY-PanTumor02 Phase II trial showed trastuzumab deruxtecan met the prespecified target for objective response rate (ORR) and demonstrated durable response across multiple HER2-expressing advanced solid tumours in heavily pretreated patients.

The DESTINY-PanTumor02 Phase II trial is evaluating the efficacy and safety of trastuzumab deruxtecan in patients with locally advanced, unresectable, or metastatic previously treated, HER2-expressing solid tumours not eligible for curative therapy, including biliary tract, bladder, cervical, endometrial, ovarian, pancreatic, and rare cancers. The primary endpoint of the trial is investigator-assessed confirmed ORR and investigator-assessed duration of response (DoR) is a key secondary endpoint.

The data will be presented at an upcoming medical meeting and shared with global regulatory authorities."

https://www.astrazeneca.com/media-centre/press-releases/2023/enhertu-destiny-pantumor02-shows-positive-results.html

Efficacy and Safety of Trastuzumab Deruxtecan (T-DXd) in Patients (Pts) with HER2-Expressing Solid Tumors: DESTINY-PanTumor02 (DP-02) Interim Results

Meric-Bernstam F et al.

ASCO 2023;Abstract LBA3000.
Monday, June 5th, 8:00 AM CDT

Questions from General Medical Oncologists

- **Role of T-DXd and in which line? Does pertuzumab add benefit to trastuzumab, and should it be combined with chemotherapy/ICI?**
- **Should trastuzumab be added with cisplatin/gem/durva? Should T-DXd be used as the 2nd line?**
- **72 yo patient with HER2-positive biliary tract cancer has progressed after 1 year on combined chemotherapy with trastuzumab and pertuzumab. Would you continue any anti-HER therapeutic options?**
- **How should we manage HER2-low tumors?**

Survey of US-based general medical oncologists, May 2023. N = 75

Impediments you have encountered in delivering high-quality care to patients with hepatobiliary cancers

- **Access to surgical expertise**
- **Definitely the rapid deterioration of performance status is a major challenge**
- **Patients with persistent biliary obstruction are frequently in and out of the hospital due to complications**
- **I am always unsure as to the role of radiation in these patients.**
- **Patients tend to be very sick and debilitated at diagnosis. Their ability to tolerate combination platinum-containing regimens is limited. If an obstruction cannot be stented, they tend not to do well with percutaneous drains, which severely limits my ability to resume systemic therapy.**

Survey of US-based general medical oncologists, May 2023. N = 75

RTP RESEARCH TO PRACTICE

APPENDIX

MODULE 1: First-Line Therapy for Advanced Hepatocellular Carcinoma (HCC) and Biliary Tract Cancers (BTCs)

RTP
RESEARCH
TO PRACTICE

IMbrave050: Phase 3 Study of Adjuvant Atezolizumab + Bevacizumab versus Active Surveillance in Patients with Hepatocellular Carcinoma (HCC) at High Risk of Disease Recurrence Following Resection or Ablation

Chow P et al.

AACR 2023;Abstract CT003.

IMbrave050: Safety

AE of any grade with an incident rate of ≥ 10% in either treatment group by preferred term

Event, n (%)	Atezo + bev (n=332)		Active surveillance (n=330)	
	Any grade	Grade 3 or 4	Any grade	Grade 3 or 4
Proteinuria	154 (46.4)	29 (8.7)	12 (3.6)	0
Hypertension	127 (38.3)	61 (18.4)	10 (3.0)	3 (0.9)
Platelet count decreased	66 (19.9)	15 (4.5)	22 (6.7)	4 (1.2)
Aspartate aminotransferase increased	52 (15.7)	3 (0.9)	18 (5.5)	2 (0.6)
Alanine aminotransferase increased	47 (14.2)	2 (0.6)	18 (5.5)	3 (0.9)
Hypothyroidism	47 (14.2)	0	1 (0.3)	0
Arthralgia	40 (12.0)	1 (0.3)	8 (2.4)	1 (0.3)
Pruritus	40 (12.0)	1 (0.3)	3 (0.9)	0
Rash	40 (12.0)	0	1 (0.3)	0
Blood bilirubin increased	34 (10.2)	1 (0.3)	23 (7.0)	1 (0.3)
Pyrexia	34 (10.2)	0	7 (2.1)	0

AE = adverse event; atezo = atezolizumab; bev = bevacizumab

Chow P et al. AACR 2023;Abstract CT003.

Research Article
Hepatic and Biliary Cancer

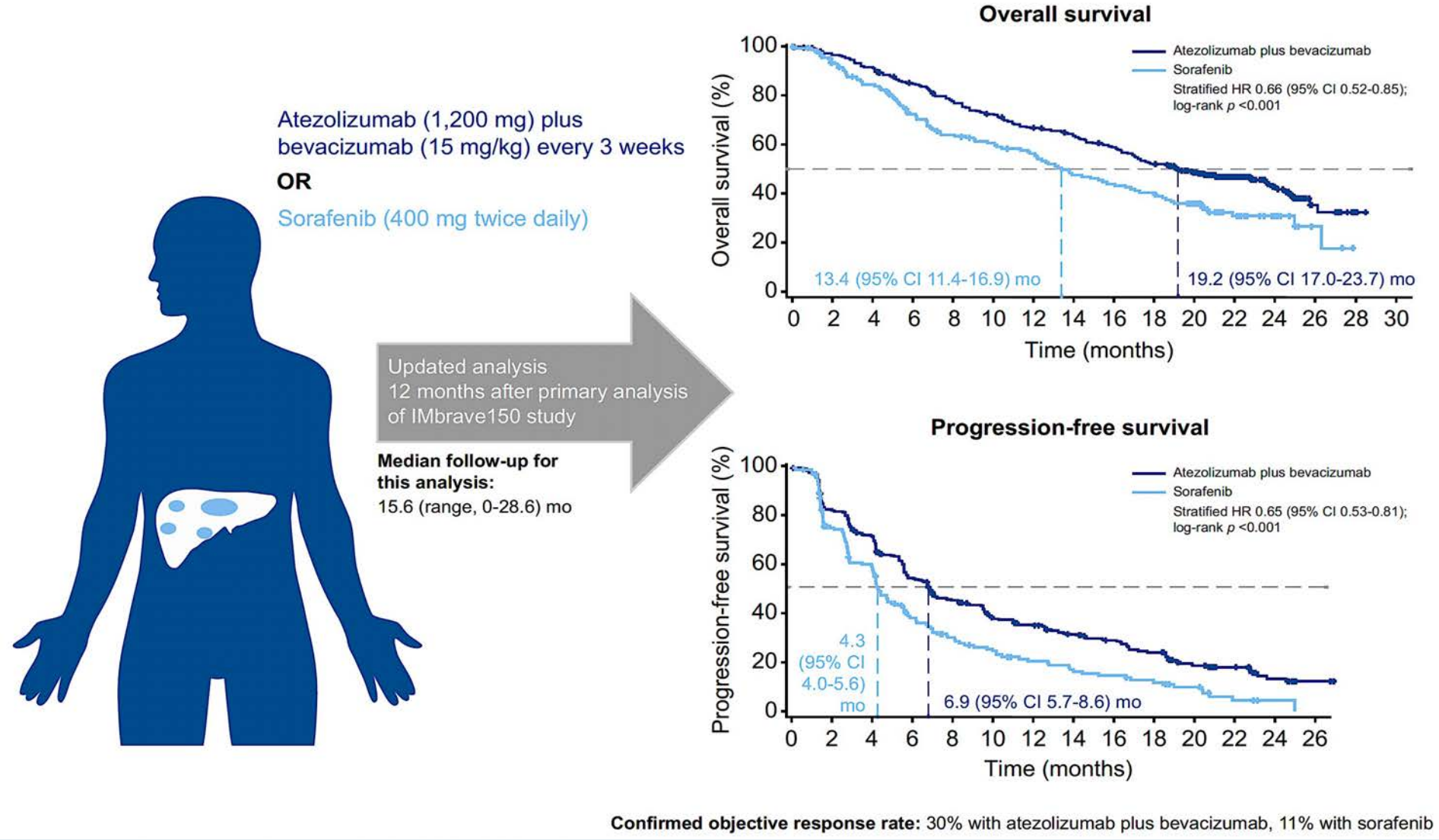
JOURNAL
OF HEPATOLOGY

Updated efficacy and safety data from IMbrave150: Atezolizumab plus bevacizumab *vs.* sorafenib for unresectable hepatocellular carcinoma

Ann-Lii Cheng[1,*], Shukui Qin[2], Masafumi Ikeda[3], Peter R. Galle[4], Michel Ducreux[5], Tae-You Kim[6], Ho Yeong Lim[7], Masatoshi Kudo[8], Valeriy Breder[9], Philippe Merle[10], Ahmed O. Kaseb[11], Daneng Li[12], Wendy Verret[13], Ning Ma[14], Alan Nicholas[15], Yifan Wang[16], Lindong Li[17], Andrew X. Zhu[18,19], Richard S. Finn[20,*]

2022;76(4):862-73.

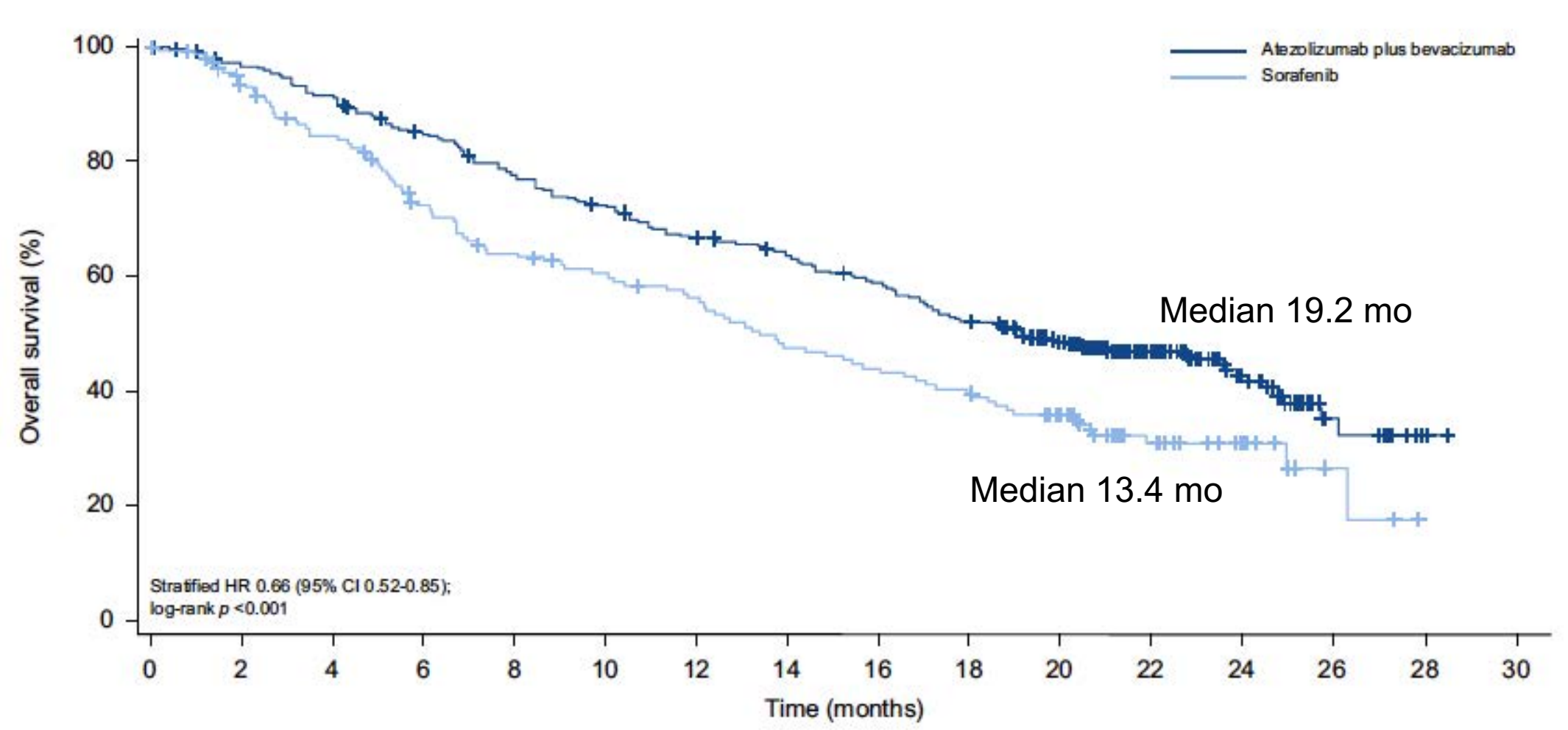
IMbrave150: Updated OS and PFS with Atezolizumab and Bevacizumab (Median Follow-Up 15.6 Months)



Confirmed objective response rate: 30% with atezolizumab plus bevacizumab, 11% with sorafenib

Cheng A-L et al. *J Hepatol* 2022;76(4):862-73.

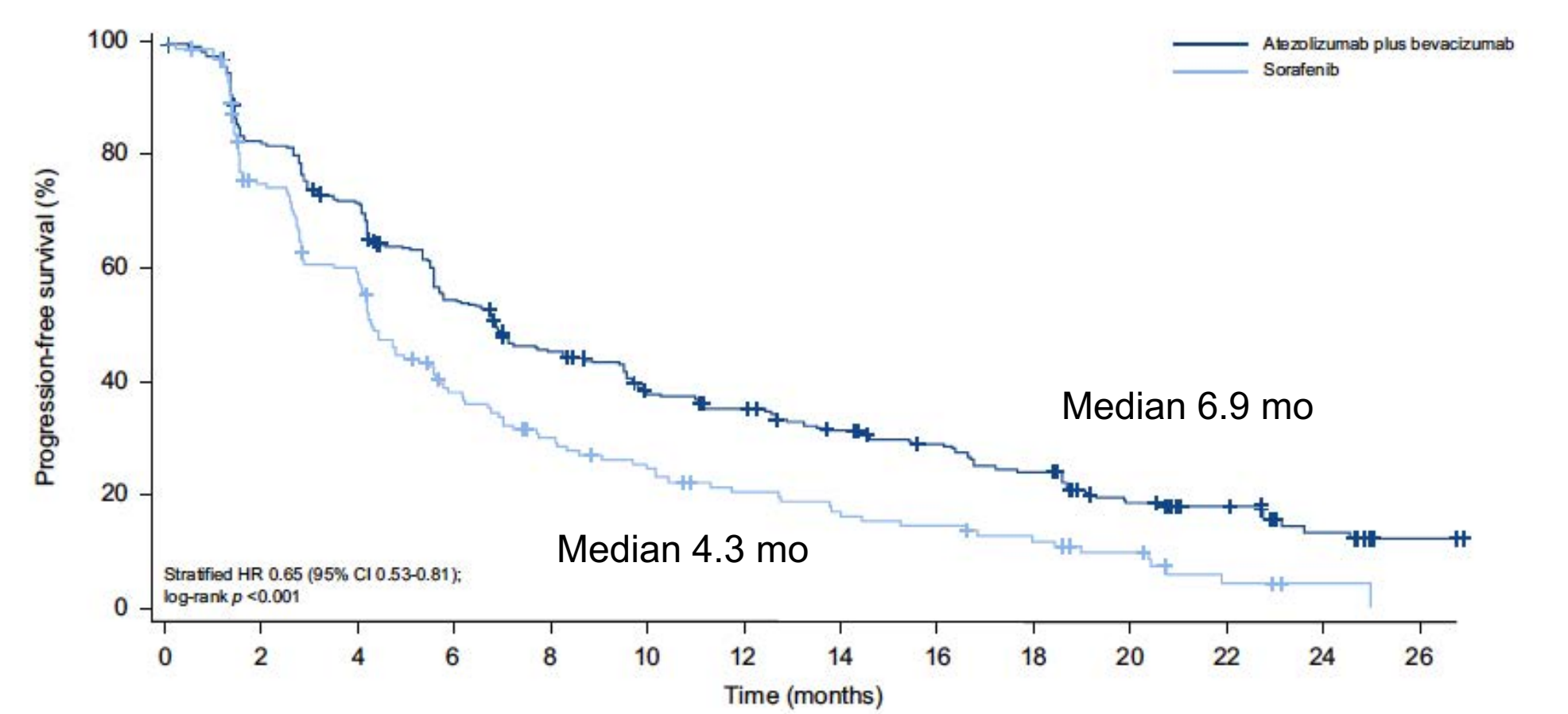
IMbrave150: Updated OS with Atezolizumab and Bevacizumab (Median Follow-Up 15.6 Months)



Cheng A-L et al. *J Hepatol* 2022;76(4):862-73.

RTP RESEARCH TO PRACTICE

IMbrave150: Updated PFS with Atezolizumab and Bevacizumab (Median Follow-Up 15.6 Months)



Cheng A-L et al. *J Hepatol* 2022;76(4):862-73.

RTP RESEARCH TO PRACTICE

FDA Approves Tremelimumab in Combination with Durvalumab for Unresectable Hepatocellular Carcinoma

Press Release – October 21, 2022

"The Food and Drug Administration approved tremelimumab in combination with durvalumab for adult patients with unresectable hepatocellular carcinoma (uHCC).

Efficacy was evaluated in HIMALAYA (NCT03298451), a randomized (1:1:1), open-label, multicenter study in patients with confirmed uHCC who had not received prior systemic treatment for HCC. Patients were randomized to one of three arms: tremelimumab 300 mg as a one-time single intravenous (IV) infusion plus durvalumab 1500 mg IV on the same day, followed by durvalumab 1500 mg IV every 4 weeks; durvalumab 1500 mg IV every 4 weeks; or sorafenib 400 mg orally twice daily until disease progression or unacceptable toxicity. This approval is based on a comparison of the 782 patients randomized to tremelimumab plus durvalumab to sorafenib."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tremelimumab-combination-durvalumab-unresectable-hepatocellular-carcinoma

NEJM Evidence

Published June 6, 2022

DOI: 10.1056/EVIDoa2100070

ORIGINAL ARTICLE

Tremelimumab Plus Durvalumab in Unresectable Hepatocellular Carcinoma

Ghassan K. Abou-Alfa, M.D., M.B.A.,[1,2] George Lau, M.D., F.R.C.P.,[3] Masatoshi Kudo, M.D., Ph.D.,[4] Stephen L. Chan, M.D.,[5] Robin Kate Kelley, M.D.,[6] Junji Furuse, M.D., Ph.D.,[7] Wattana Sukeepaisarnjaroen, M.D.,[8] Yoon-Koo Kang, M.D., Ph.D.,[9] Tu Van Dao, M.D., Ph.D.,[10] Enrico N. De Toni, M.D., Ph.D.,[11] Lorenza Rimassa, M.D.,[12,13] Valeriy Breder, M.D., Ph.D.,[14] Alexander Vasilyev, M.D.,[15] Alexandra Heurgué, M.D.,[16] Vincent C. Tam, M.D.,[17] Kabir Mody, M.D.,[18] Satheesh Chiradoni Thungappa, M.D.,[19] Yuriy Ostapenko, M.D.,[20] Thomas Yau, M.D.,[21] Sergio Azevedo, M.D.,[22] María Varela, M.D., Ph.D.,[23] Ann-Lii Cheng, M.D., Ph.D.,[24] Shukui Qin, M.D., Ph.D.,[25] Peter R. Galle, M.D., Ph.D.,[26] Sajid Ali, M.D.,[27] Michelle Marcovitz, Ph.D.,[27] Mallory Makowsky, Pharm.D.,[27] Philip He, Ph.D.,[27] John F. Kurland, Ph.D.,[27] Alejandra Negro, Ph.D.,[27] and Bruno Sangro, M.D., Ph.D.[28]

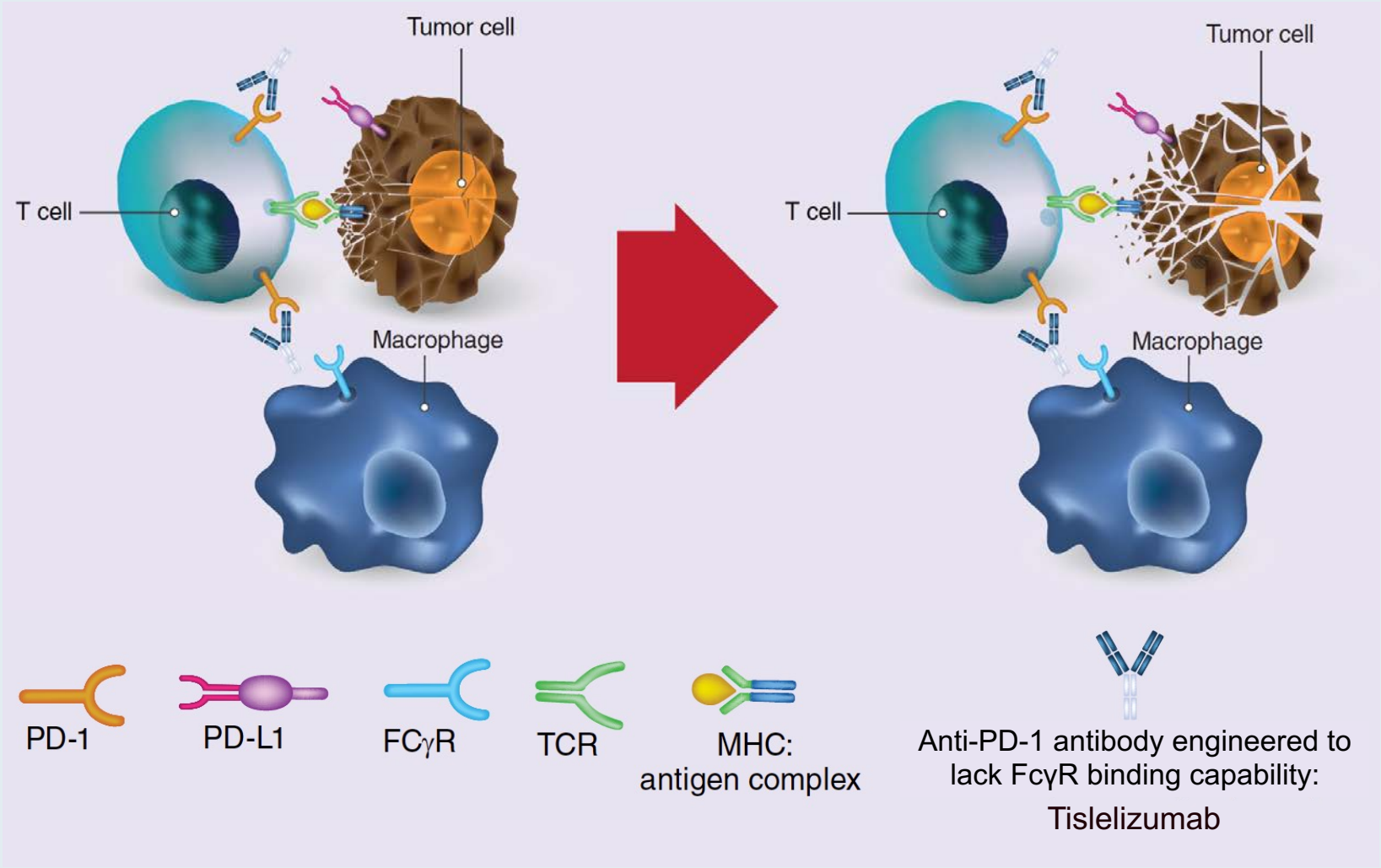
2022;1(8).

HIMALAYA: Response Outcomes (Intent-to-Treat Population)

Parameter	STRIDE (n=393)	Durvalumab (n=389)	Sorafenib (n=389)
Response — no. (%)			
Objective†	79 (20.1)	66 (17.0)	20 (5.1)
Complete	12 (3.1)	6 (1.5)	0
Partial	67 (17.0)	60 (15.4)	20 (5.1)
Stable disease — no. (%)	157 (39.9)	147 (37.8)	216 (55.5)
Disease control rate — %	236 (60.1)	213 (54.8)	236 (60.7)
Duration of response — mo‡			
Median	22.34	16.82	18.43
IQR	8.54–NR	7.43–NR	6.51–25.99
Time to response — mo			
Median	2.17	2.09	3.78

Abou-Alfa G et al. *NEJM Evid* 2022;1(8).

Tislelizumab Mechanism of Action



Tislelizumab is an anti-PD-1 antibody engineered to minimize binding to FcγR on macrophages in order to stop antibody-dependent phagocytosis, a potential mechanism of resistance to anti-PD-1 therapy.

FcγR = Fc gamma receptor; TCR = T cell receptor; MHC = major histocompatibility complex

Qin S et al. *Future Oncol* 2019;15(16):1811-22.

Abstract LBA36

PARIS 2022 ESMO congress

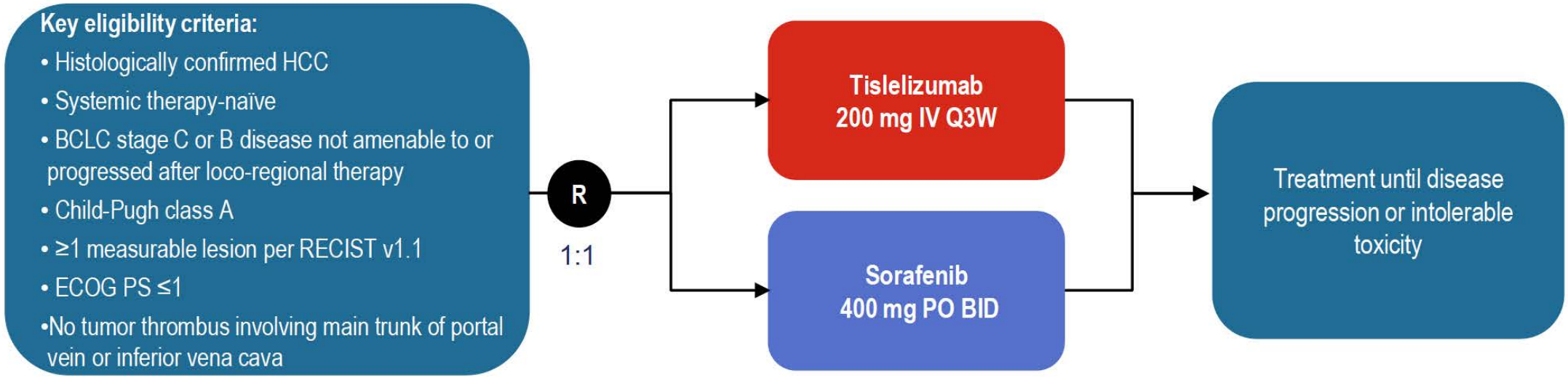
Final Analysis of RATIONALE-301: Randomized, Phase 3 Study of Tislelizumab Versus Sorafenib as First-Line Treatment for Unresectable Hepatocellular Carcinoma

Shukui Qin,[1] Masatoshi Kudo,[2] Tim Meyer,[3] Richard S. Finn,[4] Arndt Vogel,[5] Yuxian Bai,[6] Yabing Guo,[7] Zhiqiang Meng,[8] Tao Zhang,[9] Taroh Satoh,[10] Atsushi Hiraoka,[11] Donatella Marino,[12] Eric Assenat,[13] Lucjan Wyrwicz,[14] Mariona Calvo Campos,[15] Kuo Hsing-Tao,[16] Frederic Boisserie,[17] Songzi Li,[18] Yaxi Chen,[19] Andrew X. Zhu[20]

[1]Cancer Center, Qinhuai Medical District, General Hospital of Eastern Theater of PLA, Nanjing, China; [2]Department of Gastroenterology and Hepatology, Kindai University Faculty of Medicine, Osaka, Japan; [3]Department of Oncology, Royal Free Hospital NHS Trust and UCL Cancer Institute, London, UK; [4]Department of Medicine, Division of Hematology/Oncology, University of California Los Angeles, Los Angeles, CA, USA; [5]Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany; [6]Department of Gastrointestinal Oncology, Harbin Medical University Cancer Hospital, Harbin, China; [7]Center for Infectious Diseases and Liver Diseases, Nanfang Hospital, Southern Medical University, Guangzhou, China; [8]Department of Integrative Oncology, Fudan University Shanghai Cancer Hospital, Shanghai, China; [9]Cancer Center, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China; [10]Department of Frontier Science for Cancer and Chemotherapy, Osaka University, Osaka, Japan; [11]Gastroenterology Center, Ehime Prefectural Central Hospital, Matsuyama, Japan; [12]Division of Medical Oncology, Ordine Mauriziano Hospital, Turin, Italy; [13]Department of Medical Oncology, Montpellier University Hospital, Montpellier, France; [14]Department of Oncology and Radiotherapy, Maria Sklodowska-Curie National Cancer Research Institute, Warsaw, Poland; [15]Department of Medical Oncology, Institut Català d'Oncologia, Barcelona, Spain; [16]Department of Gastroenterology, Chi Mei Medical Center, Tainan, Taiwan; [17]Clinical Development – Solid Tumor, BeiGene, Ltd., Ridgefield Park, NJ, USA; [18]Statistics and Data Science, BeiGene, Ltd., Ridgefield Park, NJ, USA; [19]Clinical Development – Solid Tumor, BeiGene (Beijing) Co., Ltd., Beijing, China; [20]Department of Medicine, Massachusetts General Hospital Cancer Center, Boston, MA, USA; Jiahui International Cancer Center, Jiahui Health, Shanghai, China

RTP RESEARCH TO PRACTICE

RATIONALE-301 Phase III Trial Design



Primary endpoint: OS in the ITT population

Key secondary endpoints: ORR, PFS, and DoR by BIRC per RECIST v1.1, and safety

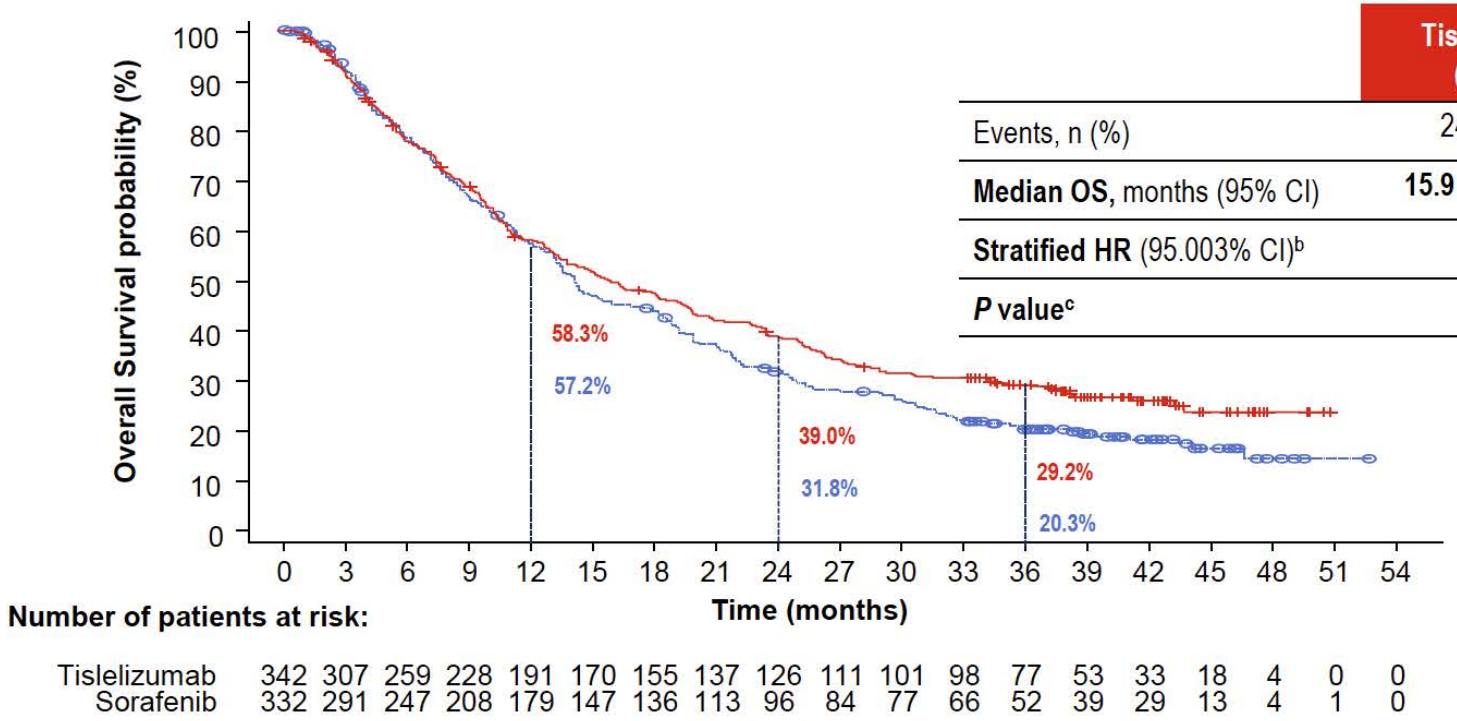
Stratification factors: Macrovascular invasion (present vs absent), extrahepatic spread (present vs absent), ECOG PS (0 vs 1), etiology (HCV vs other[a]), geography (Asia [excluding Japan], vs Japan vs rest of world)

[a]Includes HBV. Abbreviations: BCLC, Barcelona Clinic Liver Cancer; BID, twice daily; BIRC, blinded independent review committee; DoR, duration of response; ECOG PS, European Cooperative Oncology Group performance status; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ITT, intent-to-treat; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, oral; Q3W, once every 3 weeks; RECIST, Response Evaluation Criteria In Solid Tumors.

Qin S et al. ESMO 2022;Abstract LBA36.

RATIONALE-301: Overall Survival (OS)

Tislelizumab demonstrated OS noninferiority[a] vs sorafenib; OS superiority vs sorafenib was not met



	Tislelizumab (n=342)	Sorafenib (n=332)
Events, n (%)	242 (70.8)	255 (76.8)
Median OS, months (95% CI)	**15.9** (13.2, 19.7)	**14.1** (12.6, 17.4)
Stratified HR (95.003% CI)[b]	**0.85** (0.712, 1.019)	
***P* value**[c]	**0.0398**	

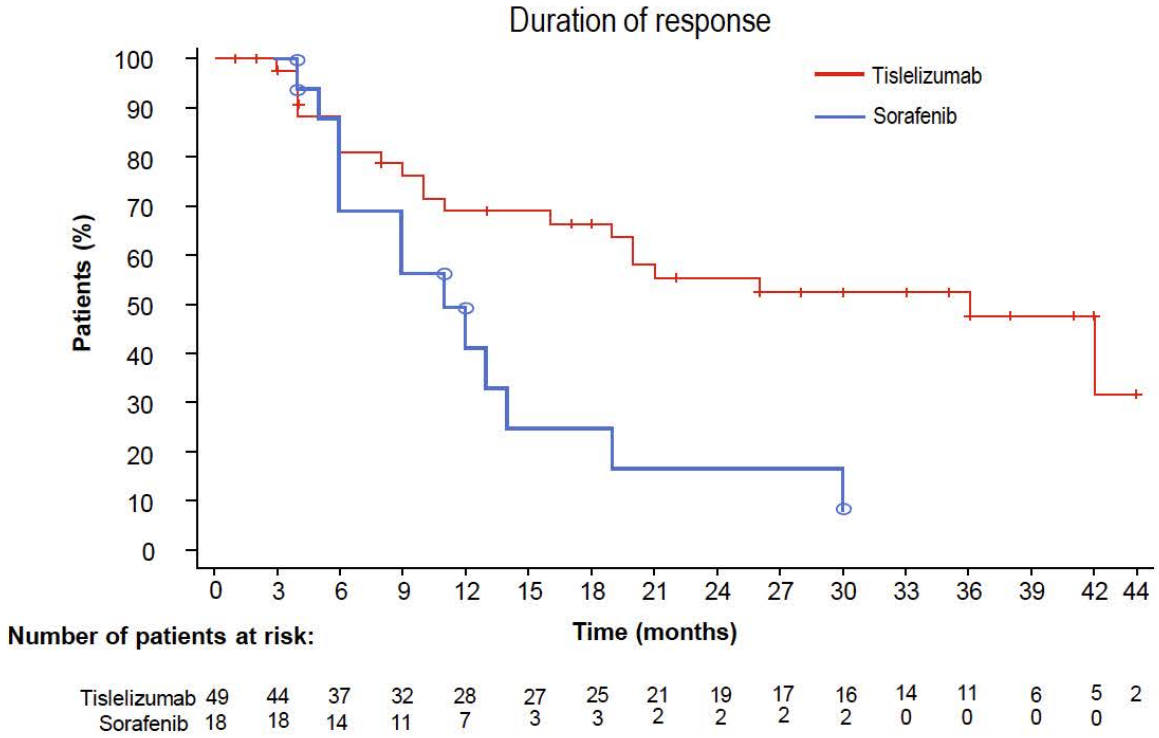
The OS results in the overall population were consistently observed across all subgroups.

Qin S et al. ESMO 2022;Abstract LBA36.

RATIONALE-301: Overall Response Rate by Independent Review Committee

Tislelizumab was associated with a higher ORR and more durable responses vs sorafenib

	Tislelizumab (n=342)	Sorafenib (n=332)
ORR, n (%) [95% CI][a]	49 (14.3) [10.8, 18.5]	18 (5.4) [3.2, 8.4]
Best overall response, n (%)[a]		
CR	10 (2.9)	1 (0.3)
PR	39 (11.4)	17 (5.1)
SD	94 (27.5)	139 (41.9)
PD	169 (49.4)	121 (36.4)
Undetermined[b]	22 (6.4)	44 (13.3)
Non-CR/non-PD[c]	8 (2.3)	10 (3.0)
Responders	**Tislelizumab (n=49)**	**Sorafenib (n=18)**
Median DoR, months (95% CI)	36.1 (16.8, NE)	11.0 (6.2, 14.7)
Patients with ongoing response, n (%)[d]	20/28 (71.4)	2/5 (40.0)

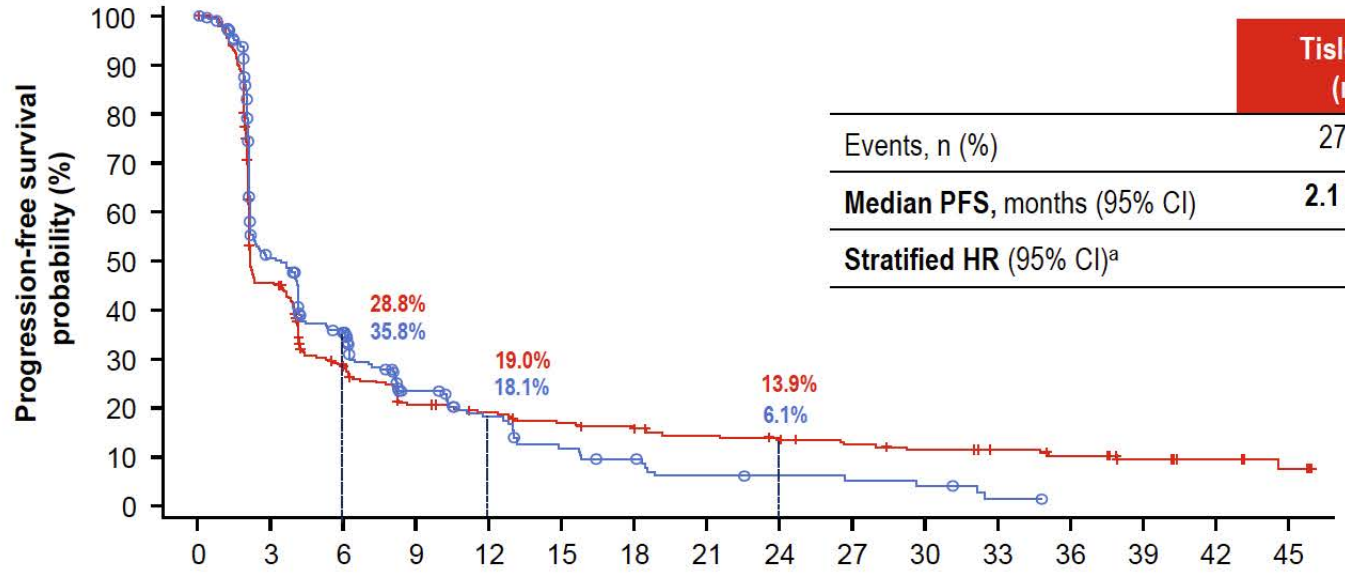


Qin S et al. ESMO 2022;Abstract LBA36.

RTP RESEARCH TO PRACTICE

RATIONALE-301: Progression-Free Survival (PFS)

The median PFS was longer with sorafenib versus tislelizumab



	Tislelizumab (n=342)	Sorafenib (n=332)
Events, n (%)	276 (80.7)	224 (67.5)
Median PFS, months (95% CI)	**2.1** (2.1, 3.5)	**3.4** (2.2, 4.1)
Stratified HR (95% CI)[a]	**1.11** (0.92, 1.33)	

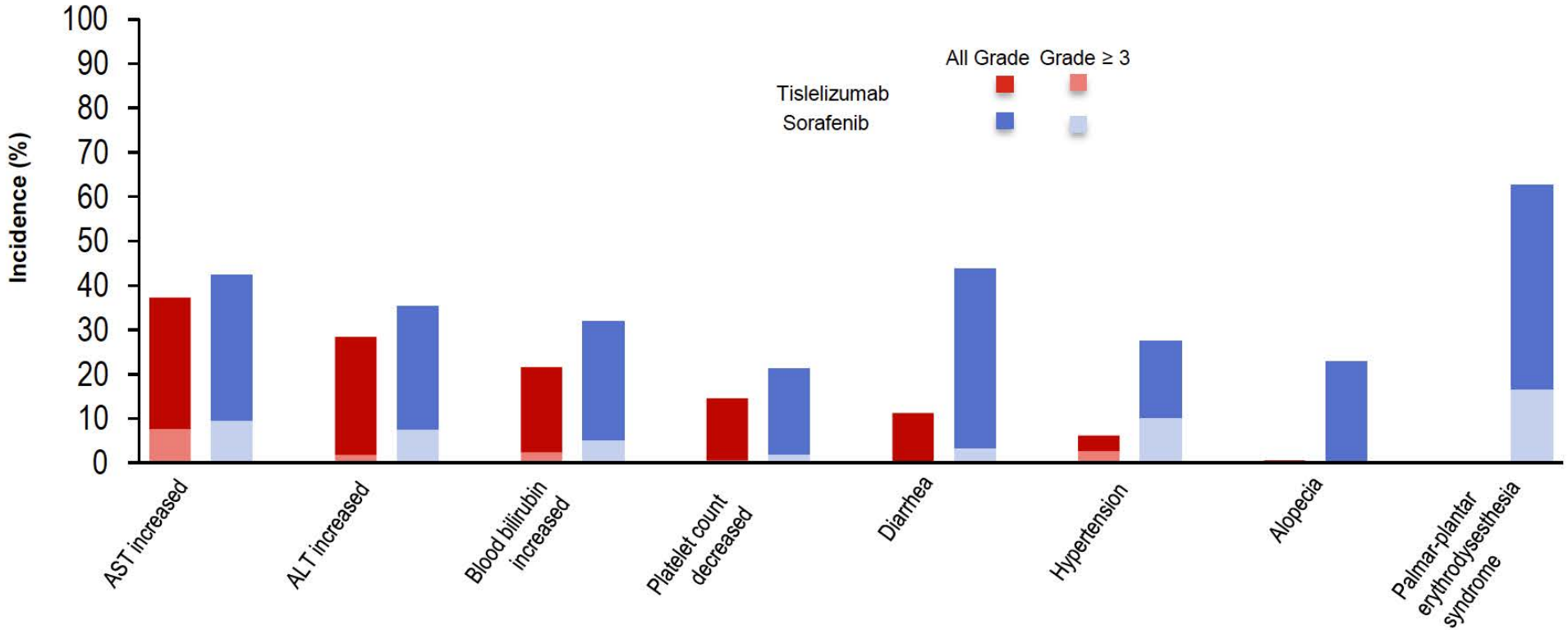
Number of patients at risk:

Tislelizumab	342	145	79	54	47	41	38	32	30	25	22	19	16	11	7	4
Sorafenib	332	125	80	38	26	17	12	7	6	5	4	1	0	0	0	0

Qin S et al. ESMO 2022;Abstract LBA36.

RATIONALE-301: Treatment-Emergent Adverse Events (TEAEs) in ≥20% of Patients

The incidence of TEAEs at any grade and at ≥grade 3 were lower with tislelizumab vs sorafenib; grade ≥3 hypertension and palmar-plantar erythrodysesthesia syndrome were more common with sorafenib

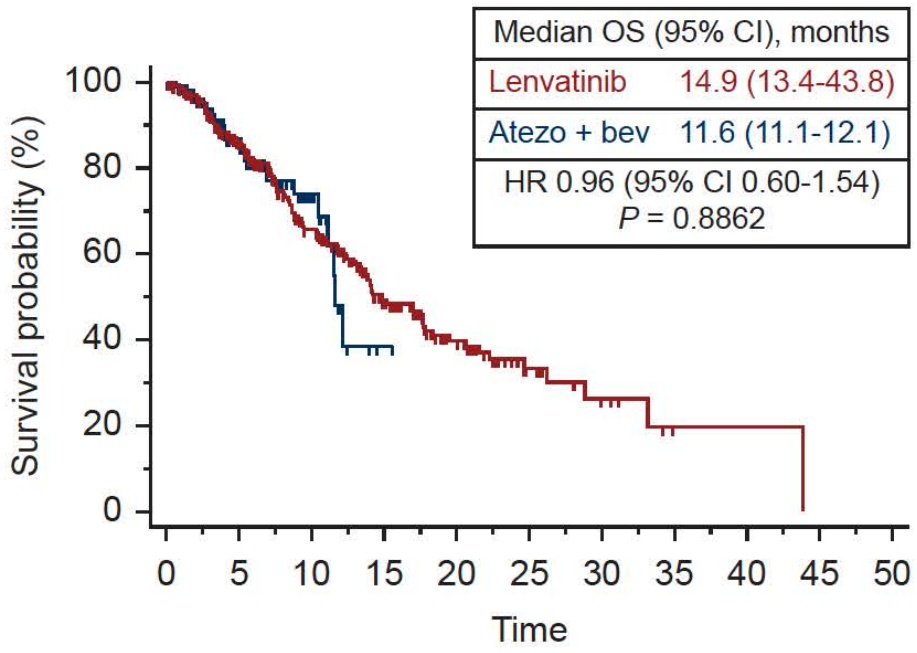


Qin S et al. ESMO 2022;Abstract LBA36.

Atezolizumab/Bevacizumab versus Lenvatinib for Nonviral Unresectable Hepatocellular Carcinoma: Non-NASH/NAFLD Population

NON-NASH/NAFLD population

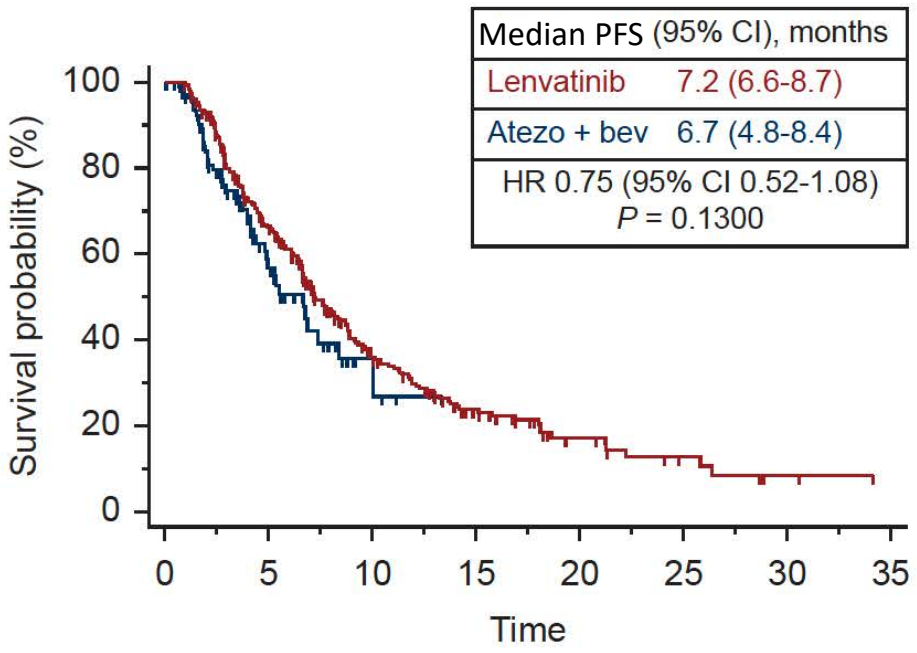
Overall Survival



Number at risk

Group: atezo + bev	108	52	15	1	0	0	0	0	0	0
Group: lenvatinib	315	226	138	69	33	13	6	1	1	0

Progression-Free Survival



Number at risk

Group: atezo + bev	108	30	4	0	0	0	0	0
Group: lenvatinib	315	183	73	33	13	6	2	0

NASH = nonalcoholic steatohepatitis; NAFLD = nonalcoholic fatty liver disease

Rimini M et al. *ESMO Open* 2022 December;7(6):100591.

FDA Approves Durvalumab for Locally Advanced or Metastatic Biliary Tract Cancer

Press Release – September 2, 2022

"The Food and Drug Administration approved durvalumab in combination with gemcitabine and cisplatin for adult patients with locally advanced or metastatic biliary tract cancer (BTC).

Efficacy was evaluated in TOPAZ-1 (NCT03875235), a randomized, double-blind, placebo-controlled, multiregional trial that enrolled 685 patients with histologically confirmed locally advanced unresectable or metastatic BTC who had not previously received systemic therapy for advanced disease.

Patients were randomized 1:1 to receive:

- durvalumab 1,500 mg on Day 1 + gemcitabine 1,000 mg/m^2 and cisplatin 25 mg/m^2 on Days 1 and 8 of each 21-day cycle up to 8 cycles, followed by durvalumab 1,500 mg every 4 weeks, or
- placebo on Day 1 + gemcitabine 1,000 mg/m^2 and cisplatin 25 mg/m^2 on Days 1 and 8 of each 21-day cycle up to 8 cycles, followed by placebo every 4 weeks.

Durvalumab or placebo were continued until disease progression or unacceptable toxicity. Treatment was permitted beyond disease progression if the patient was clinically stable and deriving clinical benefit, as determined by the investigator."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-locally-advanced-or-metastatic-biliary-tract-cancer

Poster 56P

ESMO 2022

Updated overall survival from the Phase 3 TOPAZ-1 study of durvalumab or placebo plus gemcitabine and cisplatin in patients with advanced biliary tract cancer

Do-Youn Oh,[1] Aiwu Ruth He,[2] Shukui Qin,[3] Li-Tzong Chen,[4] Takuji Okusaka,[5] Arndt Vogel,[6] Jin Won Kim,[7] Thatthan Suksomboon charoen,[8] Myung Ah Lee,[9] Masayuki Kitano,[10] Howard Burris,[11] Mohamed Bouattour,[12] Suebpong Tanasanvimon,[13] Renata Zaucha,[14] Antonio Avallone,[15] Juan Cundom,[16] Benjamin Tan,[17] Nana Rokutanda,[18] Magdalena Watras,[19] Gordon Cohen,[18] Juan W. Valle[20]

[1]Division of Medical Oncology, Department of Internal Medicine, Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Seoul, South Korea; [2]Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; [3]Cancer Center of Nanjing, Jinling Hospital, Nanjing, China; [4]National Institute of Cancer Research, National Health Research Institutes, Zhunan, Taiwan; [5]National Cancer Center Hospital, Tokyo, Japan; [6]Hanover Medical School, Hanover, Germany; [7]Division of Medical Oncology, Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, South Korea; [8]Department of Internal Medicine, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand; [9]Seoul St. Mary's Hospital, Catholic University, Seoul, South Korea; [10]Second Department of Internal Medicine, Wakayama Medical University, Wakayama, Japan; [11]Sarah Cannon Research Institute, Tennessee Oncology, Nashville, TN, USA; [12]AP-HP Hôpital Beaujon, Paris, France; [13]Department of Internal Medicine, Faculty of Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand; [14]Department of Oncology and Radiotherapy, Medical University of Gdańsk, Gdańsk, Poland; [15]Istituto Nazionale Tumori-IRCCS Fondazione G. Pascale, Naples, Italy; [16]Instituto de Investigaciones Metabólicas, Buenos Aires, Argentina; [17]Department of Medicine, Washington University School of Medicine, St. Louis, MO, USA; [18]AstraZeneca, Gaithersburg, MD, USA; [19]AstraZeneca, Warsaw, Poland; [20]University of Manchester and the Christie NHS Foundation Trust, Manchester, UK

KEYNOTE-966: Response Summary at the First Interim Analysis

Clinical endpoint	Pembrolizumab with gemcitabine/cisplatin (n = 533)	Placebo with gemcitabine/cisplatin (n = 536)
Objective response rate	29%	29%
Complete response	2%	1%
Partial response	27%	27%
Disease control rate	75%	76%
Time to response	2.8 mo	2.8 mo
Median duration of response	9.7 mo	6.9 mo

Kelley RK et al. *Lancet* 2023 April 14;[Online ahead of print].

KEYNOTE-966: Select Adverse Events

Adverse event	Pembrolizumab with gemcitabine/cisplatin (n = 529)			Placebo with gemcitabine/cisplatin (n = 534)		
	Grades 1 to 2	Grade 3	Grade 4	Grades 1 to 2	Grade 3	Grade 4
Decreased neutrophil count	14%	32%	17%	14%	32%	15%
Decreased platelet count	22%	12%	6%	20%	13%	7%
Anemia	32%	28%	<1%	30%	25%	1%
Decreased white blood cell count	15%	11%	1%	15%	8%	1%

- Thirty-one (6%) participants in the pembrolizumab group and 49 (9%) in the placebo group died due to adverse events, including 8 (2%) in the pembrolizumab group and 3 (1%) in the placebo group who died due to treatment-related adverse events.

Kelley RK et al. *Lancet* 2023 April 14;[Online ahead of print].

RTP RESEARCH TO PRACTICE

MODULE 2: Selection and Sequencing of Therapy for Relapsed/Refractory (R/R) HCC

RTP
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Anti-Angiogenic Agents for Progressive HCC

Clinical endpoint	RESORCE[1,2]		CELESTIAL[3]		REACH-2[4]	
	Regorafenib (n = 379)	Placebo (n = 194)	Cabozantinib (n = 470)	Placebo (n = 237)	Ramucirumab (n = 197)	Placebo (n = 95)
Median PFS	3.1 mo	1.5 mo	5.2 mo	1.9 mo	2.8 mo	1.6 mo
Median OS	10.7 mo	7.9 mo	10.2 mo	8.0 mo	8.5 mo	7.3 mo
ORR	11%	4%	4%	<1%	5%	1%

[1] Bruix J et al. *Lancet* 2017;389(10064):56-66; [2] Bruix J et al. ILCA 2018;Abstract O-023; [3] Abou-Alfa G, et al. *N Engl J Med* 2018;379(1):54-63; [4] Zhu AX et al. *Lancet Oncol* 2019;20(2):282-96.

KEYNOTE-224 and KEYNOTE-240: Updated Results with Pembrolizumab Monotherapy for Advanced HCC Previously Treated with Sorafenib

Clinical endpoint	KEYNOTE-224[1]	KEYNOTE-240[2]	
	Pembrolizumab (n = 104)	Pembrolizumab (n = 278)	Placebo (n = 135)
Median PFS	4.9 mo	3.0 mo	2.8 mo
Median OS	13.2 mo	13.9 mo	10.6 mo
ORR	18.3%	18.3%	4.4%

[1] Kudo M et al. *Eur J Cancer* 2022;167:1-12; [2] Merle P et al. *Liver Cancer* 2023;0:1-12.

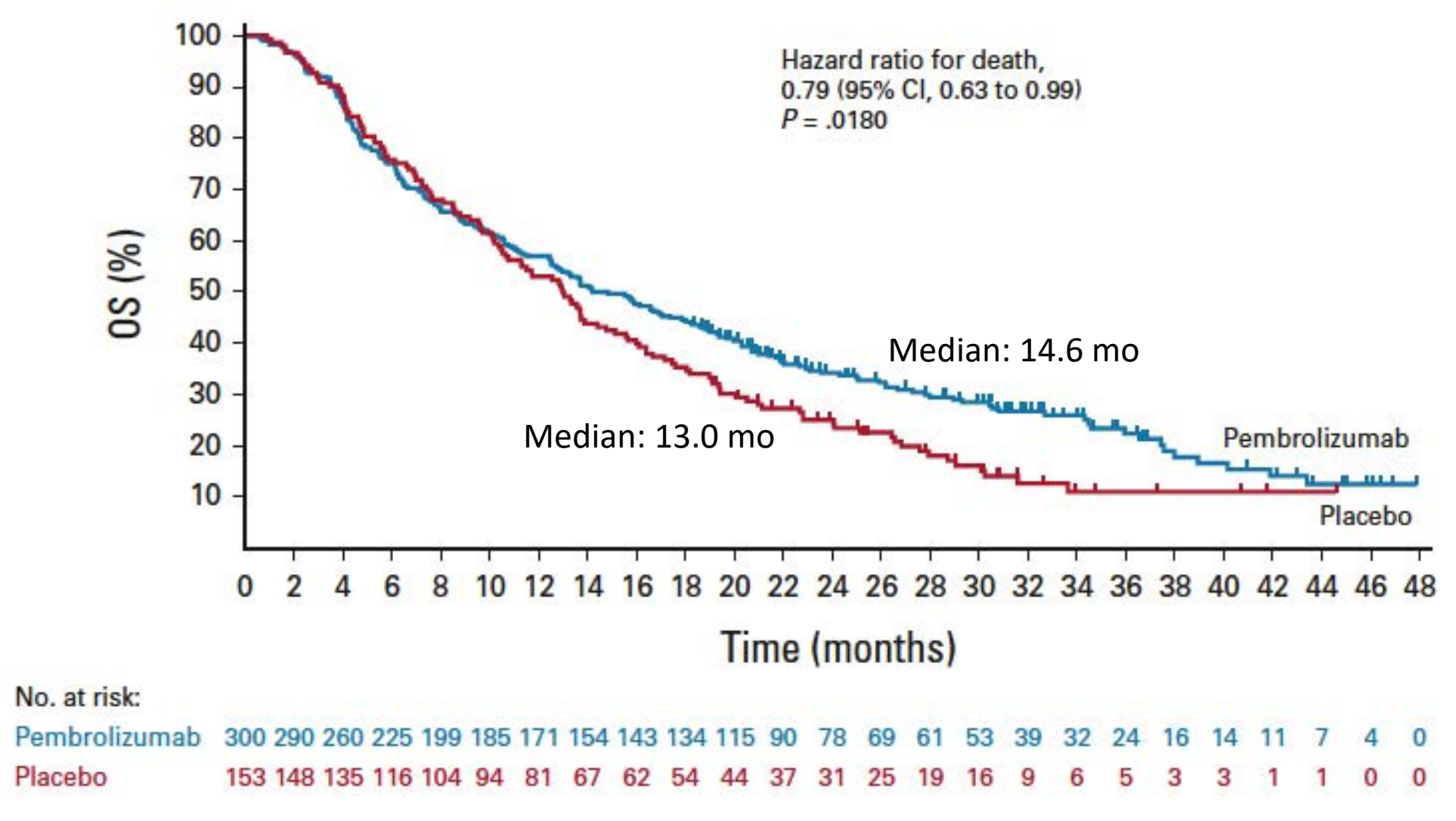
original reports

Pembrolizumab Versus Placebo as Second-Line Therapy in Patients From Asia With Advanced Hepatocellular Carcinoma: A Randomized, Double-Blind, Phase III Trial

Shukui Qin, MD[1]; Zhendong Chen, MD[2]; Weijia Fang, MD[3]; Zhenggang Ren, MD[4]; Ruocai Xu, MD[5]; Baek-Yeol Ryoo, MD[6]; Zhiqiang Meng, MD[7]; Yuxian Bai, MD[8]; Xiaoming Chen, MD[9,10]; Xiufeng Liu, MD[1]; Juxiang Xiao, MD[11]; Gwo Fuang Ho, MRCP, MBChB[12]; Yimin Mao, MD[13]; Xin Wang, MD[14]; Jieer Ying, MD[15]; Jianfeng Li, MD[16]; Wenyan Zhong, PhD[17]; Yu Zhou, MD[17]; Abby B. Siegel, MD[18]; and Chunyi Hao, MD[19]

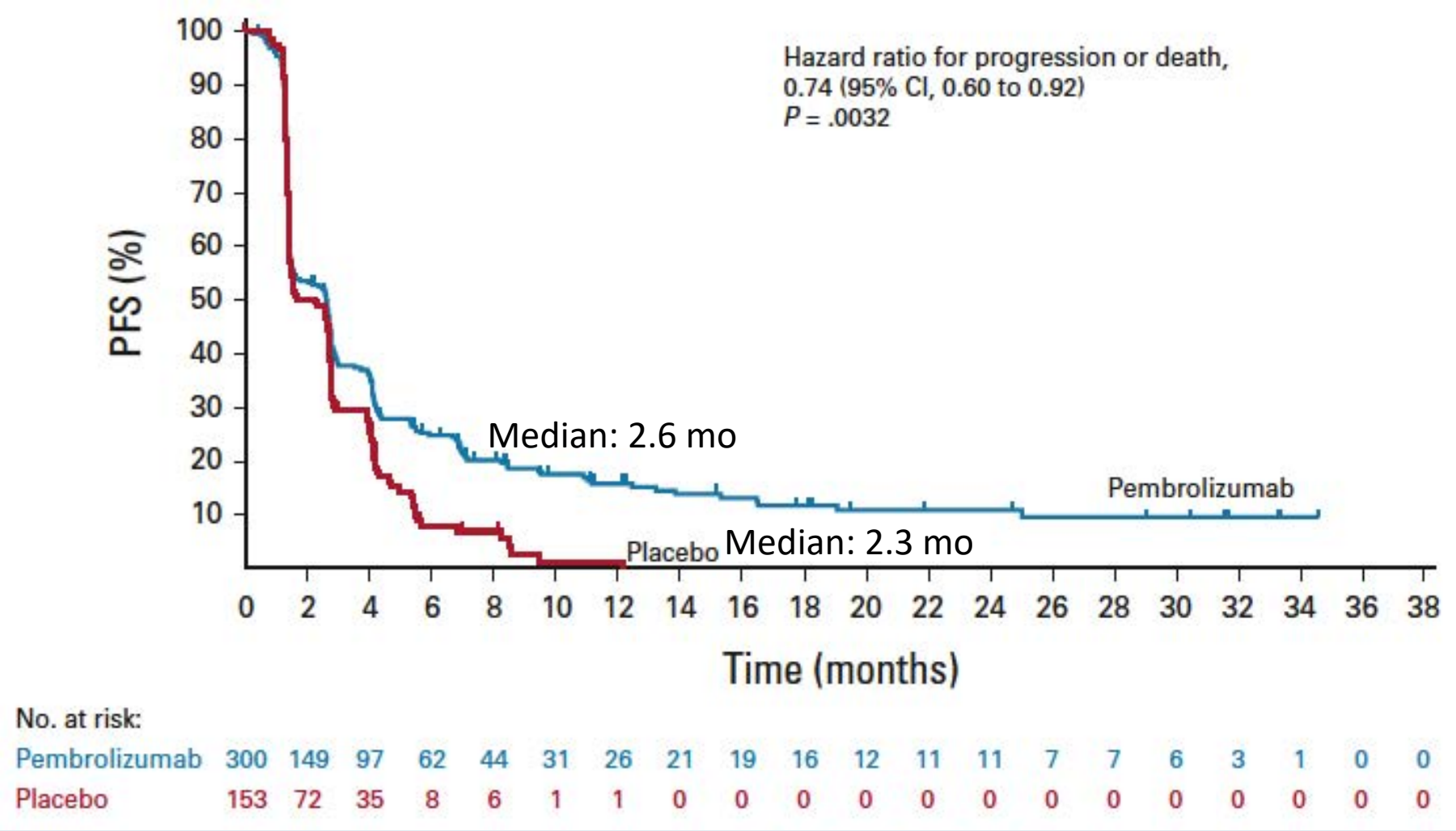
J Clin Oncol 2023;41:1434-43.

KEYNOTE-394 Primary Endpoint: Overall Survival



Qin S et al. *J Clin Oncol* 2023;41:1434-43.

KEYNOTE-394: Progression-Free Survival



Qin S et al. *J Clin Oncol* 2023;41:1434-43.

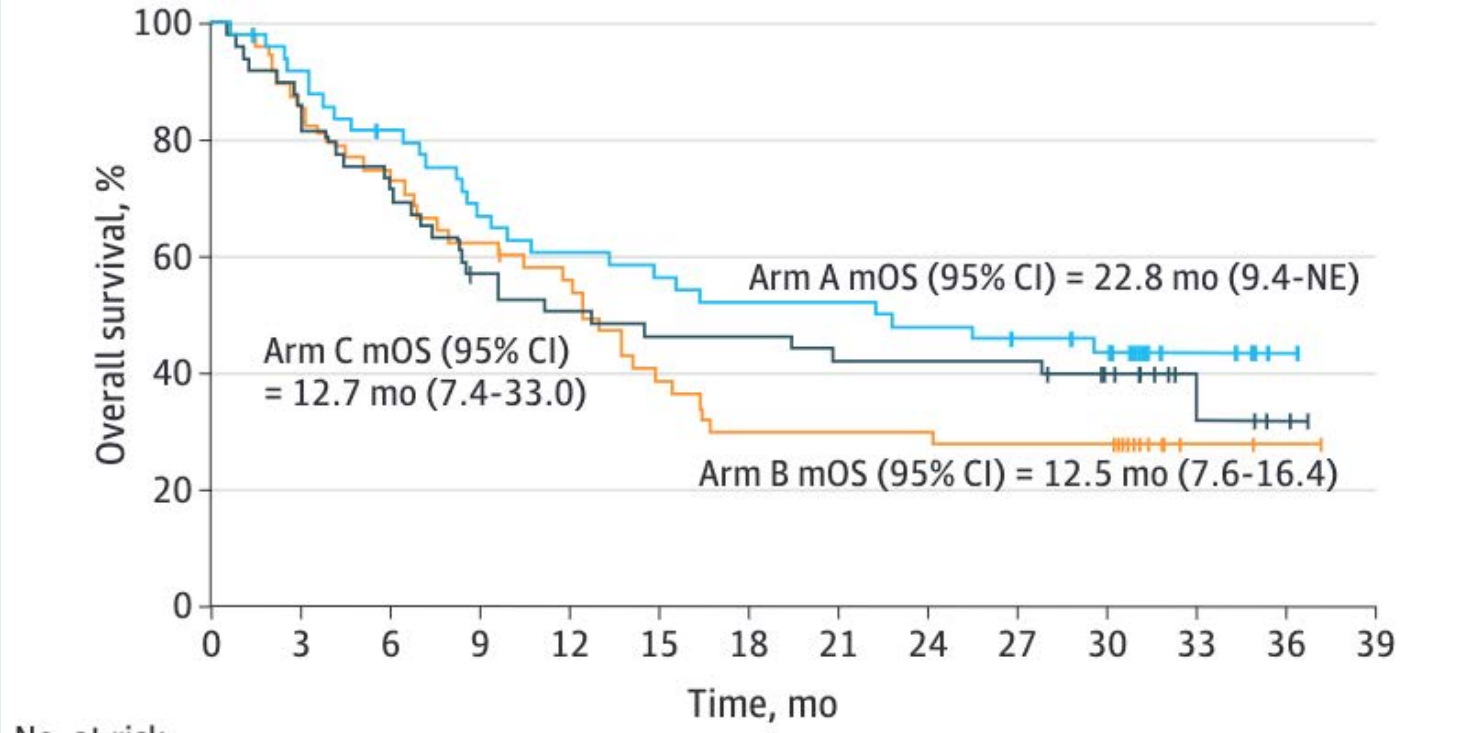
RTP RESEARCH TO PRACTICE

KEYNOTE-394: Confirmed Response at Second Interim Analysis

Confirmed Response	Pembrolizumab + Best Supportive Care (n = 300)	Placebo + Best Supportive Care (n = 153)
Objective response rate, % (95% CI)	12.7 (9.1 to 17.0)	1.3 (0.2 to 4.6)
Estimated treatment difference (95% CI)	11.4 (6.7 to 16.0)[b]	
P[c]	< .0001	
Disease control, No. (%)	153 (51.0)	72 (47.1)
Best overall response, No. (%)		
Complete response	6 (2.0)	1 (0.7)
Partial response	32 (10.7)	1 (0.7)
Stable disease	115 (38.3)	70 (45.8)
Sustained stable disease[d]	26 (8.7)	8 (5.2)
Progressive disease	129 (43.0)	72 (47.1)
Not evaluable	10 (3.3)	1 (0.7)
No assessment[e]	8 (2.7)	8 (5.2)
Duration of response, months, median (range)[f]	23.9 (2.8 to 32.0+)	5.6 (3.0+ to 5.6)

Qin S et al. *J Clin Oncol* 2023;41:1434-43.

CheckMate 040: Nivolumab with Ipilimumab for Patients with Advanced HCC Previously Treated with Sorafenib



No. at risk (censored)

Arm A	50	45	39	32	29	27	25	25	23	21	19	7	2	0
	(0)	(1)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(3)	(4)	(16)	(21)	(23)
Arm B	49	41	36	30	26	18	14	14	14	13	13	2	1	0
	(0)	(1)	(1)	(1)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(13)	(14)	(15)
Arm C	49	42	36	27	24	22	22	20	20	20	15	4	2	0
	(0)	(0)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(5)	(15)	(17)	(19)

- Arm A: Nivolumab 1 mg/kg with ipilimumab 3 mg/kg every 3 weeks (4 doses), followed by nivolumab 240 mg intravenously every 2 weeks
- Arm B: Nivolumab 3 mg/kg with ipilimumab 1 mg/kg every 3 weeks (4 doses), followed by nivolumab 240 mg intravenously every 2 weeks
- Arm C: Nivolumab 3 mg/kg every 2 weeks and ipilimumab 1 mg/kg every 6 weeks

mOS = median overall survival

Yau T et al. *JAMA Oncol* 2020;6(11):e204564.

Retrospective Analysis of Nivolumab/Ipilimumab for Patients with Advanced HCC Previously Treated with Immune Checkpoint Inhibitor-Based Combination Therapies

- Of 109 patients treated with atezolizumab and bevacizumab or other immune checkpoint inhibitor-based combinations, 10 patients received subsequent treatment with nivolumab/ipilimumab

Overall response per RECIST v1.1 and mRECIST

Variable	RECIST v1.1 % (*n*)	mRECIST % (*n*)
Overall response rate	30 (3)	30 (3)
Complete response	0 (0)	10 (1)
Partial response	30 (3)	25 (2)
Stable disease	10 (1)	10 (1)
Disease control rate	40 (4)	40 (4)
Progressive disease	60 (6)	60 (6)
Ongoing response at cut-off	30 (3)	30 (3)

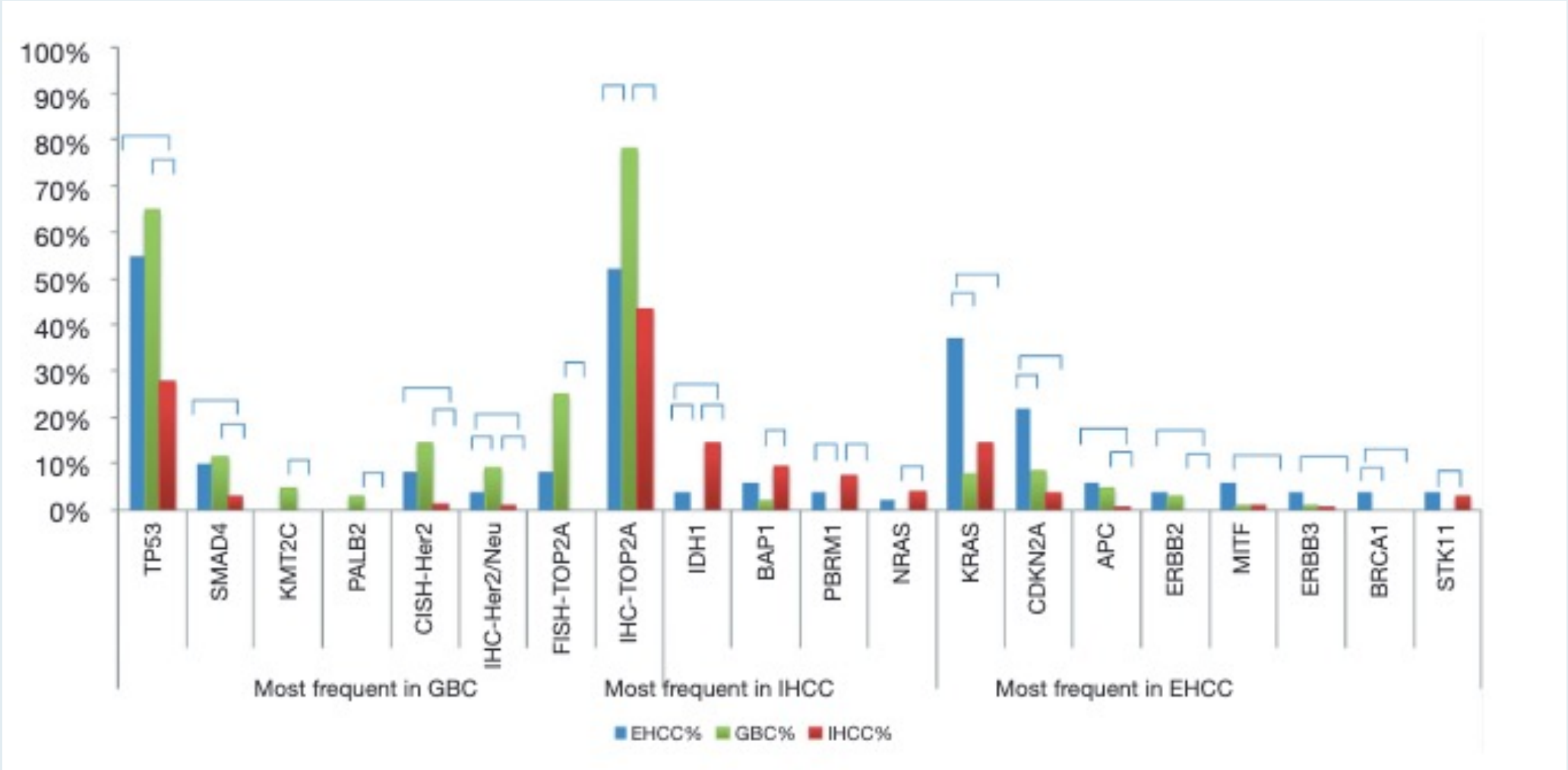
mRECIST modified Response Evaluation Criteria in Solid Tumors, *RECIST v1.1* RECIST version 1.1

Roessler D et al. *J Cancer Res Clin Oncol* 2022 July 21;[Online ahead of print].

MODULE 3: Integration of Targeted Therapy into the Management of Advanced BTCs

RTP
RESEARCH
TO PRACTICE

Most Frequent Gene Mutation Rates in Biliary Tract Cancers



GBC = gall bladder cancer; IHCC = intrahepatic cholangiocarcinoma; EHCC = extrahepatic cholangiocarcinoma

Weinberg BA et al. *J Gastrointest Oncol* 2019;10(4):652-62.

RTP RESEARCH TO PRACTICE

WORLD CONGRESS ON Gastrointestinal Cancer

O-2

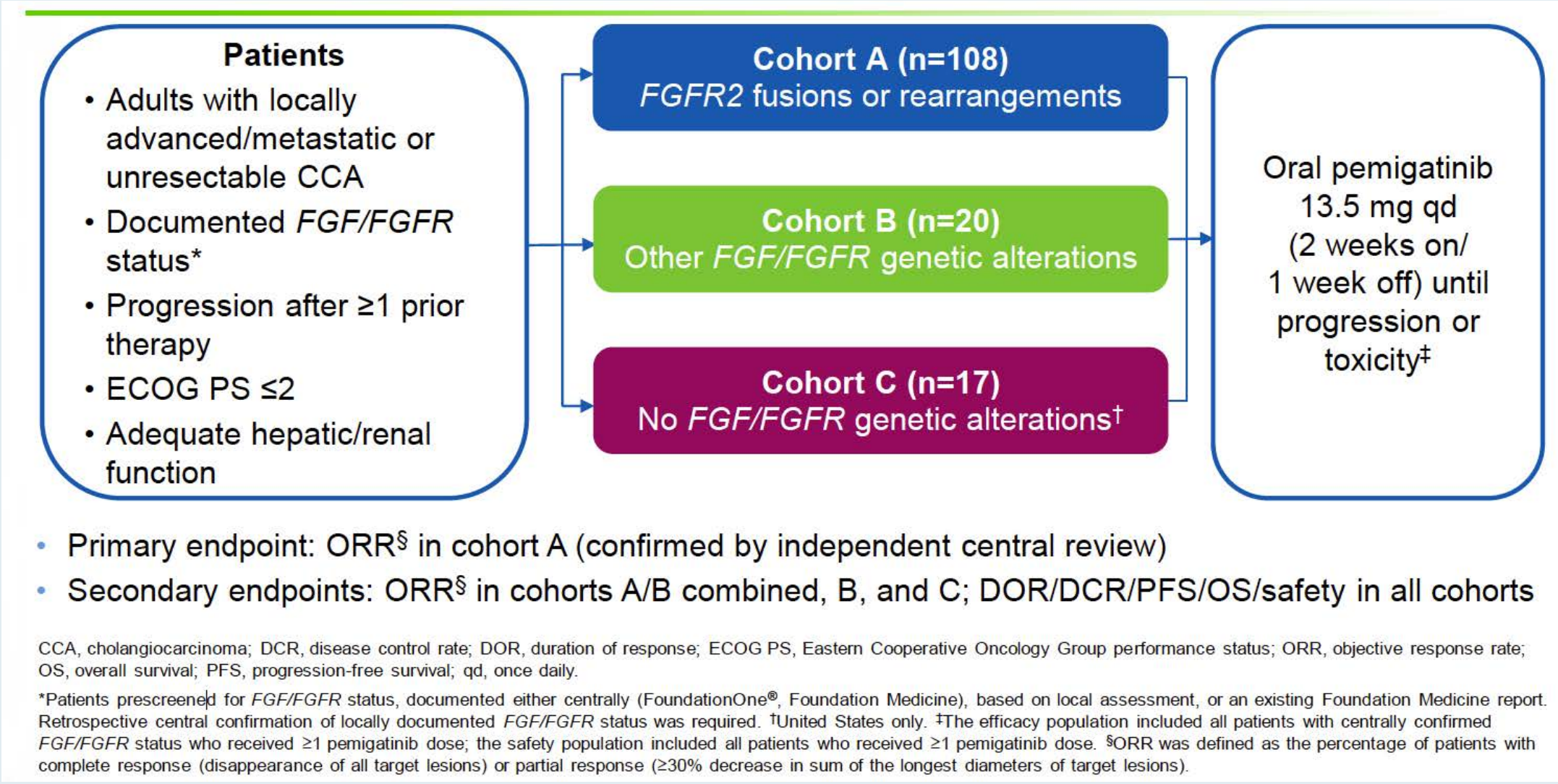
#575

Presented at the 2022 ESMO World Congress on Gastrointestinal Cancer; 29 June–2 July, 2022; Barcelona, Spain

Pemigatinib for Previously Treated Locally Advanced or Metastatic Cholangiocarcinoma: Final Results From FIGHT-202

Arndt Vogel, MD,[1] Vaibhav Sahai, MBBS, MS,[2] Antoine Hollebecque, MD,[3] Gina M. Vaccaro, MD,[4] Davide Melisi, MD, PhD,[5] Raed M. Al Rajabi, MD,[6] Andrew S. Paulson, MD,[7] Mitesh J. Borad, MD,[8] David Gallinson, DO,[9] Adrian G. Murphy, MD,[10] Do-Youn Oh, MD, PhD,[11] Efrat Dotan, MD,[12] Daniel V. Catenacci, MD,[13] Eric Van Cutsem, MD, PhD,[14] Christine F. Lihou, BS,[15] Huiling Zhen, PhD,[15] Luisa Veronese, MD,[16] Ghassan K. Abou-Alfa, MD[17]

FIGHT-202 Trial Schema



- Primary endpoint: ORR§ in cohort A (confirmed by independent central review)
- Secondary endpoints: ORR§ in cohorts A/B combined, B, and C; DOR/DCR/PFS/OS/safety in all cohorts

CCA, cholangiocarcinoma; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; qd, once daily.

*Patients prescreened for *FGF/FGFR* status, documented either centrally (FoundationOne®, Foundation Medicine), based on local assessment, or an existing Foundation Medicine report. Retrospective central confirmation of locally documented *FGF/FGFR* status was required. †United States only. ‡The efficacy population included all patients with centrally confirmed *FGF/FGFR* status who received ≥1 pemigatinib dose; the safety population included all patients who received ≥1 pemigatinib dose. §ORR was defined as the percentage of patients with complete response (disappearance of all target lesions) or partial response (≥30% decrease in sum of the longest diameters of target lesions).

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.

FIGHT-202 Final Results: Response to Pemigatinib

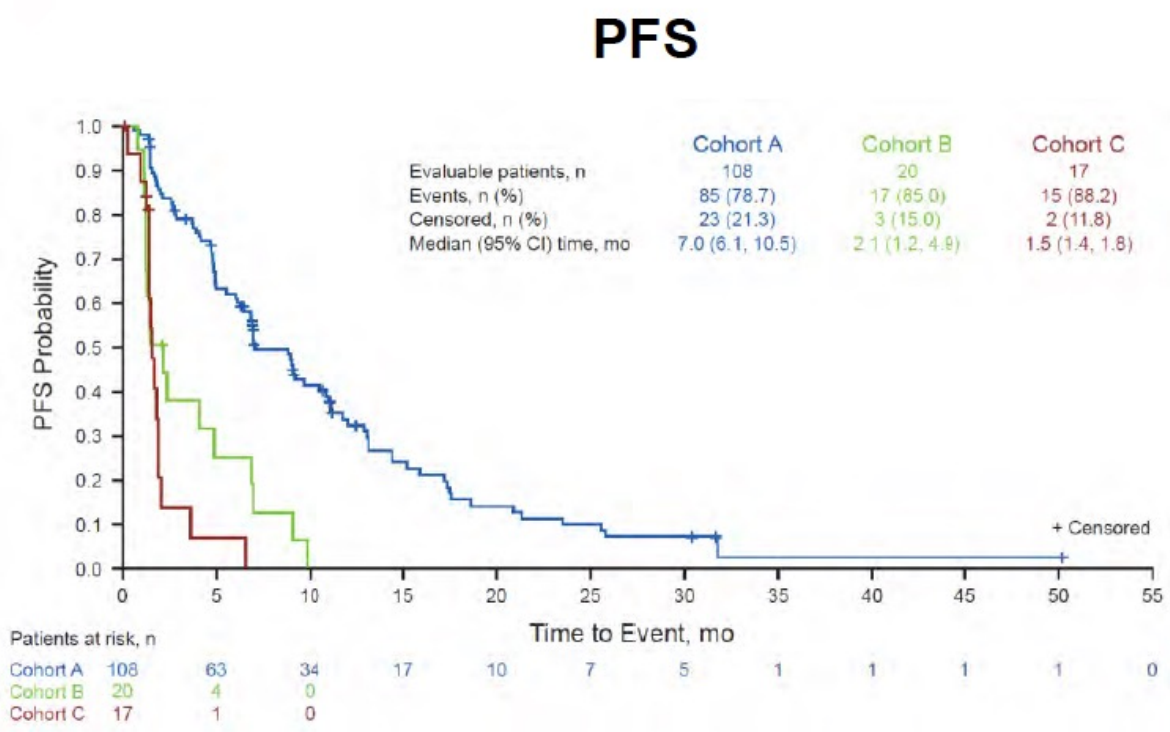
Parameter	Cohort A (n=108)	Cohort B (n=20)	Cohort C (n=17)
Duration of follow-up, median (range), mo	42.9 (19.9–52.2)	47.5 (43.7–51.1)	51.9 (49.5–53.7)
ORR,* % (95% CI)	37 (28, 47)	0 (0, 17)	0 (0, 20)
DCR,† % (95% CI)	82 (74, 89)	40 (19, 64)	18 (4, 43)
Best overall response, %			
Complete response	3	0	0
Partial response	34	0	0
Stable disease	45	40	18
Progressive disease	15	35	65
Not evaluable	3	25	18
DOR, median (95% CI), mo	9.1 (6.0, 14.5)	—	—

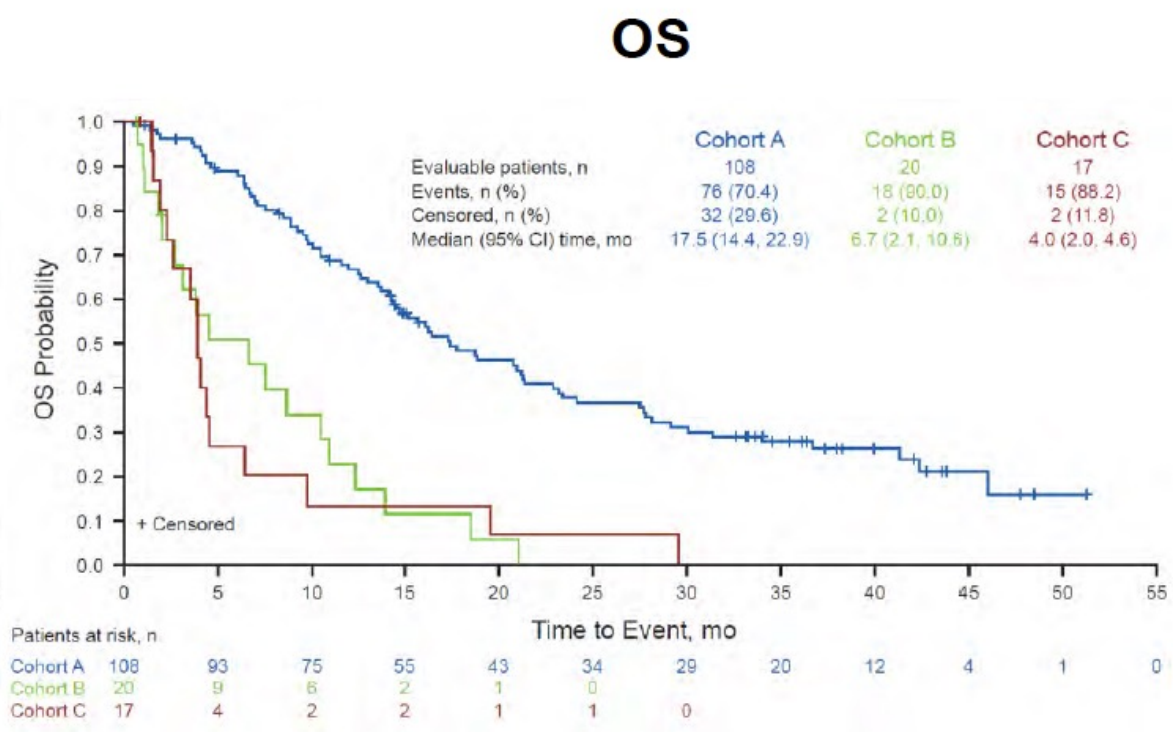
DCR, disease control rate; DOR, duration of response; ORR, objective response rate.

*ORR is complete response + partial response; †DCR is complete response + partial response + stable disease.

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.

FIGHT-202 Final Results: Progression-Free Survival (PFS) and Overall Survival (OS) for All Patients





- Median PFS in cohort A was 7.0 months (95% CI: 6.1, 10.5)
- Median OS in cohort A was 17.5 months (95% CI: 14.4, 22.9)

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.

RTP RESEARCH TO PRACTICE

FIGHT-202: Treatment-Emergent Adverse Events Occurring in ≥25% of Patients

Event	Cohort A (n=108)		Cohort B (n=20)		Cohort C (n=17)		Total (N=147)*	
	All Grades	Grade ≥3	All Grades	Grade ≥3	All Grades	Grade ≥3	All Grades	Grade ≥3
Any TEAE, %	100	67	100	75	100	76	100	69
Hyperphosphatemia	56	0	65	0	71	0	59	0
Alopecia	59	0	20	0	18	0	50	0
Diarrhoea	54	4	25	0	35	6	48	3
Fatigue	46	5	25	0	53	18	44	5
Nausea	43	3	35	0	41	0	41	2
Stomatitis	43	9	30	0	18	0	38	7
Constipation	43	1	25	0	12	0	37	1
Dysgeusia	42	0	15	0	18	0	36	0
Decreased appetite	31	1	40	5	41	6	34	2
Dry mouth	39	0	25	0	6	0	34	0
Arthralgia	34	6	25	10	12	0	30	6
Vomiting	33	2	15	0	24	0	29	1
Dry eye	35	0	5	0	6	0	28	1

- The safety profile remained consistent with the primary publication[1]; no new safety signals were observed

TEAE, treatment-emergent adverse event.

*The total includes 2 patients for whom *FGF/FGFR* status could not be centrally determined; the 2 patients were not assigned to a cohort and were evaluated for safety but not for efficacy.

1. Abou-Alfa GH, et al. *Lancet Oncol.* 2020;21(5):671-684.

Vogel A et al. ESMO World Congress on Gastrointestinal Cancer 2022;Abstract O-2.

The NEW ENGLAND JOURNAL of MEDICINE

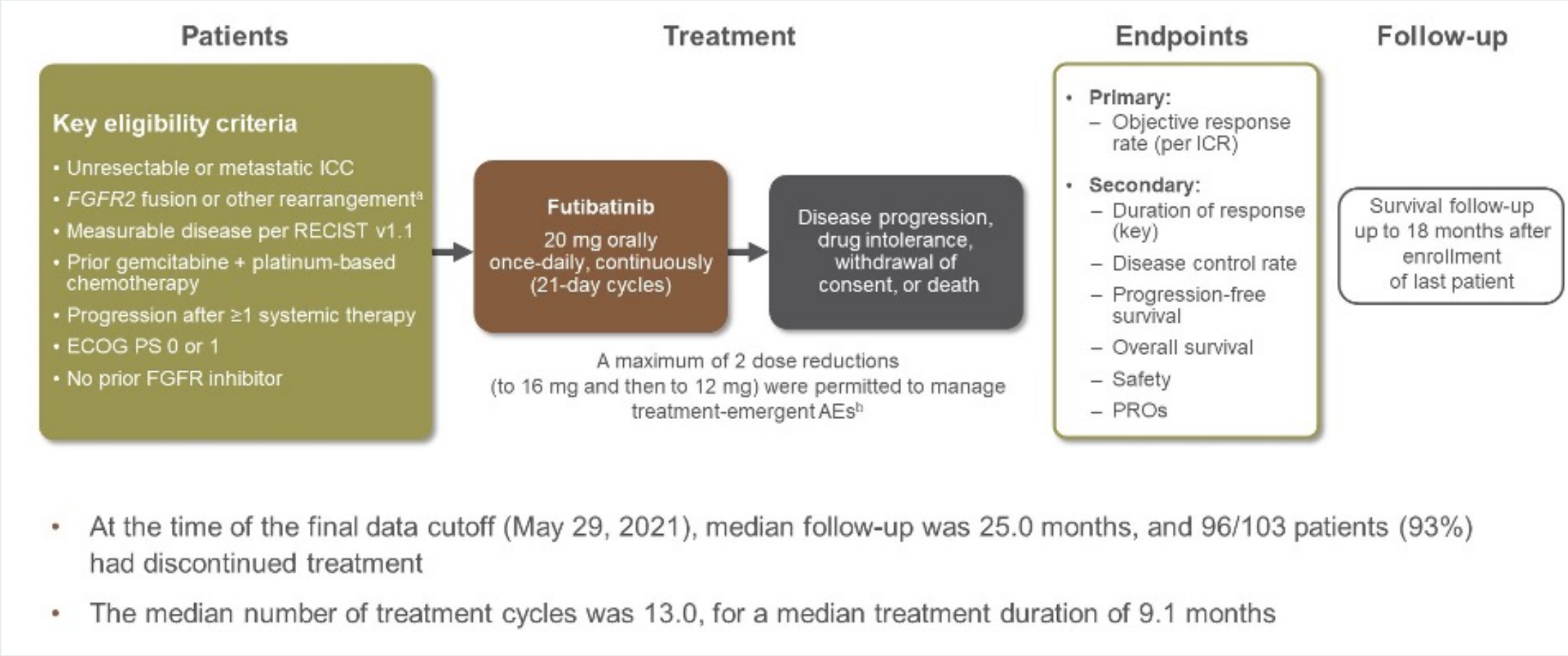
ORIGINAL ARTICLE

Futibatinib for *FGFR2*-Rearranged Intrahepatic Cholangiocarcinoma

L. Goyal, F. Meric-Bernstam, A. Hollebecque, J.W. Valle, C. Morizane, T.B. Karasic, T.A. Abrams, J. Furuse, R.K. Kelley, P.A. Cassier, H.-J. Klümpen, H.-M. Chang, L.-T. Chen, J. Tabernero, D.-Y. Oh, A. Mahipal, M. Moehler, E.P. Mitchell, Y. Komatsu, K. Masuda, D. Ahn, R.S. Epstein, A.-B. Halim, Y. Fu, T. Salimi, V. Wacheck, Y. He, M. Liu, K.A. Benhadji, and J.A. Bridgewater, for the FOENIX-CCA2 Study Investigators*

2023;388:228-39.

FOENIX-CCA2 (TAS-120-101): Phase II Study Design



- At the time of the final data cutoff (May 29, 2021), median follow-up was 25.0 months, and 96/103 patients (93%) had discontinued treatment
- The median number of treatment cycles was 13.0, for a median treatment duration of 9.1 months

ICC = intrahepatic cholangiocarcinoma; AEs = adverse events; PROs = patient-reported outcomes

Goyal L et al. ASCO 2022;Abstract 4009.

FOENIX-CCA2: Select Treatment-Related Adverse Events with Futibatinib for Intrahepatic Cholangiocarcinoma

Event (%)	All patients (N = 103)				
	Any grade	Grade 1	Grade 2	Grade 3	Grade 4
Any adverse event	99	8	34	56	1
Hyperphosphatemia	85	10	46	30	0
Dry mouth	30	27	3	0	0
Palmar-plantar erythrodysesthesia syndrome	21	3	14	5	0
Increased aspartate aminotransferase level	18	11	1	7	0
Increased alanine aminotransferase level	15	5	5	4	1

Goyal L et al. *N Engl J Med* 2023;388:228-39.

Research

JAMA Oncology | Original Investigation

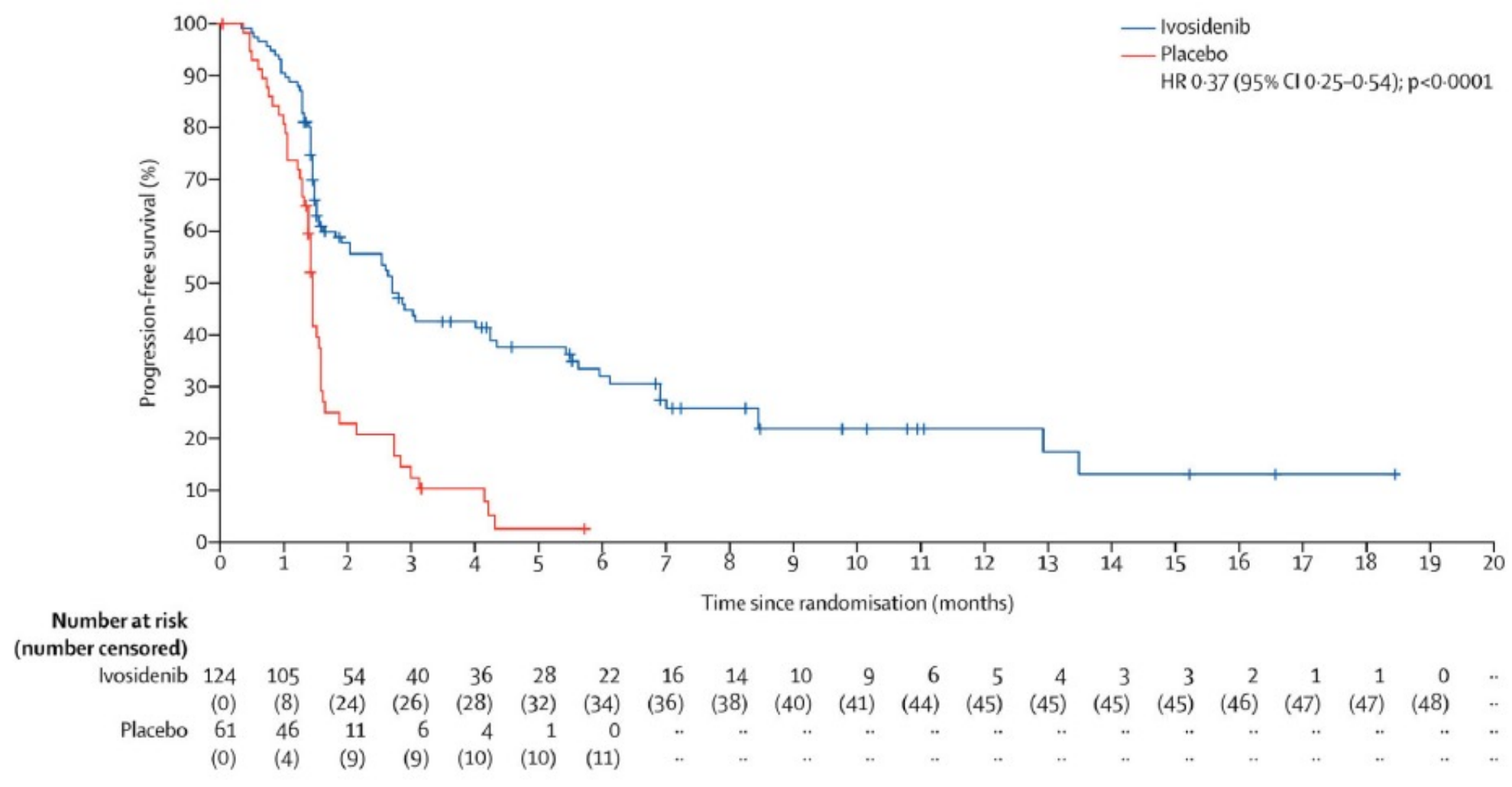
Final Overall Survival Efficacy Results of Ivosidenib for Patients With Advanced Cholangiocarcinoma With *IDH1* Mutation

The Phase 3 Randomized Clinical ClarIDHy Trial

Andrew X. Zhu, MD, PhD; Teresa Macarulla, MD; Milind M. Javle, MD; R. Kate Kelley, MD; Sam J. Lubner, MD; Jorge Adeva, MD; James M. Cleary, MD; Daniel V. T. Catenacci, MD; Mitesh J. Borad, MD; John A. Bridgewater, PhD; William P. Harris, MD; Adrian G. Murphy, MD; Do-Youn Oh, MD; Jonathan R. Whisenant, MD; Maeve A. Lowery, MD; Lipika Goyal, MD; Rachna T. Shroff, MD; Anthony B. El-Khoueiry, MD; Christina X. Chamberlain, PhD; Elia Aguado-Fraile, PhD; Sung Choe, PhD; Bin Wu, PhD; Hua Liu, PhD; Camelia Gliser, BS; Shuchi S. Pandya, MD; Juan W. Valle, MD; Ghassan K. Abou-Alfa, MD

2021;7(11):1669-77.

ClarIDHy: Progression-Free Survival with Ivosidenib for Advanced Cholangiocarcinoma with an IDH1 Mutation



Abou-Alfa GK et al. *Lancet Oncol* 2020;21(6):796-807.

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ClarIDHy: Select Adverse Events

Adverse event	Ivosidenib (n = 121)			Placebo (n = 59)		
	Grades 1 to 2	Grade 3	Grade 4	Grades 1 to 2	Grade 3	Grade 4
Diarrhea	33%	2%	0	24%	2%	0
Fatigue	23%	3%	0	15%	0	0
Ascites	13%	7%	0	8%	7%	0
Electrocardiogram QT prolongation	8%	1%	0	2%	0	0
ALT increase	7%	2%	0	2%	0	0
AST increase	6%	5%	0	3%	2%	0
Hyponatremia	5%	3%	2%	2%	8%	2%
Blood bilirubin increase	4%	6%	0	5%	2%	0

Abou-Alfa GK et al. *Lancet Oncol* 2020;21(6):796-807.

Ongoing Phase III Studies of FGFR Inhibitors for Advanced Cholangiocarcinoma

Study	N	Eligibility	Randomization arms	Estimated primary completion
FIGHT-302	434	• Previously untreated • Unresectable and/or metastatic • FGFR2 rearrangement	• Pemigatinib • Gemcitabine + cisplatin	October 2027
FOENIX-CCA3	216	• Previously untreated • Unresectable and/or metastatic • FGFR2 rearrangement	• Futibatinib • Gemcitabine + cisplatin	September 2023

www.clinicaltrials.gov. Accessed May 2023.

2022 ASCO ANNUAL MEETING

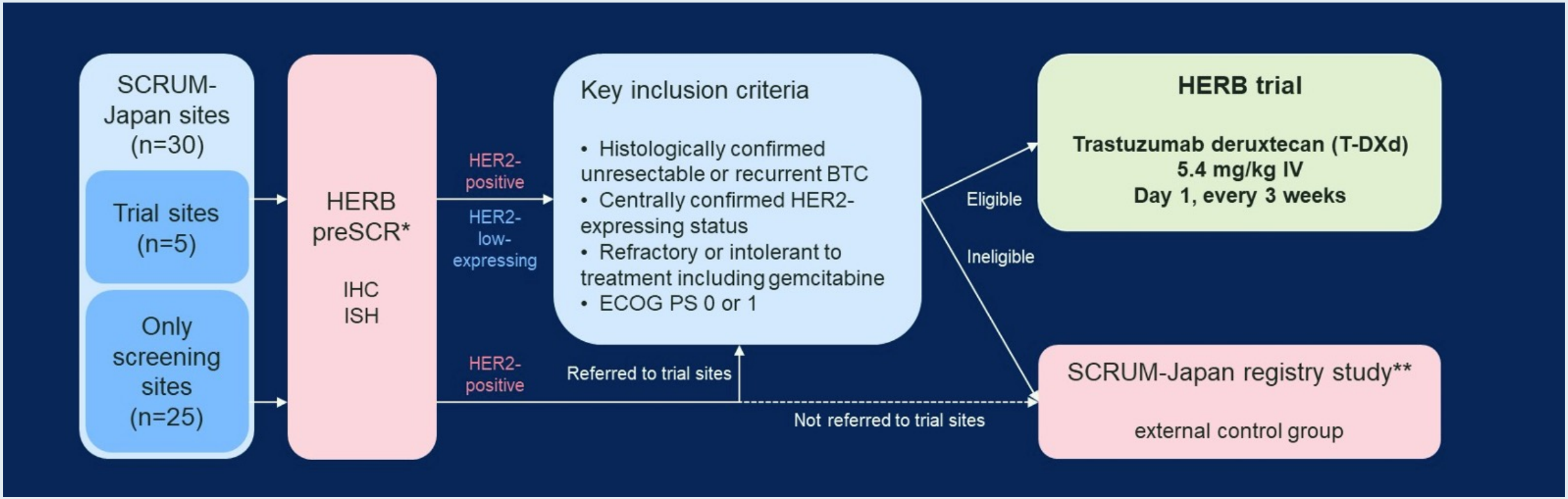
Abstract 4006

Trastuzumab deruxtecan (T-DXd; DS-8201) in patients (pts) with HER2-expressing unresectable or recurrent biliary tract cancer (BTC): An investigator-initiated multicenter phase 2 study (HERB trial)

Akihiro Ohba[1], Chigusa Morizane[1], Yasuyuki Kawamoto[2], Yoshito Komatsu[2], Makoto Ueno[3], Satoshi Kobayashi[3], Masafumi Ikeda[4], Mitsuhito Sasaki[4], Junji Furuse[5], Naohiro Okano[5], Nobuyoshi Hiraoka[1], Hiroshi Yoshida[1], Aya Kuchiba[1], Ryo Sadachi[1], Kenichi Nakamura[1], Naoko Matsui[1], Yoshiaki Nakamura[4], Wataru Okamoto[6], Takayuki Yoshino[4], Takuji Okusaka[1]

[1]National Cancer Center Hospital, [2]Hokkaido University Hospital, [3]Kanagawa Cancer Center, [4]National Cancer Center Hospital East, [5]Kyorin University Faculty of Medicine, [6]Hiroshima University Hospital

HERB: A Phase II Study of Trastuzumab Deruxtecan (T-DXd) for HER2-Expressing Biliary Tract Cancer



IHC = immunohistochemistry; ISH = in situ hybridization

Ohba A et al. ASCO 2022;Abstract 4006.

HERB Secondary Endpoints: Progression-Free Survival (PFS) and Overall Survival (OS) with Trastuzumab Deruxtecan for Biliary Tract Cancer

	HER2-positive disease (n = 22)	HER2 low-expressing disease (n = 8)
Median PFS	5.1 mo	3.5 mo
6-month PFS rate	40.9%	0
Median OS	7.1 mo	8.9 mo
6-month OS rate	63.6%	75.0%

Ohba A et al. ASCO 2022;Abstract 4006.

HERB: Treatment-Emergent Adverse Events with Trastuzumab Deruxtecan for Biliary Tract Cancer

Event	Any grade, n (%)	Grade ≥ 3, n (%)
Anemia	22 (68.8)	17 (53.1)
Neutrophil count decreased	18 (56.3)	10 (31.3)
White blood cell count decreased	18 (56.3)	10 (31.3)
Platelet count decreased	14 (43.8)	3 (9.4)
Nausea	14 (43.8)	0 (0)
Alopecia	13 (40.6)	0 (0)
Anorexia	12 (37.5)	1 (3.1)
Lymphocyte count decreased	11 (34.4)	7 (21.9)
Fatigue / Malaise	11 (34.4)	0 (0)
Interstitial lung disease / Pneumonitis	8 (25.0)	4 (12.5)
Hypoalbuminemia	7 (21.9)	1 (3.1)
Vomiting	7 (21.9)	0 (0)
Mucositis oral	5 (15.6)	0 (0)

Ohba A et al. ASCO 2022;Abstract 4006.

Breakfast with the Investigators: Hepatobiliary Cancers

A CME Symposium Held in Conjunction with the 2023 ASCO® Annual Meeting

Saturday, June 3, 2023

6:45 AM – 7:45 AM CT

Faculty

Anthony El-Khoueiry, MD

Robin K (Katie) Kelley, MD

Prof Arndt Vogel, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

POSTMEETING SURVEY – Available Now

Clinicians in Attendance: The postmeeting survey is now available on the iPads for attendees in the room and on Zoom for those attending virtually. We appreciate your completing this survey before the end of the program.

Thank you for your input.

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Second Opinion: Investigators Discuss How They and Their Colleagues Apply Available Clinical Research in the Care of Patients with Prostate Cancer

A CME Symposium Held in Conjunction with the 2023 ASCO® Annual Meeting

Saturday, June 3, 2023

7:00 PM – 9:00 PM CT

Faculty

Emmanuel S Antonarakis, MD

Prof Karim Fizazi, MD, PhD

Rana R McKay, MD

Alicia K Morgans, MD, MPH

A Oliver Sartor, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Thank you for joining us!
Your feedback is very important to us.

Please complete the survey currently up on the iPads for attendees in the room and on Zoom for those attending virtually. The survey will remain open up to 5 minutes after the meeting ends.

How to Obtain CME Credit

In-person attendees: Please refer to the program syllabus for the CME credit link or QR code. You may also use the iPads available in the meeting room to complete the course evaluation.

Online/Zoom attendees: The CME credit link is posted in the chat room.

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