Year in Review:
Hepatobiliary and Pancreatic Cancers

Wednesday, April 13, 2022
5:00 PM – 6:00 PM ET

Faculty

Tanios Bekaii-Saab, MD
Philip A Philip, MD, PhD, FRCP

Moderator

Neil Love, MD

RTP Year in Review 2022

YiR Hepatobiliary and Pancreatic Cancers Faculty

Tanios Bekaii-Saab, MD
Professor, Mayo Clinic College of Medicine and Science
Program Leader, Gastrointestinal Cancer
Mayo Clinic Cancer Center
Consultant, Mayo Clinic in Arizona
Chair, ACCRU Research Consortium
Phoenix, Arizona

Philip A Philip, MD, PhD, FRCP
Professor of Oncology and Pharmacology
Leader, GI and Neuroendocrine Oncology
Henry Ford Cancer Institute
Wayne State University
Detroit, Michigan

Commercial Support

This activity is supported by educational grants from Exelixis Inc and Novocure Inc.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: AbbVie Inc, Adaptive Biotechnologies Corporation, ADC Therapeutics, Agios Pharmaceuticals Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeiGene Ltd, BeyondSpring Pharmaceuticals Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Coherus BioSciences, CTI BioPharma Corp, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, EMD Serono Inc, Epizyme Inc, Exact Sciences, Exelixis Inc, Five Prime Therapeutics Inc, Foundation Medicine, G1 Therapeutics Inc, Genentech, a member of the Roche Group, Genmab, Gilead Sciences Inc, GlaxoSmithKline, Grail Inc, Halozyme Inc, Helsinn Healthcare SA, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Karyopharm Therapeutics, Kite, A Gilead Company, Lilly, Loxo Oncology Inc, a wholly owned subsidiary of Eli Lilly & Company, Merck, Mersana Therapeutics Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Oncopeptides, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seagen Inc, Servier Pharmaceuticals LLC, Sumitomo Dainippon Pharma Oncology Inc, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, Tesaro, A GSK Company, TG Therapeutics Inc, Turning Point Therapeutics Inc, Verastem Inc and Zymeworks Inc.

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Dr Bekaii-Saab — Disclosures

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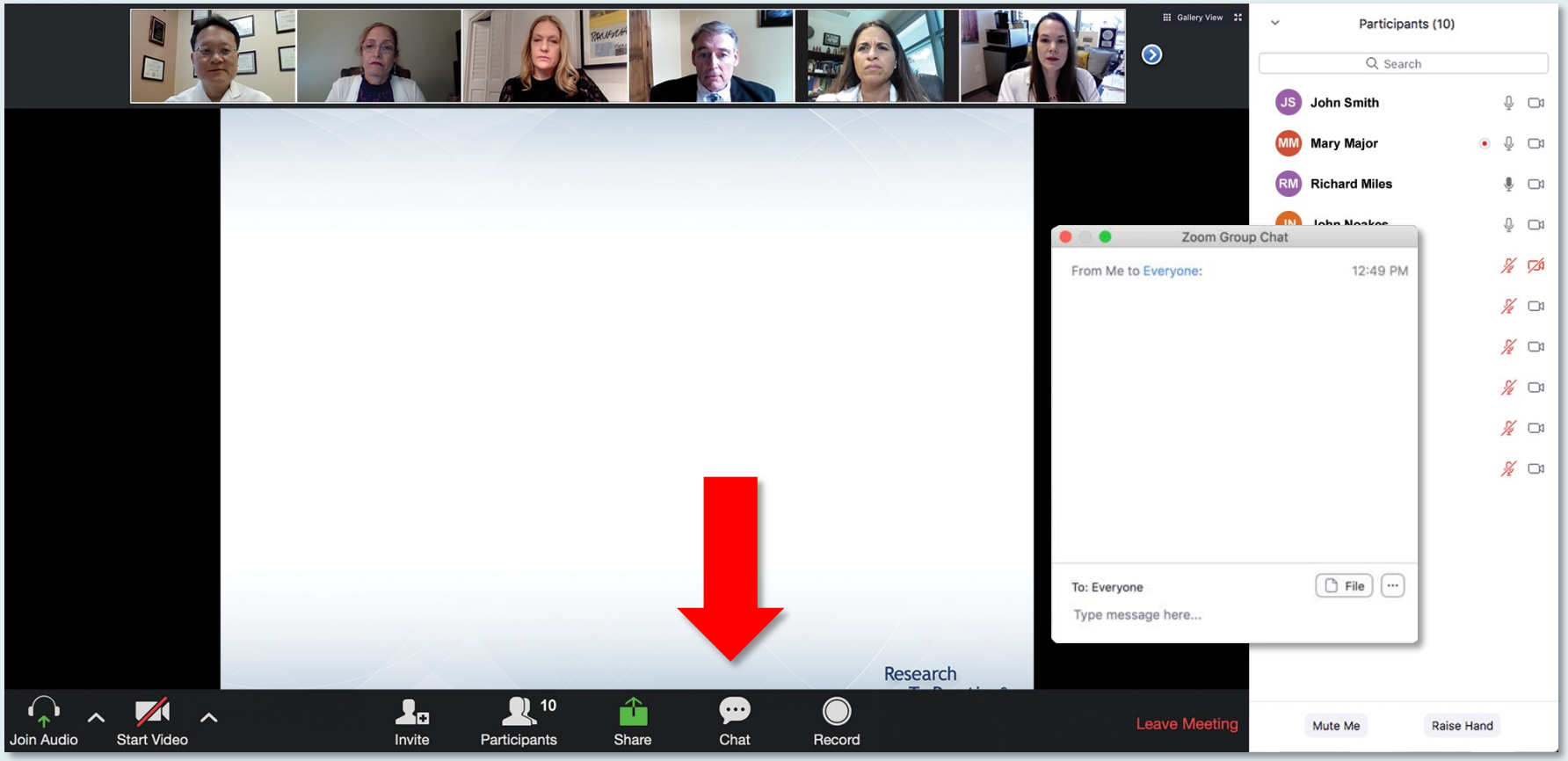
Consulting Agreements (to Self)	AbbVie Inc, Aptitude Health, AstraZeneca Pharmaceuticals LP, BeiGene Ltd, Boehringer Ingelheim Pharmaceuticals Inc, Celularity, Daiichi Sankyo Inc, Deciphera Pharmaceuticals Inc, Exact Sciences, Foundation Medicine, Illumina, Janssen Biotech Inc, Kanaph Therapeutics, MJH Life Sciences, Natera Inc, Swedish Orphan Biovitrum AB, Stemline Therapeutics Inc, Treos Bio
Data and Safety Monitoring Board/Committee	1Globe Health Institute, AstraZeneca Pharmaceuticals LP, Eisai Inc, Exelixis Inc, FibroGen Inc, Merck, Pancreatic Cancer Action Network, Suzhou Kintor
Inventions/Patents	WO/2018/183488 licensed to Imugene, WO/2019/055687 licensed to Recursion
Research Funding (to Institution)	AbGenomics, Agios Pharmaceuticals Inc, Arcus Biosciences, Arrys Therapeutics, a wholly owned subsidiary of Kyn Therapeutics, Atreca, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Eisai Inc, Genentech, a member of the Roche Group, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Lilly, Merus BV, Mirati Therapeutics, Novartis, Pfizer Inc, Seagen Inc, Sumitomo Dainippon Pharma Oncology Inc
Scientific Advisory Board	Immuneering Corporation, Imugene, Replimune, Sun Biopharma, Xilis

Dr Philip — Disclosures

No relevant conflicts of interest to disclose.

We Encourage Clinicians in Practice to Submit Questions



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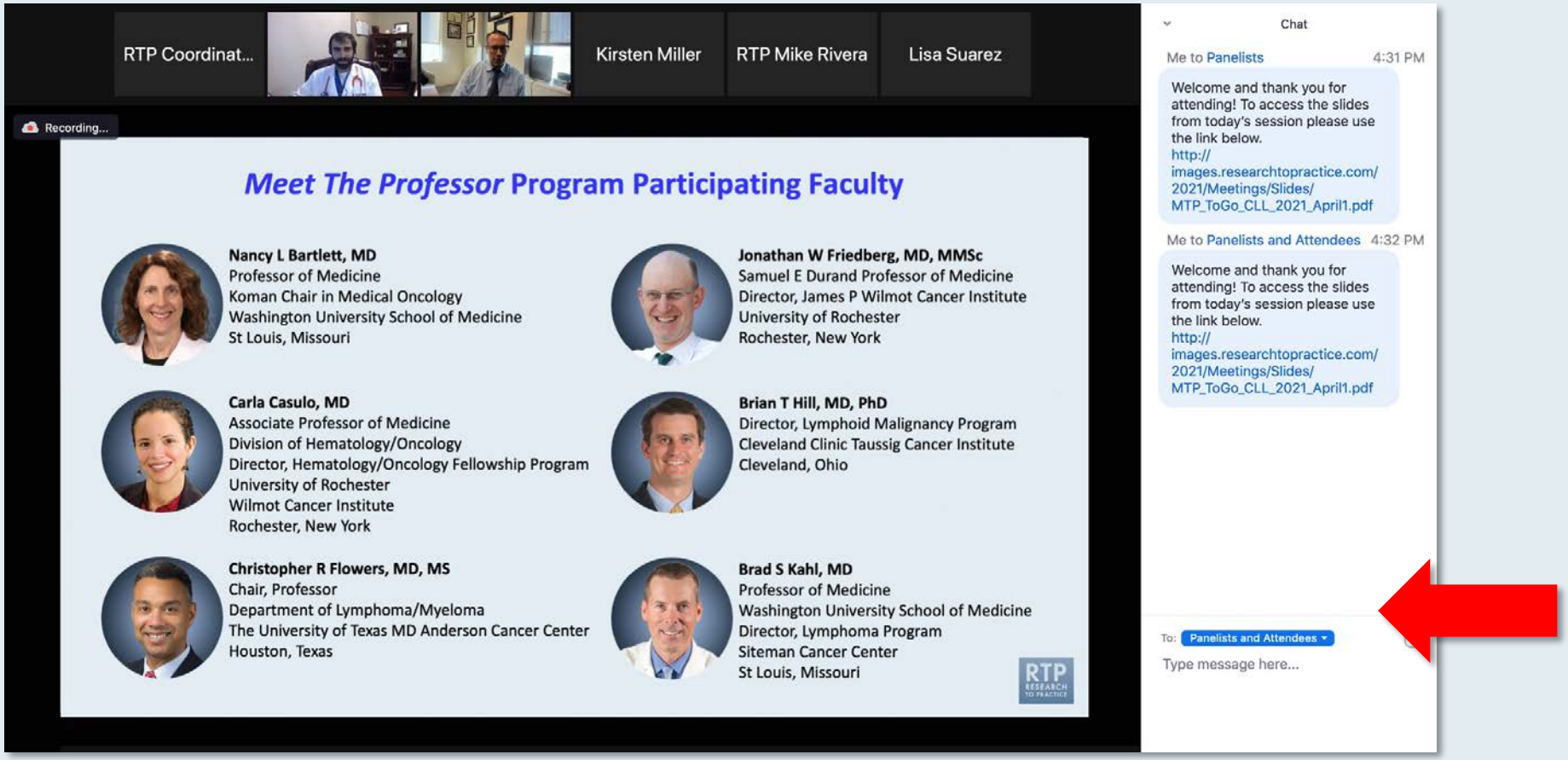

Drag the white line above the submission box up to create more space for your message.

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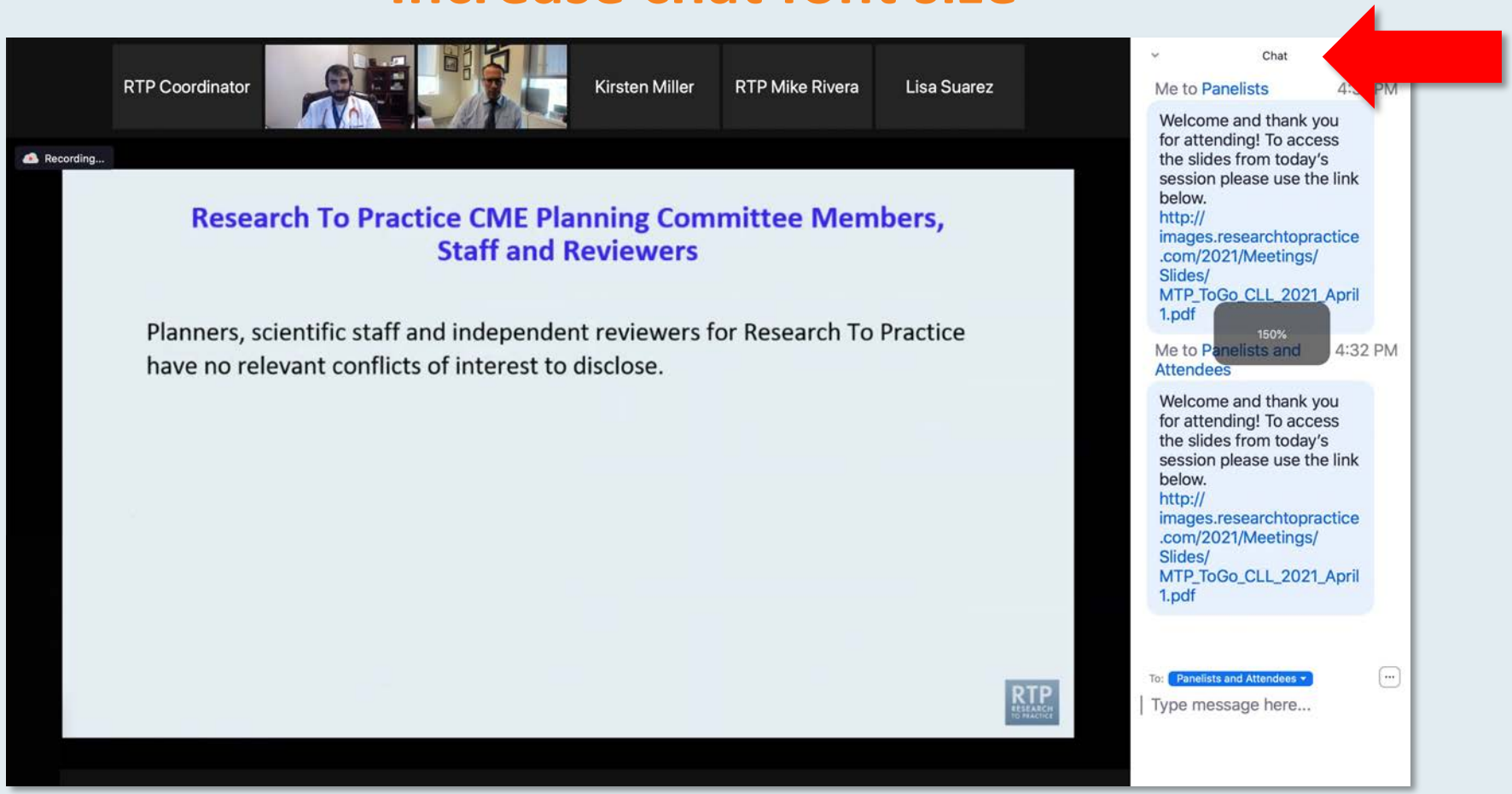
Familiarizing Yourself with the Zoom Interface

Increase chat font size



Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.

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WITH DR NEIL LOVE

PARP Inhibition in Pancreatic Cancer

DR MICHAEL PISHVAIAN

JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

WASHINGTON, DC

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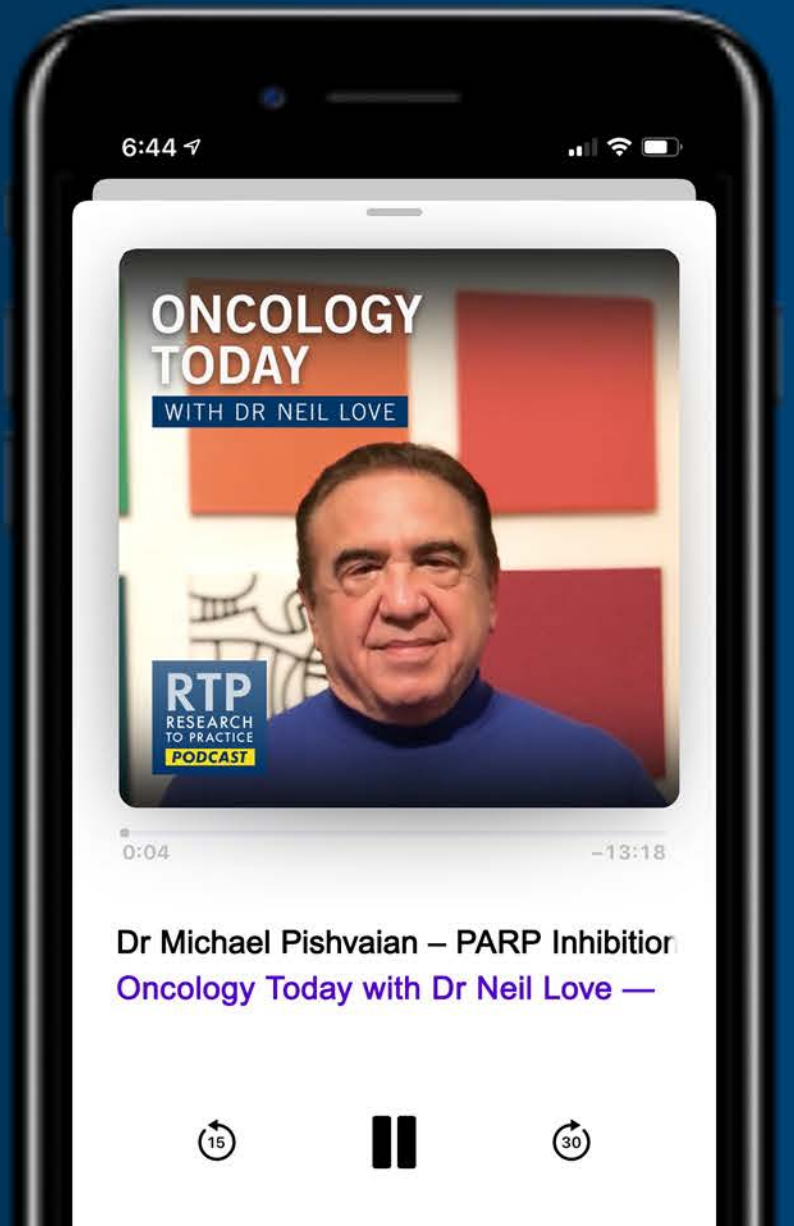

Meet The Professor
Chronic Lymphocytic Leukemia

Thursday, April 14, 2022
5:00 PM – 6:00 PM ET

Faculty

Jennifer R Brown, MD, PhD

Special Topics

- **Pirtobrutinib**
- **GLOW study**

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What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

A Complimentary NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Prostate Cancer

Thursday, April 28, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Robert Dreicer, MD, MS
Sandy Srinivas, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Non-Small Cell Lung Cancer

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Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Anne S Tsao, MD, MBA

Ovarian Cancer

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12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

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Kathleen N Moore, MD, MS
Krishnansu S Tewari, MD
Deborah Wright, MSN, APRN, AGCNS-BC

Hepatobiliary Cancers

Thursday, April 28, 2022
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Richard S Finn, MD
Amanda K Wagner, APRN-CNP, AOCNP

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Matthew Gubens, MD, MS
Lowell L Hart, MD
Chaely J Medley, MSN, AGNP

Breast Cancer

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Shilpa Gupta, MD
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Sumanta Kumar Pal, MD

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Optimizing the Management of Gastroesophageal Cancers

Thursday, May 5, 2022
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Faculty

Yelena Y Janjigian, MD

Moderator

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Cases from the Community: Urologic Oncology Investigators Provide Perspectives on the Optimal Management of Prostate Cancer

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8:00 AM – 10:00 AM CT (9:00 AM – 11:00 AM ET)

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Fred Saad, MD

Matthew R Smith, MD, PhD

Additional faculty to be announced.

Moderator

Emmanuel S Antonarakis, MD

RTP RESEARCH TO PRACTICE

Cases from the Community: Urologic Oncology Investigators Provide Perspectives on the Optimal Management of Urothelial Bladder Cancer

Friday, May 13, 2022

6:00 PM – 8:00 PM CT (7:00 PM – 9:00 PM ET)

Faculty

Matthew D Galsky, MD
Ashish M Kamat, MD, MBBS
Stephen B Williams, MD, MBA, MS

Moderator

Sumanta Kumar Pal, MD

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Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

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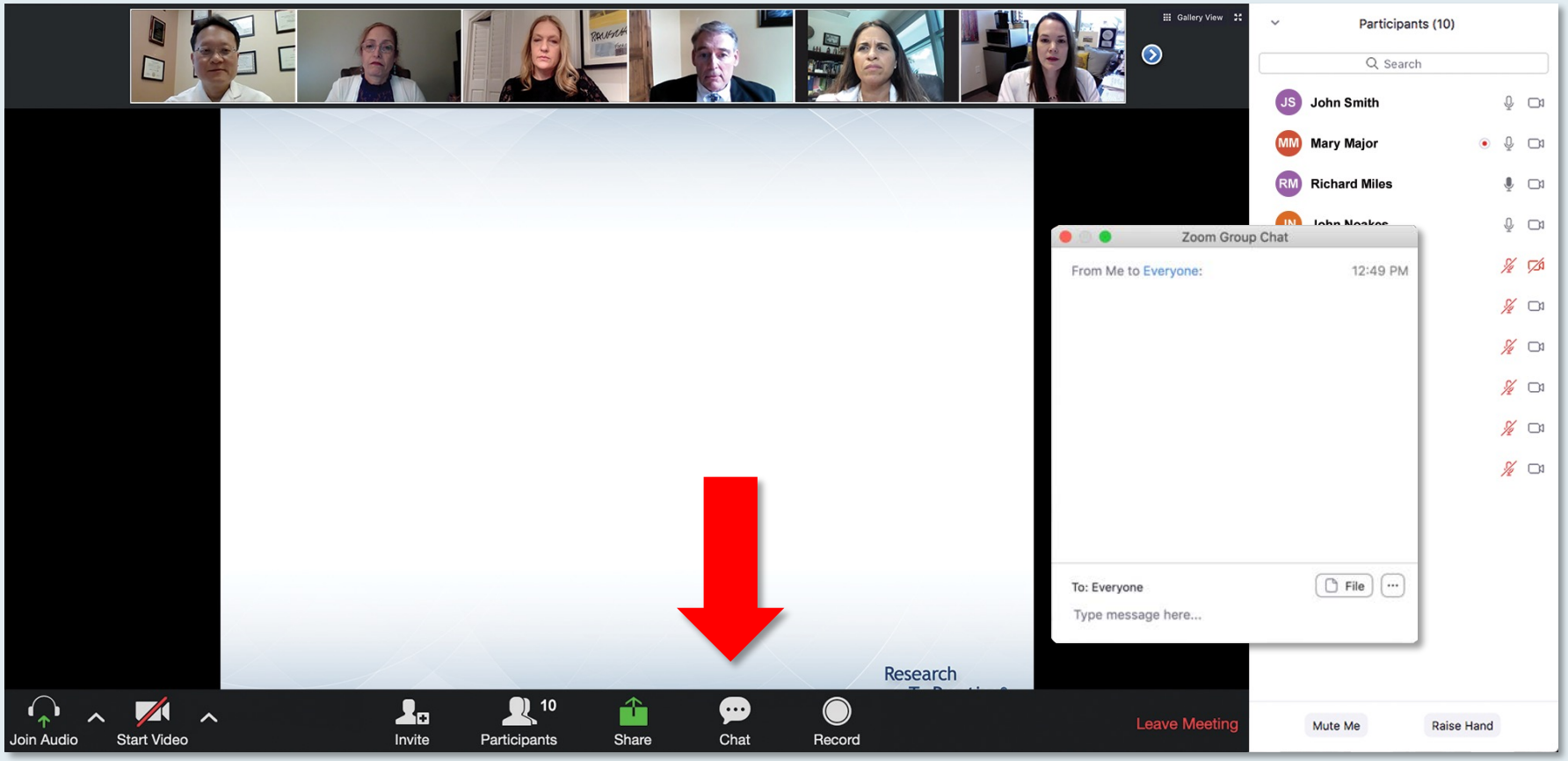

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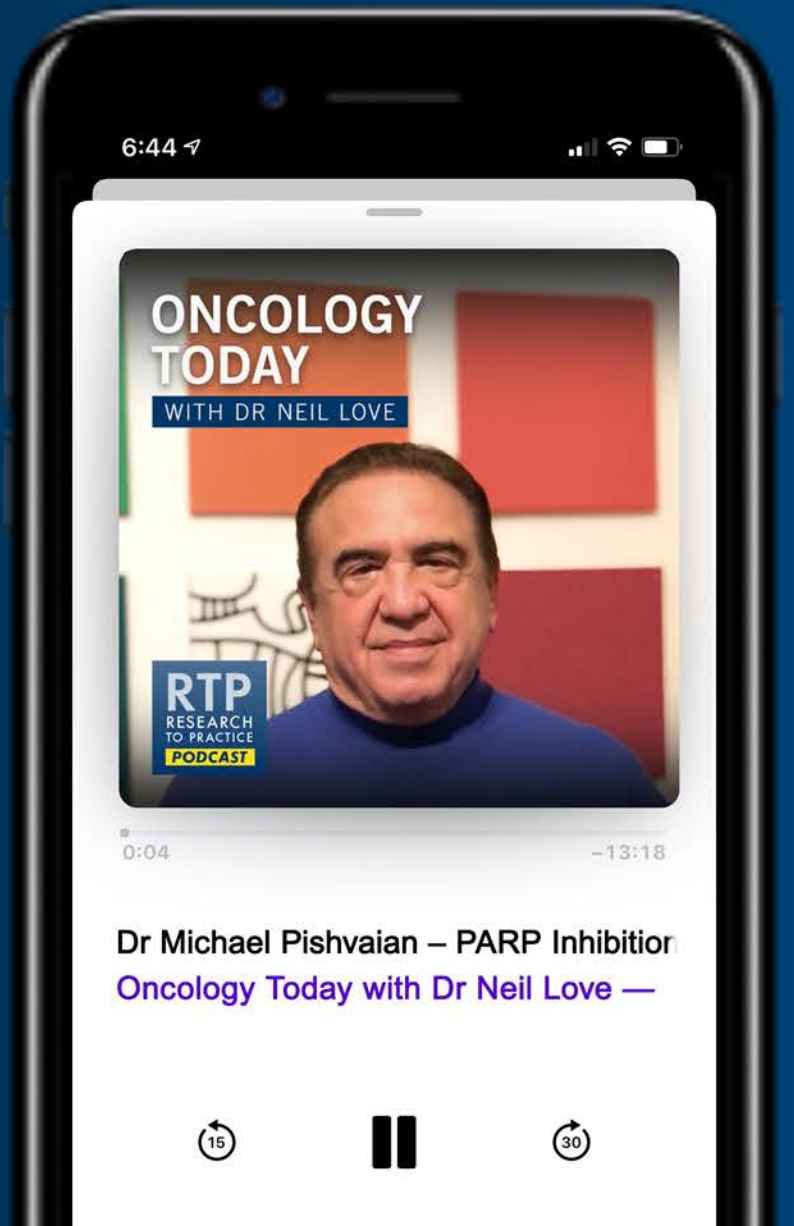

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Dr Philip — Disclosures

No relevant conflicts of interest to disclose.

Agenda

Introduction

Module 1: Hepatocellular Carcinoma

Module 2: Biliary Tract Cancers

Module 3: Pancreatic Cancer

Agenda

Introduction

Module 1: Hepatocellular Carcinoma

Module 2: Biliary Tract Cancers

Module 3: Pancreatic Cancer

ASCO Gastrointestinal Cancers Symposium

KRYSTAL-1: Updated Activity and Safety of Adagrasib (MRTX849) in Patients (Pts) With Unresectable or Metastatic Pancreatic Cancer (PDAC) and Other Gastrointestinal (GI) Tumors Harboring a KRAS^{G12C} Mutation

TS Bekaii-Saab[1], AI Spira[2], R Yaeger[3], GL Buchschacher Jr.[4], AJ McRee[5], JK Sabari[6], ML Johnson[7], M Barve[8], N Hafez[9], K Velastegui[10], JG Christensen[10], T Kheoh[10], H Der-Torossian[10], SM Gadgeel[11]

[1]Department of Medical Oncology and Hematology, Mayo Clinic, Scottsdale, Arizona, USA; [2]Virginia Cancer Specialists, Fairfax, Virginia, NEXT Oncology, Virginia, US Oncology Research, The Woodlands, Texas, USA; [3]Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, New York, USA; [4]Kaiser Permanente Southern California, Los Angeles, California, USA; [5]Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC, USA; [6]Perlmutter Cancer Center, New York University Langone Health, New York, New York, USA; [7]Sarah Cannon Research Institute, Tennessee Oncology, Nashville, Tennessee, USA; [8]Mary Crowley Cancer Research, Dallas, Texas, USA; [9]Yale Cancer Center, New Haven, Connecticut, USA; [10]Mirati Therapeutics, Inc., San Diego, California, USA; [11]Henry Ford Cancer Institute/Henry Ford Health System, Detroit, Michigan, USA

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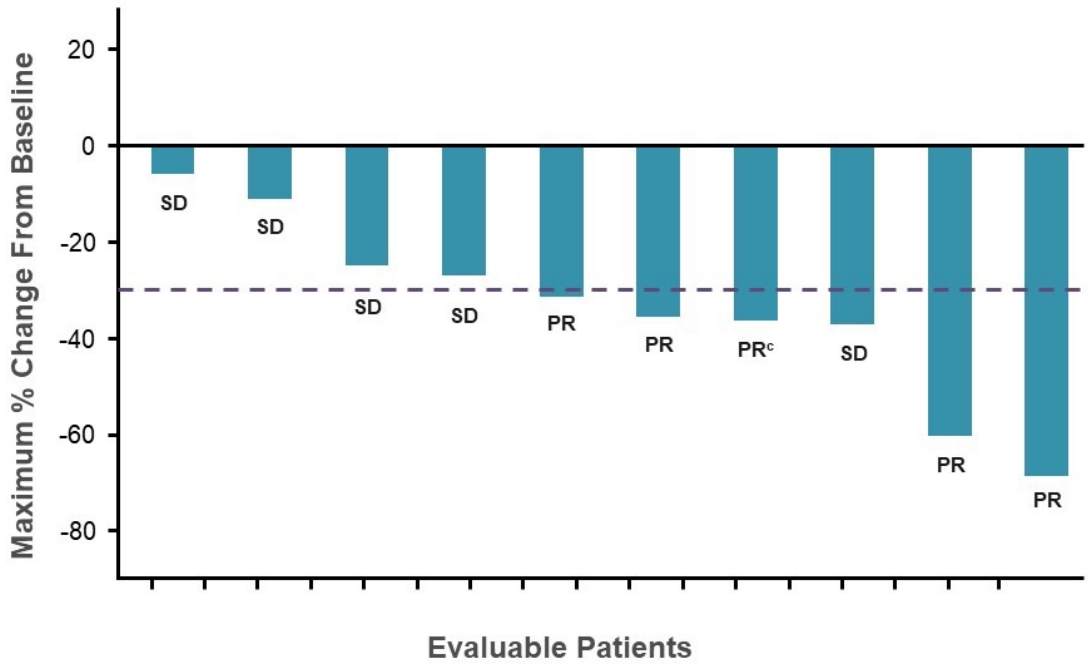
Abstract 519.

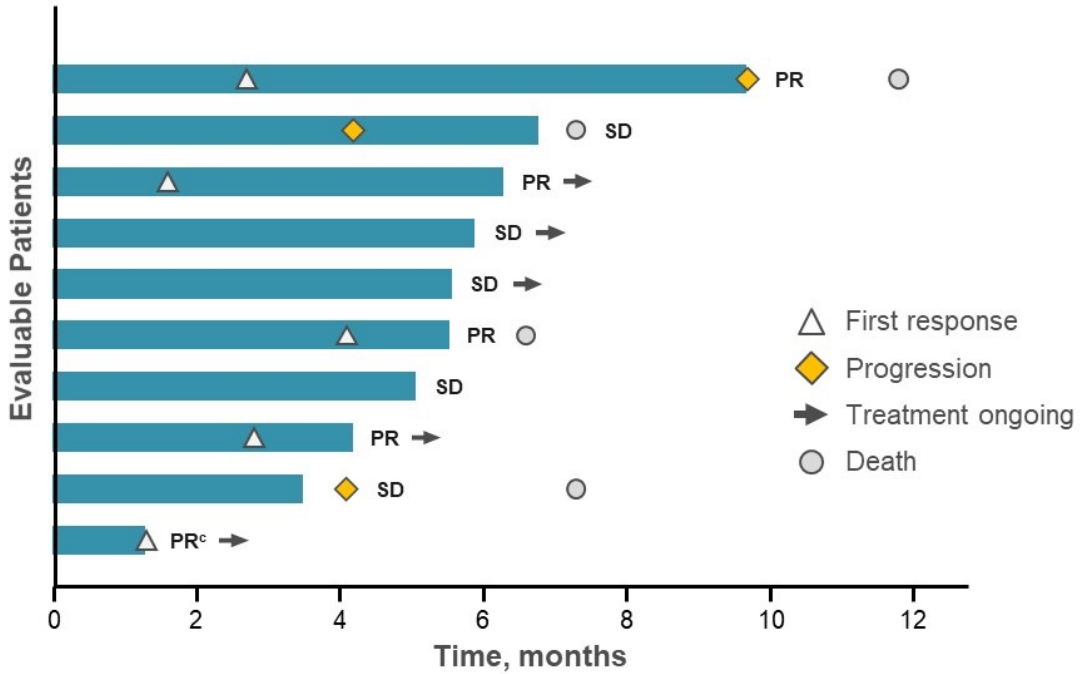
KRYSTAL-1: Adagrasib in Patients with Unresectable or Metastatic PDAC — Best Tumor Change from Baseline and Duration of Treatment

Best Tumor Change From Baseline (n=10)[a,b]



- Response rate: 50% (5/10), including 1 unconfirmed PR
- SD: 50% (5/10 patients)
- DCR: 100% (10/10 patients)

Duration of Treatment (n=10)[a,b]



- Median TTR: 2.8 months
- Median DOR: 6.97 months
- Median PFS: 6.6 months (95% CI 1.0–9.7)
- Treatment ongoing in 50% (5/10) of patients

Bekaii-Saab TS et al. Gastrointestinal Cancers Symposium 2022;Abstract 519.

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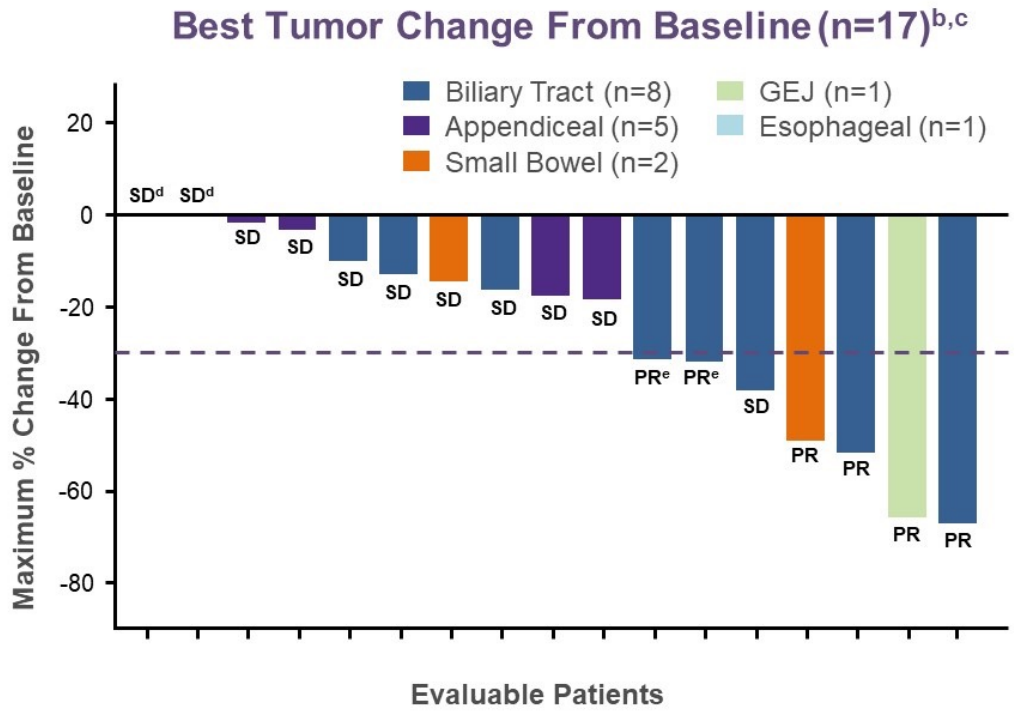
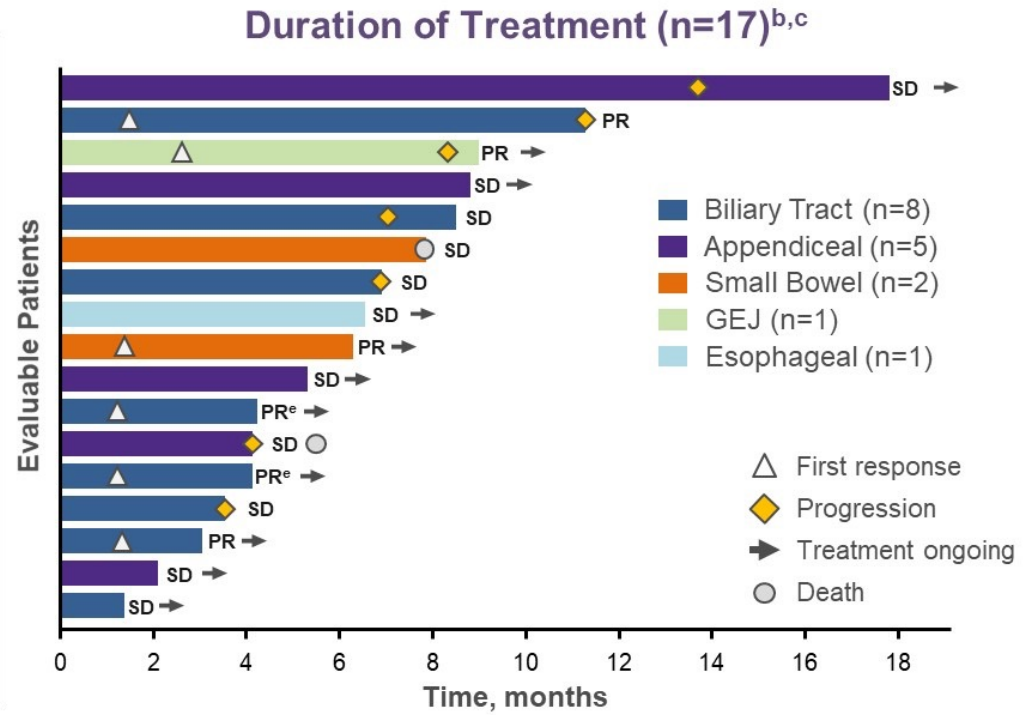
KRYSTAL-1: Adagrasib in Patients with Other GI Tumors — Best Tumor Change from Baseline and Duration of Treatment





- Response rate:
  - Biliary tract cancer: 50% (4/8), including 2 unconfirmed PRs
  - GEJ and small bowel cancer: 1 PR each
- DCR: 100% (17/17 patients)

- Median TTR: 1.3 months
- Median DOR: 7.85 months
- Median PFS: 7.85 months (95% CI 6.90–11.30)
- Treatment ongoing in 65% (11/17) of patients

Bekaii-Saab TS et al. Gastrointestinal Cancers Symposium 2022;Abstract 519.

RTP Year in Review 2022

First data for sotorasib in patients with pancreatic cancer with *KRAS* p.G12C mutation: a phase 1/2 study evaluating efficacy and safety

John H. Strickler[1], Hironaga Satake[2], Antoine Hollebecque[3], Yu Sunakawa[4], Pascale Tomasini[5], David L Bajor[6], Martin Schuler[7], Rona Yaeger[8], Thomas J. George[9], Ignacio Garrido-Laguna[10], Andrew L. Coveler[11], Mark David Vincent[12], Gerald Steven Falchook[13], Timothy F. Burns[14], Sun Young Rha[15], Charlotte Rose Lemech[16], Dejan Juric[17], Pegah Jafarinasabian[18], Qui Tran[18], David S. Hong[19]

ASCO Monthly Plenary Series 2022;Abstract 360490.

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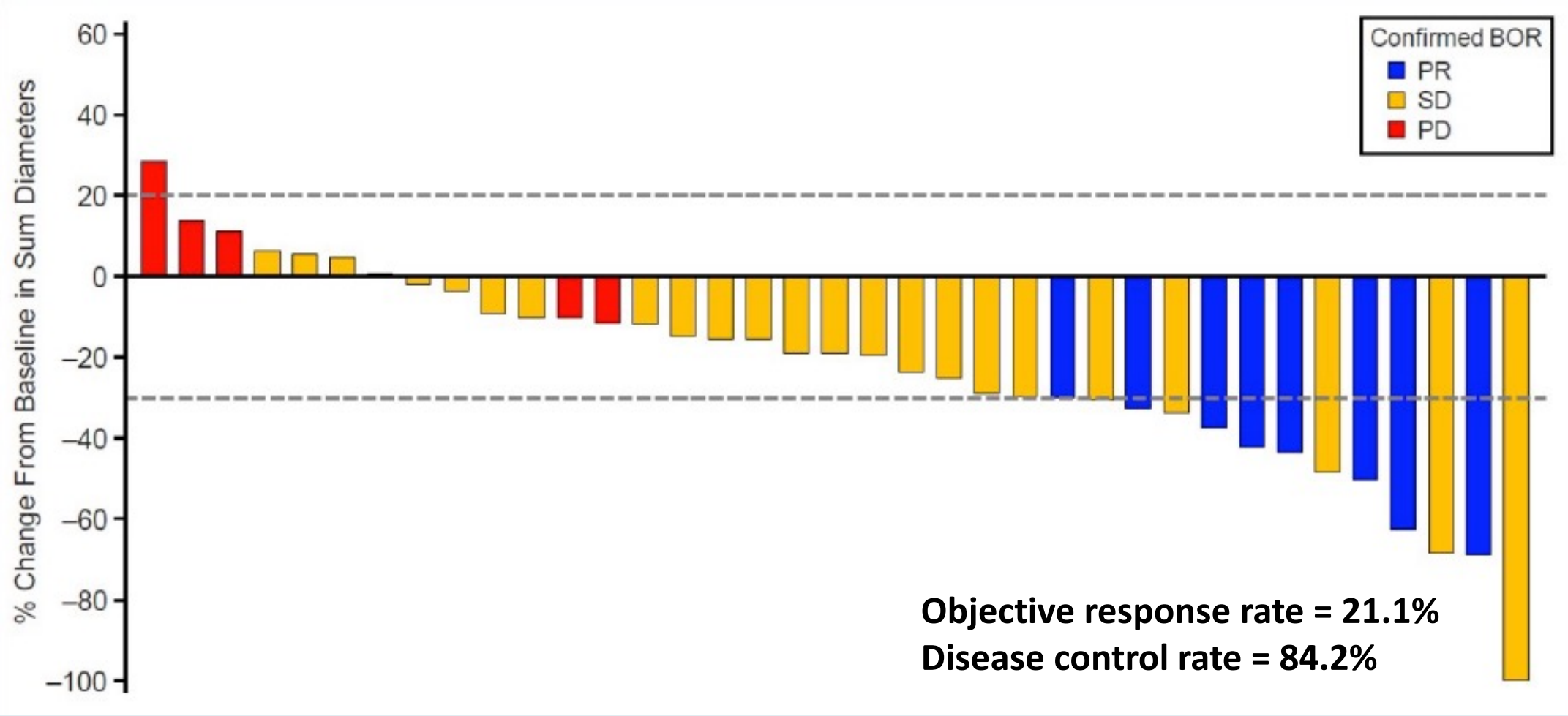
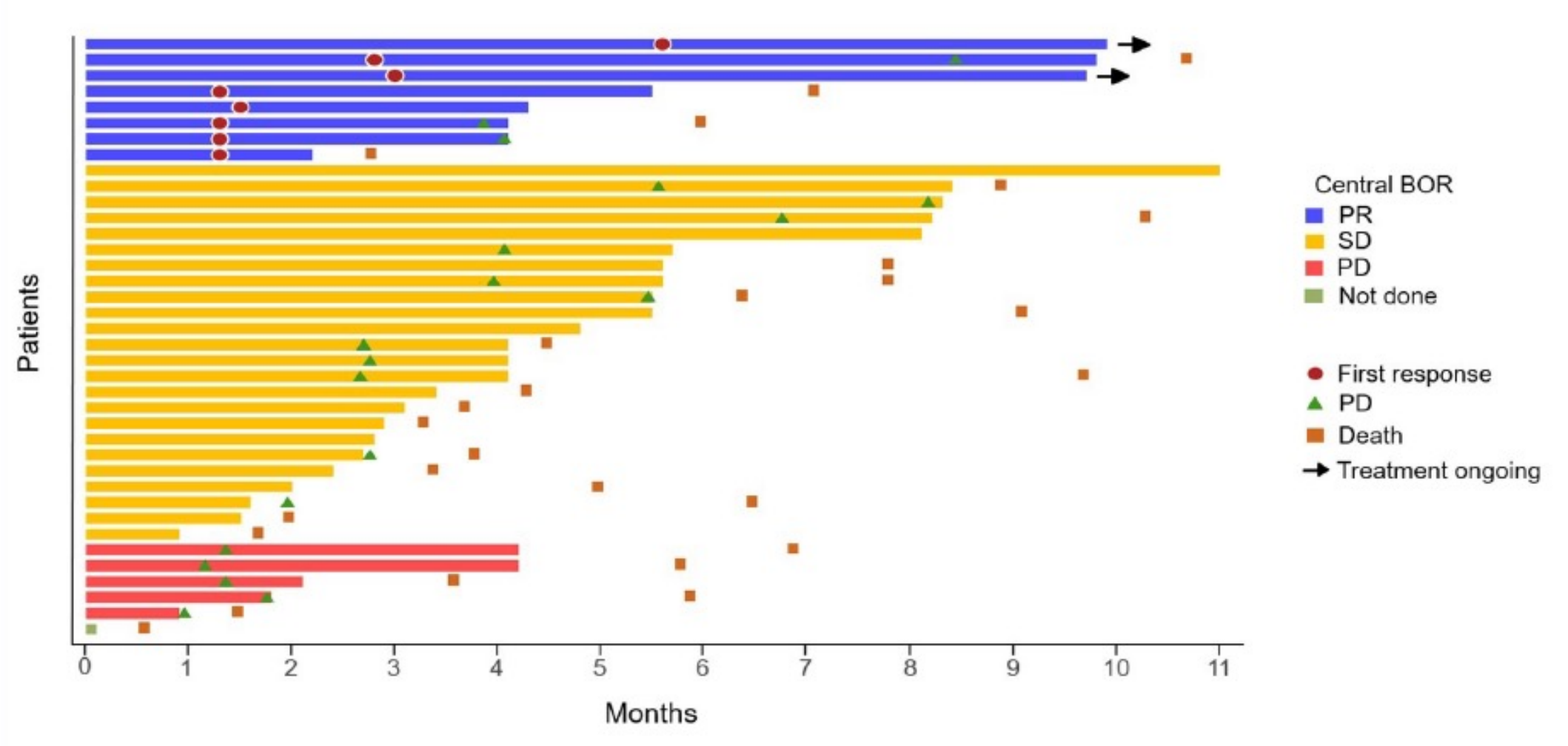
CodeBreaK 100: Best Tumor Shrinkage by Central Review



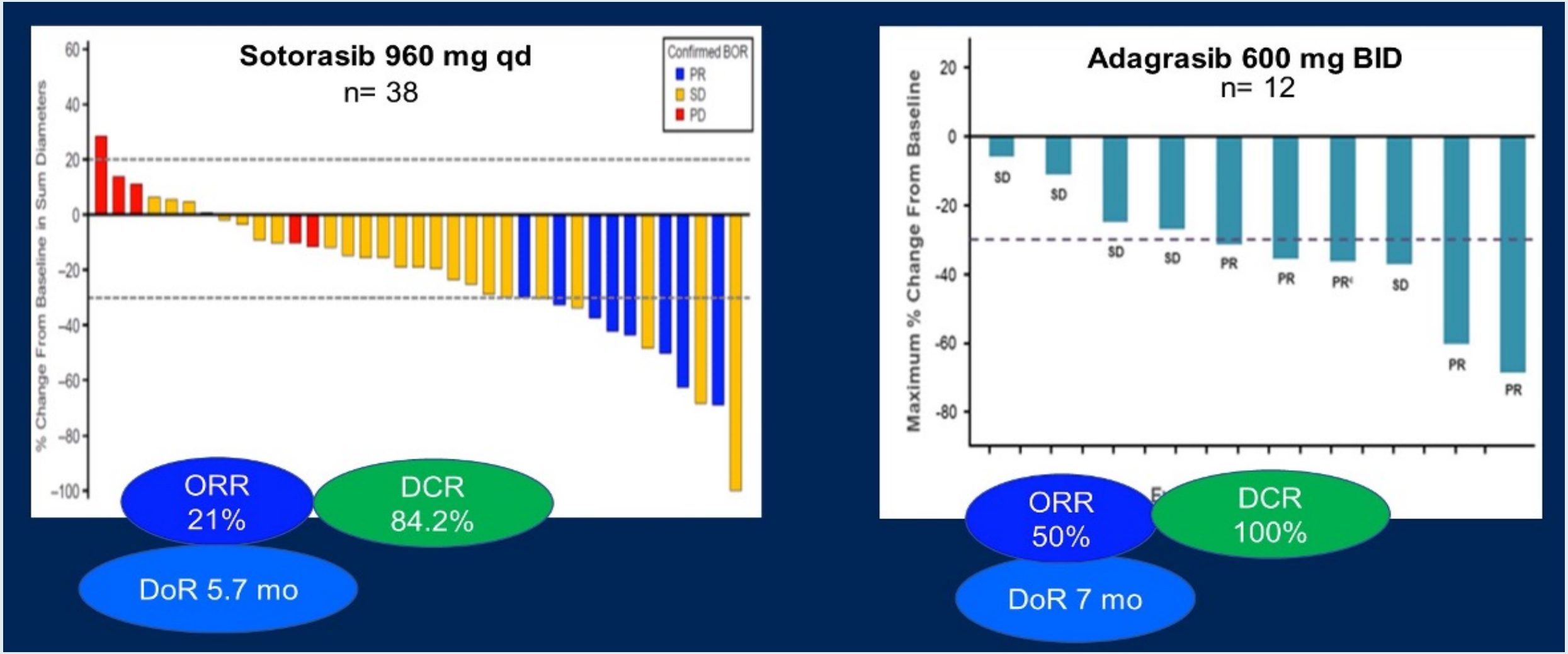
Strickler JH et al. ASCO Monthly Plenary Series 2022;Abstract 360490.

CodeBreaK 100: Duration of Treatment



Strickler JH et al. ASCO Monthly Plenary Series 2022;Abstract 360490.

Efficacy of KRAS G12C Inhibitors in Pancreatic Cancer



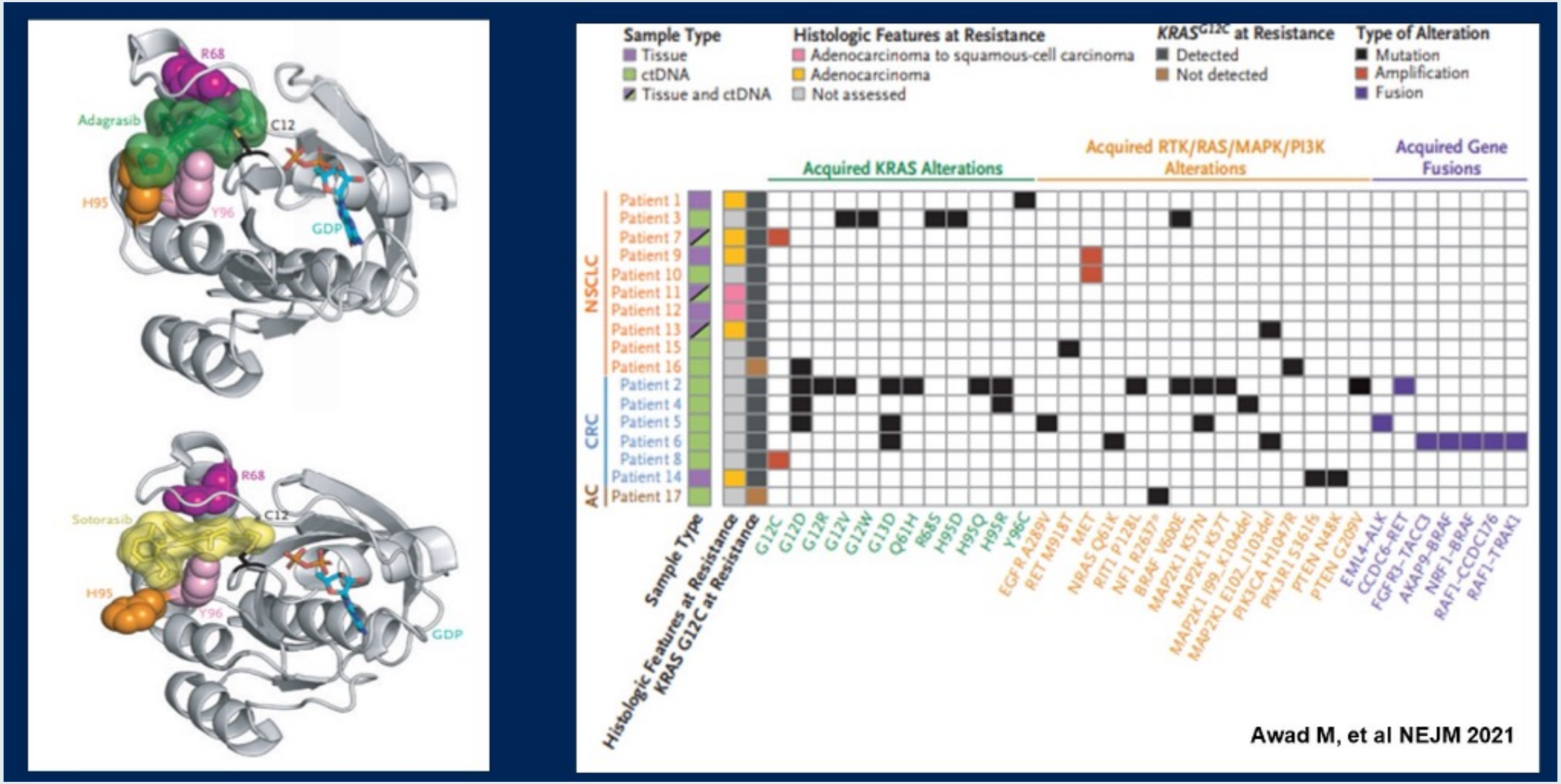
Chiorean EG et al. ASCO Monthly Plenary Series 2022;Abstract 360490 Discussant.

Key Safety Data with KRAS G12C Inhibitors

	Sotorasib		Adagrasib	
	Any grade	Grade 3	Any grade	Grade 3
Diarrhea	29%	5.3%	37%	0%
Fatigue	23%	5.3%	33%	10%
Nausea	21%	1.6%	50%	3%
ALT, AST	12%	2.6%	20%	3%
QT prolonged	0%	0%	13%	7%

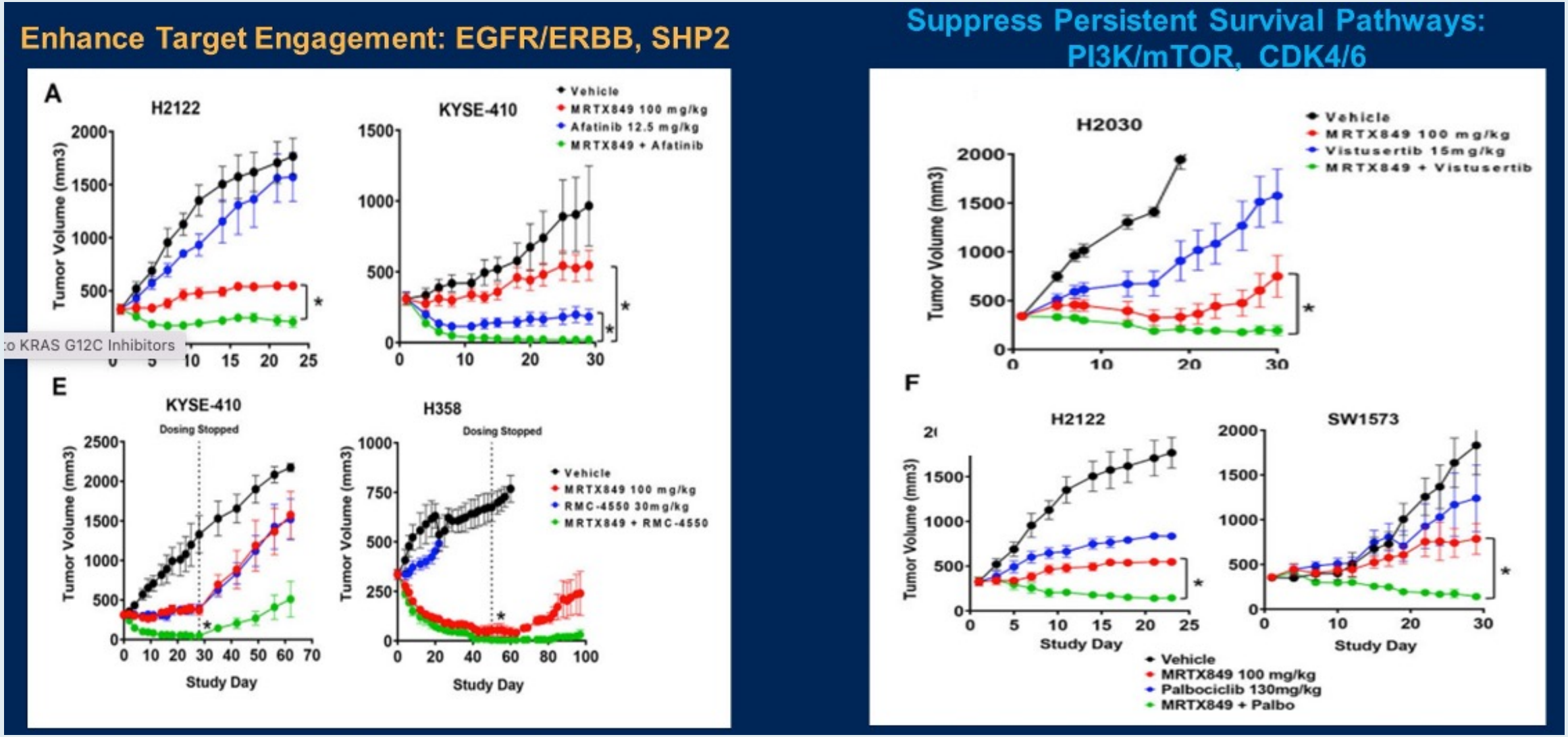
Chiorean EG et al. ASCO Monthly Plenary Series 2022;Abstract 360490 Discussant.

Mechanisms of Resistance to KRAS G12C Inhibitors



Chiorean EG et al. ASCO Monthly Plenary Series 2022;Abstract 360490 Discussant.

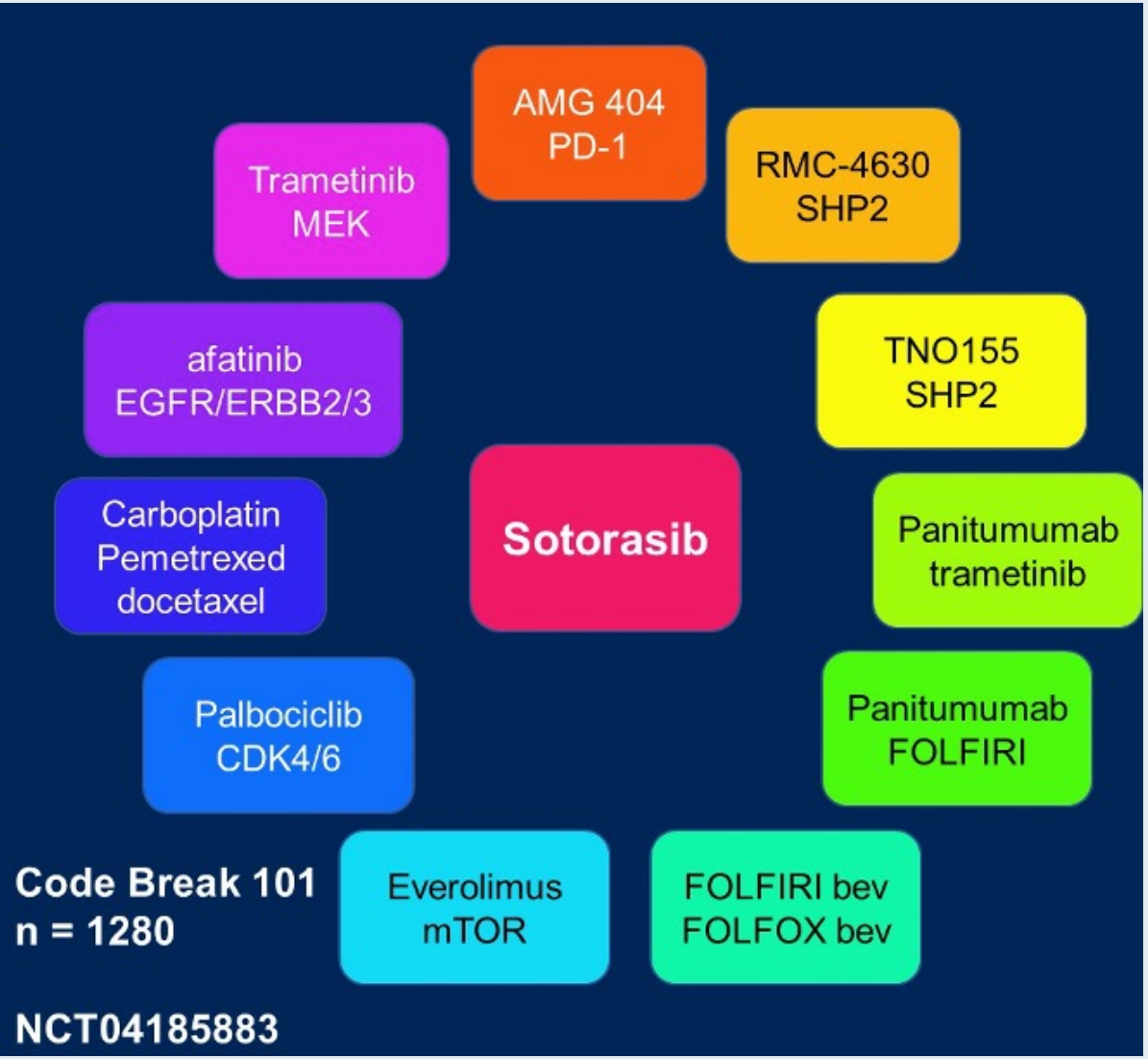
Synergistic Activity with KRAS G12C Inhibitors



Chiorean EG et al. ASCO Monthly Plenary Series 2022;Abstract 360490 Discussant.

Clinical Trials with KRAS-Targeted Therapies

Agent	Target	Clinical trial number (Clinicaltrials.gov)	Remarks
Sotorasib (AMG-510)	Direct mutant KRAS G12C covalent inhibitor	NCT03600883 NCT04185883 NCT04933695 NCT04303780	Sotorasib obtained accelerated FDA approval. Ongoing phase Ib, II, and III trials for patients with G12C mutations
MRTX849	Direct mutant KRAS G12C covalent inhibitor	NCT04330664, NCT03785249 NCT04685135 NCT04793958 NCT04613596	KRYSTAL trials: Phase I/II trials for patients with G12C mutations. Phases II and III trials for NSCLC and CRC patients with G12C mutations
LY3499446	Direct mutant KRAS G12C covalent inhibitor	NCT04165031	Trial terminated due to unanticipated toxicities
JNJ-74699157	Direct mutant KRAS G12C inhibitor	NCT04006301	Trial completed, no results reported
GDC 6036	Direct mutant KRAS G12C inhibitor	NCT04449874	Phase I trial for tumors with G12C mutations
D-1553	Direct mutant KRAS G12C inhibitor	NCT04585035	Phase I/II trial for tumors with G12C mutations
BI-1701963	SOS1 inhibitor	NCT04111458	Phase I trial for solid KRAS mutated tumors
RMC-4630	SHP2 inhibitor	NCT03634982 NCT04916236	Phase I/Ib trial for tumors with MAPK pathway hyperactivation, including KRAS mutated
TNO155	SHP2 inhibitor	NCT04000529 NCT03114319 NCT04330664	Phase I and II trials
ERAS-601	SHP2 inhibitor	NCT04670679	FLAGSHP-1 phase I/Ib trial in advanced or metastatic solid tumors as a single agent or in combination with MEK inhibitor
JAB-3312	SHP2 inhibitor	NCT04045496 NCT04720976 NCT04121286	Phase I/IIa clinical trials for patients with solid tumors
BBP-398	SHP2 inhibitor	NCT04528836	Phase I trial for patients with advanced solid tumors
RLY-1971	SHP2 inhibitor	NCT04252339	Phase I trial for patients with advanced solid tumors. However, it excludes patients with KRAS G12D, G12V, G13X, and Q61X mutations
mRNA-5671/V941	Mutant KRAS mRNA vaccine	NCT03948763	Phase I trial for KRAS mutated solid tumors
KRAS peptide vaccine	Mutant KRAS long peptide vaccine	NCT04117087	Phase I trial in CRC and PDAC
mDC3/8-KRAS Vaccine	Dendritic cell vaccine	NCT03592888	Phase I trial in KRAS mutated resectable PDAC



Chiorean EG et al. ASCO Monthly Plenary Series 2022;Abstract 360490 Discussant.

RTP Year in Review 2022

Agenda

Introduction

Module 1: Hepatocellular Carcinoma

- IMbrave150
- HIMALAYA
- COSMIC-312
- HEPANOVA
- Activity of Multikinase Inhibitors After Disease Progression on Atezolizumab/Bevacizumab
- REACH-2

Module 2: Biliary Tract Cancers

Module 3: Pancreatic Cancer

Research Article
Hepatic and Biliary Cancer

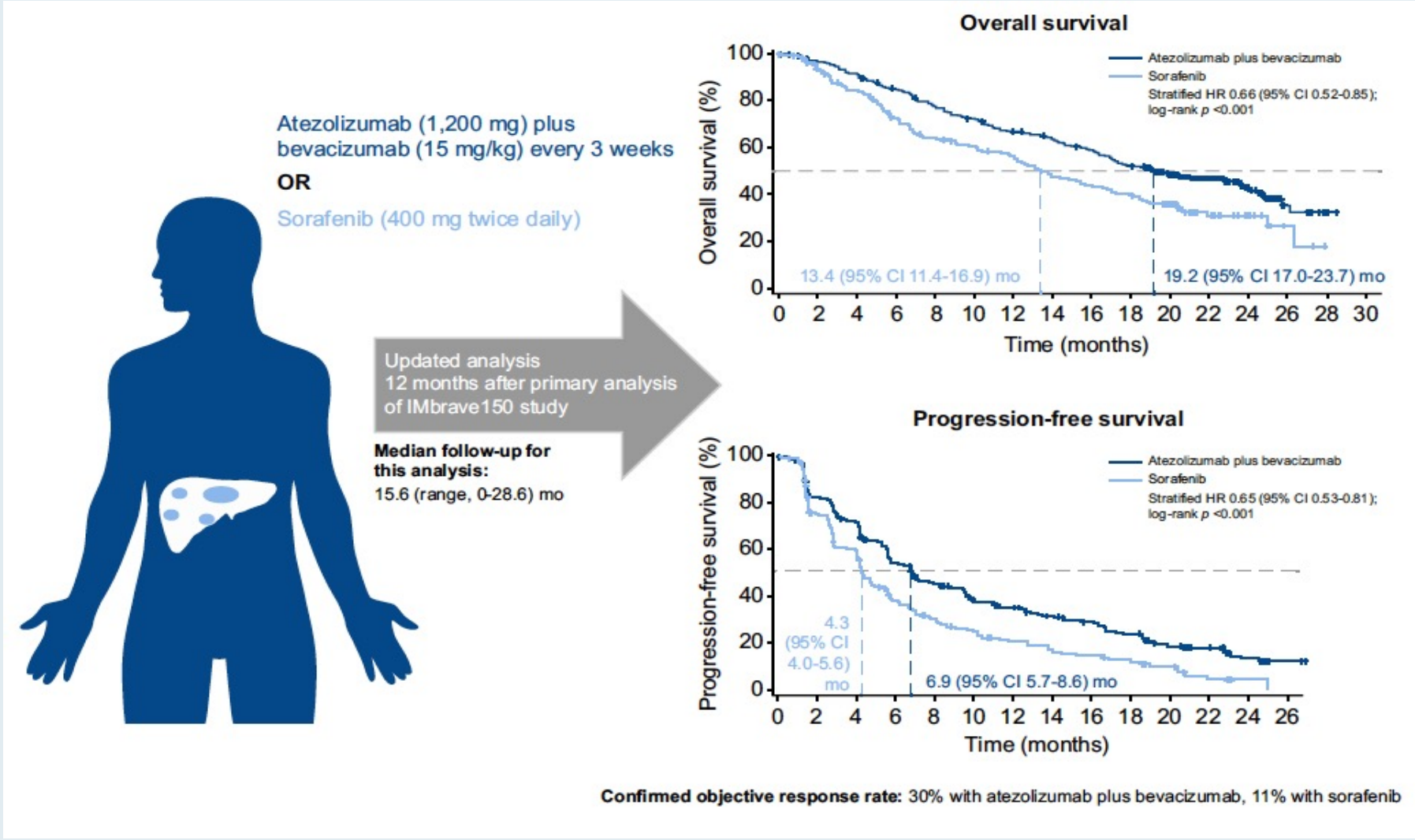
JOURNAL
OF HEPATOLOGY

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

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

RTP Year in Review 2022

IMbrave150: Updated Overall Survival and Progression-Free Survival Outcomes



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

RTP Year in Review 2022

ASCO Gastrointestinal Cancers Symposium

2022;Abstract 379

Phase 3 randomized, open-label, multicenter study of tremelimumab and durvalumab as first-line therapy in patients with unresectable hepatocellular carcinoma: HIMALAYA

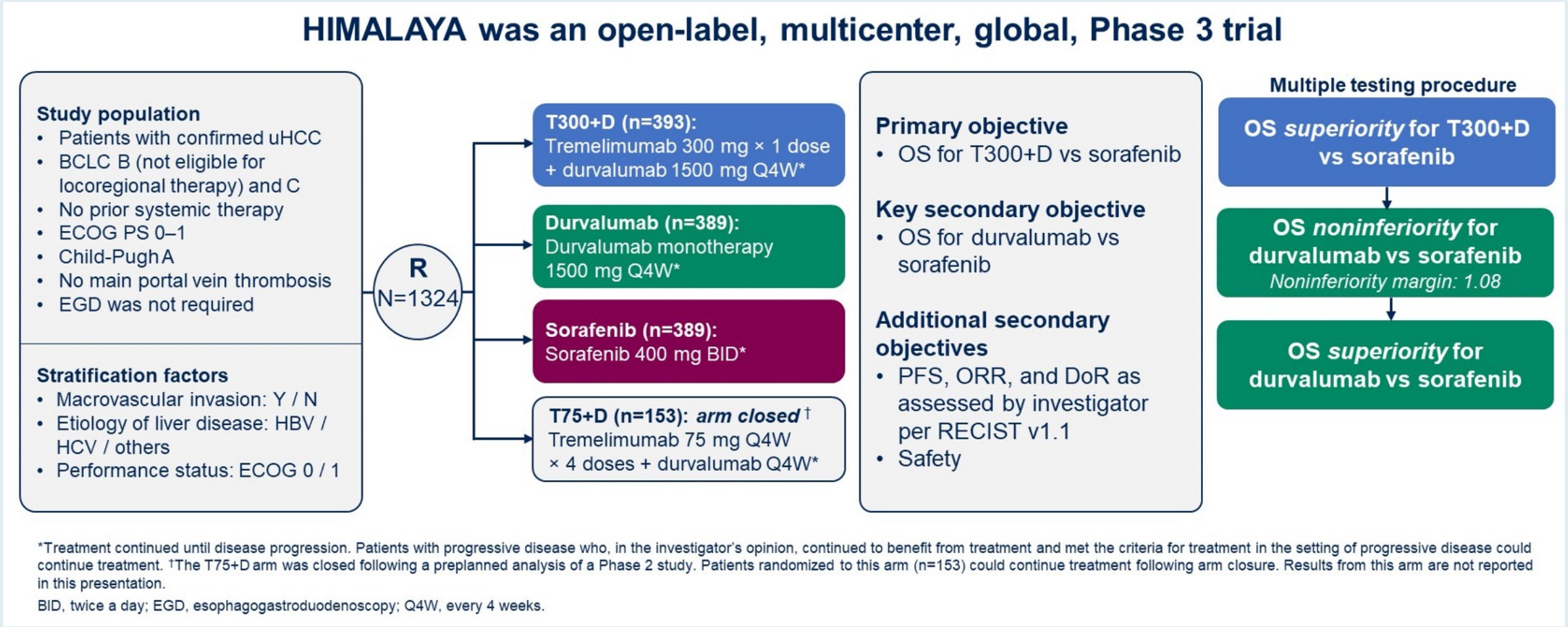
Ghassan K Abou-Alfa,[1,2*] Stephen L Chan,[3*] Masatoshi Kudo,[4*] George Lau,[5*] Robin Kate Kelley,[6] Junji Furuse,[7] Wattana Sukeepaisarnjaroen,[8] Yoon-Koo Kang,[9] Tu V Dao,[10] Enrico N De Toni,[11] Lorenza Rimassa,[12,13] Valery Breder,[14] Alexander Vasilyev,[15] Alexandra Heurgué,[16] Vincent C Tam,[17] Kabir Mody,[18] Satheesh Chiradoni Thungappa,[19] Philip He,[20] Alejandra Negro,[20] and Bruno Sangro[21]

[1]Department of Medicine, Memorial Sloan Kettering Center, New York, NY, USA; [2]Weill Medical College, Cornell University, New York, NY, USA; [3]State Key Laboratory of Translational Oncology, Department of Clinical Oncology, Sir Yue-Kong Pao Center for Cancer, The Chinese University of Hong Kong, Hong Kong, China; [4]Department of Gastroenterology and Hepatology, Kindai University Faculty of Medicine, Osaka, Japan; [5]Humanity and Health Clinical Trial Center, Humanity and Health Medical Group, Hong Kong, China; [6]Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, CA, USA; [7]Department of Medical Oncology, Kyorin University Faculty of Medicine, Mitaka, Japan; [8]Department of Medicine, Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand; [9]Department of Oncology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea; [10]Cancer Research and Clinical Trial Center, National Cancer Hospital, Hanoi, Vietnam; [11]Department of Medicine II, University Hospital, LMU Munich, Munich, Germany; [12]Department of Biomedical Sciences, Humanitas University, Pieve Emanuele, Milan, Italy; [13]Humanitas Cancer Center, IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy; [14]Chemotherapy Department No17, N.N. Blokhin Russian Cancer Research Center, Moscow, Russia; [15]Railway Clinical Hospital, St. Petersburg, Russia; [16]Service d'Hépato-Gastro-entérologie, Hôpital Robert-Debré, Reims, France; [17]Tom Baker Cancer Centre, University of Calgary, Calgary, AB, Canada; [18]Division of Hematology/Oncology, Department of Medicine, Mayo Clinic, Jacksonville, FL, USA; [19] Sri Venkateshwara Hospital, Bangalore, India; [20]AstraZeneca, Gaithersburg, MD, USA; [21]Liver Unit and HPB Oncology Area, Clinica Universidad de Navarra and CIBEREHD, Pamplona, Spain

*Drs Ghassan K Abou-Alfa, Stephen L Chan, Masatoshi Kudo, and George Lau contributed equally to this work.

RTP Year in Review 2022

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.

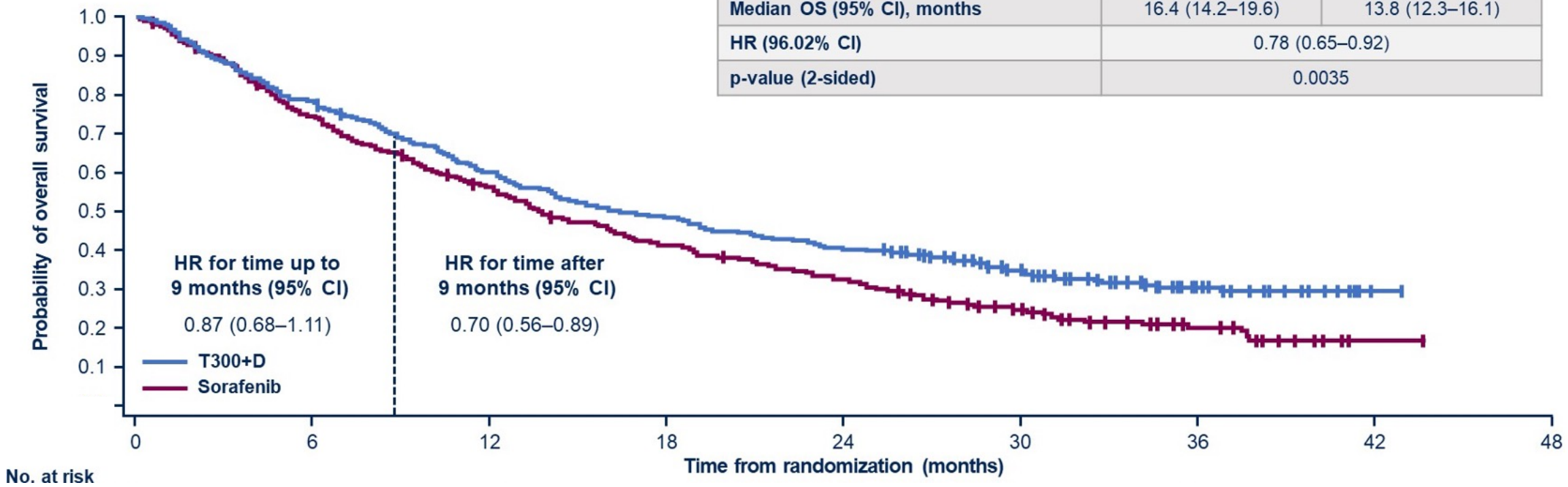
BID, twice a day; EGD, esophagogastroduodenoscopy; Q4W, every 4 weeks.

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

RTP Year in Review 2022

HIMALAYA Primary Endpoint: Overall Survival (OS) with Tremelimumab 300 and Durvalumab as First-Line Therapy for Unresectable HCC

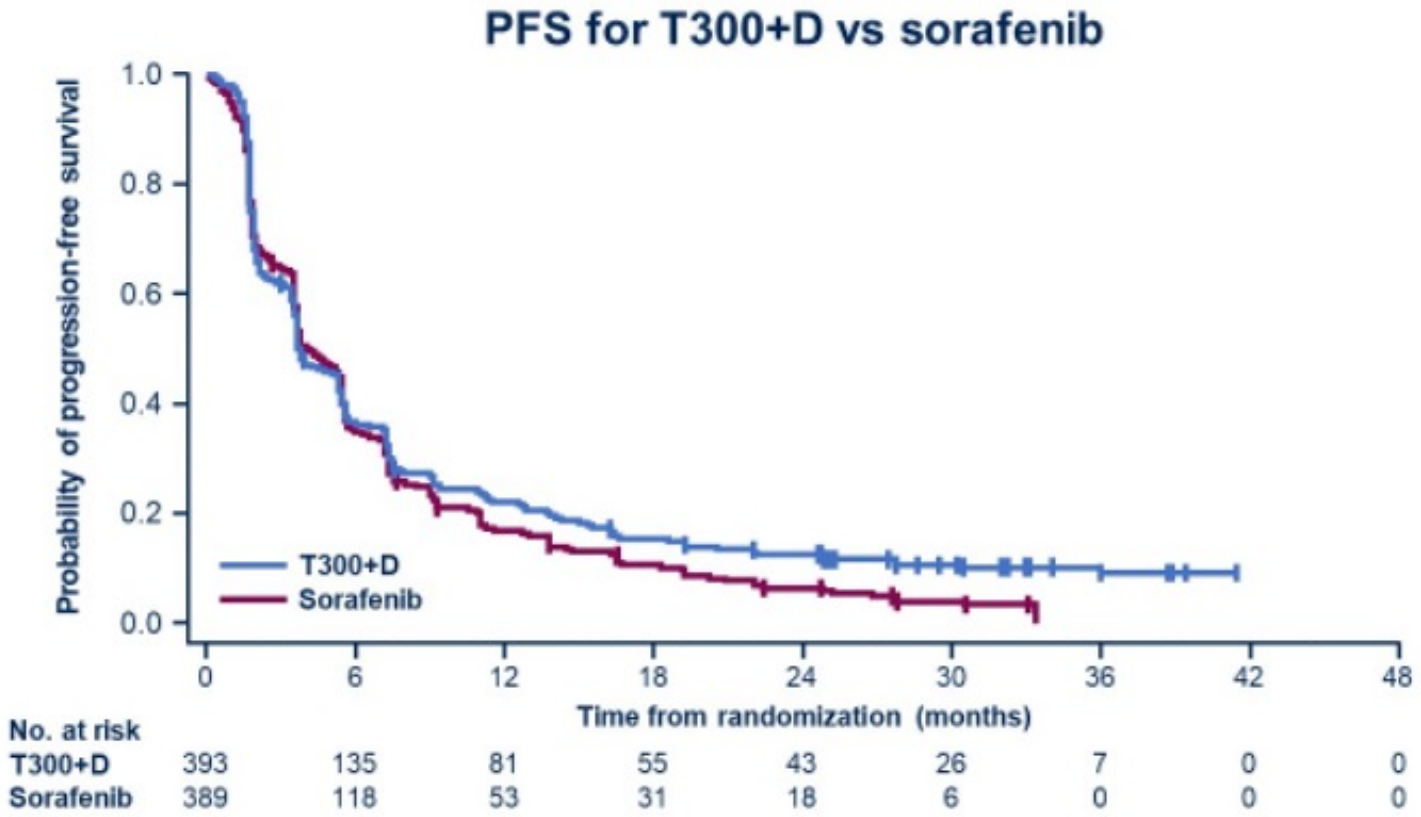
	T300+D (n=393)	Sorafenib (n=389)
OS events, n (%)	262 (66.7)	293 (75.3)
Median OS (95% CI), months	16.4 (14.2–19.6)	13.8 (12.3–16.1)
HR (96.02% CI)	0.78 (0.65–0.92)	
p-value (2-sided)	0.0035	



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

RTP Year in Review 2022

HIMALAYA: Progression-Free Survival



	T300+D (n=393)	Durvalumab (n=389)	Sorafenib (n=389)
PFS events, n (%)	335 (85.2)	345 (88.7)	327 (84.1)
Median PFS (95% CI), months	3.78 (3.68–5.32)	3.65 (3.19–3.75)	4.07 (3.75–5.49)
PFS HR* (95% CI)	0.90 (0.77–1.05)	1.02 (0.88–1.19)	–
Progression-free at DCO, n (%)	49 (12.5)	32 (8.2)	19 (4.9)
Median TTP (95% CI), months	5.42 (3.81–5.62)	3.75 (3.68–5.42)	5.55 (5.13–5.75)
Treated ≥1 cycle beyond progression, n (%)†	182 (46.9)	188 (48.5)	134 (34.4)

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

HIMALAYA: Safety and Tolerability

Event, n (%)	T300+D (n=388)	Durvalumab (n=388)	Sorafenib (n=374)
Any AE	378 (97.4)	345 (88.9)	357 (95.5)
Any TRAE*	294 (75.8)	202 (52.1)	317 (84.8)
Any grade 3/4 AE	196 (50.5)	144 (37.1)	196 (52.4)
Any grade 3/4 TRAE	100 (25.8)	50 (12.9)	138 (36.9)
Any serious TRAE	68 (17.5)	32 (8.2)	35 (9.4)
Any TRAE leading to death	9 (2.3)†	0	3 (0.8)‡
Any TRAE leading to discontinuation	32 (8.2)	16 (4.1)	41 (11.0)

Includes AEs with onset or increase in severity on or after the date of the first dose through 90 days following the date of the last dose or the date of initiation of the first subsequent therapy.

*Treatment-related was as assessed by investigator. †Nervous system disorder (n=1), acute respiratory distress syndrome (n=1), hepatitis (n=1), myocarditis (n=1), immune-mediated hepatitis (n=2), pneumonitis (n=1), hepatic failure (n=1), myasthenia gravis (n=1). ‡Hematuria (n=1), cerebral hematoma (n=1), hepatic failure (n=1).

AE, adverse event; SMQ, Standardized MedDRA Query; T300+D, tremelimumab 300 mg × 1 dose + durvalumab 1500 mg Q4W; TRAE, treatment-related adverse event.

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

ESMO ASIA VIRTUAL ONCOLOGY WEEK

ESMO VIRTUAL PLENARY

ABSTRACT VP10-2021

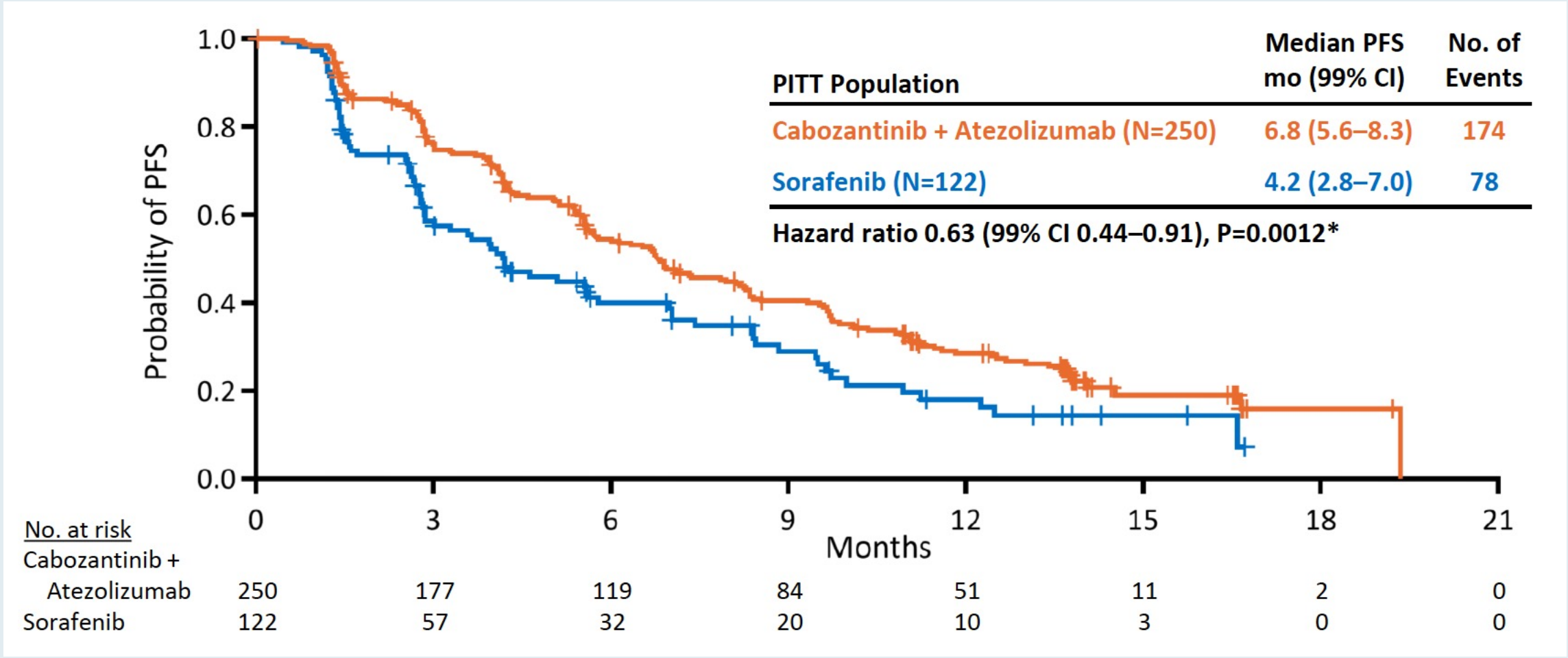
Cabozantinib plus atezolizumab versus sorafenib as first-line systemic treatment for advanced hepatocellular carcinoma: results from the randomized phase 3 COSMIC-312 trial

Robin Kate Kelley, Thomas Yau, Ann-Lii Cheng, Ahmed Kaseb, Shukui Qin, Andrew Zhu, Stephen Chan, Wattana Sukeepaisarnjaroen, Valery Breder, Gontran Verset, Edward Gane, Ivan Borbath, Jose David Gomez Rangel, Philippe Merle, Fawzi Benzaghou, Kamalika Banerjee, Saswati Hazra, Jonathan Fawcett, Lorenza Rimassa

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

RTP Year in Review 2022

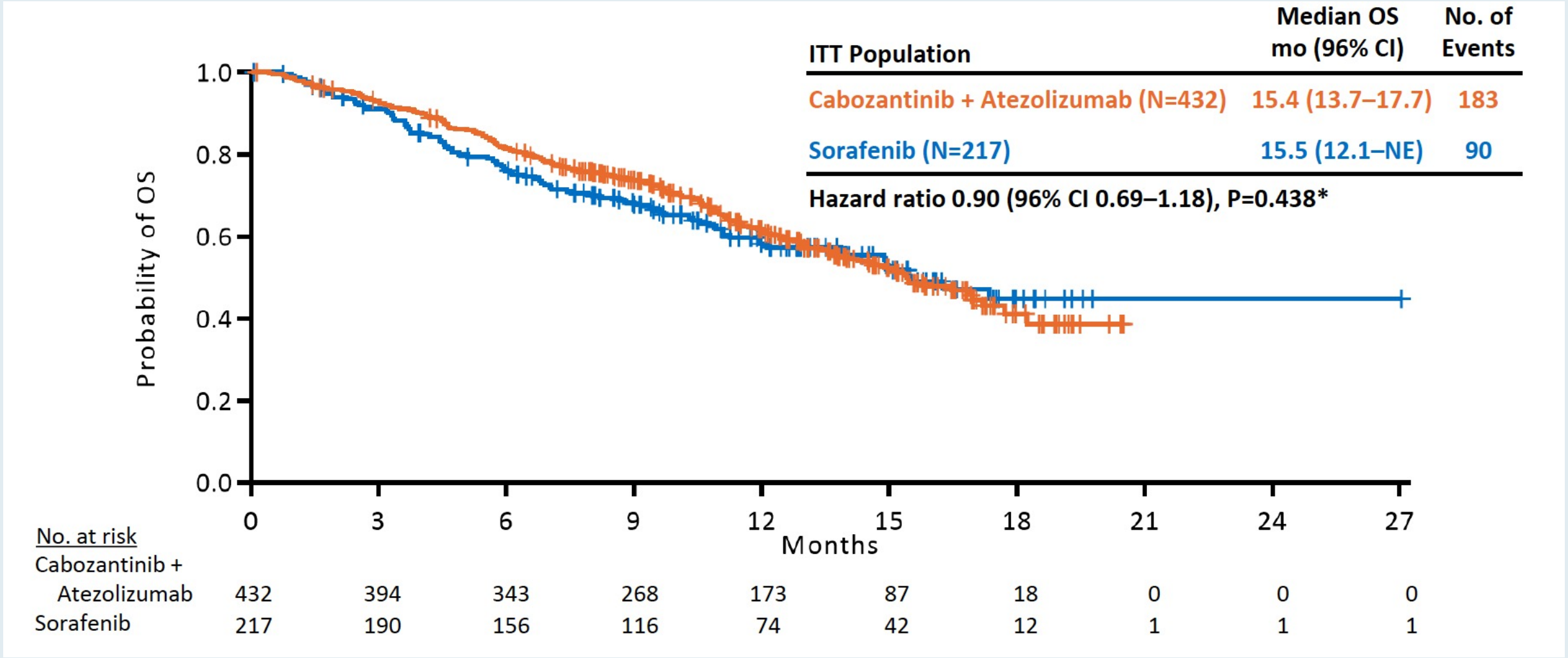
COSMIC-312 Primary Endpoint of Progression-Free Survival (PFS): Final Analysis



Kelley RK et al. ESMO Asia Virtual Oncology Week 2021;Abstract VP10-2021.

RTP Year in Review 2022

COSMIC-312 Primary Endpoint of OS: Interim Analysis



Kelley RK et al. ESMO Asia Virtual Oncology Week 2021;Abstract VP10-2021.

RTP Year in Review 2022

ESMO WORLD CONGRESS ON Gastrointestinal Cancer

HEPANOVA: Final Efficacy and Safety Results From a Phase 2 Study of Tumor Treating Fields (TTFields, 150 kHz) Concomitant with Sorafenib in Advanced Hepatocellular Carcinoma (HCC)

*Eleni Gkika[1], Yann Touchefeu[2], Teresa Macarulla Mercade[3], Antonio Cubillo Gracián[4], Monika Pazgan-Simon[5], Thomas Seufferlein[6], **Anca-Ligia Grosu[1]***

[1]University of Freiburg, Freiburg, Germany; [2]IMAD CHU Nantes, France; [3]Vall d'Hebrón University Hospital, Barcelona, Spain; [4]Hospital Universitario HM Sanchinarro ,Madrid, Spain. [5]Wroclaw Medical University, Wrocław, Poland. [6]University Hospital Ulm, Ulm, Germany

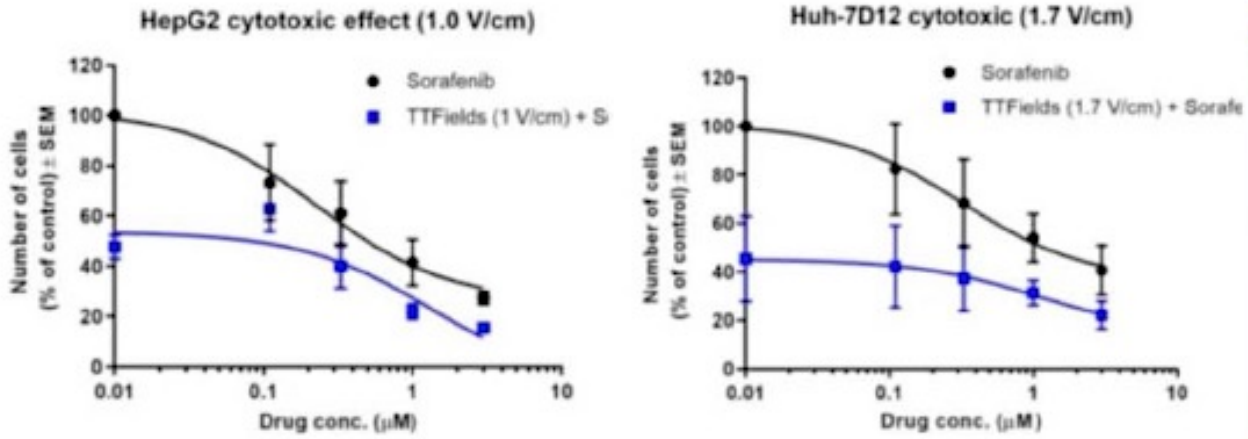
30 JUNE – 3 JULY 2021

Abstract O-16

RTP Year in Review 2022

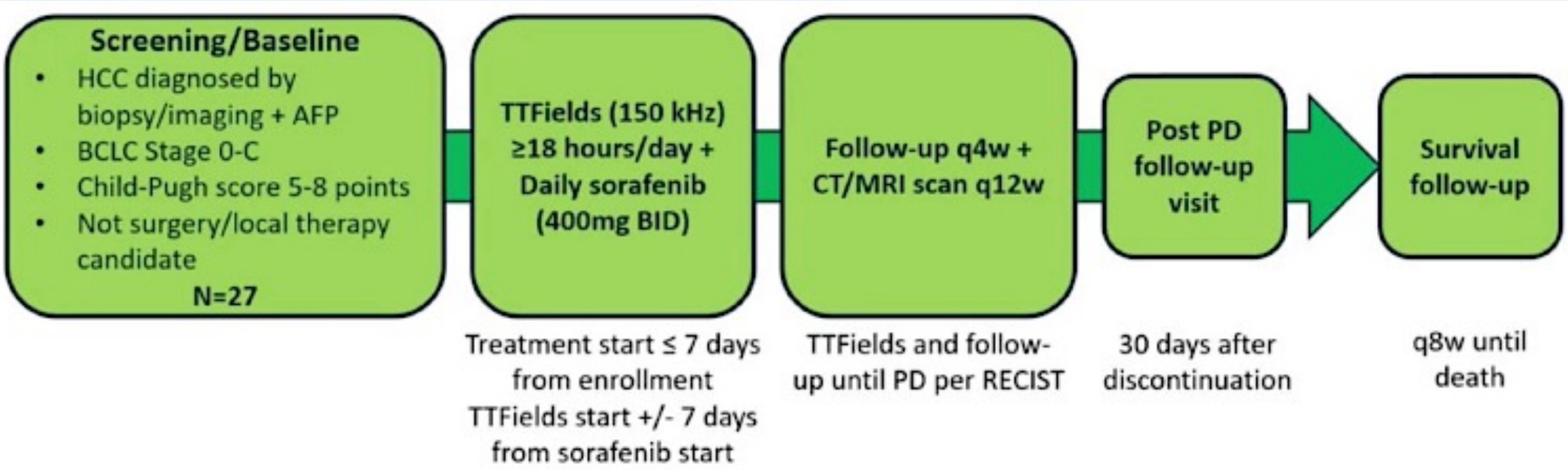
Tumor Treating Fields: Background

- Tumor Treating Fields (TTFields) are an anti-mitotic, regional treatment modality, utilizing low intensity alternating electric fields delivered non-invasively to the tumor using a portable medical device.
- TTFields are approved by the FDA for the treatment of glioblastoma and malignant pleural mesothelioma.
- *In vitro* and *in vivo* TTFields at 150 kHz reduced the proliferative potential of hepatocelluar carcinoma (HCC) cell lines.[2]



Gkika E et al. ESMO World Congress on Gastrointestinal Cancer 2021;Abstract O-16.

HEPANOVA: Phase II Study Design



A sample size of 25 patients provides 80% (α, 0.05) to detect an ORR of 20% vs 4.5% calculated from historical data[1-4]

Primary Endpoint: Investigator-assessed ORR per RECIST
Main Secondary Endpoints: PFS12; 1 year survival rate; distant metastases-free survival rate at 1 year; safety.

Gkika E et al. ESMO World Congress on Gastrointestinal Cancer 2021;Abstract O-16.

HEPANOVA: Efficacy Outcomes

Outcome	TTFields ≥ 12 weeks + Sorafenib* (N=11)	TTFields + Sorafenib (N=21)
Overall Response Rate, %	18	9.5 (P=0.24)
Level of response, %		
Complete	0	0
Partial	18	9.5
Stable disease	73	66.5
Disease Control Rate, %	91	76

Outcome	TTFields + Sorafenib (N=27)
In-field control rate at 1 year, % (95% CI)	9.5%
Median PFS, months (95% CI)	5.8 (3.0-8.9)
Median time to progression, months (95% CI)	8.9 months (3.1, not reached)
PFS12, % (95% CI)	23 (7-45)
1 year survival rate, % (95% CI)	30 (11-52)
Distant metastases-free survival rate at 1 year, % (95% CI)	26 (8-49)

* Six patients (22%) survived less than 12 weeks

Gkika E et al. ESMO World Congress on Gastrointestinal Cancer 2021;Abstract O-16.

HEPANOVA: Adverse Events (AEs)

AEs with incidence ≥5%, by SOC, n (%)	TTFields + Sorafenib (N=27) Grade 3-4
Blood and lymphatic	2 (7%)
Cardiac	2 (7%)
Gastrointestinal	7 (26%)
General disorders/administration site	4 (15%)
Hepatobiliary	2 (7%)
Infections	2 (7%)
Laboratory investigations	4 (15%)
Metabolism	5 (19%)
Musculoskeletal	3 (11%)
Renal and urinary	2 (7%)
Respiratory	4 (15%)
Skin	2 (7%)
Vascular	3 (11%)

- Thirteen patients (48%) experienced SAEs. No SAEs were TTFields related
- Eighteen patients (67%) had grade 1-2 TTFields related skin toxicity
- One patient (3%) had grade 3 skin toxicity

Gkika E et al. ESMO World Congress on Gastrointestinal Cancer 2021;Abstract O-16.

FDA Grants Breakthrough Device Designation to the NovoTTF-200T™ System for Advanced Liver Cancer

Press Release: September 9, 2021

"Today [it was] announced the United States Food and Drug Administration (FDA) has granted breakthrough designation to the NovoTTF-200T System, a Tumor Treating Fields (TTFields) delivery system intended for use together with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer. The designation offers [the company] an opportunity to interact with FDA experts through several different program options to address regulatory topics efficiently as they arise during the premarket review phase and allows for prioritized review of regulatory submissions.

The FDA granted breakthrough device designation in part based on clinical data from [the] Phase 2 pilot HEPANOVA trial testing the safety and efficacy of TTFields together with sorafenib for the treatment of advanced liver cancer. In granting the designation, the FDA determined that the TTFields delivery system for advanced liver cancer is a breakthrough technology that has the potential to be a more effective treatment for this life-threatening condition, and therefore meets the FDA's stringent requirements for breakthrough device designation."

https://www.novocure.com/fda-grants-breakthrough-device-designation-to-the-novottf-200t-system-for-advanced-liver-cancer/

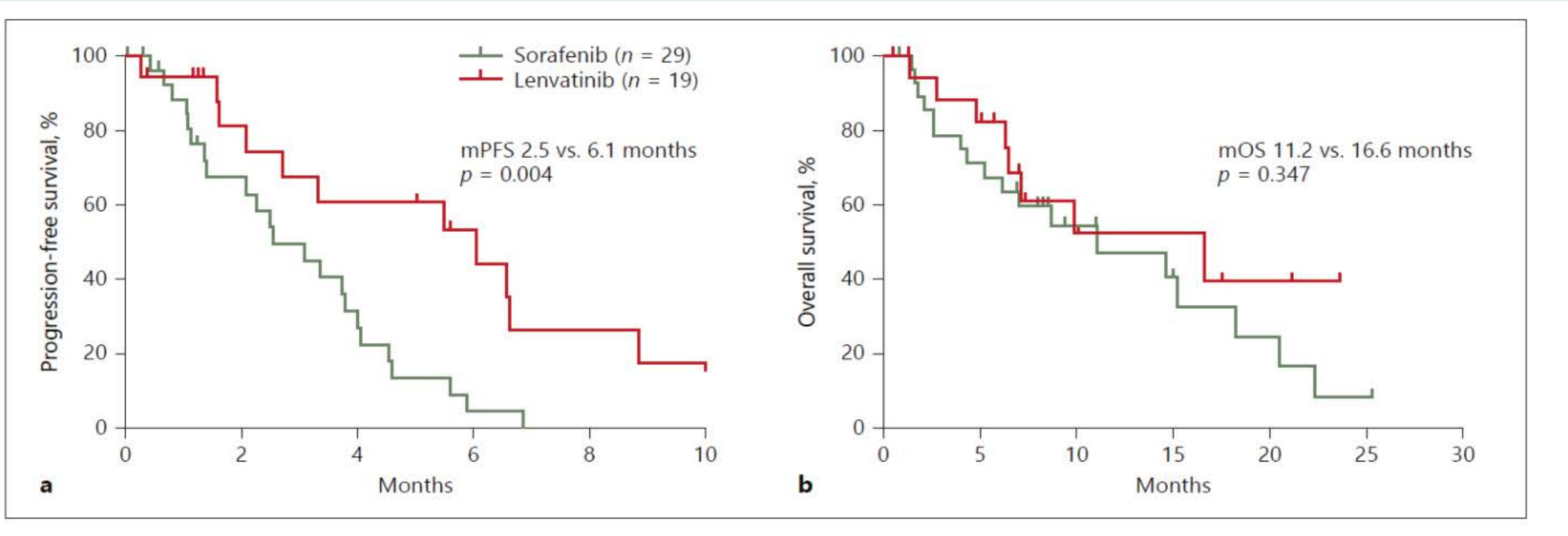
Clinical Outcomes with Multikinase Inhibitors after Progression on First-Line Atezolizumab plus Bevacizumab in Patients with Advanced Hepatocellular Carcinoma: A Multinational Multicenter Retrospective Study

Changhoon Yoo[a] Jwa Hoon Kim[a] Min-Hee Ryu[a] Sook Ryun Park[a]
Danbi Lee[b] Kang Mo Kim[b] Ju Hyun Shim[b] Young-Suk Lim[b] Han Chu Lee[b]
Joycelyn Lee[c] David Tai[c] Stephen Lam Chan[d] Baek-Yeol Ryoo[a]

Liver Cancer 2021;10(2):107-14.

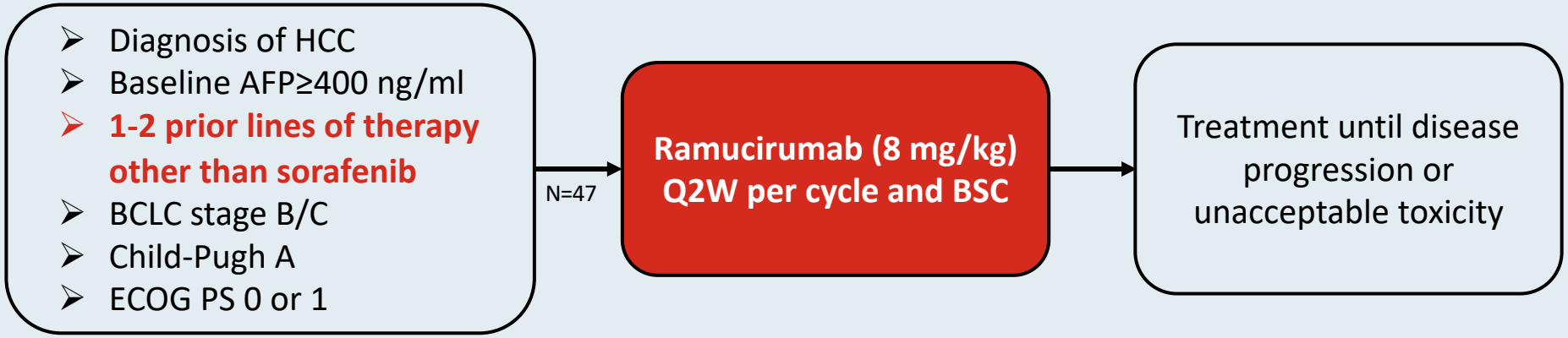
RTP Year in Review 2022

Activity of Multikinase Inhibitors After Disease Progression on First-Line Atezolizumab/Bevacizumab in Patients with Advanced HCC



Yoo C et al. *Liver Cancer* 2021;10(2):107-14.

REACH-2 Trial: Open Label Expansion



ClinicalTrials.gov: NCT02435433

- **Primary endpoint:** Safety
- **Secondary endpoints:** OS, PFS (RECIST v1.1), TTP, ORR, PK, patient-reported outcomes, immunogenicity
- **Pooled analysis:** open-label cohort was indirectly compared to patients from REACH (AFP ≥400 ng/mL) and REACH-2 who received prior sorafenib using individual patient data meta-analysis

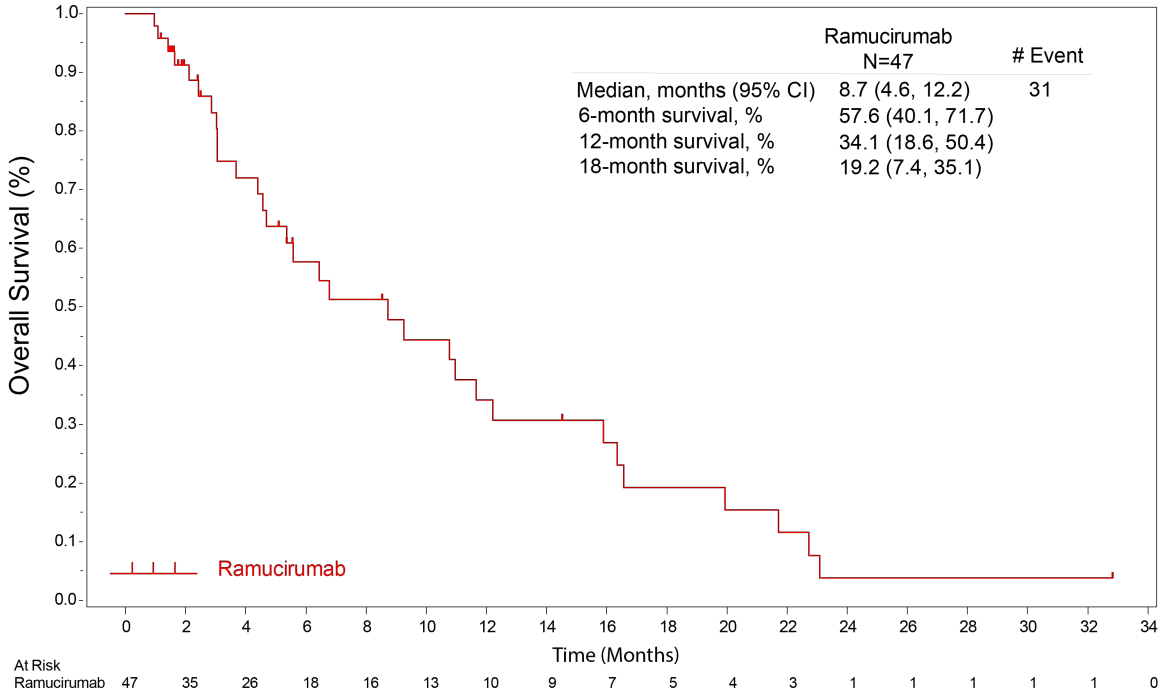
Analysis of single arm Open-Label Expansion Cohort will be independent of Main Cohort. The final analysis of the primary and secondary endpoints will occur after all patients enrolled in the OLE cohort have completed at least 3 cycles of ramucirumab or discontinued for any reason.

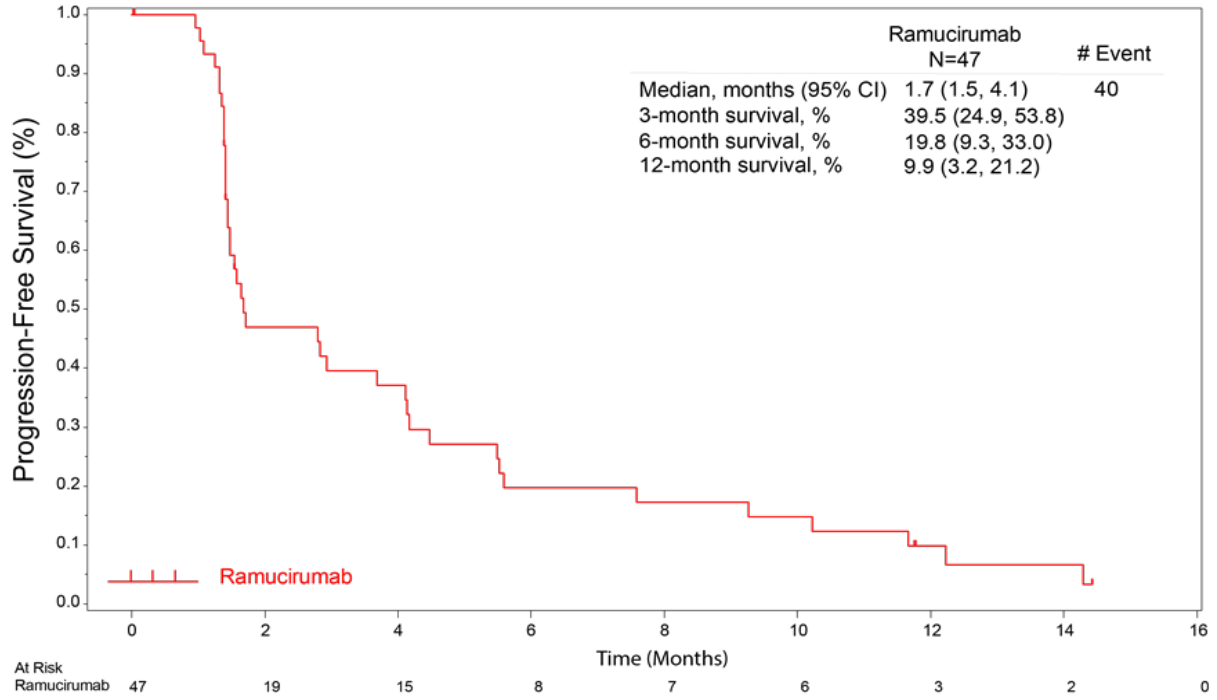
AFP= alpha-fetoprotein; BCLC= Barcelona Clinic Liver Cancer; BSC= best supportive care; ECOG PS= Eastern Cooperative Oncology Group Performance Status; ORR= objective response rate; OS= overall survival; PFS= progression-free survival; PK= pharmacokinetics; Q2W= every 2 weeks; TTP= time-to-progression

Data cut-off date was May 11, 2021

Finn RS et al. ASCO Gastrointestinal Cancers Symposium 2022;Abstract 423.

REACH-2: Survival





Finn RS et al. ASCO Gastrointestinal Cancers Symposium 2022;Abstract 423.

RTP Year in Review 2022

Agenda

Introduction

Module 1: Hepatocellular Carcinoma

Module 2: Biliary Tract Cancers

- TOPAZ-1
- ClarIDHy
- Phase II Study of Infigratinib
- FIGHT-202
- FOENIX-CCA2

Module 3: Pancreatic Cancer

ASCO Gastrointestinal Cancers Symposium

Abstract 378

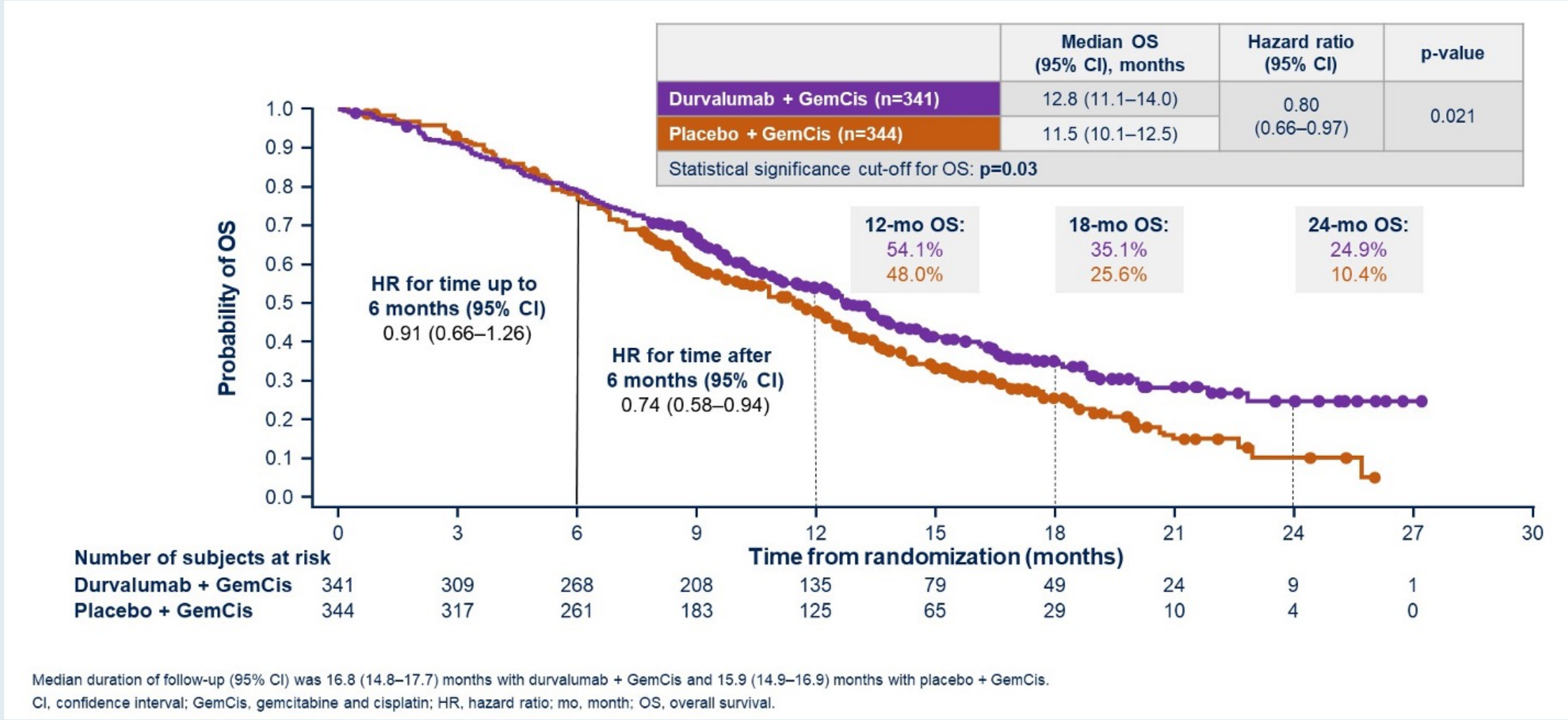
A Phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin in patients with advanced biliary tract cancer: TOPAZ-1

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] Nana Rokutanda,[17] Julia Xiong,[17] Gordon Cohen,[17] Juan W. Valle[18]

[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]Division of Hematology and Oncology, Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; [3]Cancer Center of Nanjing, Jinling Hospital, Nanjing, China; [4]Kaohsiung Medical University Hospital, Kaohsiung Medical University, Kaohsiung, and National Institute of Cancer Research, Tainan, and National Cheng Kung University Hospital, National Cheng Kung University, Tainan, Taiwan; [5]Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; [6]Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Germany; [7]Division of Medical Oncology, Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul, South Korea; [8]Department of Internal Medicine, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand; [9]Division of Medical Oncology, Department of Internal Medicine, Seoul St. Mary's Hospital, College of Medicine, The 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]Department of Liver Cancer Unit, AP-HP Hôpital Beaujon, Paris, France; [13]Department of Internal Medicine, Faculty of Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital, 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]AstraZeneca, Gaithersburg, MD, USA; [18]Division of Cancer Sciences, The University of Manchester and The Christie NHS Foundation Trust, Manchester, UK

RTP Year in Review 2022

TOPAZ-1 Primary Endpoint: OS



Median duration of follow-up (95% CI) was 16.8 (14.8–17.7) months with durvalumab + GemCis and 15.9 (14.9–16.9) months with placebo + GemCis.
CI, confidence interval; GemCis, gemcitabine and cisplatin; HR, hazard ratio; mo, month; OS, overall survival.

Oh D-Y et al. Gastrointestinal Cancers Symposium 2022;Abstract 378.

RTP Year in Review 2022

FDA Approves Ivosidenib for Advanced or Metastatic Cholangiocarcinoma

Press Release – August 25, 2021

"The Food and Drug Administration approved ivosidenib for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Today, the FDA also approved the Oncomine Dx Target Test as a companion diagnostic device to aid in selecting patients with cholangiocarcinoma for treatment with ivosidenib.

Ivosidenib was investigated in a randomized (2:1), multicenter, double-blind, placebo-controlled clinical trial (Study AG120-C-005, NCT02989857) of 185 adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation. The patient's disease must have progressed following at least one, but not more than two prior regimens, including at least one gemcitabine- or 5-flurouracil-containing regimen. Patients were randomized to receive either ivosidenib 500 mg orally once daily or matched placebo until disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-advanced-or-metastatic-cholangiocarcinoma

Research

JAMA Oncology | Original Investigation

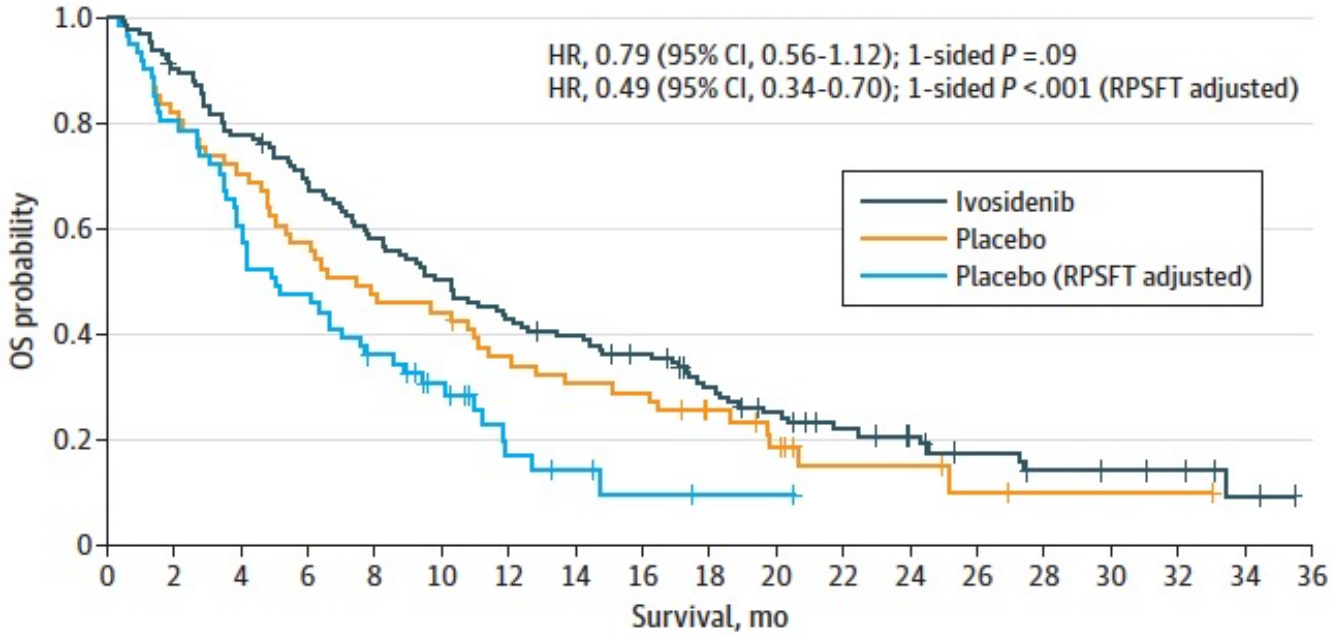
Final Overall Survival Efficacy Results of Ivosidenib for Patients With Advanced Cholangiocarcinoma With *IDH1* Mutation

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

JAMA Oncol 2021;7(11):1669-77.

ClarIDHy: Final OS with Ivosidenib for Patients with Advanced Cholangiocarcinoma with IDH1 Mutation



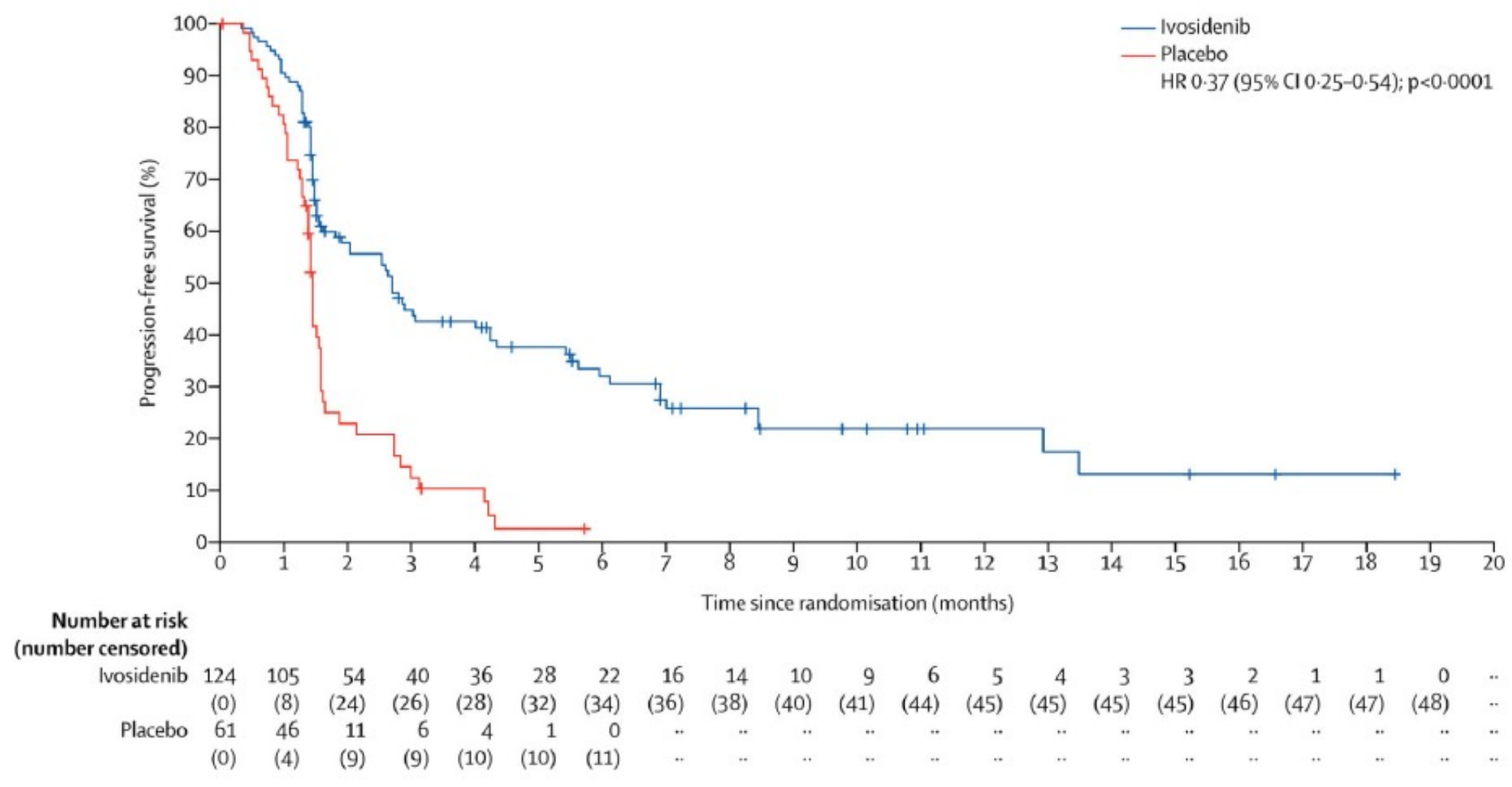
No. at risk

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)

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

ClarIDHy: PFS with Ivosidenib for Patients with Advanced Cholangiocarcinoma with IDH1 Mutation



Number at risk (number censored)																					
Ivosidenib	124	105	54	40	36	28	22	16	14	10	9	6	5	4	3	3	2	1	1	0	..
	(0)	(8)	(24)	(26)	(28)	(32)	(34)	(36)	(38)	(40)	(41)	(44)	(45)	(45)	(45)	(45)	(46)	(47)	(47)	(48)	..
Placebo	61	46	11	6	4	1	0	..	..	..	..	..	..	..	..	..	..	..	..	..	..
	(0)	(4)	(9)	(9)	(10)	(10)	(11)	..	..	..	..	..	..	..	..	..	..	..	..	..	..

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

RTP Year in Review 2022

FDA Grants Accelerated Approval to Infigratinib for Metastatic Cholangiocarcinoma

Press Release – May 28, 2021

"The Food and Drug Administration granted accelerated approval to infigratinib, a kinase inhibitor for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

The FDA also approved FoundationOne® CDx for selection of patients with FGFR2 fusion or other rearrangement as a companion diagnostic device for treatment with infigratinib.

Efficacy was demonstrated in CBGJ398X2204 (NCT02150967), a multicenter open-label single-arm trial, that enrolled 108 patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or rearrangement as determined by local or central testing. Patients received infigratinib 125 mg orally once daily for 21 consecutive days followed by 7 days off therapy, in 28-day cycles until disease progression or unacceptable toxicity."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-infigratinib-metastatic-cholangiocarcinoma

Lancet Gasteroenterol Hepatol 2021;6(10):803-15.

Infigratinib (BGJ398) in previously treated patients with advanced or metastatic cholangiocarcinoma with *FGFR2* fusions or rearrangements: mature results from a multicentre, open-label, single-arm, phase 2 study

Milind Javle, Sameek Roychowdhury, Robin Kate Kelley, Saeed Sadeghi, Teresa Macarulla, Karl Heinz Weiss, Dirk-Thomas Waldschmidt, Lipika Goyal, Ivan Borbath, Anthony El-Khoueiry, Mitesh J Borad, Wei Peng Yong, Philip A Philip, Michael Bitzer, Surbpong Tanasanvimon, Ai Li, Amit Pande, Harris S Soifer, Stacie Peacock Shepherd, Susan Moran, Andrew X Zhu, Tanios S Bekaii-Saab, Ghassan K Abou-Alfa

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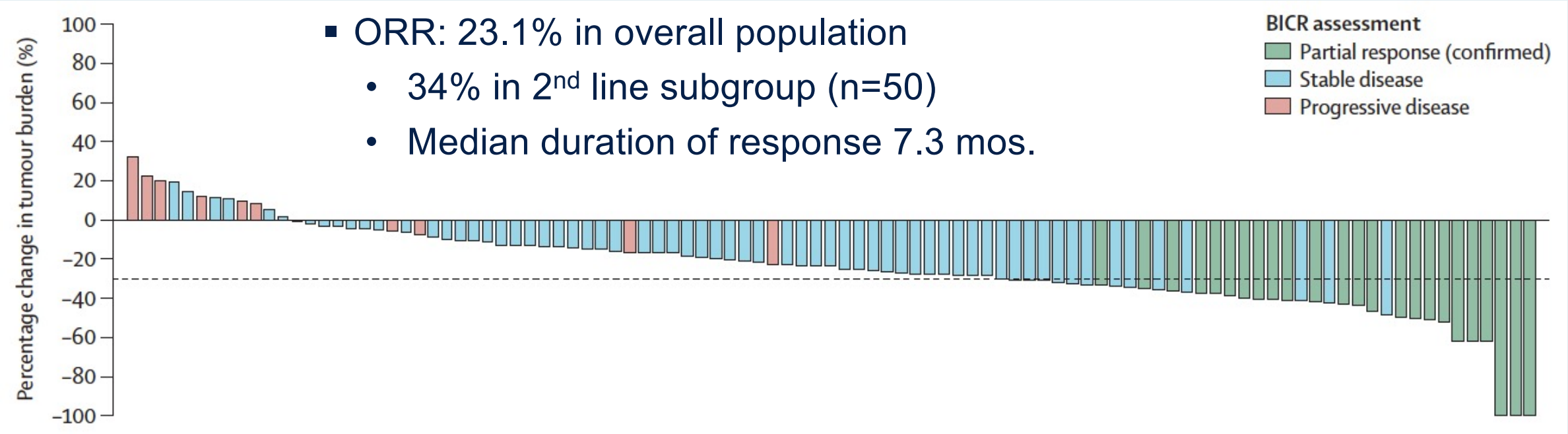
Phase II Study of Infigratinib for Advanced or Metastatic Cholangiocarcinoma Harboring FGFR2 Fusions or Rearrangements

- ORR: 23.1% in overall population
  - 34% in 2nd line subgroup (n=50)
  - Median duration of response 7.3 mos.



Javle M et al. *Lancet Gasteroenterol Hepatol* 2021;6(10):803-15.

Pemigatinib for Previously Treated Locally Advanced or Metastatic Cholangiocarcinoma: Update of FIGHT-202

Abou-Alfa GK,[1,2] Sahai V,[3] Hollebecque A,[4] Vaccaro G,[5] Melisi D,[6] Al-Rajabi R,[7] Paulson AS,[8] Borad MJ,[9] Gallinson D,[10] Murphy AG,[11] Oh D-Y,[12] Dotan E,[13] Catenacci DV,[14] Van Cutsem E,[15] Lihou C,[16] Zhen H,[16] Féliz L,[17] Vogel A[18]

[1]Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY, USA; [2]Weill Medical College at Cornell University, New York, NY, USA; [3]Division of Hematology and Oncology, Department of Internal Medicine, University of Michigan, Ann Arbor, MI, USA; [4]Department of Adult Medicine, Gustave Roussy, Villejuif, France; [5]Providence Cancer Center Oncology and Hematology Care Clinic, Portland, OR, USA; [6]Digestive Molecular Clinical Oncology Research Unit, Department of Medicine, Università degli studi di Verona, Verona, Italy; [7]Department of Internal Medicine, Division of Hematology/Oncology, University of Kansas Cancer Center, Kansas City, KS, USA; [8]Baylor Charles A. Sammons Cancer Center, Baylor University Medical Center, Dallas, TX, USA; [9]Department of Internal Medicine, Mayo Clinic Cancer Center, Scottsdale, AZ, USA; [10]Department of Hematology/Oncology, Morristown Memorial Hospital, Carol Cancer Center, Morristown, NJ, USA; [11]Department of Oncology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine, Baltimore, MD, USA; [12]Department of Internal Medicine, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, South Korea; [13]Department of Hematology/Oncology, Fox Chase Cancer Center, Philadelphia, PA, USA; [14]Department of Medicine, University of Chicago Medicine, Chicago, IL, USA; [15]Department of Digestive Oncology, University Hospitals Leuven and KU Leuven, Leuven, Belgium; [16]Incyte Corporation, Wilmington, DE, USA; [17]Incyte Biosciences International Sàrl, Morges, Switzerland; [18]Department of Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, Hannover, Niedersachsen, Germany

2021 American Society of Clinical Oncology (ASCO) Annual Meeting, June 4–8, 2021: Poster 4086

RTP Year in Review 2022

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

- The ORR for cohort A was 37.0% in this updated analysis with 4 complete responses (CRs) and 36 partial responses (PRs), and a median duration of response of 8.1 months (**Table 1**)
- The updated median PFS was 7.0 months, and the updated median OS was 17.5 months (**Table 1**)
- No changes in the numbers of patients with CR or PR occurred in cohorts B and C in the current vs the primary analysis

Table 1. Efficacy Outcomes in Patients With *FGFR2* Fusions or Rearrangements (Cohort A)

Variable	Primary Analysis[1] (n = 107)	Current Analysis (n = 108)*
ORR (95% CI), %	35.5 (26.5–45.4)	**37.0 (27.9–46.9)**
Best OR, † n (%)		
CR	3 (2.8)	4 (3.7)
PR	35 (32.7)	36 (33.3)
SD	50 (46.7)	49 (45.4)
PD	16 (14.9)	16 (14.8)
Not evaluable‡	3 (2.8)	3 (2.8)
DCR (95% CI), %	82 (74–89)	82.4 (73.9–89.1)
mDOR (95% CI), mo	7.5 (5.7–14.5)	8.1 (5.7–13.1)
mPFS (95% CI), mo	6.9 (6.2–9.6)	7.0 (6.1–10.5)
mOS (95% CI), mo	21.1 (14·8–NE)§	17.5 (14.4–23.0)
Responders	–	30.1 (21.5–NE)
Nonresponders	–	13.7 (9.6–16.2)

*Includes 1 patient from Japan who was enrolled in cohort A after the primary cutoff date (enrollment was held open in Japan for this patient because they were already in screening). †Assessed and confirmed by independent central review. ‡Postbaseline tumor assessment was not performed owing to study discontinuation (2 participants in cohort A, 4 participants in cohort B, 3 participants in cohort C) or was performed prior to the minimum interval of 39 days for an assessment of SD (1 patient in cohort A, 1 patient in cohort B). §OS not mature at data cutoff used for the primary analysis (March 22, 2019).
mDOR, median duration of response; mOS, median overall survival; mPFS, median progression-free survival; NE, not estimable; OR, objective response; PD, progressive disease; SD, stable disease.

1. Abou-Alfa GK, et al. *Lancet Oncol.* 2020;21:671–668.

About-Alfa GK et al. ASCO 2021;Abstract 4086.

Primary Results of Phase 2 FOENIX-CCA2: The Irreversible FGFR1-4 Inhibitor Futibatinib in Intrahepatic Cholangiocarcinoma (iCCA) with FGFR2 Fusions/Rearrangements

Goyal L et al.
AACR 2021;Abstract CT010.

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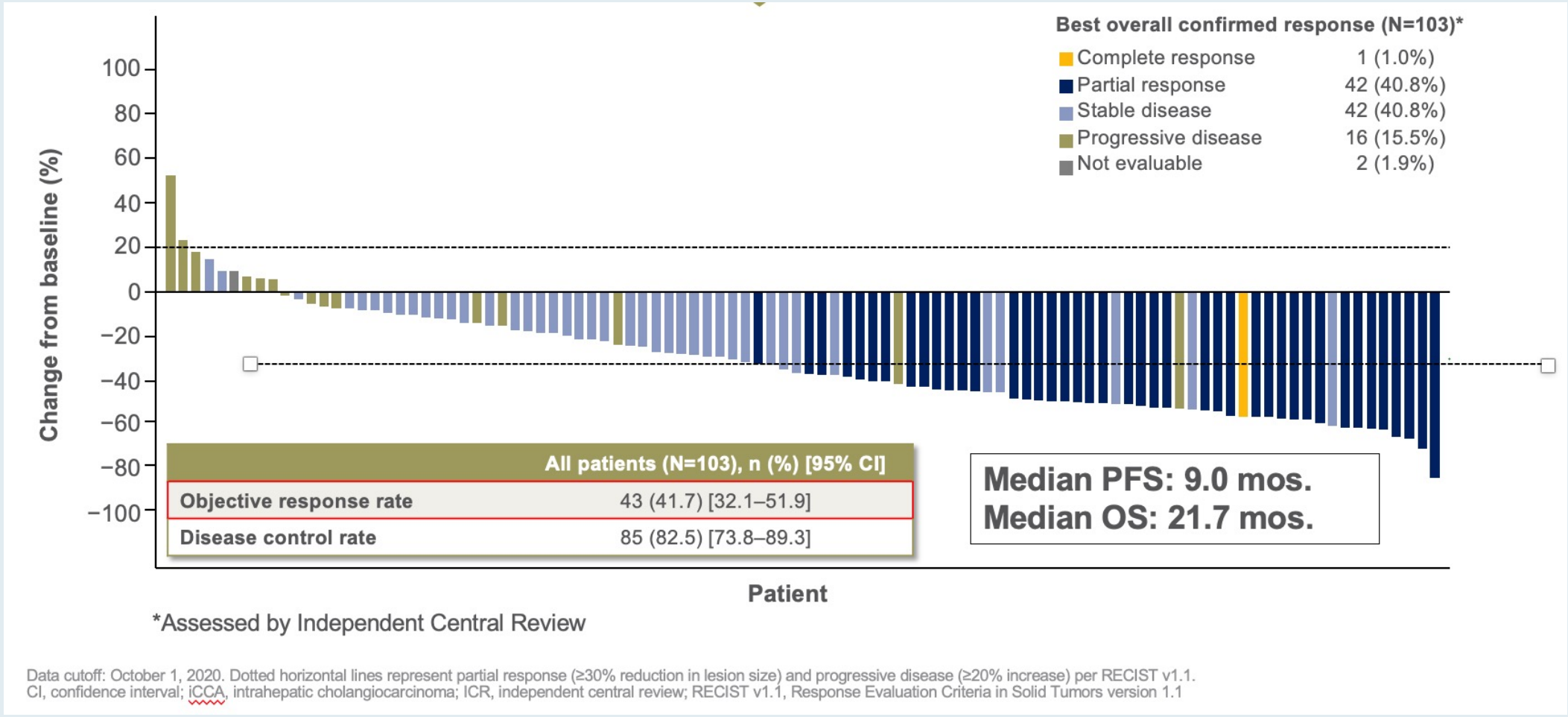
FOENIX-CCA2: Phase II Study of Futibatinib for Intrahepatic Cholangiocarcinoma with FGFR2 Fusions or Rearrangements



Data cutoff: October 1, 2020. Dotted horizontal lines represent partial response (≥30% reduction in lesion size) and progressive disease (≥20% increase) per RECIST v1.1.
CI, confidence interval; iCCA, intrahepatic cholangiocarcinoma; ICR, independent central review; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1

Goyal L et al. AACR 2021;Abstract CT010.

Agenda

Introduction

Module 1: Hepatocellular Carcinoma

Module 2: Biliary Tract Cancers

Module 3: Pancreatic Cancer

- Unicancer PRODIGE 24/CCTG PA.6
- PREOPANC
- PREOPANC-2
- APACT
- PETRA
- Olaparib Monotherapy for Patients with DNA Damage Repair Alterations Other Than Germline BRCA Variants
- Real-World Use of PARP Inhibitors for Pancreatic Cancer with BRCA Mutation

2021 ESMO congress

Abstract LBA57

Unicancer PRODIGE 24/CCTG PA6 trial: Updated results of a multicenter international randomized phase 3 trial of adjuvant mFOLFIRINOX versus gemcitabine in patients with resected pancreatic ductal adenocarcinomas.

T. Conroy, P. Hammel, A. Turpin, C. Belletier, A. C. Wei, E. Mitry, A. Lopez, E. François, P. Artru, J. Biagi, T. Lecomte, E. Assenat, R. Faroux, M. Ychou, O. Bouché, A. Lambert, L. Monard, P. Rat, F. Castan, J.B. Bachet

PRODIGE
PARTENARIAT DE RECHERCHE EN ONCOLOGIE DIGESTIVE

unicancer

Canadian Cancer Trials Group

Groupe canadien des essais sur le cancer

RTP Year in Review 2022

Unicancer PRODIGE 24/CCTG PA.6: Phase III Trial Schema

Patients:
- R0 or R1 resected pancreatic cancer
- Mandatory postoperative CT-scan
- CA19-9 level < 180 U/mL
- Inclusion within 12 weeks after surgery

Stratification:
- center
- resection margin (R0 vs R1)
- CA19-9 level (≤ 90 vs 91-179 U/mL)
- pN0 (< 12 vs ≥ 12 examined nodes) vs pN1

RANDOMIZE 1:1

mFOLFIRINOX
Oxaliplatin 85 mg/m² at D1
Leucovorin 400 mg/m² at D1
Irinotecan 150-180 mg/m² at D1
Fluorouracil continuous IV infusion 2.4 g/m² over 46 hours
Every 2 weeks; 12 cycles

Gemcitabine
1000 mg/m², qw 3/4 *weeks*
6 cycles

Primary endpoint: DFS

Secondary endpoints:
- overall survival
- metastasis-free survival
- cancer-specific survival
- safety.

for both arms:
- 6 months of adjuvant chemotherapy
- CT scans: every 3 months

Conroy T et al. ESMO 2021;Abstract LBA57.

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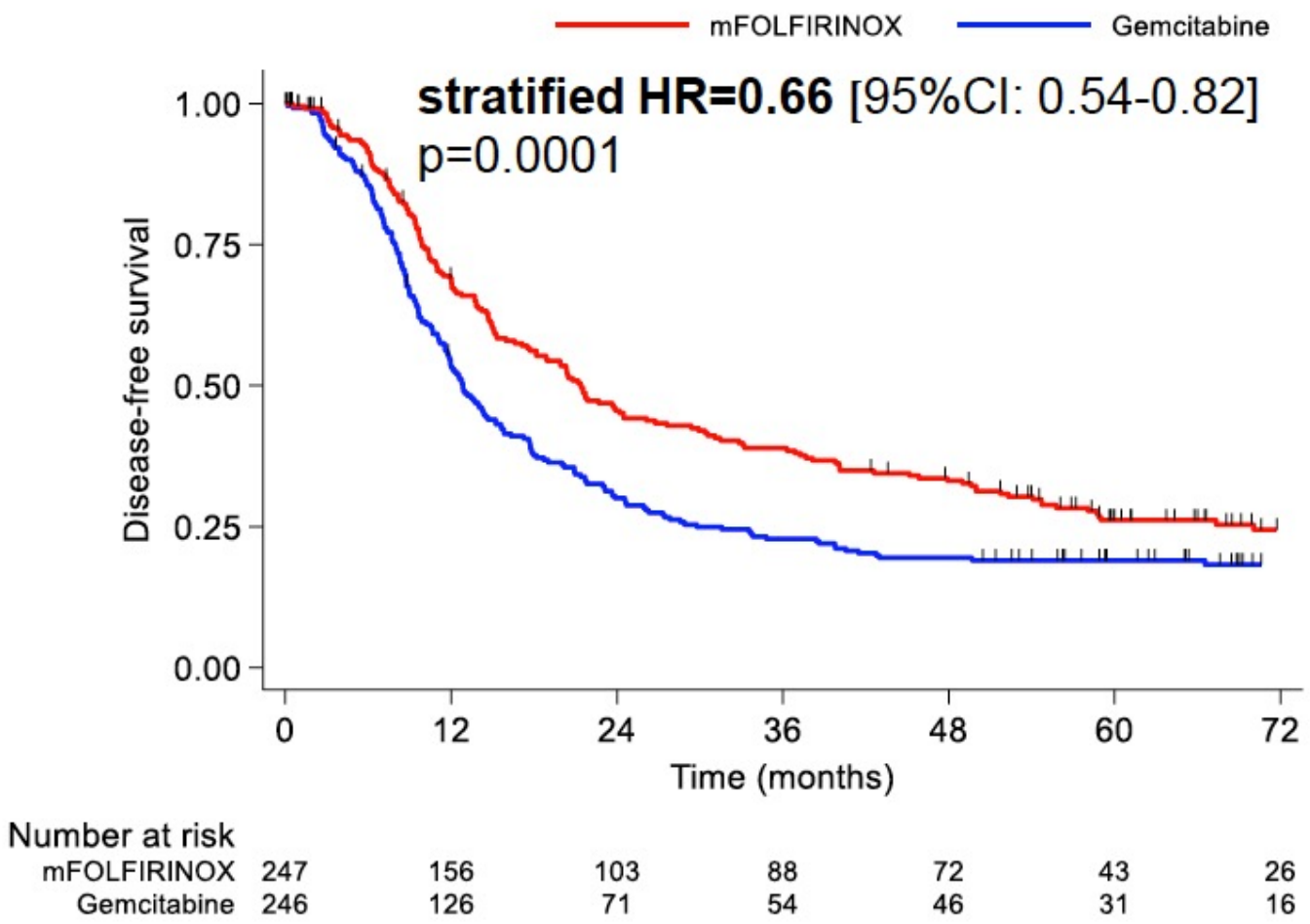
Unicancer PRODIGE 24/CCTG PA.6: Disease-Free Survival (DFS)



 # DFS events: 367

5-year DFS:

- **26.1%** [95%CI: 20.5-32.1] **with mFOLFIRINOX**
- **19.0%** [95%CI: 14.3-24.3] **with gemcitabine**

Median DFS:

- **21.4 months** [95%CI: 17.5-26.7] **with mFOLFIRINOX**
- **12.8 months** [95%CI: 11.6-15.2] **with gemcitabine**

Conroy T et al. ESMO 2021;Abstract LBA57.

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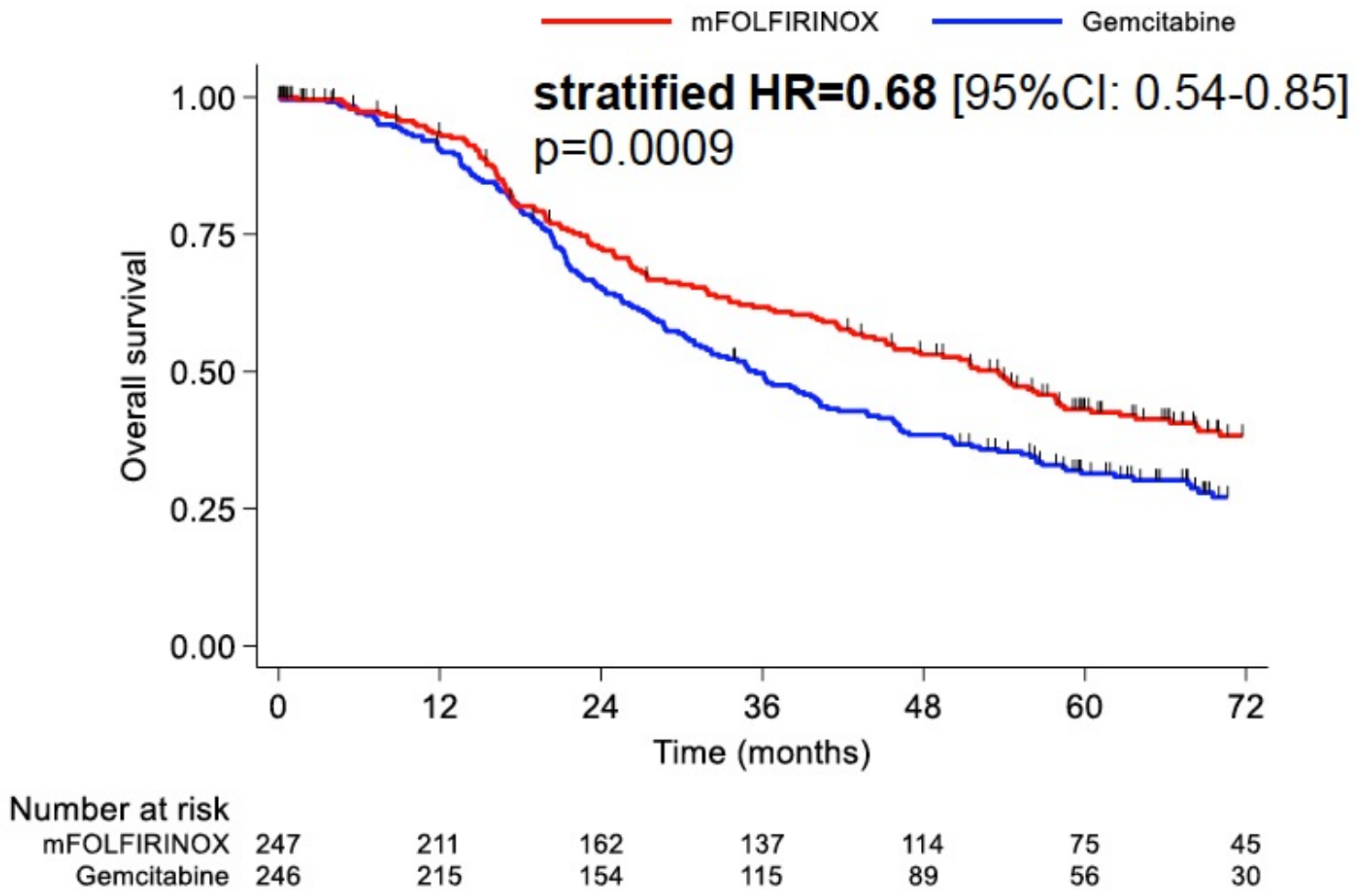
Unicancer PRODIGE 24/CCTG PA.6: Overall Survival



 # OS events=304

5-year overall survival:

- **43.2%** [95%CI: 36.5-49.7] **with mFOLFIRINOX**
- **31.4%** [95%CI: 25.5-37.5] **with gemcitabine**

Median overall survival:

- **53.5 months** [95%CI: 43.5-58.4] **with mFOLFIRINOX**
- **35.5 months** [95%CI: 30.1-40.3] **with gemcitabine**

Conroy T et al. EMSO 2021;Abstract LBA57.

RTP Year in Review 2022

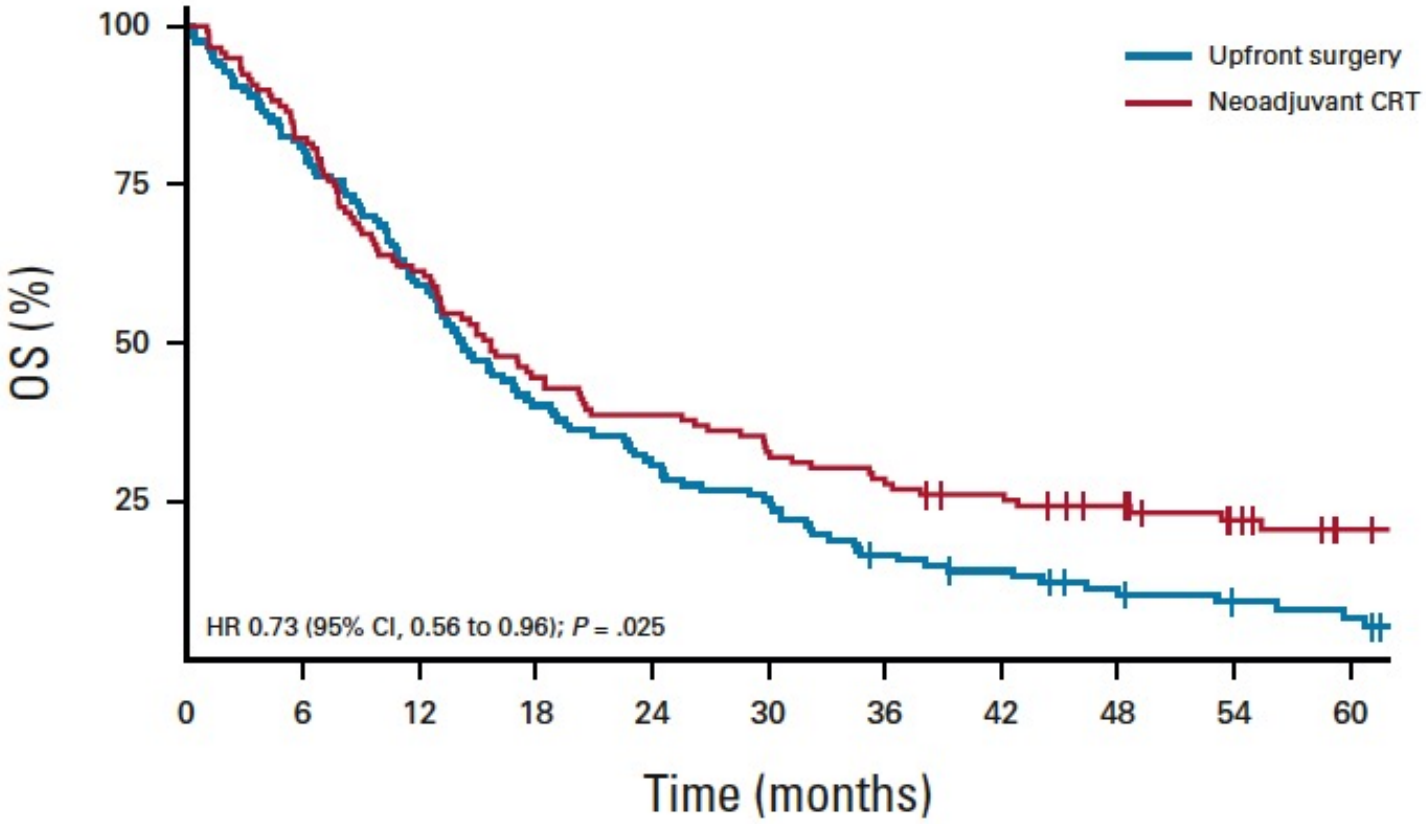
original reports

Neoadjuvant Chemoradiotherapy Versus Upfront Surgery for Resectable and Borderline Resectable Pancreatic Cancer: Long-Term Results of the Dutch Randomized PREOPANC Trial

Eva Versteijne, MD, PhD[1]; Jacob L. van Dam, MD[2]; Mustafa Suker, MD, PhD[2]; Quisette P. Janssen, MD[2]; Karin Groothuis, MSc[3]; Janine M. Akkermans-Vogelaar, BSc[3]; Marc G. Besselink, MD, PhD[4]; Bert A. Bonsing, MD, PhD[5]; Jeroen Buijsen, MD, PhD[6]; Olivier R. Busch, MD, PhD[4]; Geert-Jan M. Creemers, MD, PhD[7]; Ronald M. van Dam, MD, PhD[8,9,10]; Ferry A. L. M. Eskens, MD, PhD[11]; Sebastiaan Festen, MD, PhD[12]; Jan Willem B. de Groot, MD, PhD[13]; Bas Groot Koerkamp, MD, PhD[2]; Ignace H. de Hingh, MD, PhD[14]; Marjolein Y. V. Homs, MD, PhD[11]; Jeanin E. van Hooft, MD, PhD[15,16]; Emile D. Kerver, MD[17]; Saskia A. C. Luelmo, MD[18]; Karen J. Neelis, MD, PhD[19]; Joost Nuyttens, MD, PhD[20]; Gabriel M. R. M. Paardekooper, MD[21]; Gijs A. Patijn, MD, PhD[22]; Maurice J. C. van der Sangen, MD, PhD[23]; Judith de Vos-Geelen, MD, PhD[24]; Johanna W. Wilmink, MD, PhD[25]; Aeilko H. Zwinderman, PhD[26]; Cornelis J. Punt, MD, PhD[27]; Geertjan van Tienhoven, MD, PhD[1]; and Casper H. J. van Eijck, MD, PhD[2]; for the Dutch Pancreatic Cancer Group

J Clin Oncol 2022;40(11):1220-30.

PREOPANC Long-Term Follow-Up: Overall Survival (OS)



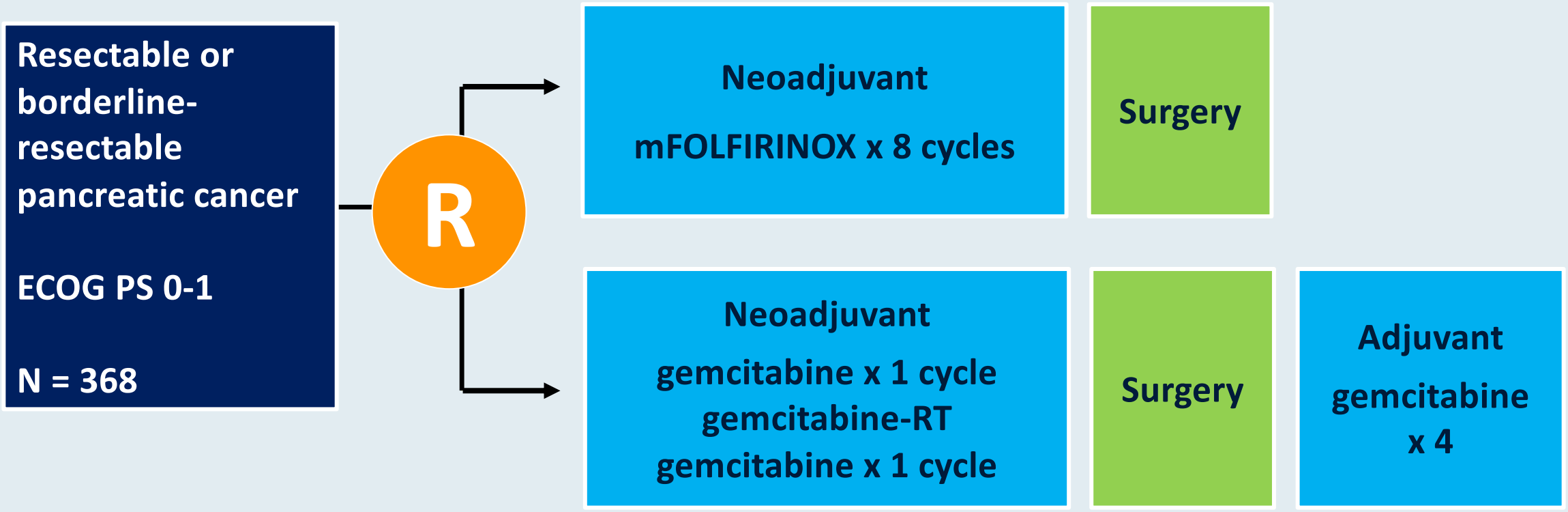
	Median OS	5-Year OS
Neoadjuvant CRT	15.7 mo	20.5%
Up-front surgery	14.3 mo	6.5%

Versteijne E et al. *J Clin Oncol* 2022;40(11):1220-30.

RTP Year in Review 2022

PREOPANC-2: Ongoing Phase III Trial Schema

Completed Recruitment 2021 — Results Pending



Primary endpoint: Overall survival

Stratification: Resectability, Institution

NL7094 Dutch Pancreatic Cancer Group

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Phase III APACT Trial of Adjuvant *Nab*-Paclitaxel plus Gemcitabine vs Gemcitabine Alone in Patients with Resected Pancreatic Cancer: Updated 5-Year Overall Survival

Tempero M et al.

ESMO World Congress on Gastrointestinal Cancer 2021;Abstract LBA-1.

RTP Year in Review 2022

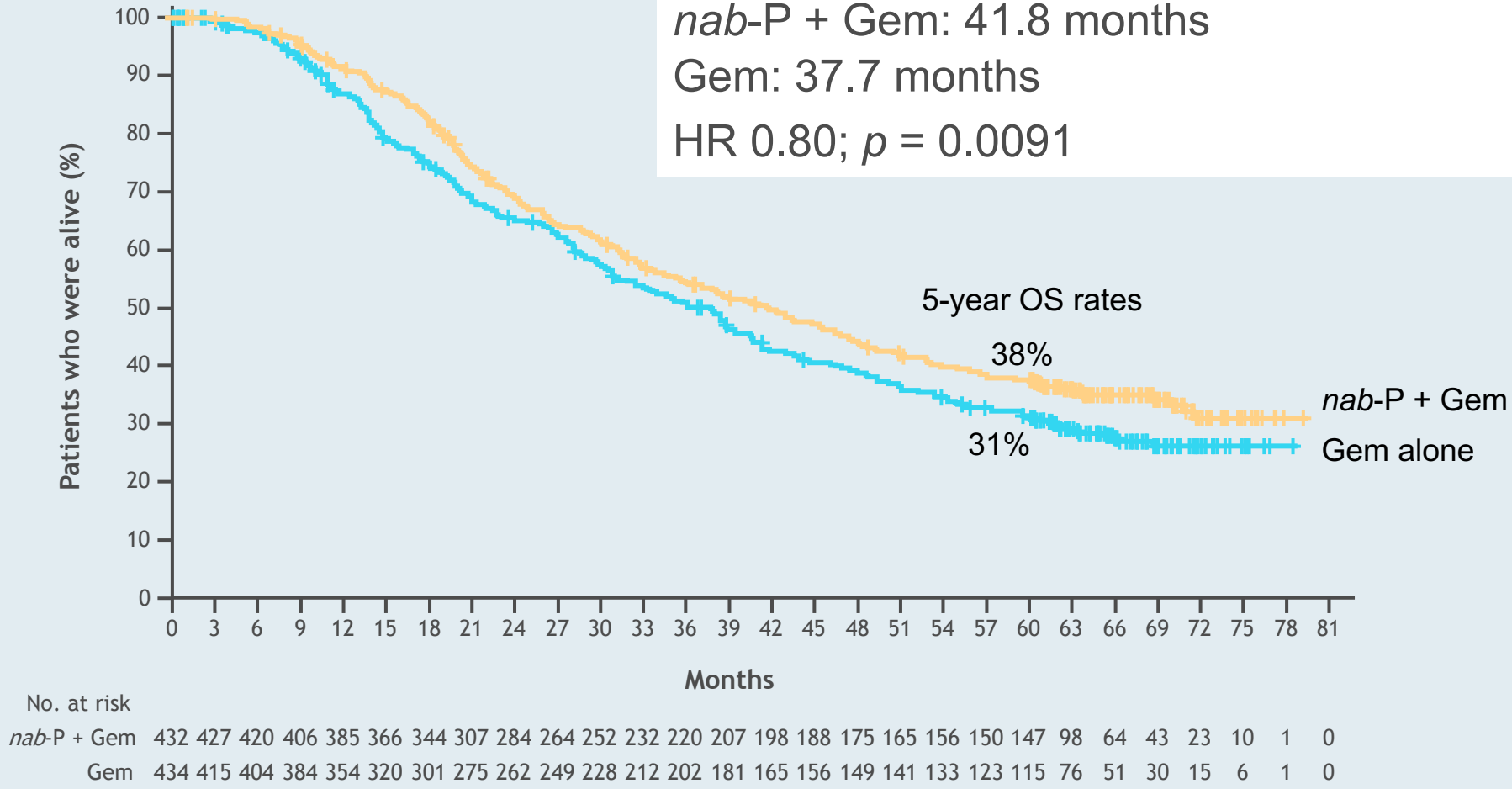
APACT: 5-Year Overall Survival (OS)

Five-year OS (median follow-up 63 months)

nab-P + Gem: 41.8 months

Gem: 37.7 months

HR 0.80; $p = 0.0091$



Tempero M. et al. ESMO World Congress on Gastrointestinal Cancer 2021;Abstract LBA1.

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PETRA: A first-in-class, first-in-human trial of the next-generation PARP1-selective inhibitor AZD5305 in patients with *BRCA1/2*, *PALB2* or *RAD51C/D* mutations

CT007

Speaker

Timothy A. Yap, MBBS, PhD, FRCP

University of Texas MD Anderson Cancer Center, USA

Authors

Timothy A. Yap[1], Seock-Ah Im[2], Alison M. Schram[3], Adam Sharp[4], Judith Balmana[5], Richard D. Baird[6], Jessica S. Brown[7], Maria Schwaederle[8], Elizabeth A. Pilling[9], Ganesh Moorthy[10], Spiros Linardopoulos[11], Adam Dowson[7], Carol Pound[12], Edit Lukacs[13], Sabina Cosulich[14], Stephen J. Luen[15]

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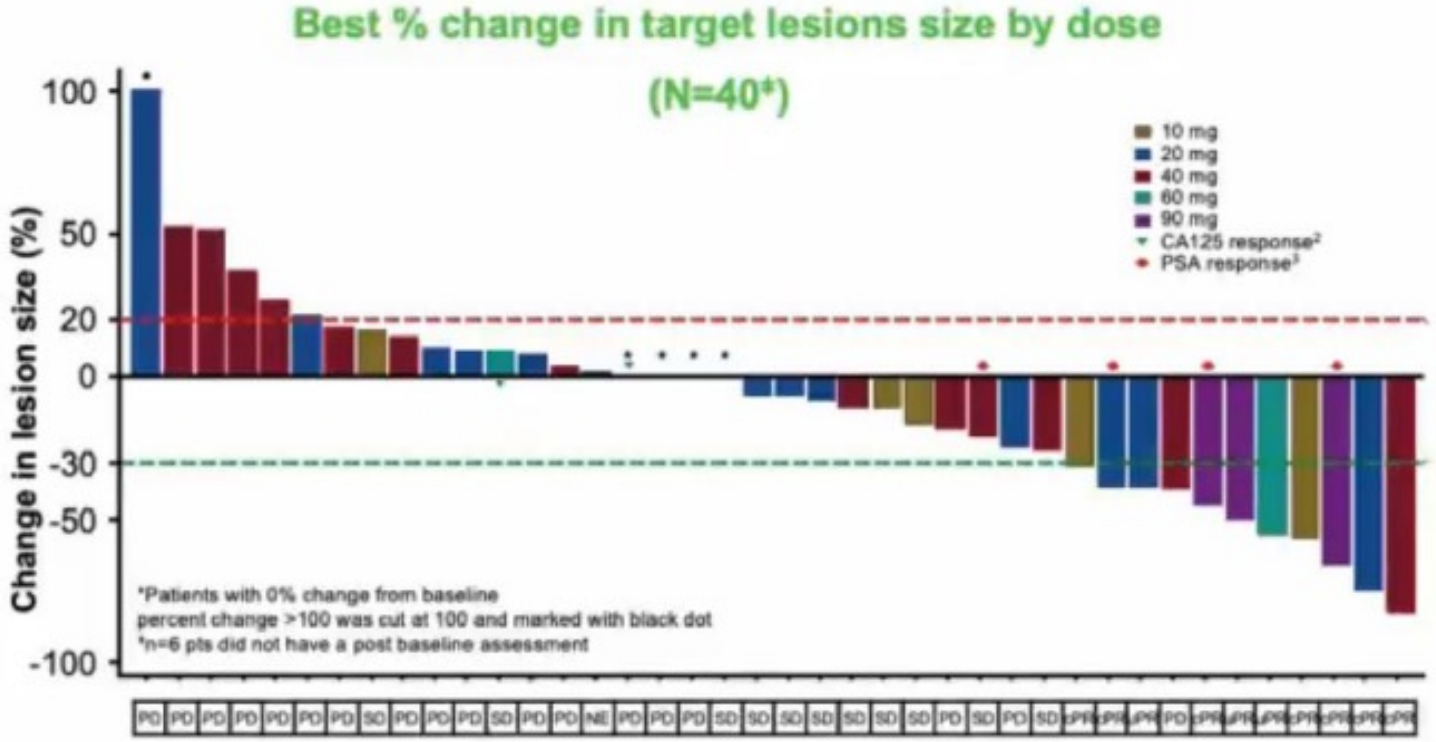
PETRA: Responses Observed Starting at Lowest Dose Level

- 46 patients were included in the interim response analysis set[1]
- 6 patients were not evaluable[2] for RECIST v1.1 assessment
- Of 40 evaluable patients, by RECIST v1.1, we observed:
  10 PRs (7 confirmed; 3 unconfirmed[4]), 11 SD, and 19 PD
- Responses seen across:
  - Doses



Yap TA et al. AACR 2022;Abstract CT007.

RTP Year in Review 2022

Research

JAMA Oncol 2021;7(5):693-9.

JAMA Oncology | Original Investigation

Olaparib Monotherapy for Previously Treated Pancreatic Cancer With DNA Damage Repair Genetic Alterations Other Than Germline *BRCA* Variants

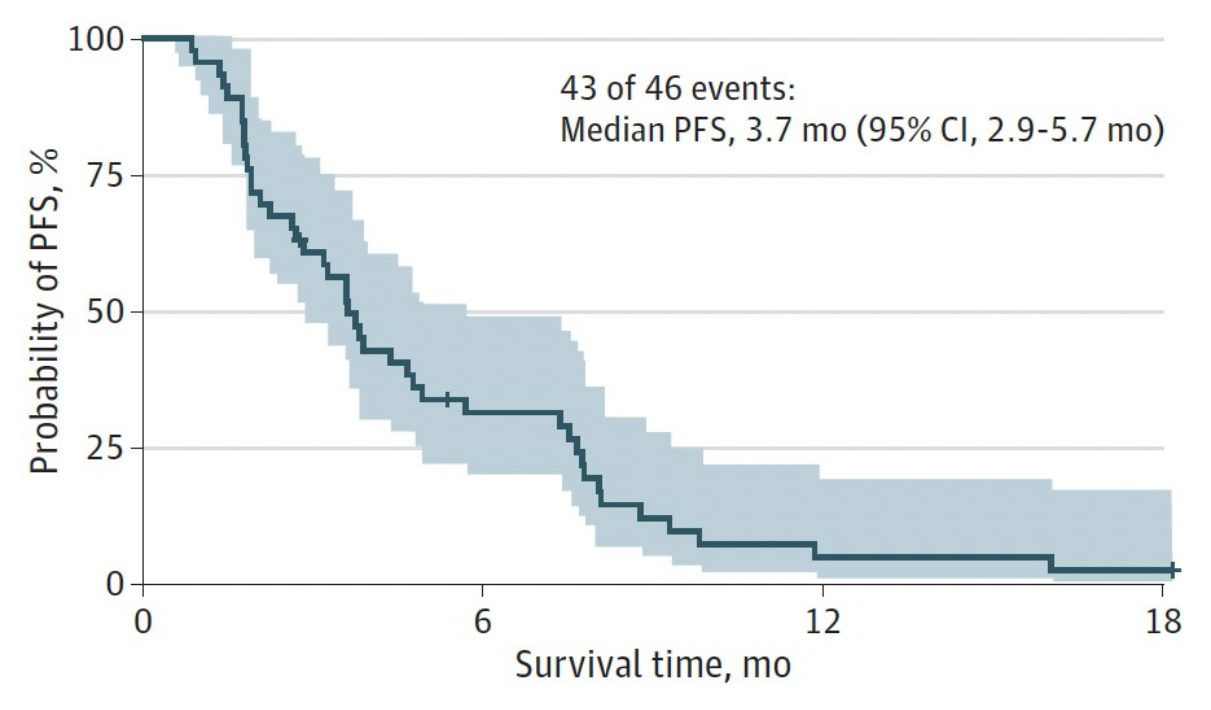
Findings From 2 Phase 2 Nonrandomized Clinical Trials

Milind Javle, MD; Einat Shacham-Shmueli, MD; Lianchun Xiao, MS; Gauri Varadhachary, MBBS, MD; Naama Halpern, MD, MBA; David Fogelman, MD; Ben Boursi, MD; Syeda Uruba, MBBS, MPH; Ofer Margalit, MD, PhD; Robert A. Wolff, MD; Talia Golan, MD

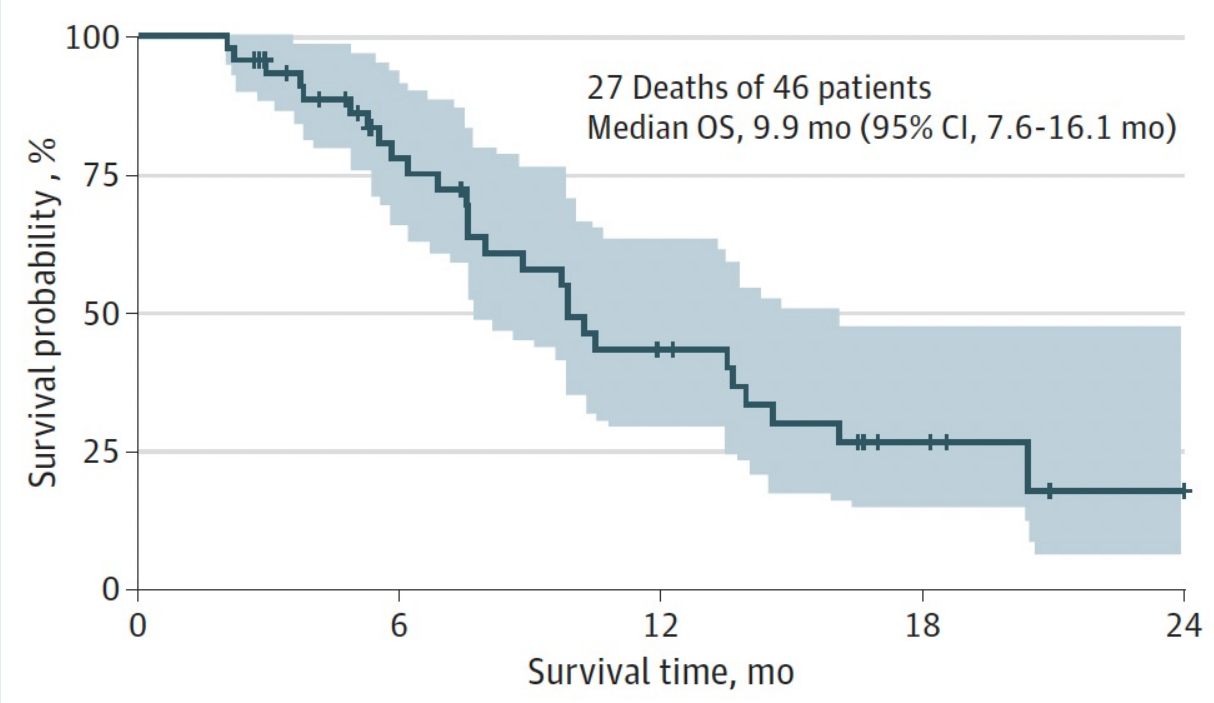
RTP Year in Review 2022

Olaparib Monotherapy for Previously Treated Pancreatic Cancer with DNA Damage Repair Genetic Alterations Other Than Germline BRCA Variants

Progression-free survival



Overall survival



Javle M et al. *JAMA Oncol* 2021;7(5):693-9.

RTP Year in Review 2022

Abstract 599

Gastrointestinal Cancers Symposium 2022

Real-World Use of PARP inhibitors in *BRCA*-Mutated Pancreatic Cancer: A Retrospective Analysis

Suvina Amin[1], **Weiyan Li[1]**, Seongjung Joo[2], Gboyega Adeboyeje[2], Patricia DeArbeloa[3], Emanuel F Petricoin III[3,4], Edik M Blais[3], Michael J Pishvaian[3,5]

RTP Year in Review 2022

PARPi Usage Summary Relative to Platinum Sensitivity and Line of Therapy in a Worldwide Registry Study

More ← ← ← ← Less Platinum Exposure Before First PARPi Use (Real-World Scenarios Only)	PARPi-Switch Context	# PARPi-Users (N = 21, %)	Treatment settings of first platinum use	Treatment settings of first PARP inhibitor use
	Platinum-Naïve	2 (10%)	1st line (1); Censored (1)	1st line (2)
	Platinum-Exposed	5 (24%)	Neoadjuvant (3); 2nd line (1); Censored (1)	Neoadjuvant (1); 1st line (1); 2nd line (3)
	Platinum-Sensitive	8 (38%)	Neoadjuvant (1); 1st line (3); 2nd line (4)	1st line (3); 2nd line (3); 3rd line (2)
	Platinum-Resistant	6 (28%)	1st line (4); 2nd line (2)	2nd line (1); 3rd line (3); 5th line (2)

Amin S et al. Gastrointestinal Cancers Symposium 2022;Abstract 599.

RTP Year in Review 2022

Meet The Professor
Chronic Lymphocytic Leukemia

Thursday, April 14, 2022
5:00 PM – 6:00 PM ET

Faculty

Jennifer R Brown, MD, PhD

Special Topics

- **Pirtobrutinib**
- **GLOW study**

RTP
RESEARCH
TO PRACTICE

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

A Complimentary NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Prostate Cancer

Thursday, April 28, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Robert Dreicer, MD, MS
Sandy Srinivas, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Non-Small Cell Lung Cancer

Thursday, April 28, 2022
6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty
Edward B Garon, MD, MS
Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Anne S Tsao, MD, MBA

Ovarian Cancer

Thursday, April 28, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Jennifer Filipi, MSN, NP
Kathleen N Moore, MD, MS
Krishnansu S Tewari, MD
Deborah Wright, MSN, APRN, AGCNS-BC

Hepatobiliary Cancers

Thursday, April 28, 2022
8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty
Richard S Finn, MD
Amanda K Wagner, APRN-CNP, AOCNP

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

A Complimentary NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Small Cell Lung Cancer

Friday, April 29, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Marianne J Davies, DNP, MSN, RN, APRN
Matthew Gubens, MD, MS
Lowell L Hart, MD
Chaely J Medley, MSN, AGNP

Breast Cancer

Friday, April 29, 2022
6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty
Jamie Carroll, APRN, MSN, CNP
Sara A Hurvitz, MD
Kelly Leonard, MSN, FNP-BC
Hope S Rugo, MD

Chronic Lymphocytic Leukemia

Friday, April 29, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Lesley Camille Ballance, MSN, FNP-BC
Amy Goodrich, CRNP
Anthony R Mato, MD, MSCE
Susan O'Brien, MD

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Friday, April 29, 2022
8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty
Ilene Galinsky, NP
Eunice S Wang, MD

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

A Complimentary NCPD Hybrid Symposium Series Held During the 47th Annual ONS Congress

Cervical and Endometrial Cancer

Saturday, April 30, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Paula J Anastasia, MN, RN, AOCN
Robert L Coleman, MD
David M O'Malley, MD
Jaclyn Shaver, MS, APRN, CNP, WHNP

Bladder Cancer

Saturday, April 30, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Monica Averia, MSN, AOCNP, NP-C
Shilpa Gupta, MD
Brenda Martone, MSN, NP-BC, AOCNP
Sumanta Kumar Pal, MD

Thank you for joining us!

CME and MOC credit information will be emailed to each participant within 5 business days.

RTP Year in Review 2022