GI connect®

POWERED BY COR2ED

MEETING SUMMARY
ASCO 2020, San Francisco, USA

Assoc. Prof Yu Sunakawa

Department of Clinical Oncology

St. Marianna University School of Medicine, Kanagawa, Japan

HIGHLIGHTS ON LIVER, SMALL INTESTINE AND PANCREAS TRACT

January 2020

DISCLAIMER

Please note: The views expressed within this presentation are the personal opinions of the authors. They do not necessarily represent the views of the authors' academic institutions or the rest of the GI CONNECT group.

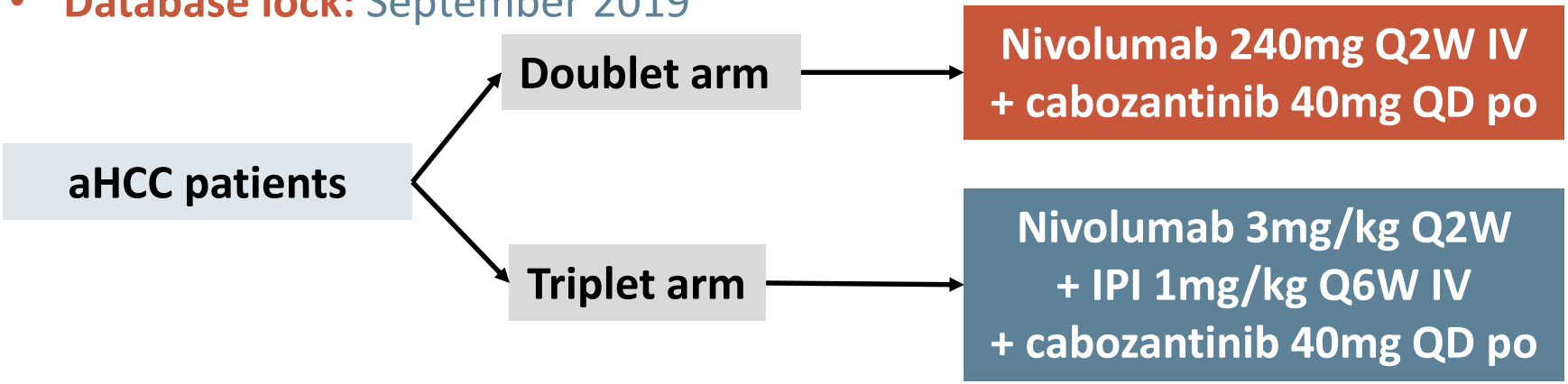
This content is supported by an Independent Educational Grant from Bayer.

NIVOLUMAB (NIVO) + IPILIMUMAB (IPI) + CABOZANTINIB (CABO) COMBINATION THERAPY IN PATIENTS (PTS) WITH ADVANCED HEPATOCELLULAR CARCINOMA (AHCC): RESULTS FROM CHECKMATE 040

Yau T, et al. ASCO GI 2020, abst #478

CHECKMATE 040 STUDY: OVERVIEW

- A Phase 1/2, Dose-escalation, Open-label, Non-comparative Study in Advanced Hepatocellular Carcinoma Subjects With or Without Chronic Viral Hepatitis (NCT01658878)
- **Presented data:** Efficacy and safety of cabozantinib cohort: nivolumab + cabozantinib +/- ipilimumab in patients with aHCC
- **Database lock:** September 2019



- **Primary endpoint:** ORR, safety and tolerability
- **Secondary endpoints:** DCR, DOR, TTR, TTP, PFS, OS

aHCC, advanced hepatocellular carcinoma; DCR, disease control rate; DOR, duration of response; IPI, ipilimumab; IV, intravenous; ORR; objective response rate; OS, overall survival: PFS; progression-free survival; po, per os; Q2W, every 2 weeks; Q6W, every 6 weeks; QD, one a day; TTP, time to progression; TTR, time to response

CHECKMATE 040 STUDY: CABOZANTINIB COHORT: ENDPOINTS RESULTS (1/2)

	Doublet arm n=36	Triplet arm n=35
ORR using RECIST v1.1, n(%)		
Investigator assessment	7 (19)	10 (29)
BICR	5 (14)	11 (31)
DCR, n(%)		
Investigator assessment	27 (75)	29 (83)
BICR	28 (78)	28 (80)
Median TTR (range), months		
Investigator assessment	4.8 (2.7-20.7)	3.5 (1.3-9.9)
BICR	N/A	N/A
Median DOR (range), months		
Investigator assessment	8.3 (0.0-NA)	N/A
BICR	NA	N/A

BICR, blinded independent central review; DCR, disease control rate; DOR, duration of response; ORR; objective response rate; RECIST, Response evaluation criteria in solid tumors; TTR, time to response

CHECKMATE 040 STUDY: CABOZANTINIB COHORT: ENDPOINTS RESULTS (2/2)

	Doublet arm n=36	Triplet arm n=35
Median PFS by Investigator assessment (95% CI), months	5.4 (3.2-10.9)	6.8 (4.0-14.3)
Median OS (95% CI), months	21.5 (13.1-NR)	NR (15.1-NR)
15-months OS rate, % (95% CI)	64 (45-78)	70 (51-83)

CI, confidence interval; NR, not reached; OS, overall survival; PFS, progression-free survival

CHECKMATE 040 STUDY: SAFETY RESULTS

	Doublet arm n=36	Triplet arm n=35
TRAE, n (%)		
Any grade	**32 (89)**	**33 (94)**
Grade 3/4	**17 (47)**	**25 (71)**
Grade 4	**1 (3)**	**7 (30)**

TRAE, treatment-related adverse event

CHECKMATE 040 STUDY: CONCLUSION

- The triplet arm resulted in numerically higher ORR, DCR, PFS and OS compared to the doublet arm in aHCC patients
- The triplet arm resulted in higher number of AEs compared to the doublet arm
- Longer follow up assessment is ongoing and will help to define the benefit/risk of the doublet and triplet arms

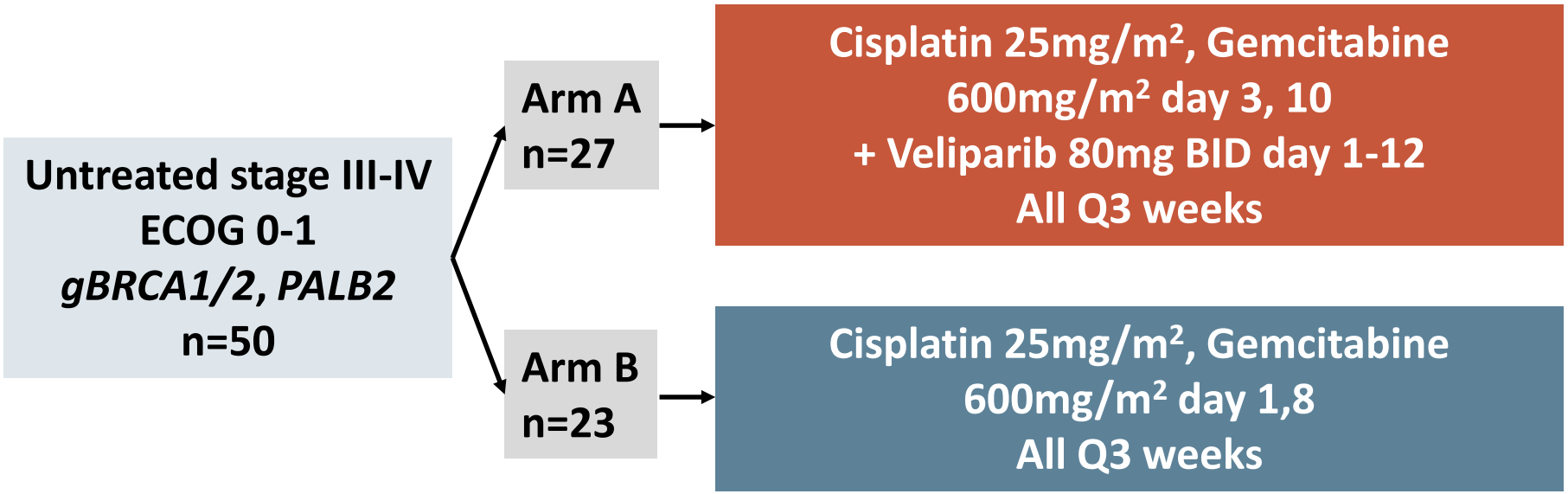
AE, adverse event; aHCC, advanced hepatocellular carcinoma; DCR, disease control rate; ORR, objective response rate; OS, overall survival; PFS, progression-free survival

A RANDOMIZED, MULTICENTER, PHASE II TRIAL OF GEMCITABINE (G), CISPLATIN (C) +/- VELIPARIB (V) IN PATIENTS WITH PANCREAS ADENOCARCINOMA (PDAC) AND A KNOWN GERMLINE (G)BRCA/ PALB2 MUTATION

O'Reilly EM, et al. ASCO GI 2020, abst #639

STUDY: OVERVIEW

- Open label, randomized 2-parts Phase II trial (NCT01585805)
- **Objective:** to assess whether veliparib together with gemcitabine hydrochloride and cisplatin is an effective treatment for pancreatic cancer



- **Primary endpoint:** RR
- **Secondary endpoints:** PFS, DCR, OS

BID, twice a day; DCR, disease control rate; ECOG, Eastern Cooperative Oncology Group; gBRCA1/2, germline breast cancer 1/2; OS, overall survival; PALB2, partner and localizer of BRCA2; PFS, progression-free survival; Q3 weeks, every 3 weeks; RR, response rate

STUDY:
ENDPOINTS RESULTS

	Arm A n=27	Arm B n=23
RR	74.1%	65.2%
DCR	100%	78.3%
PFS, months (95% CI)	10.1 (6.7-11.5)	9.7 (4.2-13.6)
OS, months (95% CI)	15.5 (12.2-24.3)	16.4 (11.7-23.4)

CI; confidence interval; DCR, disease control rate; OS, overall survival; PFS, progression-free survival; RR, response rate

STUDY:
SAFETY RESULTS

TRAE Grade 3-4, n (%)	Arm A n=27	Arm B n=23
Anaemia	14 (52%)	8 (35%)
Thrombocytopenia	15 (55%)	2 (9%)
Neutropenia	13 (41%)	7 (30%)

TRAE, treatment-related adverse event

STUDY: CONCLUSION

- Both arms significantly exceeded pre-specified RR and data are encouraging
- Safety profile showed higher numbers of grade 3-4 TRAEs in triplet arm (arm A) vs doublet arm (arm B)
- Cisplatin, gemcitabine = standard of care for *gBRCA/PALB2* PDAC patients
- Data published during the ASCO GI conference: O'Reilly EM, et al. J Clin Oncol. 2020

gBRCA1/2, germline breast cancer 1/2; PALB2, partner and localizer of BRCA2; PDAC, pancreatic ductal adenocarcinoma; RR, response rate; TRAE, treatment-related adverse event

REACH GI CONNECT VIA TWITTER, LINKEDIN, VIMEO & EMAIL OR VISIT THE GROUP'S WEBSITE

http://www.giconnect.info

Follow us on Twitter
@giconnectinfo

Follow the
GI CONNECT
group on LinkedIn

Watch us on the
Vimeo Channel
GI CONNECT

Email
antoine.lacombe
@cor2ed.com

GI connect®
POWERED BY COR2ED

GI CONNECT
Bodenackerstrasse 17
4103 Bottmingen
SWITZERLAND

Dr. Antoine Lacombe
Pharm D, MBA
Phone: +41 79 529 42 79
antoine.lacombe@cor2ed.com

Dr. Froukje Sosef
MD
Phone: +31 6 2324 3636
froukje.sosef@cor2ed.com