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MEETING SUMMARY

WCGIC, JUNE 28TH TO JULY 1ST 2017, BARCELONA, SPAIN
ASCO, JUNE 2ND TO 6TH, CHICAGO, USA

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CANCER OF THE LIVER, SMALL
INTESTINE AND PANCREAS TRACT

OVERVIEW

- Adjuvant treatment in biliary tract cancers: The randomized BILCAP trial
- SIRT versus Sorafenib in HCC: SIRveNIB and SARA trial
- Upcoming new drugs in pancreatic cancer: PEGPH20 and Napabucasin (BBI-608)

ADJUVANT CAPECITABINE FOR BILIARY TRACT CANCER: THE BILCAP RANDOMIZED STUDY



JOHN PRIMROSE

STUDY OVERVIEW

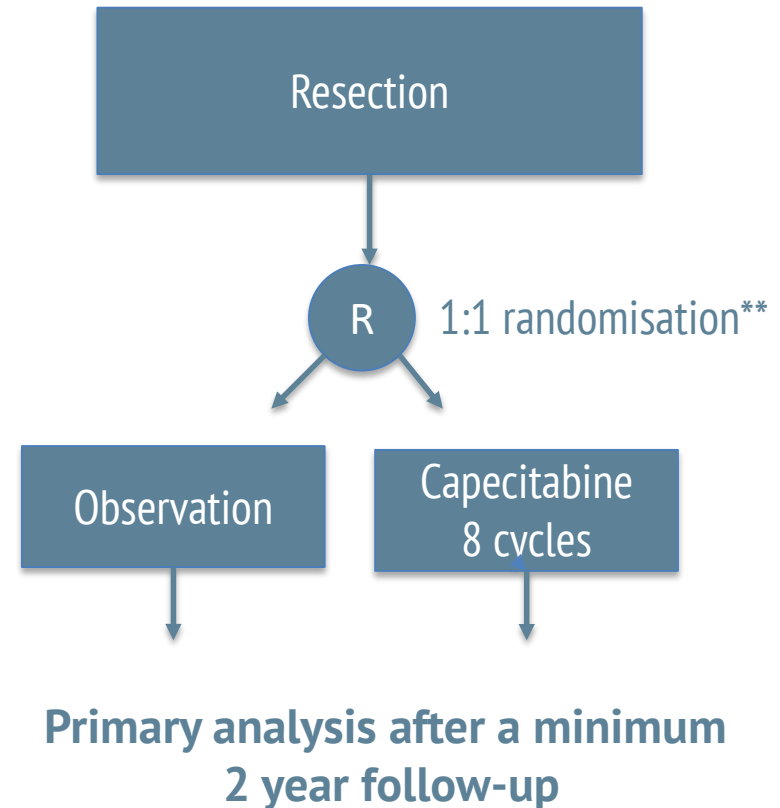
- Two arm, open label, randomised controlled clinical trial

Interventions

- Observation
- Capecitabine (1250 mg/m²) twice a day on day 1 to 14 of a 3 weekly cycle for 24 weeks (8 cycles)

Outcome measures

- Primary; overall survival (OS)
- Secondary;
 - Relapse free survival (RFS)
 - Toxicity
 - Quality of life*
 - Health economics



*EORTC QLQ-C30 & LMC-21 (latter for patients with colorectal/liver metastasis)

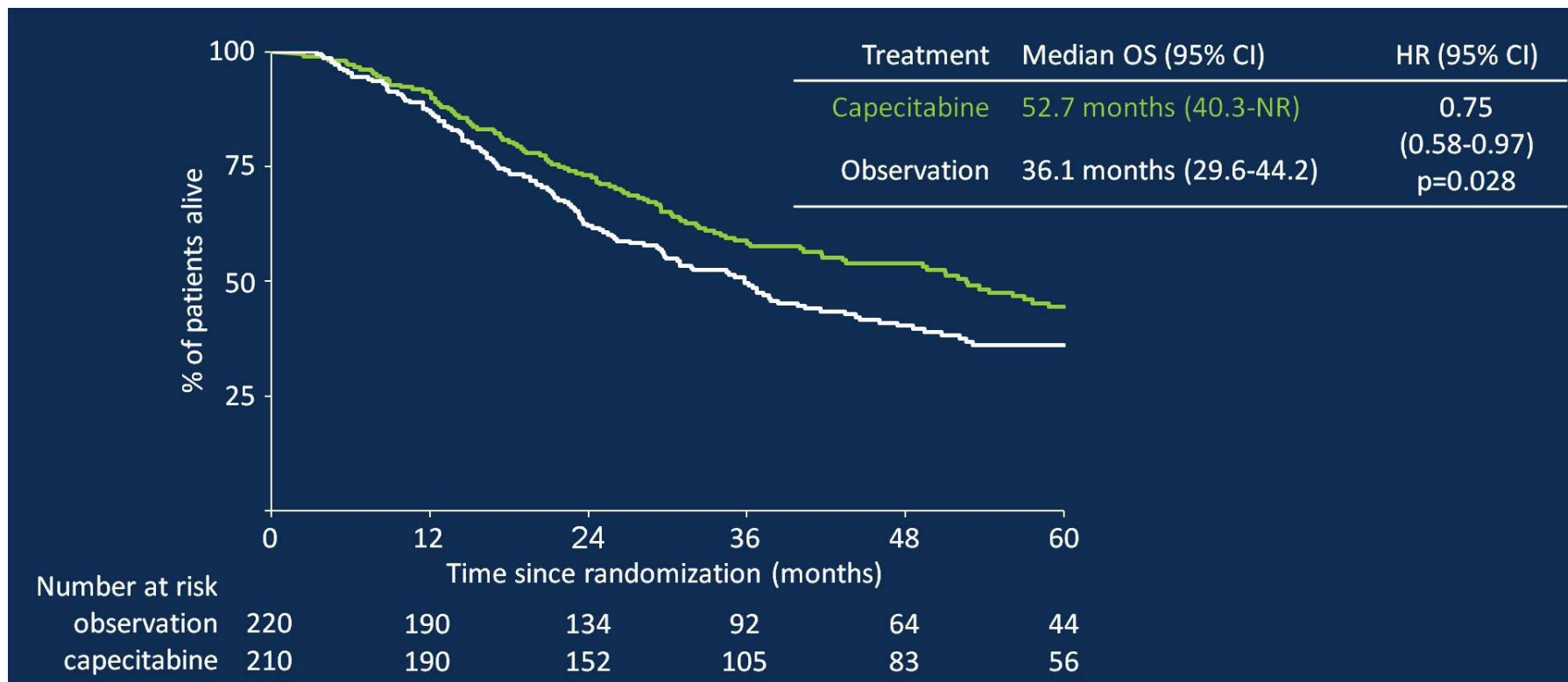
**Minimised on surgical centre, tumor site, type of resection (RO/RI) and performance status (ECOG PS 0-2)

OUTCOME MEASURES ACCORDING TO ITT AND PP ANALYSES*, ^

	Intent to Treat (ITT) analysis				Per protocol (PP) analysis			
Outcome	OS		RFS		OS		RFS	
	Cape	Obs.	Cape	Obs.	Cape	Obs.	Cape	Obs.
N (pts)	224	223	224	223	220	210	220	210
Months	51	36.4	24.6	17.6	52.7	36.1	25.9	17.6
HR	HR 0.81 p=0.097		HR 0.76 p=0.039		HR 0.75 p<0.028		HR=0.71 p=0.011	
Main AEs	HFSR, fatigue and GI toxicities							

*QOL was not compromised in the Cape vs. Obs arm. ^Subgroup analysis demonstrates benefit across Primrose J. Abs 4006. ASCO 2017. Presented by Tanios Bekaii-Saab at 2017 ASCO Annual Meeting

OS IN THE PP POPULATION

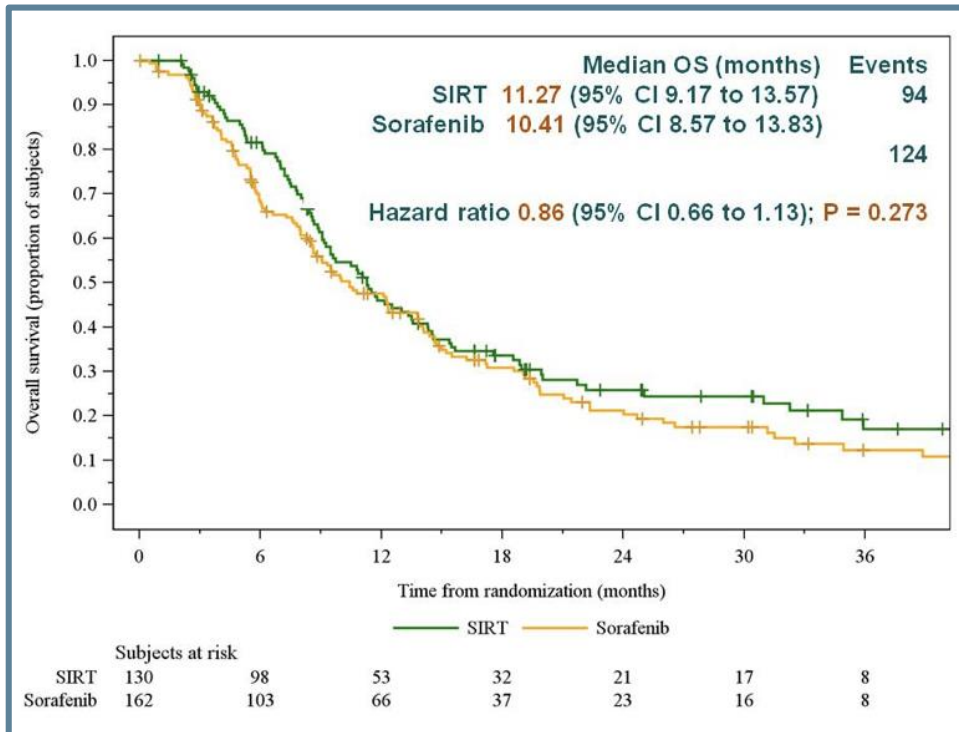


SIRT VERSUS SORAFENIB IN LOCALLY ADVANCED HCC: SIRVENIB AND SARAH TRIAL

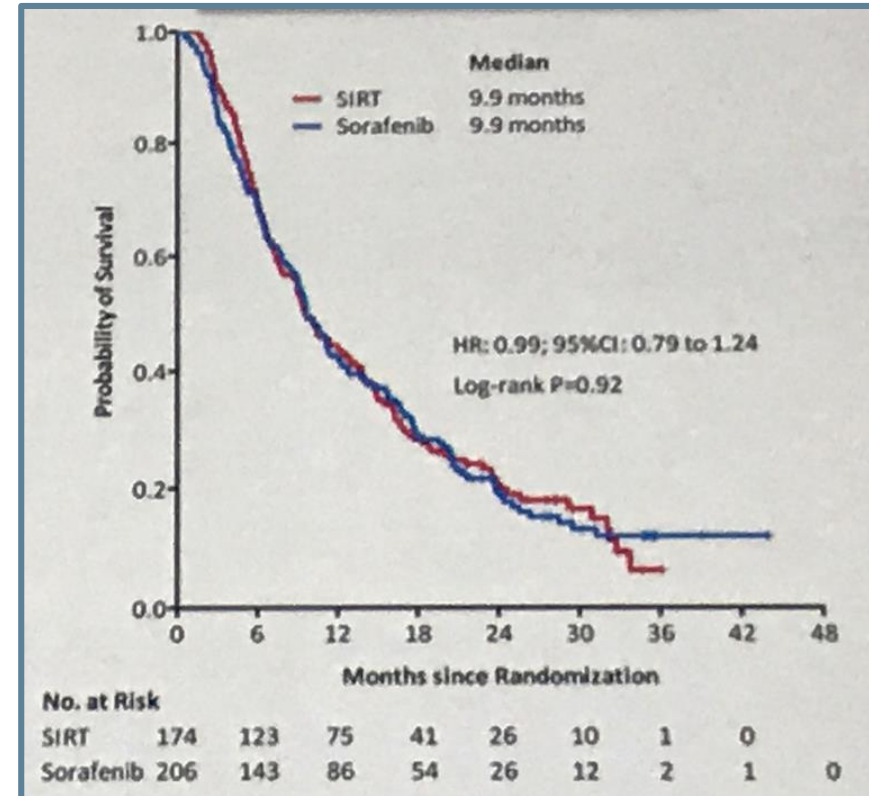
CHOW P ET AL, ASCO 2017

BOUATTOUR M ET AL, WCGIC 2017

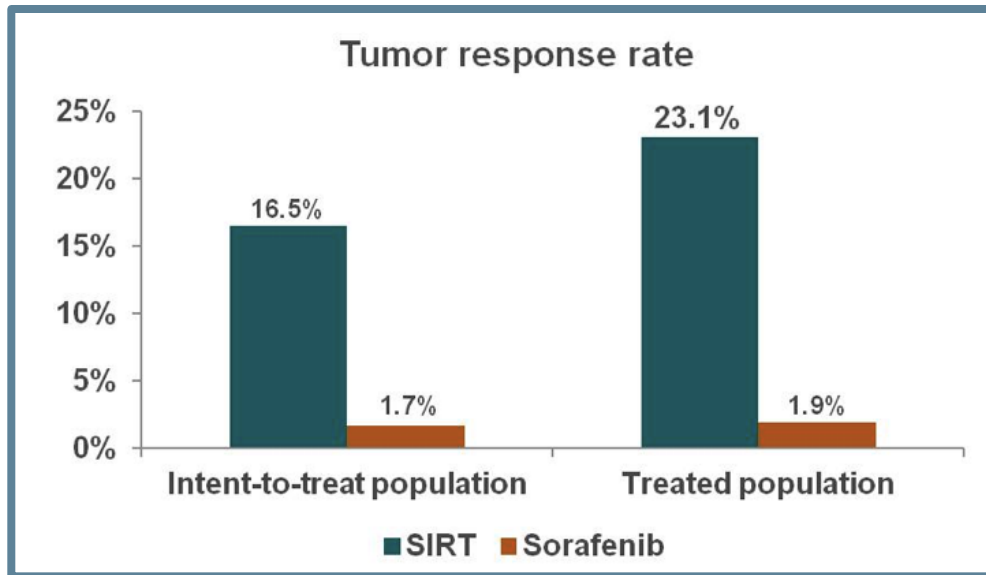
SIRveNIB trial



SARAH trial



SIRveNIB trial



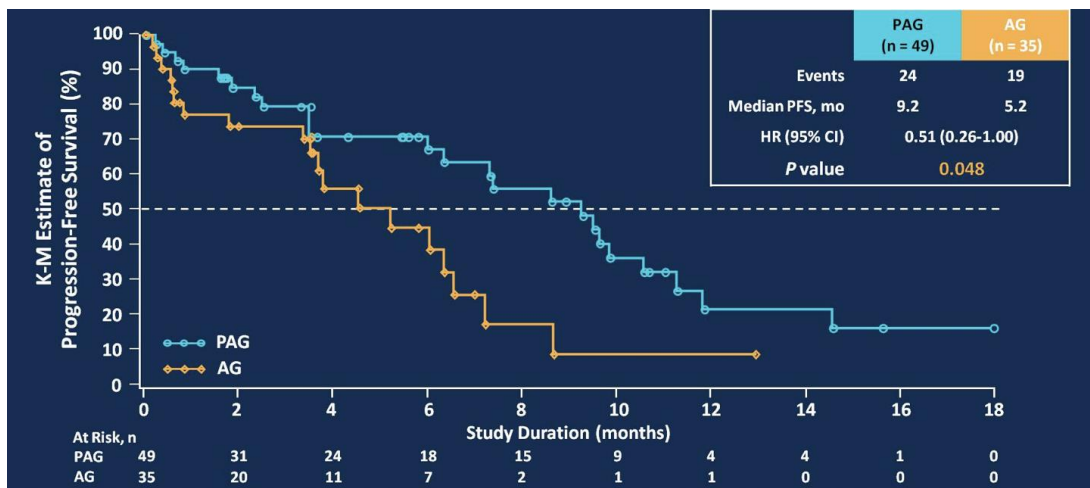
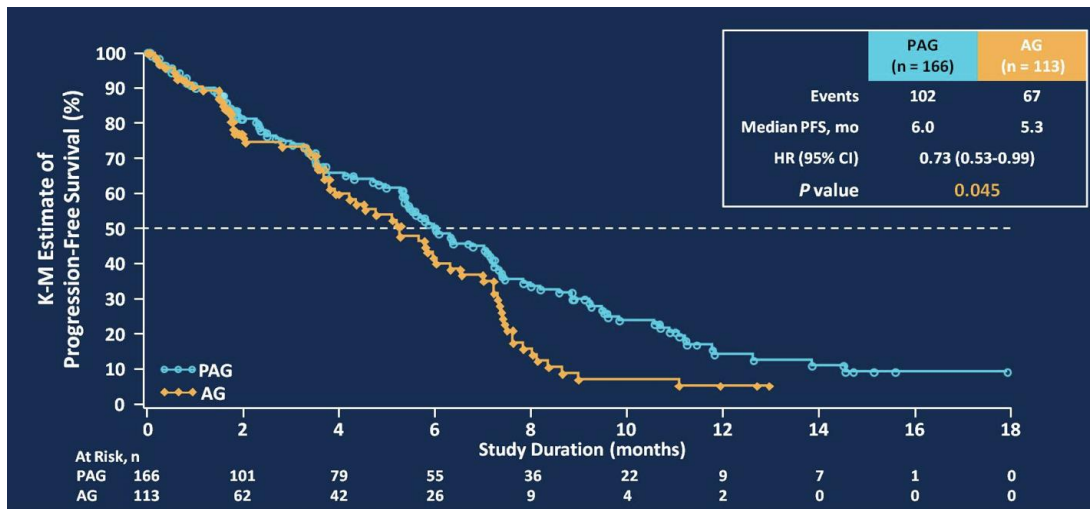
SARAH trial

	SIRT (n=190)	Sorafenib (n=198)	P value
Objective response (CR + PR)	36 (19%)	23 (15.2%)	0.042

**UPCOMING NEW DRUGS: PEGPH20 AND
NAPABUCASIN (BBI-608) IN PATIENTS
WITH METASTATIC PANCREATIC CANCER**

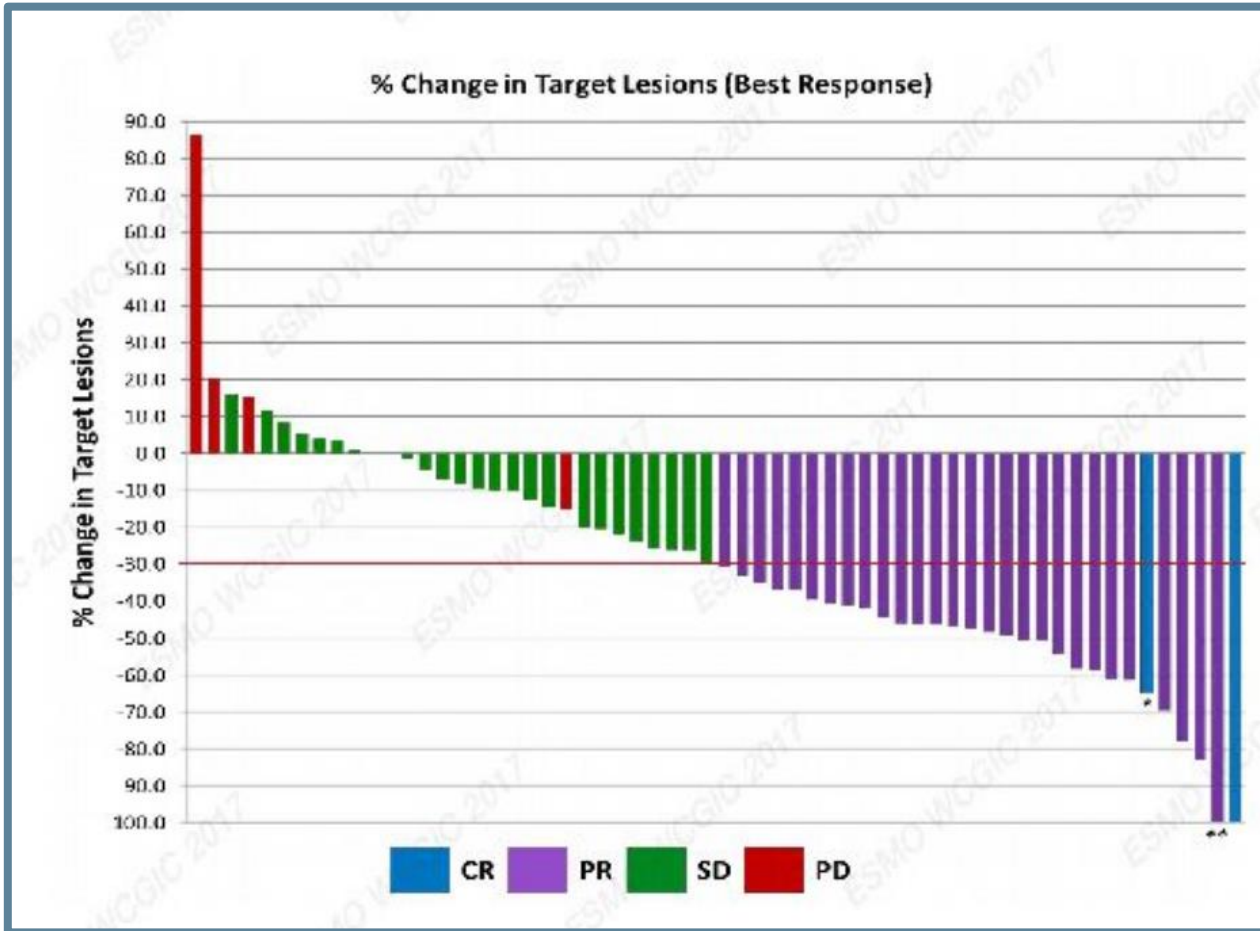
EFFICACY: PEGPH20 PLUS GEMCITABINE AND NAB-PACLITAXEL

PFS



PFS (high Hyaluronan expression)

EFFICACY: NAPABUCASIN PLUS GEMCITABINE AND NAB-PACLITAXEL



N=66
Median PFS = 7.1 months
Median OS 10.7 months
Disease control rate of 93%



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