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MEETING SUMMARY●

ASCO GI, JANUARY 19-21 2017, SAN FRANCISCO, USA

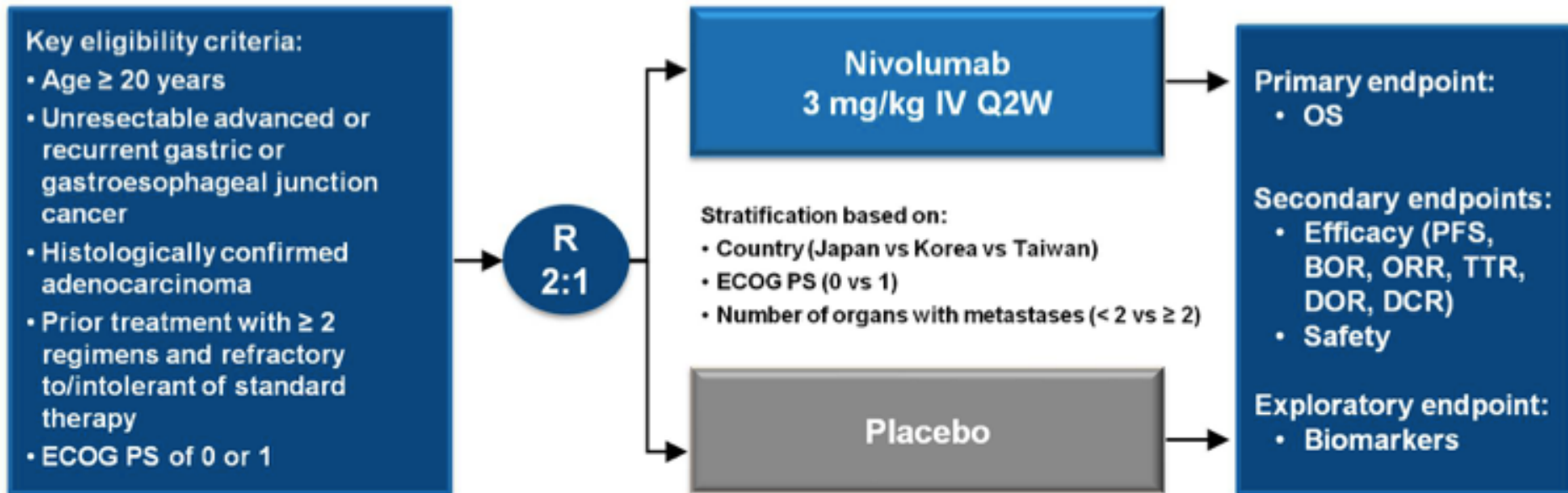
DR THOMAS WINDER
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CANCERS OF THE UPPER GI TRACT

NIVOLUMAB (ONO-4538/BMS-936558) AS
SALVAGE TREATMENT AFTER SECOND OR LATER-
LINE CHEMOTHERAPY FOR ADVANCED GASTRIC
OR GASTRO-ESOPHAGEAL JUNCTION CANCER
(AGC): A DOUBLE-BLINDED, RANDOMIZED,
PHASE III TRIAL

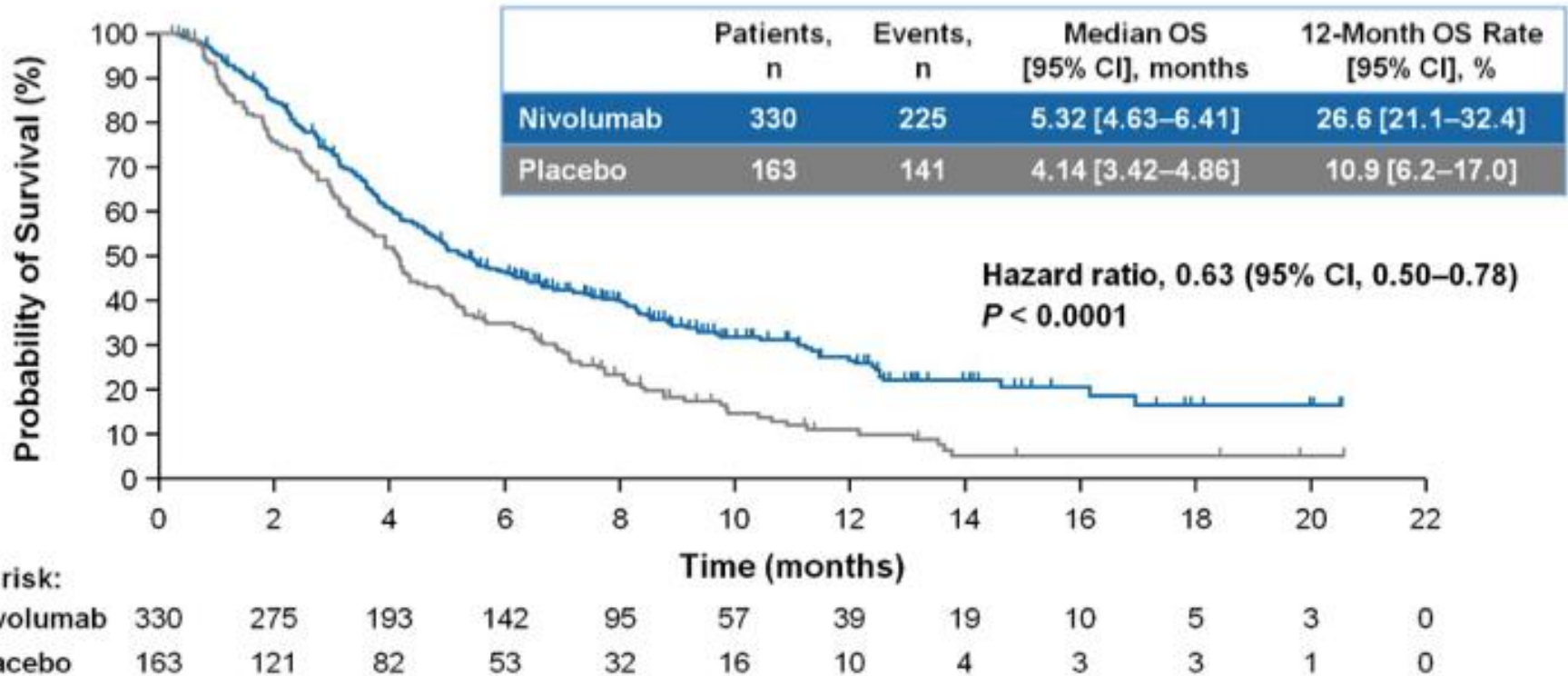
YK KANG ET AL

STUDY DESIGN AND ENDPOINTS

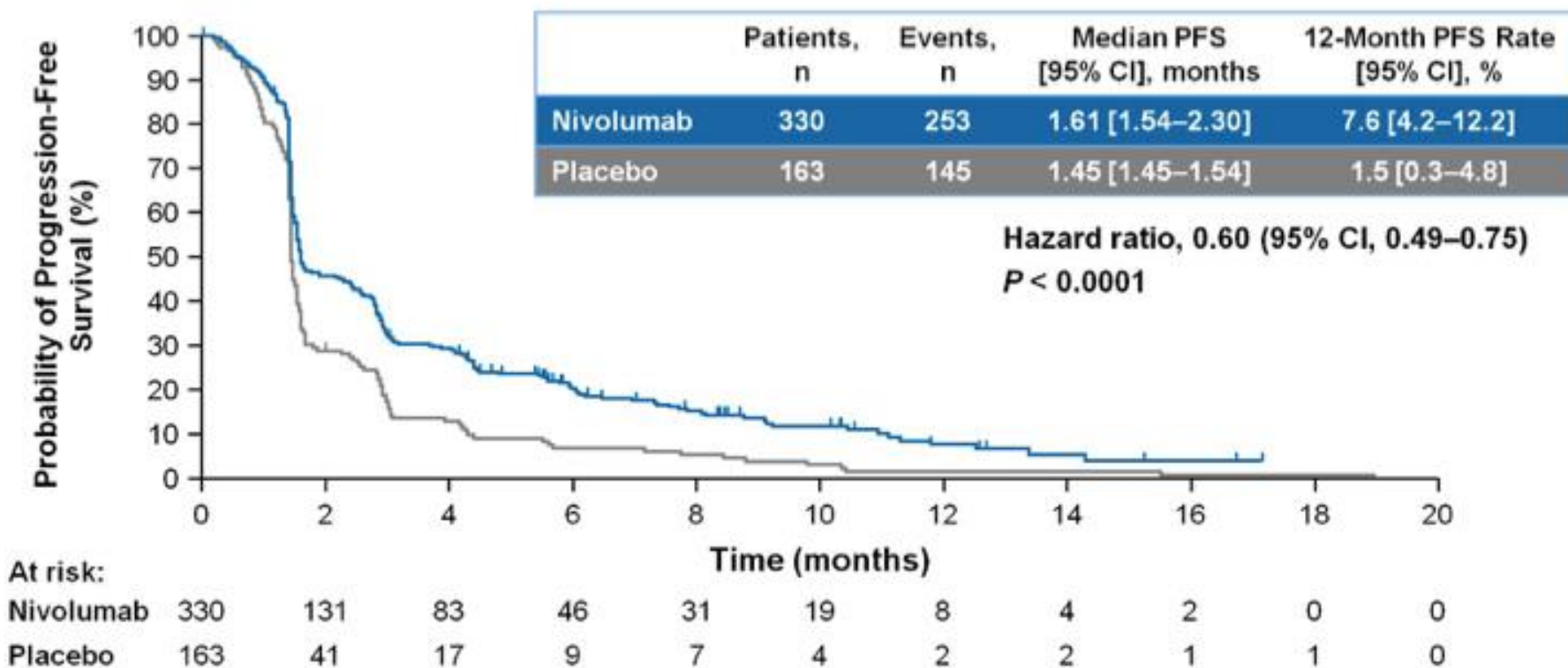


- Patients were permitted to continue treatment beyond initial RECIST v1.1–defined disease progression, as assessed by the investigator, if receiving clinical benefit and tolerating study drug

OVERALL SURVIVAL



PROGRESSION-FREE SURVIVAL



RESPONSE RATE

	Nivolumab 3 mg/kg (n = 268)	Placebo (n = 131)
ORR, n (%) [95% CI] <i>P</i> value	30 (11.2) [7.7–15.6] < 0.0001	0 [0–2.8] —
BOR, n (%)		
Complete response	0	0
Partial response	30 (11.2)	0
Stable disease	78 (29.1)	33 (25.2)
Progressive disease	124 (46.3)	79 (60.3)
DCR, n (%) [95% CI] <i>P</i> value	108 (40.3) [34.4–46.4] 0.0036	33 (25.2) [18.0–33.5] —
Median TTR (range), months	1.61 (1.4–7.0)	—
Median DOR, months [95% CI]	9.53 [6.14–9.82]	—

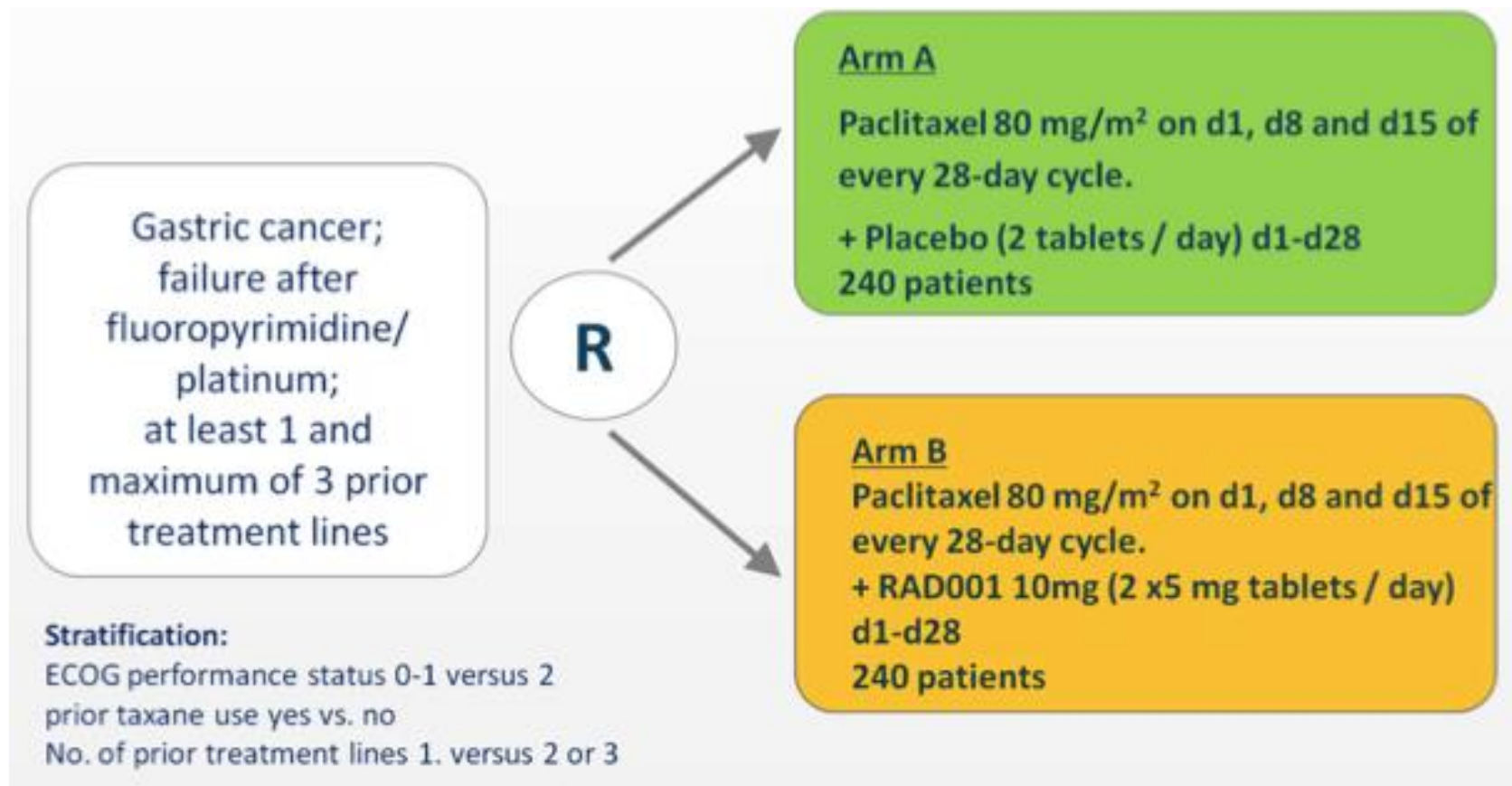
SUMMARY

- Phase III study demonstrating efficacy in terms of OS, PFS and ORR favoring Nivolumab
- Patient selection; Biomarker analysis eagerly awaited
- Open question; study transferable to non-Asian population

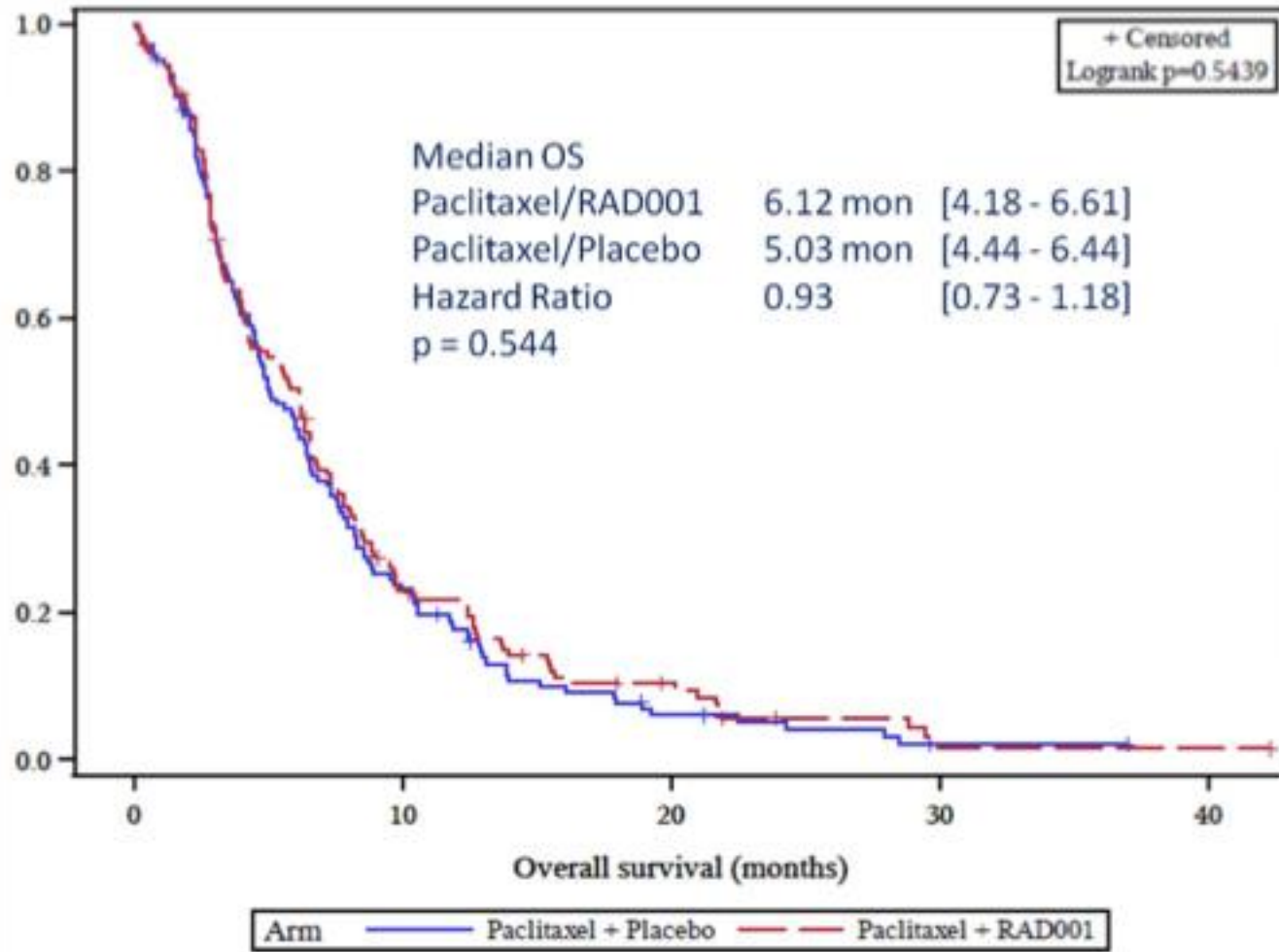
A RANDOMIZED, DOUBLE-BLIND, MULTICENTER
PHASE III STUDY EVALUATING PACLITAXEL WITH
AND WITHOUT RAD001 IN PATIENTS WITH
GASTRIC CANCER WHO HAVE PROGRESSED
AFTER THERAPY WITH A
FLUOROPYRIMIDINE/PLATINUM-CONTAINING
REGIMEN (RADPAC)

SALAH-EDDIN AL-BATRAN

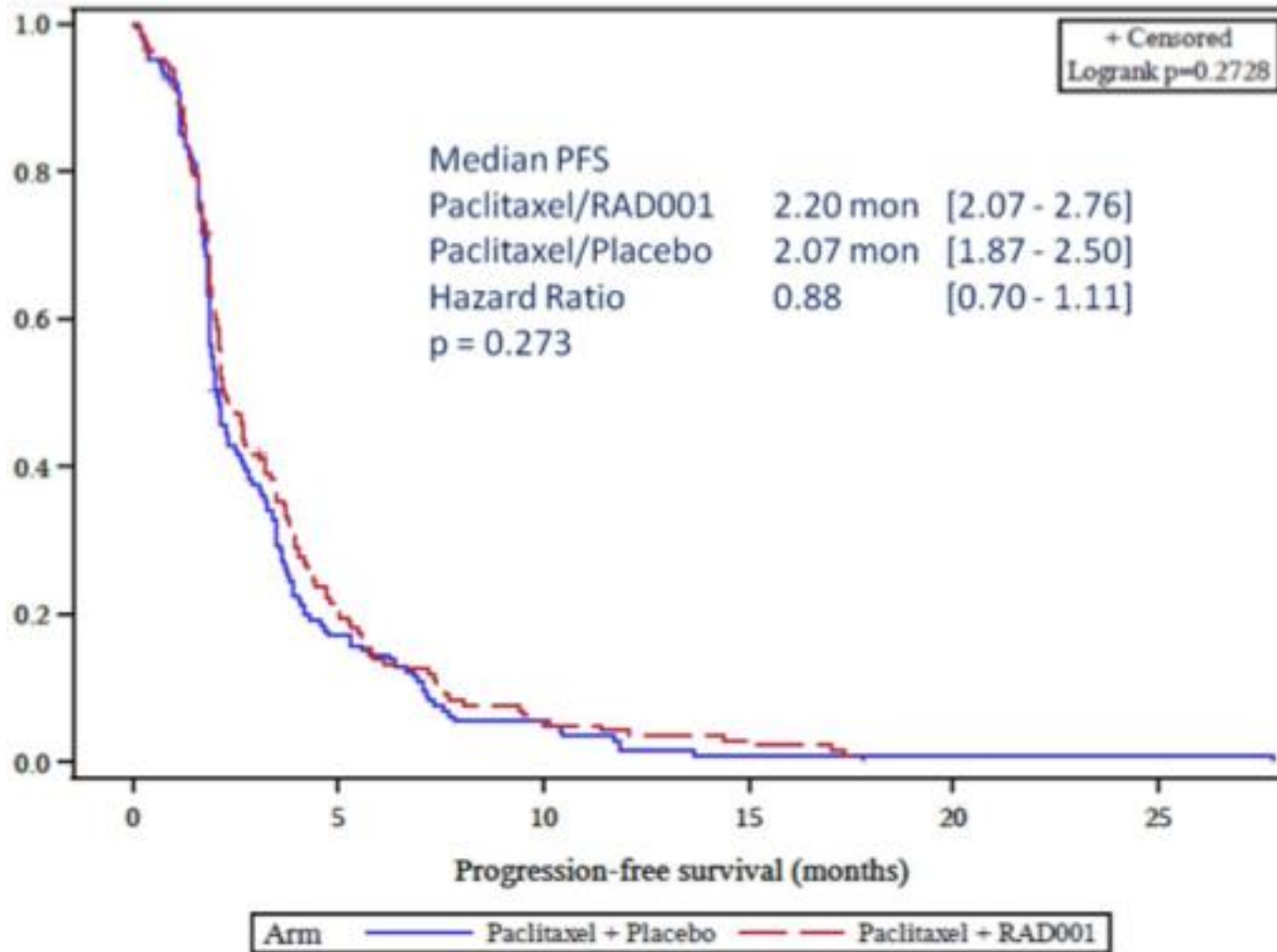
RADPAC STUDY DESIGN



OVERALL SURVIVAL



PROGRESSION-FREE SURVIVAL



SUMMARY

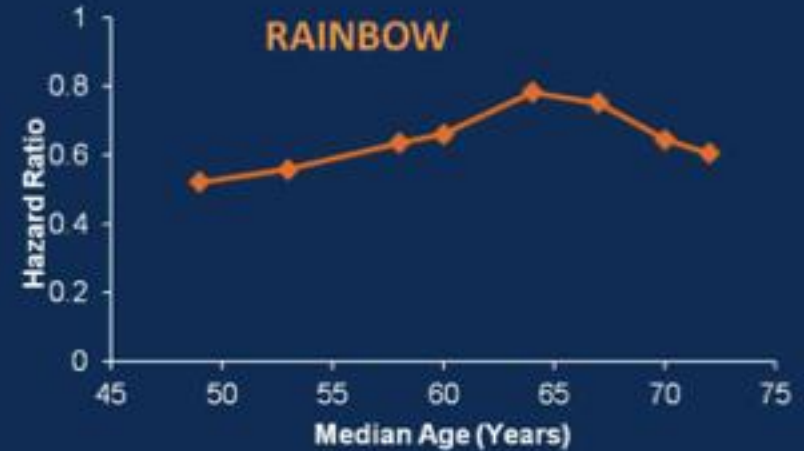
- Everolimus combined with Paclitaxel did not improve outcome as compared to Paclitaxel alone
- Biomarker analysis for better patient selection is ongoing:
 - molecular subtypes?
 - PI3K mutations?

EFFICACY AND SAFETY OF RAMUCIRUMAB (RAM)
FOR METASTATIC GASTRIC OR
GASTROESOPHAGEAL JUNCTION (GEJ)
ADENOCARCINOMA ACROSS AGE SUBGROUPS IN
TWO GLOBAL PHASE 3 TRIALS

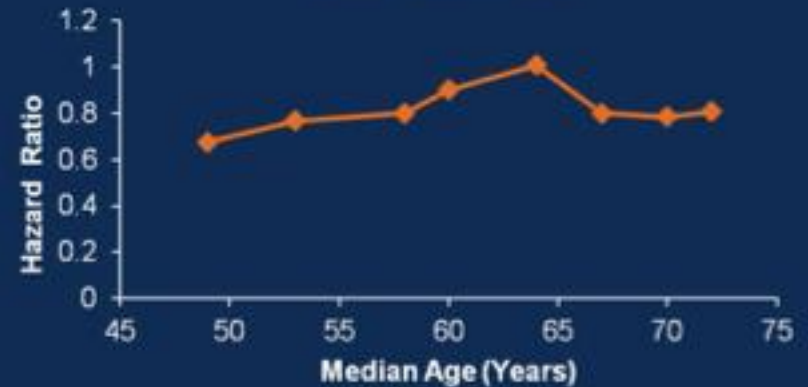
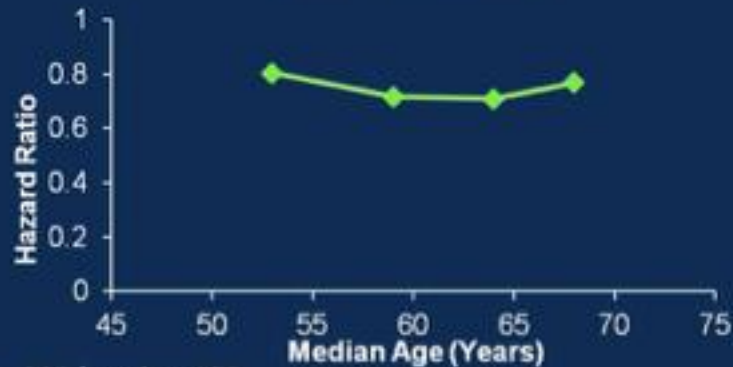
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STEPP ANALYSIS OF PFS AND OS

PFS

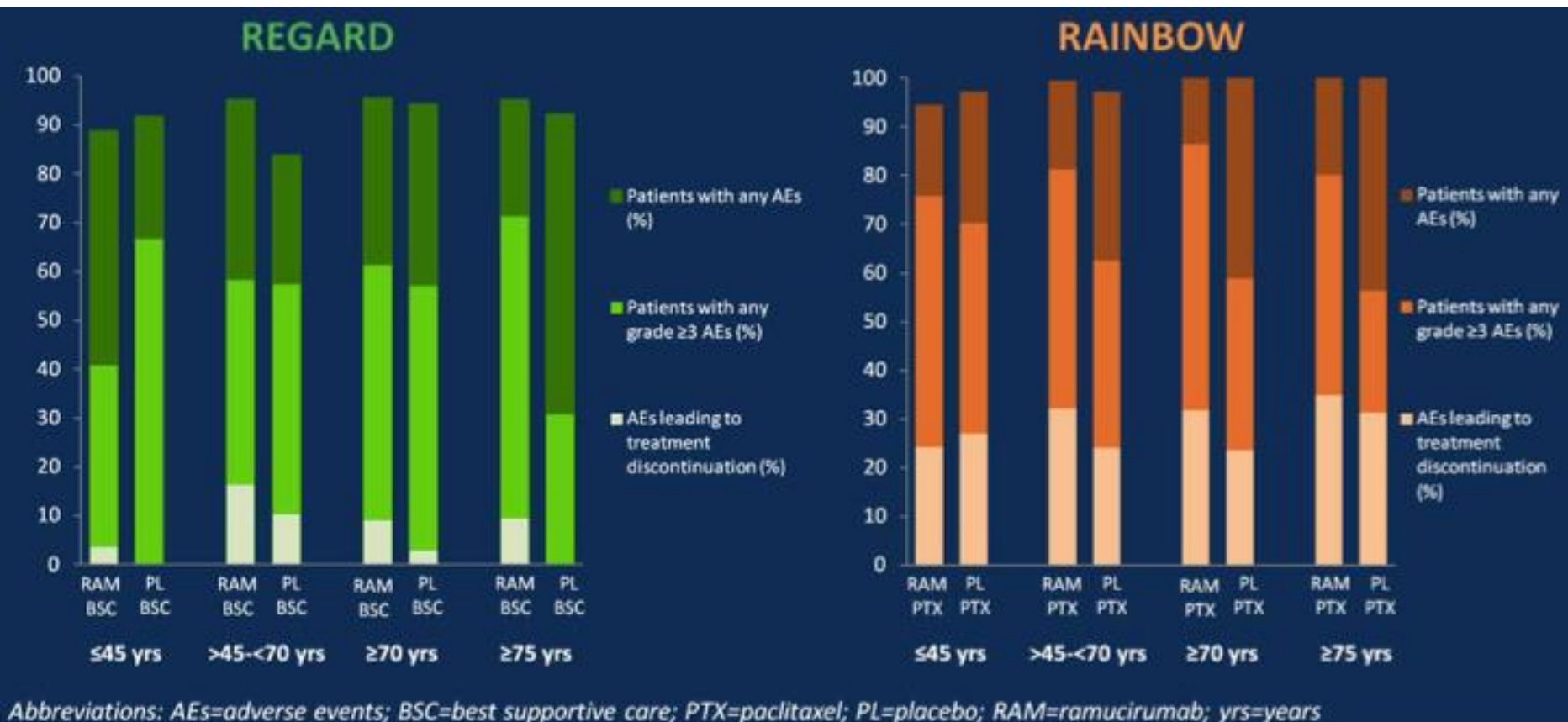


OS



Note: subgroup 200/overlap 150

TREATMENT-EMERGENT ADVERSE EVENTS BY AGE AND TREATMENT ARM



SUMMARY

- Survival curves and STEPP analysis suggest benefits of ramucirumab (RAM) treatment in terms of PFS and OS amongst young and elderly populations in REGARD and RAINBOW
 - Age does not matter for RAM treatment
 - Difference for toxicity such as hypertension and neutropenia with increasing age
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