

Supplementary Online Content

Di Maio M, Audisio M, Cardone C, et al. The use of not-negative conclusions to describe results of formally negative trials presented at oncology meetings. *JAMA Oncol*. Published online April 16, 2020. doi:10.1001/jamaoncol.2020.0475

eTable. Oral presentations of formally negative trials at ASCO or ESMO meetings between 2017 and 2019, with not-negative authors' conclusions.

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable. Oral presentations of formally negative trials at ASCO or ESMO meetings between 2017 and 2019, with not-negative authors' conclusions.

Meeting	Abstract code	First author	Disease and setting	Number of patients	Experimental treatment	Standard treatment	Authors' conclusions	Statement in Conclusions that primary endpoint was not met	Reason of not-negative authors' conclusions				Notes
									Numerically better outcome in experimental arm but not significant P value	Emphasis on subgroup analysis	Emphasis on secondary endpoints	Interpretation as "non inferiority" of a superiority negative trial	
ASCO 2017	4006	Primrose	Biliary tract cancer; adjuvant treatment	447	Capecitabine	No adjuvant treatment	Capecitabine as adjuvant improves OS and should become standard of care in this setting	No	Yes		Yes		Emphasis on sensitivity analysis
ASCO 2017	2000	Terasaki	Glioblastoma; patients refractory to temozolomide	88	Personalized peptide vaccination + best supportive care	Placebo + best supportive care	Personalized peptide vaccination was clinically beneficial for 60% of patients, by means of median OS and 1-year survival rate	No		Yes			
ASCO 2017	11000	Chawla	Soft tissue sarcoma; relapse after prior chemotherapy	433	Aldoxorubicin	Investigators' choice	Aldoxorubicin significantly prolonged PFS in North American and leiomyoliposarcoma subjects. Aldoxorubicin is a good alternative vs. standard therapies.	No	Yes	Yes		Yes	
ASCO 2017	5008	Nabid	High-risk prostate cancer; adjuvant treatment	630	Androgen deprivation treatment, 36 months	Androgen deprivation treatment, 18 months	Therapy duration can be safely reduced from 36 to 18 months, that represents a new standard of care	No				Yes	
ASCO 2017	5503	Nomura	High risk endometrial cancer; adjuvant treatment	788	Docetaxel plus cisplatin or paclitaxel plus cisplatin	Doxorubicin plus cisplatin	Since each regimen showed adequate tolerability, taxane plus platinum agent regimens may be a reasonable alternative to doxorubicin + cisplatin	Yes				Yes	
ASCO 2017	5502	de Boer	High risk endometrial cancer; adjuvant treatment	686	Chemo-radiotherapy	Radiotherapy alone	Significant 11% FFS benefit with chemo-radiotherapy. Combined chemo-radiotherapy recommended to maximize FFS.	No	Yes	Yes			

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ESMO 2017	LBA45_PR	Cohen	Recurrent/metastatic head & neck squamous cell cancer, after platinum	495	Pembrolizumab	Methotrexate or docetaxel or cetuximab	Pembrolizumab provided a 19% reduction in the risk of death over investigator's choice of SOC in patients with R/M HNSCC	Yes	Yes	Yes	Yes		Emphasis on confounding effect of post-study crossover on OS
ESMO 2017	LBA55	Casali	GIST; adjuvant treatment	908	Imatinib, 2 years	No treatment	In the high-risk subgroup, trends at 10 years (...) were seen for imatinib-free survival, OS and RFS in favour of imatinib	No		Yes			
ASCO 2018	LBA 4002	Van Thienoven	Resectable and borderline resectable pancreatic adenocarcinoma; neoadjuvant treatment	246	Preoperative radio-chemotherapy plus surgery plus adjuvant chemotherapy	Surgery plus adjuvant chemotherapy	These results suggest a benefit of neoadjuvant chemotherapy over upfront surgery	No	Yes	Yes	Yes		
ESMO 2018	1378O	Kowalski	Advanced NSCLC; after failure of 2 or more lines	292	Durvalumab	Erlotinib, gemcitabine or vinorelbine	PD-L1 ≥25%: clinically meaningful improvement in OS. PD-L1 <25%: non-significant numerical improvement in OS	No	Yes				
ESMO 2018	LBA5	Parker	Newly diagnosed metastatic prostate cancer	2061	Prostate radiotherapy + androgen deprivation therapy +/- docetaxel	Androgen deprivation therapy +/- docetaxel	Prostate radiotherapy should be a standard treatment option for men with newly diagnosed metastatic prostate cancer with a low metastatic burden	No		Yes			
ASCO 2019	11001	Bonvalot	Retroperitoneal sarcoma; neoadjuvant treatment	266	Preoperative radiotherapy plus surgery	Surgery alone	Abdominal RFS was similar in the two groups. Abdominal RFS was significantly better after radiotherapy in the liposarcoma subgroup.	No		Yes			

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ASCO 2019	4507	Zaghloul	Locally advanced bladder cancer after radical cystectomy; adjuvant treatment	123	Adjuvant chemotherapy + radiotherapy; Adjuvant chemotherapy	Adjuvant radiotherapy;	Adjuvant radiotherapy a good option for patients with locally advanced bladder cancer where an alternative to chemo is desired by the patient and/or physician	Not clear (only comparison of radiotherapy vs chemotherapy is presented, no clear hypothesis)				Yes	
ASCO 2019	1003	Schmid	Untreated locally advanced or metastatic triple-negative breast cancer; first line therapy	902	Atezolizumab + nab-paclitaxel	Placebo + nab-paclitaxel	Although not formally testable due to prespecified statistical analysis plan, a median OS improvement from 18 to 25 months was observed in the PDL1+ population	No	Yes				*Statistical test of OS in PDL1+ patients, not allowed due to hierarchical design
ASCO 2019	504	Del Mastro	Breast cancer; adjuvant treatment after 2-3 years of tamoxifen	2056	Letrozole, 5 years	Letrozole, 2-3 years	These findings are consistent with the results of previous studies and suggest that [...] extended treatment could be considered in breast cancer patients at residual risk of recurrence	No	Yes				
ASCO 2019	6002	Guigay	Recurrent/metastatic head and neck squamous cell carcinoma; first line therapy	539	Cisplatin + 5-fluorouracil + cetuximab (EXTREME)	Cisplatin + docetaxel + cetuximab (TPEX)	Despite the lack of significant OS increase, TPEX could favourably replace EXTREME as a new option for first-line treatment	Yes				Yes	
ASCO 2019	8501	Kenmotsu	Resected stage II-IIIa non-squamous NSCLC; adjuvant treatment	804	Pemetrexed + cisplatin	Vinorelbine + cisplatin	These data suggest that pemetrexed + cisplatin can be an option for adjuvant chemotherapy, especially for EGFR wild-type non-squamous NSCLC	Yes		Yes	Yes	Yes	

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ASCO 2019	9504	Tarhini	Resected high- risk melanoma; adjuvant treatment	1670	Ipilimumab 3 mg/kg; Ipilimumab 10 mg/kg	High-dose interferon	The data support the use of ipilimumab 3mg/kg over high-dose interferon, based on improved survival and similar RFS, and comparable toxicity	No	Yes				
ASCO 2019	LBA 4007	Tabernero	Advanced gastric or gastroesophageal junction adenocarcinoma, first line therapy	763	Pembrolizumab alone; Pembrolizumab plus chemotherapy	Chemotherapy	Favorable effect on overall survival of pembrolizumab vs chemotherapy in patients with CPS \geq 10*. Modest additional benefit of pembrolizumab plus chemotherapy vs chemotherapy with manageable safety profile	No	Yes				*Statistical test of pembrolizumab vs chemotherapy in CPS \geq 10 not allowed due to hierarchical design
ASCO 2019	4004	Finn	Advanced HCC -second line therapy	413	Pembrolizumab	Placebo	Taken together, these data support that the risk-benefit balance for pembrolizumab is favourable in the second-line setting for HCC	Yes	Yes		Yes		
ASCO 2019	4002	Izumi	Small HCC, early stage	293	Surgery	Radiofrequency ablation	Surgery and RFA were both safe therapeutic approaches. Both of them provided similar RFS for early stage HCC smaller than 3 cm	No				Yes	
ASCO 2019	4000	Tempero	Resectate pancreatic adenocarcinoma- adjuvant setting	866	Nab-paclitaxel + gemcitabine	Gemcitabine	Final OS will clarify the role for adjuvant nab-paclitaxel + gemcitabine in resected pancreatic cancer. Continued investigation of the regimen (eg in patients with positive lymphnodes or R1 resections as well as those non candidates for FOLFIRINOX) is warranted	Yes		Yes	Yes		Emphasis on sensitivity analyses.
ASCO 2019	3504	Seymour	Colon cancer, neoadjuvant treatment	1052	Neoadjuvant chemotherapy followed by surgery and adjuvant chemotherapy	Surgery and adjuvant chemotherapy	Neoadjuvant chemotherapy for colon cancer improves surgical outcomes and can now be considered as a treatment option	Yes	Yes		Yes		

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ESMO 2019	52300	Morton	Colon cancer, neoadjuvant treatment	1052	Neoadjuvant chemotherapy followed by surgery and adjuvant chemotherapy	Surgery and adjuvant chemotherapy	Trend towards improved survival. Neoadjuvant chemotherapy can be considered a new therapeutic option	Yes	Yes		Yes		
ESMO 2019	LBA43	Kang	Advanced / metastatic gastric cancer, who failed 2 or more lines of chemotherapy	460	Rivoceranib plus best supportive care	Placebo plus best supportive care	These findings suggest that rivoceranib has a benefit with a favorable safety profile in gastric cancer	Yes		Yes	Yes		
ESMO 2019	LBA21	Cortes	Metastatic, pretreated triple-negative breast cancer	622	Pembrolizumab	Single-agent chemotherapy	Pembrolizumab showed a clear trend in improved efficacy with PD-L1 enrichment	Yes		Yes	Yes		

ASCO: American Society of Clinical Oncology; ESMO: European Society for Medical Oncology; HCC: hepatocellular carcinoma; OS: overall survival; RPF: recurrence-free survival; RFA: radiofrequency ablation; CPS: combined positive score; NSCLC: non-small cell lung cancer; EGFR: Epidermal Growth Factor Receptor; FFS: failure-free survival; GIST: gastrointestinal stromal tumors.