Clinical trial identification: NCT03721653.

Legal entity responsible for the study: G.O.N.O. Group.

Funding: G.O.N.O. Group.

Disclosure: C. Cremolini: Financial Interests, Personal, Advisory Board: Roche; Financial Interests, Personal, Invited Speaker: Bayer; Financial Interests, Personal, Invited Speaker: Servier; Financial Interests, Personal, Advisory Board: MSD; Financial Interests, Personal, Expert Testimony: Amgen; Financial Interests, Institutional, Invited Speaker: Roche; Financial Interests, Institutional, Invited Speaker: Bayer; Financial Interests, Institutional, Invited Speaker: Servier; Financial Interests, Institutional, Invited Speaker: Merck. D. Rossini: Financial Interests, Personal, Invited Speaker: Takeda. F. Pietrantonio: Financial Interests, Personal, Invited Speaker: Amgen; Financial Interests, Personal, Invited Speaker: Merck; Financial Interests, Personal, Invited Speaker: Serono; Financial Interests, Personal, Invited Speaker: Sanofi; Financial Interests, Personal, Invited Speaker: Bayer; Financial Interests, Personal, Invited Speaker: Servier; Financial Interests, Personal, Invited Speaker: Lilly; Financial Interests, Institutional, Funding: Bristol Myers Squibb; Financial Interests, Personal, Advisory Role: Amgen; Financial Interests, Personal, Advisory Role: Merck Serono; Financial Interests, Personal, Advisory Role: Bayer; Financial Interests, Personal, Advisory Role: Lilly; Financial Interests, Personal, Advisory Role: Sanofi; Financial Interests, Personal, Advisory Role: Servier; Financial Interests, Personal, Invited Speaker: AstraZeneca; Financial Interests, Institutional, Funding: AstraZeneca. S. Lonardi: Financial Interests, Personal, Speaker's Bureau: Amgen; Financial Interests, Personal, Speaker's Bureau: Merck; Financial Interests, Personal, Speaker's Bureau: Serono; Financial Interests, Personal, Speaker's Bureau: Eli Lilly & co; Financial Interests, Personal, Speaker's Bureau: Merck Serono; Financial Interests, Institutional, Funding: Amgen; Financial Interests, Institutional, Funding: Merck Serono. A. Falcone: Financial Interests, Personal, Invited Speaker: Roche; Financial Interests, Personal, Invited Speaker: Amgen; Financial Interests, Personal, Invited Speaker: Merck Serono; Financial Interests, Personal, Invited Speaker: Celgene; Financial Interests, Personal, Invited Speaker: Bayer; Financial Interests, Personal, Invited Speaker: Sanofi; Financial Interests, Institutional, Funding: Roche; Financial Interests, Institutional, Funding: Amgen; Financial Interests, Institutional, Funding: Merck Serono. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2021.08.2094

LBA21 Radioembolization with chemotherapy for colorectal liver metastases: A randomized, open-label, international, multicenter, phase III trial (EPOCH study)

M.F. Mulcahy[1], R. Salem[2], A. Mahvash[3], M. Pracht[4], A.H. Montazeri[5], S. Bandula[6], K. Hermann[7], E. Brown[8], D. Zuckerman[9], G. Wilson[10], T-Y. Kim[11], A. Weaver[12], P. Ross[13], W.P. Harris[14], M.S. Johnson[15], C.T. Sofocleous[16], S.A. Padia[17], R.J. Lewandowski[2], E. Garin[18], P. Sinclair[19]

[1]Medical Oncology, Northwestern University, Chicago, IL, USA; [2]Interventional Radiology, Northwestern University, Chicago, IL, USA; [3]Interventional Radiology, MD Anderson Cancer Center, Houston, TX, USA; [4]Medical Oncology Department, Centre Eugene - Marquis, Rennes, France; [5]Clinical Oncology, Clatterbridge Cancer Center, Wirral - NHS Foundation Trust, Metropolitan Borough of Wirral, Merseyside, UK; [6]Interventional Radiology, University College London Hospital, London, UK; [7]Nuclear Medicine, Universitatsklinikum Essen, Essen, Germany; [8]Medical Oncology Department, Western General Hospital, Edinburgh, UK; [9]Interventional Radiology, Yale University, New Haven, CT, USA; [10]Medical Oncology Department, The Christie NHS Foundation Trust, Manchester, UK; [11]Medical Oncology Department, Seoul National University College of Medicine, Seoul, Republic of Korea; [12]Medical Oncology Department, Churchill Hospital University of Oxford, Oxford, UK; [13]Medical Oncology Department, Guy's Hospital, London, UK; [14]Medicine Oncology, University of Washington Medical Center, Seattle, WA, USA; [15]Interventional Radiology, Indiana University School of Medicine, Indianapolis, IN, USA; [16]Interventional Radiology, Memorial Sloan Kettering Cancer Center, New York, NY, USA; [17]Interventional Radiology, University of California-Los Angeles, Los Angeles, CA, USA; [18]Nuclear Medicine, Centre Eugene Marquis, Rennes, France; [19]Interventional Oncology, Boston Scientific Corporation, Marlborough, MA, USA

Background: Safety and efficacy of trans-arterial Yttrium-90 radioembolization (TARE) in combination with systemic chemotherapy in the second-line setting for colorectal liver metastases is unknown.

Methods: In this phase 3 trial, patients with colorectal liver metastases who progressed on first-line therapy were randomized 1:1 to receive second-line chemotherapy with or without glass microsphere TARE. The two primary endpoints were progression-free survival (PFS) and hepatic PFS (hPFS), assessed by blinded-independent central review. Randomization was stratified by unilobar/bilobar disease, oxaliplatin/irinotecan-based first-line chemotherapy, and KRAS mutation status.

Results: 428 patients from 94 centers were randomized to chemotherapy +/- TARE. The hazard ratio (HR) for PFS was 0.69 (95% confidence interval [CI], 0.54-0.88; 1-sided p=0.0013), with a median PFS of 8.0 (CI, 7.2-9.2) and 7.2 (CI, 5.7-7.6) months, respectively. The HR for hPFS was 0.59 (CI, 0.46-0.77; 1-sided p<0.0001), with a median hPFS of 9.1 (CI, 7.8-9.7) and 7.2 (CI, 5.7-7.6) months, respectively. Objective response rates were 34.0% (CI, 28.0-40.5%) and 21.1% (CI, 16.2-27.1%; 1-sided p=0.0019) for TARE and chemotherapy groups, respectively. Median overall survival was 14.0 (CI, 11.8-15.5) and 14.4 months (CI, 12.8-16.4; 1-sided p=0.7229) with a HR of 1.07 (CI, 0.86-1.32) for TARE and chemotherapy groups, respectively. Grade 3 adverse events were reported more frequently in the TARE group (68.4 vs 49.3%). The PFS benefit of TARE was observed for tumors with KRAS mutation (HR 0.57, CI: 0.40-0.80), left-side primary tumor (HR 0.65, CI: 0.48-0.88), hepatic tumor burden 10-25% (HR 0.43, CI: 0.26-0.72), ≤3 lesions (HR 0.33, CI: 0.14-0.76), addition of a biologic agent (HR 0.58, CI: 0.40-0.84), and resected primary (HR 0.63, CI: 0.46-0.85).

Conclusions: EPOCH study met both primary endpoints, demonstrating the addition of TARE to systemic therapy for second-line colorectal liver metastases leads to significantly longer PFS and hPFS. Further subset analyses will better define the ideal patient population benefitting from TARE.

Clinical trial identification: NCT01483027.

Legal entity responsible for the study: Boston Scientific Corporation.

Funding: Boston Scientific Corporation.

Disclosure: M.F. Mulcahy: Financial Interests, Personal, Research Grant: Boston Scientific. R. Salem: Financial Interests, Personal, Advisory Role: Boston Scientific Corporation; Financial Interests, Personal, Advisory Role: Cook; Financial Interests, Personal, Advisory Role: Eisai; Financial Interests, Personal, Advisory Role: Genentech; Financial Interests, Personal, Advisory Role: AstraZeneca; Financial Interests, Personal, Advisory Role: Becton Dickinson; Financial Interests, Personal, Advisory Role: Sirtex; Financial Interests, Personal, Advisory Role: QED Therapeutics; Financial Interests, Institutional, Funding: Boston Scientific; Financial Interests, Personal, Advisory Role: Siemens. A. Mahvash: Financial Interests, Personal, Advisory Role: Sirtex Medical; Financial Interests, Personal, Advisory Role: Boston Scientific; Financial Interests, Personal, Advisory Role: ABK Biomedical; Financial Interests, Institutional, Funding: Sirtex Medical; Financial Interests, Institutional, Funding: Boston Scientific; Financial Interests, Institutional, Funding: ABK Biomedical. M. Pracht: Financial Interests, Personal, Other, Travel: Boston Scientific . K. Hermann: Financial Interests, Personal, Advisory Role: Bayer; Financial Interests, Personal, Advisory Role: Sofie Biosciences; Financial Interests, Personal, Advisory Role: Sirtex; Non-Financial Interests, Personal, Advisory Role: ABX; Financial Interests, Personal, Advisory Role: Adacap; Financial Interests, Personal, Advisory Role: Curium; Financial Interests, Personal, Advisory Role: Endocyte; Financial Interests, Personal, Research Grant: Boston Scientific; Financial Interests, Personal, Advisory Role: Ipsen; Financial Interests, Personal, Advisory Role: Siemens Healthineers; Financial Interests, Personal, Advisory Role: GE Healthcare; Financial Interests, Personal, Advisory Role: Amgen; Financial Interests, Personal, Advisory Role: Novartis; Financial Interests, Personal, Advisory Role: ymabs; Financial Interests, Personal, Advisory Role: Aktis Oncology; Financial Interests, Personal, Advisory Role: Theragnostics; Financial Interests, Personal, Advisory Role: Pharma15. P. Ross: Financial Interests, Institutional, Funding: Sanofi; Financial Interests, Institutional, Funding: Bayer; Financial Interests, Personal, Advisory Board: SIRTEX; Financial Interests, Personal, Advisory Board: Amgen; Financial Interests, Personal, Advisory Board: Eisai; Financial Interests, Personal, Advisory Board: Roche; Financial Interests, Personal, Advisory Board: AstraZeneca; Financial Interests, Personal, Speaker's Bureau: Roche; Financial Interests, Personal, Speaker's Bureau: Servier; Financial Interests, Personal, Speaker's Bureau: Boston Scientific; Financial Interests, Personal, Speaker's Bureau: Amgen; Financial Interests, Personal, Other, Travel/Conference: Bayer; Financial Interests, Personal, Other, Travel/Conference: Servier; Financial Interests, Personal, Other, Travel/Conference: Roche; Financial Interests, Personal, Other, Travel/Conference: Ipsen. W.P. Harris: Financial Interests, Personal, Advisory Role: QED Therapeutics; Financial Interests, Personal, Advisory Role: Zymeworks; Financial Interests, Personal, Advisory Role: BD Medical; Financial Interests, Institutional, Funding: Merck; Financial Interests, Personal, Member of the Board of Directors: GI Cancers Alliance; Financial Interests, Personal, Advisory Role: BMS; Financial Interests, Personal, Advisory Role: Eisai; Financial Interests, Personal, Advisory Role: Exelixis; Financial Interests, Personal, Advisory Role: Neotherma; Financial Interests, Institutional, Funding: Agios; Financial Interests, Institutional, Funding: Basilea; Financial Interests, Institutional, Funding: Bayer; Financial Interests, Institutional, Funding: Boston Scientific; Financial Interests, Institutional, Funding: BMS; Financial Interests, Institutional, Funding: Exelixis; Financial Interests, Institutional, Funding: Koo Foundation; Financial Interests, Institutional, Funding: MedImmune. M.S. Johnson: Financial Interests, Personal, Advisory Role: Boston Scientific; Financial Interests, Institutional, Funding: Boston Scientific. C.T. Sofocleous: Financial Interests, Institutional, Funding: Ethicon J&J; Financial Interests, Institutional, Funding: Sirtex; Financial Interests, Institutional, Funding: Boston Scientific; Financial Interests, Personal, Advisory Role: Ethicon J&J; Financial Interests, Personal, Advisory Role: Terumo; Financial Interests, Personal, Advisory Role: Boston Scientific; Financial Interests, Personal, Advisory Role: Sirtex; Financial Interests, Personal, Advisory Role: Varian. S.A. Padia: Financial Interests, Personal, Advisory Role: Boston Scientific; Financial Interests, Personal, Advisory Role: Varian Medical Systems; Financial Interests, Personal, Advisory Role: Guerbet; Financial Interests, Personal, Advisory Role: Teleflex Medical; Financial Interests, Personal, Advisory Role: Bristol Meyer Squibb. R.J. Lewandowski: Financial Interests, Personal, Invited Speaker: Boston Scientific; Financial Interests, Personal, Advisory Role: Boston Scientific. E. Garin: Financial Interests, Personal, Advisory Role: Boston Scientific; Financial Interests, Institutional, Funding: Boston Scientific. P. Sinclair: Financial Interests, Personal, Full or part-time Employment: Boston Scientific; Financial Interests, Personal, Stocks/Shares: Boston Scientific; Financial Interests, Personal, Sponsor/Funding: Boston Scientific. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2021.08.2095