endpoint was Progression Free Survival 2 (PFS2), defined as the time from randomization to PD on any treatment given after first PD or death. Estimating a median PFS2 in arm A of 15 months, 466 events and 654 pts were required to detect a HR of 0.77 in favor of arm B, with overall 2-sided-α and β errors of 0.05 and 0.20, respectively. An interim analysis at 2/3 of events (303) was planned. According to the O'Brien Fleming spending rule, 2-sided-α levels of 0.0131 and 0.0455 were defined for the interim and final analysis.

Results: From February 2015 to May 2017, 679 pts (arm A/B: 342/337) were enrolled in 58 Italian sites. Main patients' characteristics were (arm A/B): median age 61/60 yrs, ECOG PS 0 86%/87%, right-sided primary 38%/38%, liver-only disease 29%/32%, RAS mutant 65%/63%, BRAF mutant 10%/10%. At a median follow-up of 22.8 mos, 547 (arm A/B 286/261) patients progressed and 423 (arm A/B 235/188) events of PFS2 were reported. As compared with FOLFOX/bev, upfront FOLFOXIRI/bev significantly improved PFS1 (median 9.9 vs 12.0 mos, HR 0.73 [95%CI: 0.62-0.87], $p < 0.001$) and RECIST response rate (61% vs 50%, OR 1.55 [95%CI: 1.14-2.10], $p = 0.005$). 247 (86%) and 197 (75%) patients received a treatment after PD in arm A and B, respectively. Patients in arm B reported significantly longer PFS2 than in arm A (median PFS2 18.9 vs 16.2 mos, HR 0.69 [95%CI: 0.57-0.83], $p < 0.001$).

Conclusions: The primary endpoint was met at the interim analysis: 4-months induction with FOLFOXIRI/bev followed by maintenance and reintroduction improves mCRC patients' outcome as compared with a sequential strategy of oxaliplatin- and irinotecan-based doublets.

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LBA20 TRIBE2: A phase III, randomized strategy study by GONO in the 1st- and 2nd-line treatment of unresectable metastatic colorectal cancer (mCRC) patients (pts)

C. Cremolini[1], C. Antoniotti[1], S. Lonardi[2], D. Rossini[1], F. Pietrantonio[3], S.S. Cordio[4], S. Murgioni[5], F. Marmorino[1], E. Maiello[6], A. Passardi[7], G. Masi[1], E. Tamburini[8], D. Santini[9], R. Grande[10], A. Zaniboni[11], C. Granetto[12], F. Loupakis[2], L. Delliponti[1], L. Boni[13], A. Falcone[1]

[1]Department of Translational Research and New Technologies in Medicine and Surgery, University of Pisa, Pisa, Italy, [2]Dip. Oncologia Clinica e Sperimentale, Istituto Oncologico Veneto IRCCS, Padua, Italy, [3]Medical Oncology Department, Istituto Nazionale dei Tumori di Milano - Fondazione IRCCS, Milan, Italy, [4]Oncologia Medica, Azienda Ospedaliera ARNAS Garibaldi, Catania, Italy, [5]Medical Oncology 1, Department of Clinical and Experimental Oncology, Istituto Oncologico Veneto IRCCS, Padua, Italy, [6]Oncology, Hospital Casa Sollievo della Sofferenza-IRCCS, San Giovanni Rotondo, Italy, [7]Medical Oncology, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS, Meldola, Italy, [8]Oncologia Medica, Ospedale Infermi, Rimini, Italy, [9]Oncology, Campus Bio-Medico di Roma, Rome, Italy, [10]Oncologia Medica, Ospedale Fabrizio Spaziani-ASL Frosinone, Frosinone, Italy, [11]Medical Oncology, Casa di Cura Poliambulanza, Brescia, Italy, [12]Oncologia Medica, Azienda Sanitaria Ospedaliera Santa Croce e Carle, Cuneo, Italy, [13]Istituto Toscano Tumori, Clinical Trial Coordinating Center, AOU Careggi, Florence, Italy

Background: TRIBE2 aimed at comparing two strategies of 1st and 2nd line treatment of mCRC with different chemotherapy intensity and a prolonged angiogenesis inhibition.

Methods: TRIBE2 (NCT02339116) was a phase 3 trial in which previously untreated pts with unresectable mCRC were randomized 1:1 to FOLFOX/bev followed by FOLFIRI/bev after disease progression (PD) (arm A) or FOLFOXIRI/bev followed by the reintroduction of the same regimen after PD (arm B). Combination treatments were administered up to 8 cycles, followed by 5-FU/bev until PD. The primary