

# LBA29

## Nivolumab plus ipilimumab vs nivolumab monotherapy for microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) metastatic colorectal cancer (mCRC): New results from CheckMate 8HW

S. Lonardi<sup>1</sup>, H.J. Lenz<sup>2</sup>, E. Elez Fernandez<sup>3</sup>, L.H. Jensen<sup>4</sup>, E. Van Cutsem<sup>5</sup>, Y. Touchefeu<sup>6</sup>, R. Garcia-Carbonero<sup>7</sup>, D. Tougeron<sup>8</sup>, G.A. Mendez<sup>9</sup>, M. Schenker<sup>10</sup>, C. de la Fouchardiere<sup>11</sup>, M.L. Limon<sup>12</sup>, T. Yoshino<sup>13</sup>, J. Li<sup>14</sup>, F.M. Aubin<sup>15</sup>, E. Cela<sup>16</sup>, L. Li<sup>17</sup>, R. Tam<sup>18</sup>, L. Jin<sup>19</sup>, T. André<sup>20</sup>

<sup>1</sup> Medical Oncology Unit 1, Veneto Institute of Oncology IOV-IRCCS, Padua, Italy, <sup>2</sup> Medical Oncology Department, University of Southern California – Norris Comprehensive Cancer Center, Los Angeles, United States of America, <sup>3</sup> Department of Medical Oncology, Vall d'Hebron University Hospital and Institute of Oncology (VHIO), Barcelona, Spain, <sup>4</sup> Department of Oncology, University Hospital of Southern Denmark, Vejle Hospital, Vejle, Denmark, <sup>5</sup> Digestive Oncology Department, University Hospitals Gasthuisberg and University of Leuven (KU Leuven), Leuven, Belgium, <sup>6</sup> Medical Oncology, Centre Hospitalier Universitaire de Nantes, Nantes, France, <sup>7</sup> Medical Oncology Department, Hospital Universitario 12 de Octubre Imas12, UCM, Madrid, Spain, <sup>8</sup> Gastroenterology, CHU Poitiers - Jean Bernard Hôpital, Poitiers, France, <sup>9</sup> Oncology Department, Hospital Universitario Fundacion Favaloro, Buenos Aires, Argentina, <sup>10</sup> Medical Oncology Department, Centrul de Oncologie Sf Nectarie, Craiova, Romania, <sup>11</sup> Medical Oncology Department, Centre Léon Bérard, Marseille, France, <sup>12</sup> Department of Oncology, Hospital Universitario Virgen del Rocío, Seville, Spain, <sup>13</sup> Department of Gastroenterology and Gastrointestinal Oncology, National Cancer Center Hospital East, Chiba, Japan, <sup>14</sup> Department of Medical Oncology, Shanghai East Hospital, Shanghai, China, <sup>15</sup> Department of Medicine, Hemato-Oncology, Centre Hospitalier de Université to Montréal, Montreal, Canada, <sup>16</sup> Oncology Global Drug Development, Bristol Myers Squibb, Princeton, United States of America, <sup>17</sup> Medical Affairs Biostatistics, Bristol Myers Squibb, Princeton, United States of America, <sup>18</sup> Translational Medicine, Bristol Myers Squibb, Princeton, United States of America, <sup>19</sup> Oncology Clinical Development, Bristol Myers Squibb, Princeton, United States of America<sup>20</sup> Medical Oncology Department, Sorbonne Université, and Hôpital Saint Antoine, Assistance Publique Hôpitaux de Paris, Paris, France

## Background

The phase 3 CheckMate 8HW trial met its dual primary endpoints of superior progression-free survival (PFS) with nivolumab + ipilimumab (NIVO + IPI) vs chemotherapy (CT) in the first line (1L) setting (HR 0.21;  $P < 0.0001$ ) and vs NIVO across all lines (HR 0.62;  $P = 0.0003$ ) in patients (pts) with centrally confirmed MSI-H/dMMR mCRC. We report new and updated efficacy and safety results for NIVO + IPI vs NIVO from a preplanned PFS final analysis based on a data cutoff of April 30, 2025.

## Methods

Pts with unresectable or mCRC and MSI-H/dMMR status by local testing were enrolled across different lines of therapy and randomized 2:2:1 to NIVO + IPI, NIVO, or CT ± targeted therapy. Newly assessed secondary endpoints for NIVO + IPI vs NIVO included PFS and objective response rate (ORR) in the 1L setting and overall survival (OS) across all lines in pts with centrally confirmed MSI-H/dMMR. Longer-term data were available for the primary endpoint of PFS and secondary endpoint of ORR for NIVO + IPI vs NIVO across all lines.

## Results

Median (range) follow-up for all randomized pts was 55.1 (24.7–68.5) months. For pts with centrally confirmed MSI-H/dMMR mCRC, PFS was improved with 1L NIVO + IPI (n = 171) vs NIVO (n = 170), with a 31% reduction in the risk of progression or death (HR 0.69 [95% CI 0.48–0.99];  $P = 0.0413$ ); ORR was higher with 1L NIVO + IPI (73%) vs NIVO (61%) (Table). At this PFS final analysis, OS was longer with NIVO + IPI vs NIVO (HR 0.61 [95% CI 0.45–0.83]) and PFS and ORR continued to show benefit for NIVO + IPI vs NIVO across all lines (Table). Incidence of grade 3–4 treatment-related AEs in all randomized pts was 24% with 1L NIVO + IPI vs 17% with 1L NIVO; there were no new safety signals.Table: LBA29

| Centrally confirmed MSI-H/dMMR mCRC     | NIVO + IPI                            | NIVO           |
|-----------------------------------------|---------------------------------------|----------------|
| 1L                                      | n = 171                               | n = 170        |
| Median PFS (95% CI), months             | NR (55.2–NE)                          | 60.8 (32.8–NE) |
| HR (95% CI); $P$ value                  | 0.69 (0.48–0.99); 0.0413 <sup>a</sup> |                |
| ORR (95% CI), % <sup>b</sup>            | 73% (65–79)                           | 61% (53–69)    |
| All lines                               | n = 296                               | n = 286        |
| Median OS (95% CI), months <sup>b</sup> | NR                                    | NR             |
| HR (95% CI)                             | 0.61 (0.45–0.83)                      |                |

|                                     |                  |                |
|-------------------------------------|------------------|----------------|
| Centrally confirmed MSI-H/dMMR mCRC | NIVO + IPI       | NIVO           |
| 1L                                  | n = 171          | n = 170        |
| Median PFS (95% CI), months         | NR               | 44.3 (22.1–NE) |
| HR (95% CI)                         | 0.62 (0.48–0.80) |                |
| ORR (95% CI), %                     | 71% (65–76)      | 58% (52–64)    |

<sup>a</sup>Boundary for statistical significance, *P* < 0.0383. <sup>b</sup>Descriptive data.NE, not estimable; NR, not reached.

## Conclusions

NIVO + IPI showed clinically meaningful efficacy improvements vs NIVO in the 1L setting and across all lines in pts with centrally confirmed MSI-H/dMMR mCRC, further supporting NIVO + IPI as the standard of care for MSI-H/dMMR mCRC.

## Clinical trial identification

NCT04008030.

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## Legal entity responsible for the study

Bristol Myers Squibb.

## Funding

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## Disclosure

S. Lonardi: Financial Interests, Personal, Advisory Board: Amgen, Merck Serono, Lilly, Servier, AstraZeneca, MSD, Incyte, Daiichi Sankyo, Bristol Myers Squibb, Astellas, GSK, Takeda, Bayer, Rottapharm, BeiGene, Nimbus Therapeutics, Helion; Financial Interests, Personal, Invited Speaker: Pierre-Fabre, GSK, Roche, Servier, Amgen, Bristol Myers Squibb, Incyte, Lilly, Merck Serono, MSD, Astra-Zeneca; Financial Interests, Institutional, Coordinating PI: Amgen, Merck Serono, Bayer, Roche, Lilly, AstraZeneca, Bristol Myers Squibb; Non-Financial Interests, Member of Board of Directors, Italian No-Profit Oncology Research Foundation supporting academic Clinical trials: GONO Foundation. H.J. Lenz: Financial Interests, Personal, Advisory Board, Advisory Role and Lectures: Bayer; Financial Interests, Personal, Advisory Board, Advisory Role and Lectures: Merck; Financial Interests, Personal, Advisory Board, Advisory Role and lecture: Roche; Financial Interests, Personal, Advisory Board: Jazz Pharmaceuticals, oncoocyte, Orion, Astellas, BMS; Financial Interests, Personal, Advisory Board, Scientific Advisory Board: 3T Bioscience, Adagene; Financial Interests, Personal, Advisory Board, Advisory Board: Fulgent, G1 Therapeutics, BioNTech, Merck KG; Financial Interests, Personal, Advisory Board, advisory board: Cardiff; Financial Interests, Personal, Stocks/Shares, Advisory Board: Fulgent; Financial Interests, Personal, Ownership Interest, stockoptions: Breakbio. E. Elez Fernandez: Financial Interests, Personal, Advisory Board: Agenus Inc., Amgen, Bayer, Boehringer Ingelheim, Cure Teq AG, Hoffman La - Roche, Janssen, MSD, Merck Serono, Pierre Fabre, RIN Institute Inc., Repare Therapeutics Inc., Sanofi, Servier, Takeda, Johnson & Johnson, Rottapharm Biotech; Financial Interests, Personal, Invited Speaker: BMS, Lilly, Medscape, Novartis, Organon, Pfizer; Financial Interests, Personal, Other, Steering Committee: GSK; Financial Interests, Personal, Other, Educational training: Seagen International GmbH; Financial Interests, Institutional, Funding: AbbVie Deutschland GmbH & Co KG, Amgen Inc., Array Biopharma Inc, AstraZeneca Pharmaceuticals LP, Bayer Pharma AG, BeiGene, Bioncotech Therapeutics, S.L., Biontech Rna Pharmaceuticals GMBH, Biontech Small Molecules GMBH, Boehringer Ingelheim, Boehringer Ingelheim de España S.A., Bristol Myers Squibb International Corporation, Celgene International SARL, Daiichi Sankyo, Inc, Debiopharm International SA, Genentech Inc, Gercor, HalioDX SAS, Hoffmann-La Roche Ltd, Hutchinson Medipharma Limited, Hutchison MediPharma International, Iovance Biotherapeutics, Inc., Janssen Research & Development, Janssen-Cilag SA, MedImmune, Menarini, Menarini Ricerche SPA, Merck Health KGAA, Merck Sharp & Dohme de España SA, Merus NV, Mirati, Nouscom SRL., Novartis Farmacéutica SA, Pfizer, PharmaMar SA, Pledpharma AB, Redx Pharma PLC, Sanofi Aventis Recherche & Développement, Scandion Oncology, Seattle Genetics Inc., Servier, Sotio A.S., Taiho Pharma USA Inc, Wntresearch AB, Exelixis Inc., GSK, SA, Agenus, Nu Cana plc, Enterome BioScience SA; Non-Financial Interests, Leadership Role, Member of the Scientific Program Committee and Developmental Therapeutics-Immunotherapy Track Leader, 2023-2024 term: American Society for Clinical Oncology (ASCO); Non-Financial Interests, Other, Speaker of the ESMO Academy: European Society for Medical Oncology (ESMO); Non-Financial Interests, Other, Member of the Scientific Committee 2024: European Society for Medical Oncology (ESMO); Non-Financial Interests, Other, Coordinator of the SEOM +MIR Section of Residents and Young Assistants: Sociedad Española de Oncología Médica (SEOM); Non-Financial Interests, Other, Member of the Scientific Committee SEOM Annual Meeting, 2024-2025 term: Sociedad Española de Oncología Médica (SEOM); Non-Financial Interests, Member: American Society of Clinical Oncology (ASCO), American Association for Cancer Research (AACR), Sociedad Española de Oncología Médica (SEOM), Asociación Española de Investigación sobre el Cáncer (ASEICA), European Organization for Research and Treatment of Cancer (EORTC),

Spanish Cooperative Gastrointestinal Tumors Group (TTD); Other, Other, Travel, accommodations, expenses.: Agenesis Inc., Amgen, BMS, Bayer, Boehringer Ingelheim, Cure Teq AG, GSK, Hoffman La-Roche, Janssen, Lilly, MSD, Medscape, Merck Serono, Novartis, Organon, Pfizer, Pierre Fabre, RIN Institute Inc., Repare Therapeutics Inc., Sanofi, Seagen, Servier, Takeda. L.H. Jensen: Financial Interests, Institutional, Local PI: MSD, Incyte, BMS, Roche, Pfizer. E. Van Cutsem: Financial Interests, Personal, Advisory Board: AbbVie, Agenesis, ALX, Arcus Biosciences, Astellas, AstraZeneca, Bayer, BeiGene, Biontech, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi, Debiopharma, Elmedix, Eisai, GSK, Ipsen, Lilly, Merck Sharp & Dohme, Merck KGaA, Mirati, Novartis, Nordic, Pierre Fabre, Seattle Genetics, Servier, Simcere, Takeda, Taiho, Cantargia, Bexon Clinical, Fosun, Galapagos, Iteos, Microbial Machines, Trishula, Sanofi, Novocure; Financial Interests, Personal, Invited Speaker: Amgen, Pfizer. Y. Toucheffeu: Financial Interests, Personal, Invited Speaker: BMS, Pierre Fabre, Roche, AstraZeneca, Amgen, AAA Pharma, Merck Serono. R. Garcia-Carbonero: Financial Interests, Personal, Advisory Board: AAA, Amgen, Astellas, Bayer, BMS, Boehringer, Esteve, GSK, Hutchmed, Ipsen, MSD, Novartis-AAA, PharmaMar, Pierre Fabre, Sanofi, Servier, Takeda; Financial Interests, Institutional, Research Grant: BMS, MSD, Pfizer; Non-Financial Interests, Leadership Role, Global PI of investigator-initiated clinical trials (AXINET, NICENEC, PEMBROLA): BMS, MSD, Pfizer; Non-Financial Interests, Leadership Role, Chair: European Neuroendocrine Tumor Society (ENETS); Non-Financial Interests, Leadership Role, Past president, Member of the Executive Committee: Grupo Español de Tumores Neuroendocrinos (GETNE); Other, Other, Honoraria received by spouse for advisory board or invited speaker roles: ABBIE, AstraZeneca, Bayer, Boehringer, BMS, Genomica, Lilly, MSD, Merck, Novartis, Pfizer, Pharma Mar, Roche, Sanofi, Servier, Takeda. D. Tougeron: Financial Interests, Personal, Advisory Board: AstraZeneca, Sanofi, AMGEN, MSD, Roche, Servier, Pierre Fabre, BMS, Bayer, Takeda, Merck Serono, Gilead, BeiGene; Financial Interests, Institutional, Funding: MSD, AstraZeneca, BeiGene, BMS, Gilead, Takeda, Amgen; Non-Financial Interests, Member of Board of Directors: Federation francophone de cancerologie digestive. G.A. Mendez: Financial Interests, Personal, Invited Speaker: BMS, MSD, Amgen, AstraZeneca, Merck Serono, BeiGene, Takeda; Financial Interests, Personal, Advisory Board: BMS, MSD, Servier; Financial Interests, Personal, Steering Committee Member: GSK; Financial Interests, Institutional, Local PI: BMS, MSD, Amgen, Roche. M. Schenker: Financial Interests, Personal and Institutional, Invited Speaker, Payment: B.M.S., M.S.D., Roche, Merck Se, Sanofi, Regenero, Astra Zen, Pfizer, G.S.K., Novartis, Astellas, Pharma M, BeiGene, Clovis Pharma, AbbVie, Bioven, Mylan, Samsung. C. de la Fouchardiere: Financial Interests, Personal, Advisory Board: Merck, Roche, Lilly, Bayer, Amgen, MSD, Servier, Pierre Fabre Oncologie, Bristol Myers Squibb, Daiichi Sankyo, Astellas, Daiichi Sankyo; Financial Interests, Personal, Invited Speaker: Ipsen, Eisai, Servier, MSD, Daiichi Sankyo, BMS; Financial Interests, Institutional, Coordinating PI: Pierre Fabre Oncologie, Servier; Financial Interests, Institutional, Coordinating PI, Clinical trial funding: Agenesis; Non-Financial Interests, Principal Investigator: MSD, Agenesis, Natera. M.L. Limon: Financial Interests, Personal, Invited Speaker: Bristol. J. Li: Financial Interests, Personal, Advisory Role: Boehringer Ingelheim. F.M. Aubin: Financial Interests, Personal, Advisory Board: Taiho, Pfizer, Merck, BMS, Incyte, Amgen, Astellas, AstraZeneca; Financial Interests, Personal, Invited Speaker: Taiho, Pfizer, Merck, BMS, Incyte, Amgen, Astellas, AstraZeneca; Financial Interests, Institutional, Local PI: BMS, Merck, GSK, Janssen, Novartis. E. Cela: Financial Interests, Personal, Full or part-time Employment: Bristol Myers Squibb International; Financial Interests, Personal, Stocks/Shares: Bristol Myers Squibb International. R. Tam: Financial Interests, Personal, Stocks/Shares, I am a BMS employee: Bristol Myers Squibbs. L. Jin: Financial Interests, Personal, Full or part-time Employment: Bristol Myers Squibb; Financial Interests, Personal, Stocks/Shares: Bristol Myers Squibb International. T. André: Financial Interests, Personal, Advisory Board, Advisory Board on February 12, 2021: Astellas pharma; Financial Interests, Personal, Advisory Board, Advisory Board on February 2021: Kaleido Biosciences; Financial Interests, Personal, Invited Speaker, and advisory board 2021: Amgen; Financial Interests, Personal, Invited Speaker, Invited speaker in a symposium december 2020: AstraZeneca; Financial Interests, Personal, Advisory Board, and consultant fees and consultant contract 2021 and 2022: Bristol Myers Squibb; Financial Interests, Personal, Advisory Board, Advisory board in January 2020: Clovis; Financial Interests, Personal, Advisory Board, Advisory board in January 2020: Gritstone Oncology; Financial Interests, Personal, Advisory Board, Advisory board 2020: HalioRx; Financial Interests, Personal, Advisory Board, and consultant fees/consultant contract and invited speaker: MSD Oncology; Financial Interests, Personal, Invited Speaker, and other: Pierre Fabre; Financial Interests, Personal, Invited Speaker, in an symposium in 2020: Roche; Financial Interests, Personal, Invited Speaker, in a meeting in 2019: Ventana; Financial Interests, Personal, Invited Speaker, In a educational meeting in 2019: Sanofi; Financial Interests, Personal, Advisory Board, in a symposium in 2020: Servier; Financial Interests, Personal, Advisory Board, Consultant with personnel fees and invited speaker: Servier; Financial Interests, Personal, Advisory Board, in 2019: GSK; Financial Interests, Personal, Invited Speaker, in 2020 and 2021: GSK; Financial Interests, Personal, Invited Speaker, Virtual symposium Lecture: 1 MSI-H CRC: Implementation of Immunotherapy in clinical practice (30 minutes) – (this will be pre-recorded) Q&A – Live Q&A – (10 minutes) (on July 2, 2021): MSD Oncology; Financial Interests, Personal, Invited Speaker, June 2022: Sanofi; Financial Interests, Personal, Advisory Board, Contract 2021, 2022, 2023: Merck & Co., Inc; Financial Interests, Personal, Advisory Board, Contrat 2019, 2020, 2021, 2022: BMS; Financial Interests, Personal, Advisory Board, Contract 2021: Gritstone Oncologie; Financial Interests, Personal, Invited Speaker, June 2022 and June 2023 during ESMO GI meeting: Seagen; Financial Interests, Personal, Writing Engagement, Contract of consulting 2021 and 2022 and 2023: MSD Oncology; Financial Interests, Personal, Advisory Board, September 2022: GSK, Seagen; Financial Interests, Personal, Writing Engagement, Contract of consulting 2022 and 2023: GSK; Financial Interests, Personal, Writing Engagement, Contract of consulting 2022: Nordic Pharma; Financial Interests, Personal, Invited Speaker, October 2022: Merck Serono; Financial Interests, Personal, Other, Educationnal in 2022: Roche; Financial Interests, Personal, Other, Contract of consulting 2020, 2021, 2022, 2023: Servier; Financial Interests, Personal, Advisory Board, Gilead Sciences Global GI Advisory Board on January 18, 2023: Aptitude Health, Gilead; Financial Interests, Personal, Other, Consultant like member of the SGNTUC-029 Steering Committee (the “Steering Committee”) Services related to the Company’s Study titled “An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer” (collectively, the “Services”). Including teleconferences and board preparation before the board (6h) Participation of the Board on September 2022 in Paris, September 10, 2022 MOUNTAINEER-03 Steering Committee Meeting during ESMO: Seagen; Financial Interests, Personal, Other, Consultant like member of the to be a member of the

Colorectal Program Scientific Advisory Committee (SAC). In charges for reviewing V940 Pembro on Engagezone (as per your contract in ref).and also an inrtview about Pembrolizumab for MSI/dMMR Metastaic colo-rectal 2023: MSD Oncology; Financial Interests, Personal, Advisory Board, but also formation for the takeda team, and consultant for TakedaContract beetween 1 sept 2023 and 15 october 2024: Takeda; Financial Interests, Personal, Advisory Board, Board Meeting (October 19, 2023): AbbVie; Financial Interests, Personal, Invited Speaker, Emerging Role of Biomarkers in Gastrointestinal Cancers Webcast Engagement reference : Wenibar: MSD; Financial Interests, Personal, Invited Speaker, Preparation and resentation at the Seagen ESMO GI 2023 Scientific Exchange HER2 as an emerging target for the treatment of mCRC in the context MOUNTAINEER03: Seagen; Financial Interests, Personal, Advisory Board, Fruqitinib: Takeda; Financial Interests, Personal, Invited Speaker, Oral speaker in a Symposuim 2 and 3 February 2024, GI ancer MSI: MSD; Financial Interests, Personal, Invited Speaker, Management of CRC 2024: Aptitude Health; Financial Interests, Personal, Invited Speaker, symposuim JFHOD GI CancerPARIS15 03-2024: Servier; Financial Interests, Personal, Advisory Board, Advisory board on fruqitinib 2024: Takeda Pharmaceuticals; Financial Interests, Personal, Invited Speaker, Symposuim 2024: BMS, Bristol Myers Squibb International; Financial Interests, Personal, Advisory Board, Advisory board 2024: Bristol Myers Squibb International; Financial Interests, Personal, Invited Speaker, Symposuim concerning MSI CRC2024: MSD; Financial Interests, Personal, Advisory Board, in London 2024: GSK; Financial Interests, Personal, Advisory Board, Consultant with contract 2024: Nimbus, BMS; Financial Interests, Personal, Advisory Board, Consultat with contract 2024: MSD; Financial Interests, Personal, Advisory Board, consultant with contract: MSD; Financial Interests, Personal, Advisory Board, ASCO GI 2025: Aptitude Health; Financial Interests, Institutional, Local PI, a randomized, open-label, phase 2 study of botensilimab (AGEN1181) as monotherapy and in combination with balstilimab (AGEN2034) or investigator's choice standard of care (regorafenib or trifluridine and tipiracil) for the treatment of refractory metastatic colorectal cancer: Agenus; Financial Interests, Institutional, Coordinating PI, SPOTLIGHT study: Astellas; Financial Interests, Institutional, Coordinating PI, BMS CA209-8HW, BMS CA209-142, BMS CA209-577: BMS; Financial Interests, Institutional, Local PI, Study with trztuzumab derxtecan in mCRC C study: Daichi; Financial Interests, Institutional, Coordinating PI, PI Garnet study: GSK; Financial Interests, Institutional, Coordinating PI, Keynote 164 and 171 and 811 and C08: MSD; Financial Interests, Personal, Steering Committee Member, MOUNTAINEER and MOUNTAINEER-03 study (PI for France) 2022, 2023: Seagen; Financial Interests, Personal, Steering Committee Member, and international PI (trial chair Solstice study): Servier; Non-Financial Interests, Member of Board of Directors, Investigator: Gercor group; Non-Financial Interests, Member of Board of Directors, President since october 2022: ARCAD Foundation; Other, Other, DMC Meeting by Teleconference o2023 and 2024 and 2025 5member of steering comittee of A randomized Phase 2 Study of ompenacilid versus placebo in combination with FOLFIRI plus bevacizumab in patients with previously treated RAS mutant advanced or metastatic colorectal cancer (RGX-202-002): Inspira. All other authors have declared no conflicts of interest.