Supplementary Appendix

List of sites

Canada

London Health Sciences Center; BC Cancer Agency; Juravinski Cancer Centre; Tom Baker Cancer Centre; Centre Hospitalier De L'universite De Montreal (CHUM); McGill University Health Centre–Glen Site; Cross Cancer Institute; BC Cancer Agency, Sindi Ahluwalia Hawkins Centre for the Southern Interior

Europe

Denmark: Rigshospitalet-Copenhagen University Hospital; Odense University Hospital
France: Centre de Lutte Contre le Cancer, Centre Oscar Lambret; Hopital Europeen Georges-Pompidou; Institut Paoli Calmettes; Centre Francois Baclesse; Institut de Cancerologie de l'Ouest–Rene Gauducheau
Italy: Fondazione IRCCS Istituto Nazionale Tumori Milano; Istituto Nazionale Tumori IRCCS Fondazione Pascale; Istituto Europeo di Oncologia
Poland: Wojewodzki Szpital Specjalistyczny w Olsztynie; Olsztynski Osrodek Onkologiczny Kopernik sp. z o. o.; Szpitale Pomorskie Spotka z ograniczona odpowiedzialnoscia
Spain: Hospital Clinico Universitario de Valencia; Fundacion Instituto Valenciano de Oncologia; Institut Catala d Oncologia de Girona; Hospital Clinic de Barcelona; Hospital Universitario La Paz Madrid; Centro Integral Oncologico Clara Campal, Hospital de Madrid Norte-San Chinarro; Institut Catala D'oncologia; Fundacion Jimenez Diaz; Hospital Vall d'Hebron; Hospital Clinico Universitario Virgen de la Victoria; HU. Virgen del Rocio; Hospital Clinico Universitario de Santiago de Compostela; Hospital Universitario Miguel Servet
UK: The Royal Marsden NHS Foundation Trust; Oxford University Hospitals NHS Foundation Trust; The Newcastle Upon Tyne Hospitals NHS Foundation Trust; The Christie NHS Foundation Trust; University College London; Guys and Saint Thomas NHS Foundation Trust; Aberdeen Royal Infirmary

USA

Stephenson Cancer Center; Karmanos Cancer Institute; Scottsdale Healthcare Hospitals DBA HonorHealth; University of Pennsylvania; Fox Chase Cancer Center; Mission Bay–UCSF Medical Center; SUNY Downstate Medical Center; Froedtert Hospital; Women & Infants Hospital; OSU Wexner Medical Center; UAB Comprehensive Cancer Center; Perlmutter Cancer Center; The University of Chicago Medical Center; Levine Cancer Institute; University of Miami Hospital & Clinics/Sylvester Comprehensive Cancer Center; Massachusetts General Hospital; Georgia Cancer Center at Augusta University; CTRC at the University of Texas Health Science Center at San Antonio; Huntsman Cancer Institute; Maine Medical Center; UT Southwestern Medical Center; University of Washington/Seattle Cancer Care Alliance; UCLA Hematology & Oncology Clinic; University of Virginia; Cancer Care Northwest; UC San Diego Moores Cancer Center; Case Western Reserve University (CWRU)–University Hospitals Case Medical Center; Georgetown University Medical Center; Highlands Oncology Group; Dana-Farber Cancer Institute; Swedish Cancer Institute; University of Kansas Cancer Center; Gynecologic Oncology Associates; San Juan Oncology

Kristeleit R, *et al. Int J Gynecol Cancer* 2022;0:1–8. doi: 10.1136/ijgc-2022-003492

Associates; Women's Cancer Care Associates, LLC; Providence Medical Research Center

Key Inclusion Criteria

Inclusion criteria included these key points: had progression on or after platinum doublet therapy, received ≤2 prior lines of treatment for recurrent or advanced disease, had measurable disease at baseline, and were anti-PD-(L)1 naive. Screening results could be based on local mismatch repair/microsatellite instability testing results using immunohistochemistry, polymerase chain reaction, or next-generation sequencing. However, patient eligibility was confirmed by mismatch repair immunohistochemistry results.

Statistical Analysis

All analyses described were conducted on the safety population, which consisted of all patients who had received any amount of dostarlimab, completed a baseline patient-reported outcome assessment, and completed at least 1 follow-up patient-reported outcome assessment. All analyses described were considered exploratory in nature, and as such, no adjustments were made for multiplicity. Baseline was defined as the last measurement taken on or prior to the first dose of dostarlimab; this date could be the same date as the first dose, if the measurement was taken before the first dose was received. For missing data, if at least half of the items from a particular scale were answered, it was assumed that the missing items had values equal to the average of those items that were present. By this method of imputation, none of the single-item measures could be imputed.

Summary statistics for the EORTC QLQ-C30 cumulative patient disposition were reported as ongoing (patients expected to complete the patient-reported outcome assessment), progressed, died, or other. The completion rate for each domain was calculated and dependent on the number of patients ongoing at that time point.

Summary statistics for each of the 15 domains in the EORTC QLQ-C30 were reported by visit. The functional scales, symptom items, and single-item measures all ranged in score from 0 to 100. The scores and changes in scores from baseline for each domain were summarized by the number of patients with values, mean, standard deviation, median, minimum, maximum, first and third quartiles, and 95% confidence interval. The distribution of the change in response from baseline at each visit was reported for symptom scale items and six single response items. The response categories were as follows: improved, defined as a 1-category decrease in response score; stable, defined as no change in response score; worsening 1, defined as a 1-category increase in response score; worsening 2, defined as a 2-category increase in response score; or worsening 3, defined as a 3-category increase in response score. All statistical analyses were conducted using Statistical Analysis System version 9.4 or higher (Cary, North Carolina).

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Supplemental Table 1 Cumulative patient disposition and completion of EORTC QLQ-C30

	Baseline	C2D1	C3D1	C4D1	C5D1	C6D1	C7D1
Patient disposition, N	88	88	88	88	88	88	88
Ongoing[a], n (%)	88 (100)	85 (96.6)	80 (90.9)	75 (85.2)	66 (75.0)	50 (56.8)	44 (50.0)
Completed forms, n (%)	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Evaluable EORTC QLQ-C30 scales, n(%)							
Global health status/QoL	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	41 (93.2)
Physical functioning	88 (100)	82 (96.5)	78 (97.5)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Role functioning	88 (100)	81 (95.3)	78 (97.5)	75 (100)	65 (98.5)	48 (96.0)	41 (93.2)
Emotional functioning	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	41 (93.2)
Cognitive functioning	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	41 (93.2)
Social functioning	88 (100)	81 (95.3)	79 (98.8)	74 (98.7)	64 (97.0)	48 (96.0)	41 (93.2)
Fatigue	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Nausea and vomiting	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Pain	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Dyspnea	87 (98.9)	81 (95.3)	79 (98.8)	74 (98.7)	64 (97.0)	49 (98.0)	42 (95.5)
Insomnia	88 (100)	81 (95.3)	79 (98.8)	73 (97.3)	65 (98.5)	48 (96.0)	41 (93.2)
Appetite loss	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	49 (98.0)	42 (95.5)
Constipation	88 (100)	82 (96.5)	79 (98.8)	75 (100)	65 (98.5)	48 (96.0)	41 (93.2)
Diarrhea	88 (100)	81 (95.3)	78 (97.5)	74 (98.7)	64 (97.0)	49 (98.0)	41 (93.2)
Financial difficulties	88 (100)	82 (96.5)	79 (98.8)	74 (98.7)	62 (93.9)	48 (96.0)	40 (90.9)

[a]Ongoing: Patients ongoing in the trial; number of PRO questionnaire forms expected to be completed by patients. The date of treatment discontinuation is used to determine the last visit at which a patient is still expected to complete the PRO questionnaire form during the study period.

C, cycle; D, day; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30; PRO, patient-reported outcome; QoL, quality of life.

Single-Item Measurement Responses

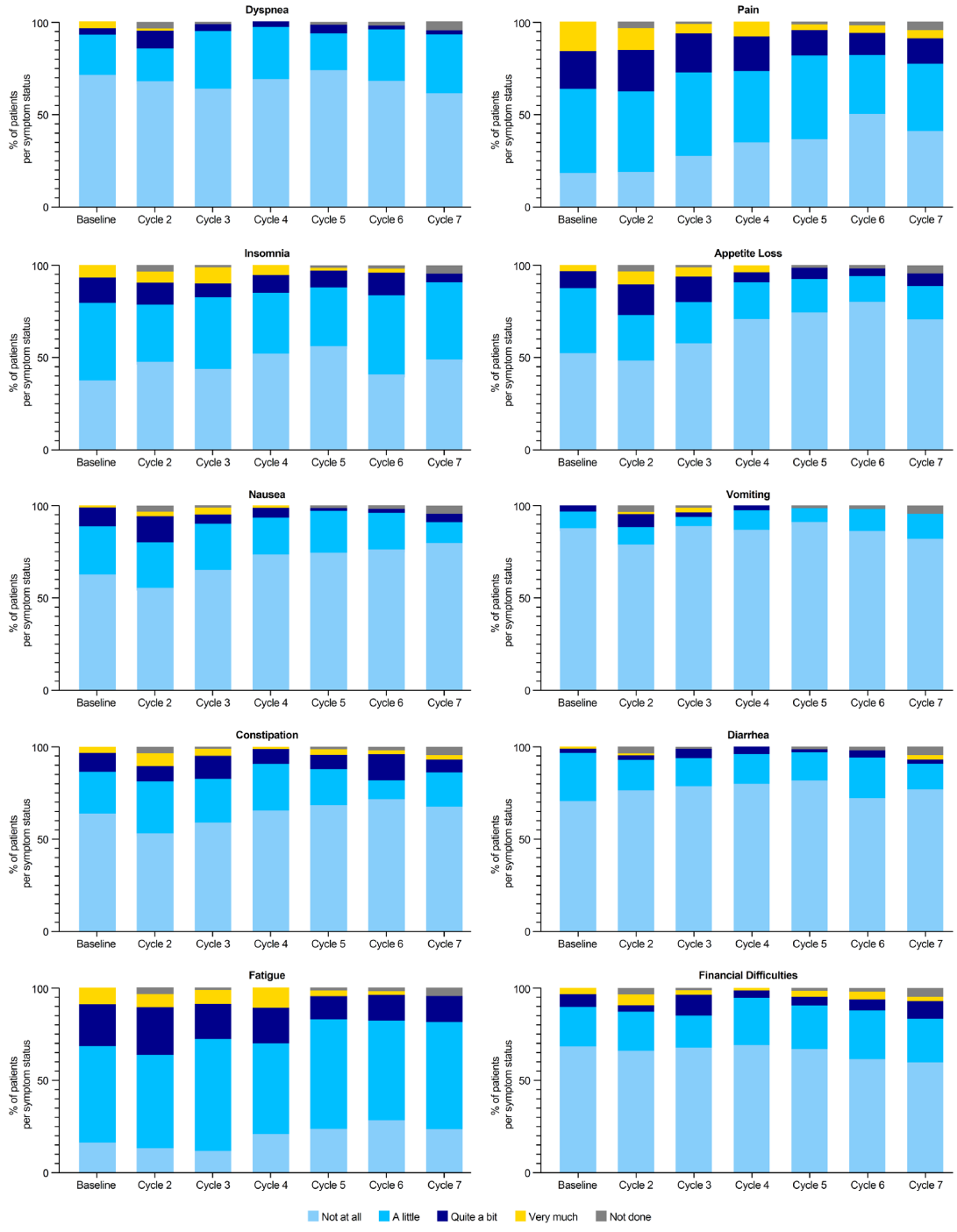
On the EORTC QLQ-C30, the pain single-item response consists of 1 single-item response question, “Have you had pain?” From baseline (63.6%) through cycle 7 (77.3%), most patients reported “a little” or “not at all” (Online Supplemental Figure 1).

Nausea and vomiting consist of 2 single-item response questions, “Have you felt nauseated?” and “Have you vomited?” From baseline through cycle 7, most patients reported “a little” (11.4–26.1%) or “not at all” (55.3–79.5%) to nausea and “a little” (5.0–13.6%) or “not at all” (78.8–90.9%) to vomiting while on dostarlimab (Online Supplemental Figure 1).

Fatigue consists of 1 single-item response question, “Were you tired?” Most patients reported “a little” (52.3%), “quite a bit” (22.7%), or “very much” (9.1%) to fatigue at baseline, but from cycle 3 to 7, most patients reported “a little” (49.3–60.8%) or “not at all” (11.4–28.0%), indicating an improvement in the change from baseline (Online Supplemental Figure 1).

On the EORTC QLQ-C30, the single-item measurement responses consist of 1 single-item response question for each measurement. For all single-item measurement responses (insomnia, appetite loss, constipation, financial difficulties, dyspnea, and diarrhea) from baseline (79.5%, 87.5%, 86.4%, 89.8%, 93.1%, 96.6%) through cycle 7 (90.7%, 88.6%, 86.0%, 83.3%, 93.2%, 90.7%), most patients reported “a little” or “not at all,” respectively (Online Supplemental Figure 1).

Supplemental Figure 1 EORTC QLQ-C30 Single-item response categories

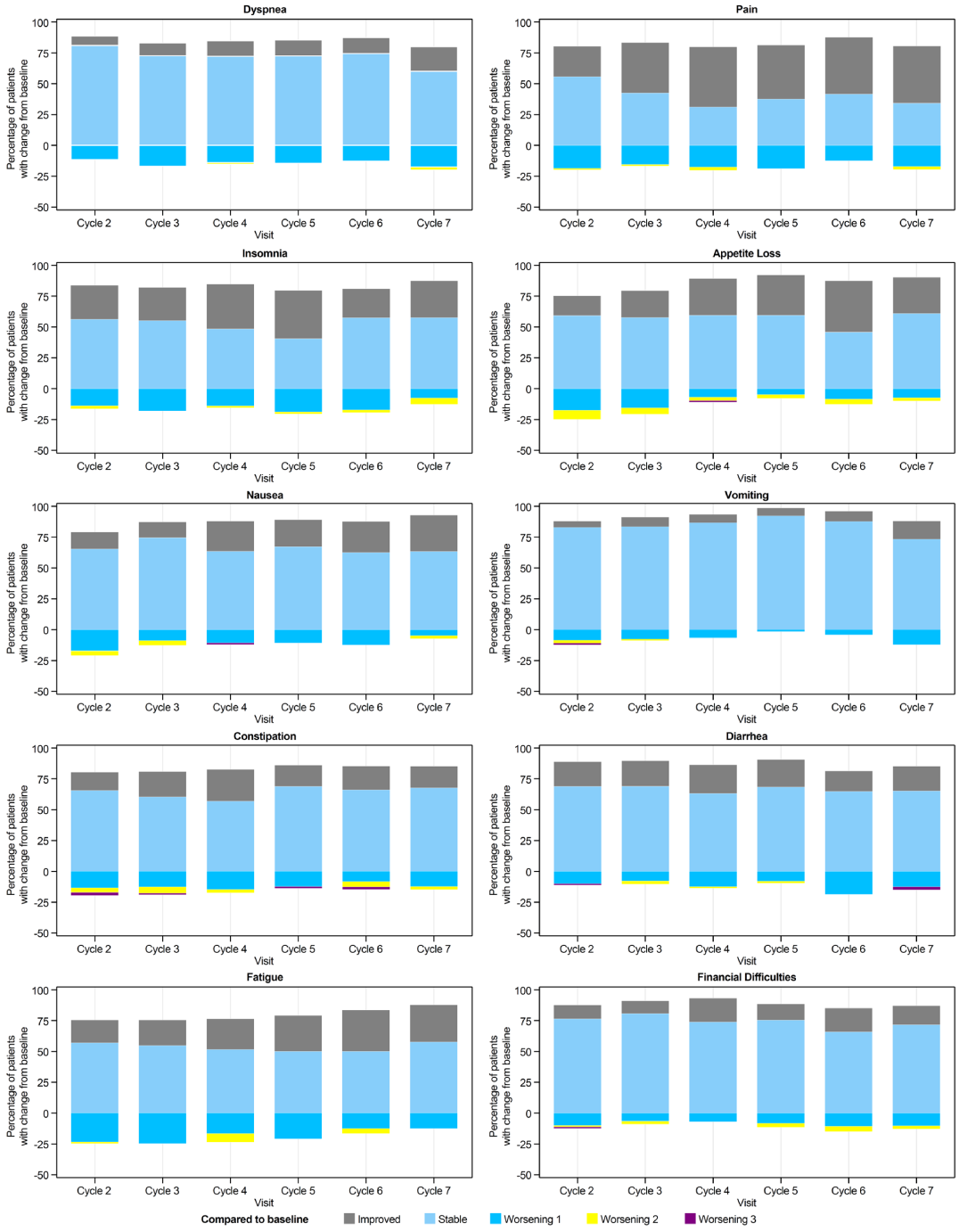


Abbreviations: EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30.

Categorical Change in Response

In addition to summary statistics, the categorical change in response from baseline was examined for symptom scale and single response items. Response categories were improved, stable, and worsening by 1, 2, or 3 categories. Across all symptom scale and single response items, most patients categorically remained stable when compared to baseline (low of 31.1% [pain, cycle 4] and high of 92.2% [vomiting, cycle 5]; Online Supplemental Figure 2). When compared to baseline, 4.9% to 48.6% (vomiting, cycle 2, and pain, cycle 4) of patients demonstrated improvement. The percentage of patients who remained stable or improved across all categories never fell below 75.3% (appetite loss, cycle 2 and fatigue, cycles 2 and 3). Worsening by 1 category was experienced by 1.6% to 24.7% (vomiting, cycle 5, and fatigue, cycle 3) of patients. Few patients experienced a 2- or 3-category worsening (high of 7.4% [appetite loss, cycle 2]). Very few patients experienced 3-category worsening with a high of 2.5% in constipation and diarrhea (cycles 2 and 7, respectively). Gastrointestinal AEs demonstrated a worsening by 2 or 3 categories most often in this cohort of patients with EC.

Supplemental Figure 2 EORTC QLQ-C30 Categorical change in response compared to baseline for single-item scores



EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30.