original reports

MILO/ENGOT-ov11: Binimetinib Versus Physician's Choice Chemotherapy in Recurrent or Persistent Low-Grade Serous Carcinomas of the Ovary, Fallopian Tube, or Primary Peritoneum

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abstract

PURPOSE Low-grade serous ovarian carcinomas (LGSOCs) have historically low chemotherapy responses. Alterations affecting the MAPK pathway, most commonly KRAS/BRAF, are present in 30%-60% of LGSOCs. The purpose of this study was to evaluate binimetinib, a potent MEK1/2 inhibitor with demonstrated activity across multiple cancers, in LGSOC.

METHODS This was a 2:1 randomized study of binimetinib (45 mg twice daily) versus physician's choice chemotherapy (PCC). Eligible patients had recurrent measurable LGSOC after ≥ 1 prior platinum-based chemotherapy but ≤ 3 prior chemotherapy lines. The primary end point was progression-free survival (PFS) by blinded independent central review (BICR); additional assessments included overall survival (OS), overall response rate (ORR), duration of response (DOR), clinical-benefit rate, biomarkers, and safety.

RESULTS A total of 303 patients were randomly assigned to an arm of the study at the time of interim analysis (January 20, 2016). Median PFS by BICR was 9.1 months (95% CI, 7.3 to 11.3) for binimetinib and 10.6 months (95% CI, 9.2 to 14.5) for PCC (hazard ratio,1.21; 95%CI, 0.79 to 1.86), resulting in early study closure according to a prespecified futility boundary after 341 patients had enrolled. Secondary efficacy end points were similar in the two groups: ORR 16% (complete response [CR]/partial responses[PRs], 32) versus 13% (CR/PRs, 13); median DOR, 8.1 months (range, 0.03 to ≥ 12.0 months) versus 6.7 months (0.03 to ≥ 9.7 months); and median OS, 25.3 versus 20.8 months for binimetinib and PCC, respectively. Safety results were consistent with the known safety profile of binimetinib; the most common grade ≥ 3 event was increased blood creatine kinase level (26%). Post hoc analysis suggests a possible association between *KRAS* mutation and response to binimetinib. Results from an updated analysis (n = 341; January 2019) were consistent.

CONCLUSION Although the MEK Inhibitor in Low-Grade Serous Ovarian Cancer Study did not meet its primary end point, binimetinib showed activity in LGSOC across the efficacy end points evaluated. A higher response to chemotherapy than expected was observed and *KRAS* mutation might predict response to binimetinib.

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ASSOCIATED CONTENT

Appendix

Data Supplement

Protocol

Author affiliations and support information (if applicable) appear at the end of this article.

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INTRODUCTION

Serous carcinoma accounts for approximately 70%-80% of epithelial ovarian, tubal, and peritoneal cancers.[1] Low-grade serous ovarian carcinoma (LGSOC) is a unique tumor that is distinguished from high-grade serous ovarian cancer not only by immunohistochemical profile but also by molecular characteristics, epidemiologic features and clinical behavior.[2]

Aberrant signaling through the RAS/RAF/MEK/ERK pathway is a characteristic feature of many cancers, including LGSOC, with, 5%-16% and 16%-47% of LGSOCs having alterations in BRAF and RAS, respectively.[3-7]

Binimetinib is an oral, potent, selective, allosteric, small-molecule inhibitor of MEK1/2 and is approved in multiple countries in combination with encorafenib for the treatment of patients with unresectable or metastatic *BRAF* V600E or V600K mutation-positive melanoma.[8,9] Inhibiting both basal and induced levels of ERK phosphorylation in numerous *BRAF*-mutated cancer cell

CONTEXT

Key Objective

The objective of the MEK Inhibitor in Low-Grade Serous Ovarian Cancer (MILO)/ENGOT-ov11 study was to evaluate the MEK1/2 inhibitor binimetinib in patients with low-grade serous ovarian carcinomas (LGSOCs).

Knowledge Generated

This study did not meet its primary end point; however, binimetinib showed activity in LGSOC across the efficacy end points evaluated. Chemotherapy responses were higher than predicted. The safety results observed in this study are generally consistent with the known safety profile of binimetinib and with MEK inhibitor class effects.

Relevance

Currently, treatment options are limited for patients with LGSOC, and few offer objective decreases in disease burden or tumor-progression delays. Although this trial did not meet its primary end point, binimetinib did display a clinically meaningful progression-free survival and overall response rate and, therefore, should be considered a viable treatment option in this setting. Forthcoming biomarker analysis may ultimately identify a subset of patients who selectively benefit from binimetinib.

lines (half maximal inhibitory concentration [IC_{50}] values as low as 5 nM), binimetinib has nanomolar activity against purified MEK enzyme (IC_{50}, 12 nM). Binimetinib has also demonstrated a decrease in pERK when tested in multiple cell lines, regardless of their mutational status and in vitro sensitivity.[10] A prior single-arm, phase II study of the MEK inhibitor selumetinib showed promising activity in recurrent LGSOC.[11]

This phase III study was designed to evaluate the efficacy and safety of binimetinib in recurrent or persistent LGSOC. Patients were not selected on the basis of molecular profile; however, archival tumor tissue was collected at the time of enrollment for retrospective mutational analysis. Blinded independent central radiology review (BICR) was used to control for potential investigator variance in assessing response.

PATIENTS AND METHODS

Patients

Patients were > 18 years of age with a diagnosis of LGSOC, fallopian tube or primary peritoneum, confirmed histologically and verified by central pathology review. Archival tissue was also collected for biomarker testing using the FoundationOne Panel (Foundation Medicine, Cambridge, MA). Eligible patients had measurable recurrent or persistent disease (as defined by RECIST V1.1, per BICR) that had progressed (defined as radiologic and/or clinical progression; an increase in CA-125 alone was not sufficient) on or after last therapy, and was not amenable to potentially curative intent surgery, as determined by the investigator. Patients were required to have received ≥ 1 prior platinum-based chemotherapy regimen but ≤ 3 prior chemotherapy regimens in total, with no limit to the number of lines of prior hormonal therapy. Patients had an Eastern Cooperative Oncology Group performance status of 0 or 1. Patients were excluded if they had previous treatment with an MEK or BRAF inhibitor. Additional details regarding inclusion and exclusion criteria are provided in the Data Supplement.

The study was approved by the institutional review board for each site. All clinical work was conducted in compliance with current Good Clinical Practices as referenced in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. All patients enrolled in the study provided written, informed consent prior to their participation.

Study Design and Treatments

The MEK Inhibitor in Low-Grade Serous Ovarian Cancer (MILO)/ARRAY-162-311/ENGOT-ov11 study was a multinational, randomized, two-arm, open-label, phase III study conducted at 102 sites in 20 countries (ClinicalTrials.gov identifier: NCT01849874; Appendix Table A1, online only). MILO was conducted in collaboration with European Network of Gynecologic Oncological Trial groups (ENGOT) according to the ENGOT Model C.[12] Patients were stratified by their last platinum-free interval (≤ *v* > 182 days) and number of prior systemic regimens (1 to 2 *v* 3) and then randomly assigned 2:1 to receive binimetinib or physician's choice chemotherapy (PCC; pegylated liposomal doxorubicin [PLD], paclitaxel, or topotecan). Patients randomly assigned to binimetinib received 45 mg orally twice daily with water irrespective of food, continuously, starting on day 1. Patients randomly assigned to PCC received one of the following: PLD (40 mg/m^2 intravenously [IV] on day 1 of every 28-day cycle), paclitaxel (80 mg/m^2 IV on days 1, 8, and 15 of every 28-day cycle), or topotecan (1.25 mg/m^2 IV on days 1-5 of every 21-day cycle). Treatment continued until one of the following: locally determined progressive disease (PD) unacceptable toxicity, or inability to continue on protocol-directed therapy (additional information is

provided in the Data Supplement). Patients randomly assigned to PCC who developed PD (by local and BICR assessment) were allowed to crossover to treatment with binimetinib provided they met the crossover eligibility requirements (Data Supplement).

Assessments

The primary end point was BICR progression-free survival (PFS). Secondary end points included overall survival (OS), overall response rate (ORR; RECIST v1.1), duration of response (DOR), disease control rate (best response of

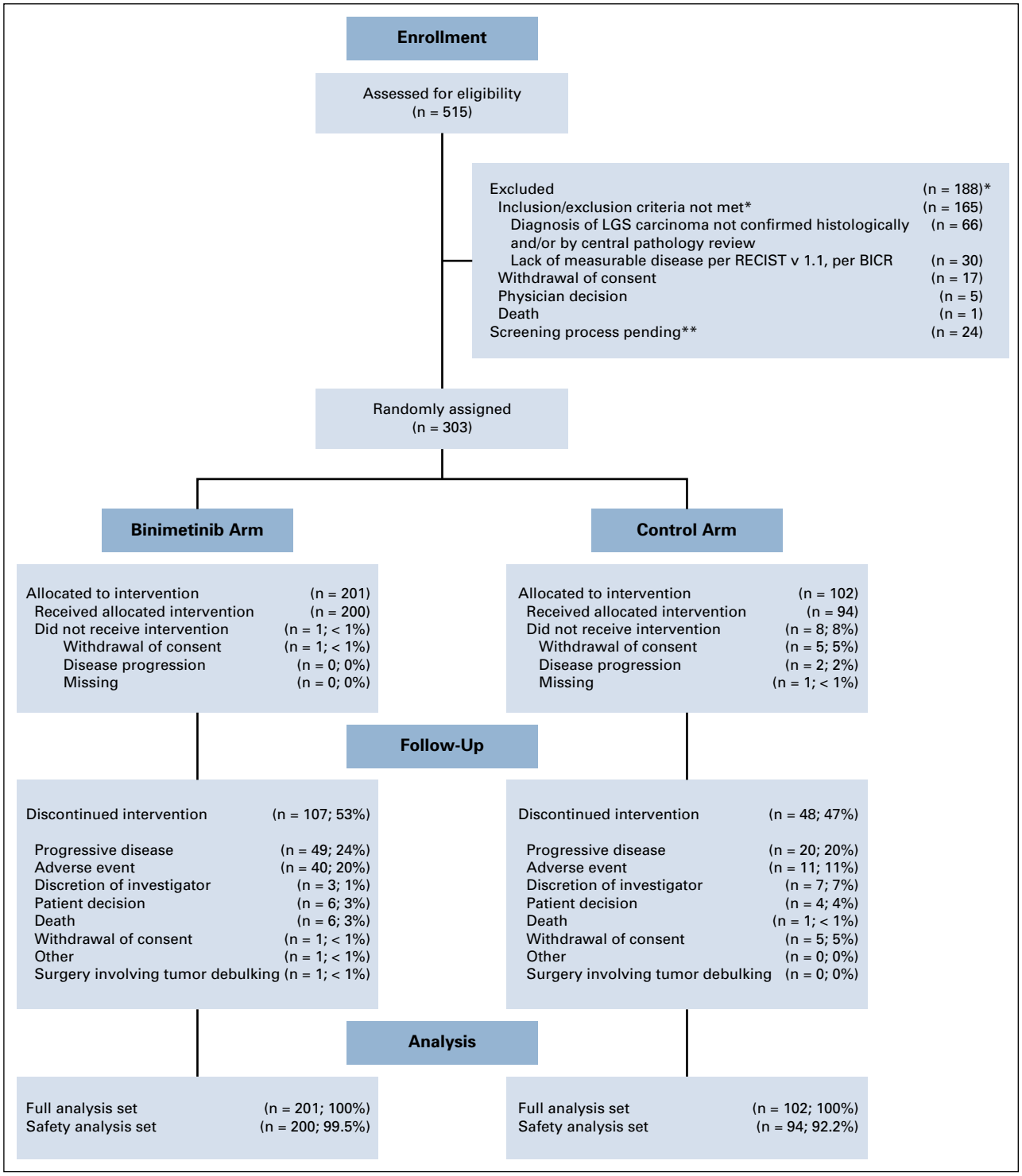

FIG 1. CONSORT diagram (data cutoff date: January 20, 2016). BICR, blinded independent central review; LGS, low-grade serous. (*) Patients may be counted as not meeting > 1 criterion; most common reasons provided. (**) These patients had signed ICF prior to the data cutoff date but the outcome of their screening process was still pending as of the cutoff date.

complete response [CR] or partial response [PR], or stable disease [SD] documented ≥ week 24) and safety.

Tumors were assessed every 8 weeks for the first 72 weeks, then every 12 weeks until PD per BICR, irrespective of the days of study- drug administration. Safety was evaluated by ongoing monitoring, including ophthalmic examinations, dermatologic examinations, electrocardiograms, and cardiac scans of ejection fraction.

Statistical Methods

For efficacy, all randomly assigned patients were included in the analyses. For safety, all patients who received binimetinib or PCC were included. PFS was defined as the date of randomization to the date of first documented BICR PD or death due to any cause, whichever occurred first. If a patient had not experienced an event at the time of the analysis cutoff or at the start of any new therapy, PFS was censored at the date of last adequate tumor assessment. PFS and OS were summarized by treatment arm using the Kaplan-Meier method with 95% CIs for medians. The primary end point was compared between treatment arms using a stratified log-rank test, and a hazard ratio [HR] from the stratified Cox model was used to summarize the treatment effect estimate.

ORR was assessed and compared between arms using the Fisher exact test. Median DOR with 95% CIs was provided, with minimum, maximum, and the number still in response (censored) at the time of data cutoff.

A total of 195 events (PD or death) provided 90% power for testing the null hypothesis of no difference in PFS distribution functions between the two treatment arms assuming a true HR of 0.60 using a stratified log-rank test, a 1-tailed α of 0.025, and a 2:1 binimetinib arm to control arm randomization ratio. The HR required to achieve the final critical value was approximately 0.74. Historical evidence suggests that the median PFS in recurrent LGSOC is approximately 7 months.[6,7] For exponential PFS, a HR of 0.60 translates to a median PFS of approximately 11.7 months in the binimetinib arm. A total of approximately 360 patients were planned. An interim analysis for early stopping for futility was planned at 40% information fraction (ie, n = 78 total progression events per BICR or deaths). The futility boundary was from the unified family of group sequential test designs with parameter $P = 0.5$.[13] At 40% information fraction, this corresponds to an approximate boundary of 0.90 on the HR scale. A data cutoff date was set by the sponsor in advance of the occurrence of the 78th event. FoundationOne Panel genes that were prevalent in at least 5% of sequenced patients were tested for association with binary response (CR or PR *v* SD or PD) using two-sided Fisher exact tests.

TABLE 1. Baseline Demographics and Disease Characteristics

Characteristic	Binimetinib (n = 201)	PCC (n = 102)
Age, median (range), years	51.6 (23-79)	50.2 (22-78)
Race		
White	184 (92)	93 (91)
Black or African American	2 (< 1)	3 (3)
Asian	6 (3)	2 (2)
American Indian/Alaskan Native	0	1 (< 1)
Other	0	1 (< 1)
Missing	9 (4)	2 (2)
Region		
United States/Canada	84 (42)	45 (44)
Australia	6 (3)	6 (6)
Europe	111 (55)	51 (50)
ECOG PS 0	124 (62)	66 (65)
No. of prior systemic regimens		
Median (range)	2 (1-8)	2 (1-6)
1	86 (43)	42 (41)
2	60 (30)	30 (29)
3	34 (17)	22 (22)
≥ 4	21 (10)	8 (8)
Prior treatment		
Radiation	15 (7)	7 (7)
Surgery	201 (100)	102 (100)
Hormonal therapy	69 (34)	34 (33)
Response to prior platinum-based therapy	83 (46)	59 (58)
Response to prior paclitaxel	61 (30)	43 (43)
PCC[a]		
Pegylated liposomal doxorubicin	—	64 (68)
Paclitaxel	—	25 (27)
Topotecan	—	5 (5)

NOTE. Data are reported as No. (%) unless otherwise indicated.

Abbreviations: —, characteristic is not relevant for the binimetinib arm; ECOG PS, Eastern Cooperative Oncology Group performance status; PCC, physician's choice chemotherapy.

[a]Data are from the Safety Set. All other data from the Full Analysis Set

RESULTS

Patient Characteristics and Drug Exposure

Patients were enrolled from June 28, 2013, to April 1, 2016. Per recommendation of the data monitoring committee, enrollment was discontinued after the planned interim analysis showed the HR for PFS crossed the predefined futility boundary. The interim analysis was conducted with 303 patients and then, at the time of the decision to discontinue enrollment for the study, 341 patients. Results presented here include an assessment of end points during the randomized period, up to the data cutoff date for the interim analysis of January 20, 2016, for a total of 303 patients (n = 201 patients receiving binimetinib; n = 102 receiving PCC) in the full analysis set and 294 patients (n = 200 receiving binimetinib; n = 94

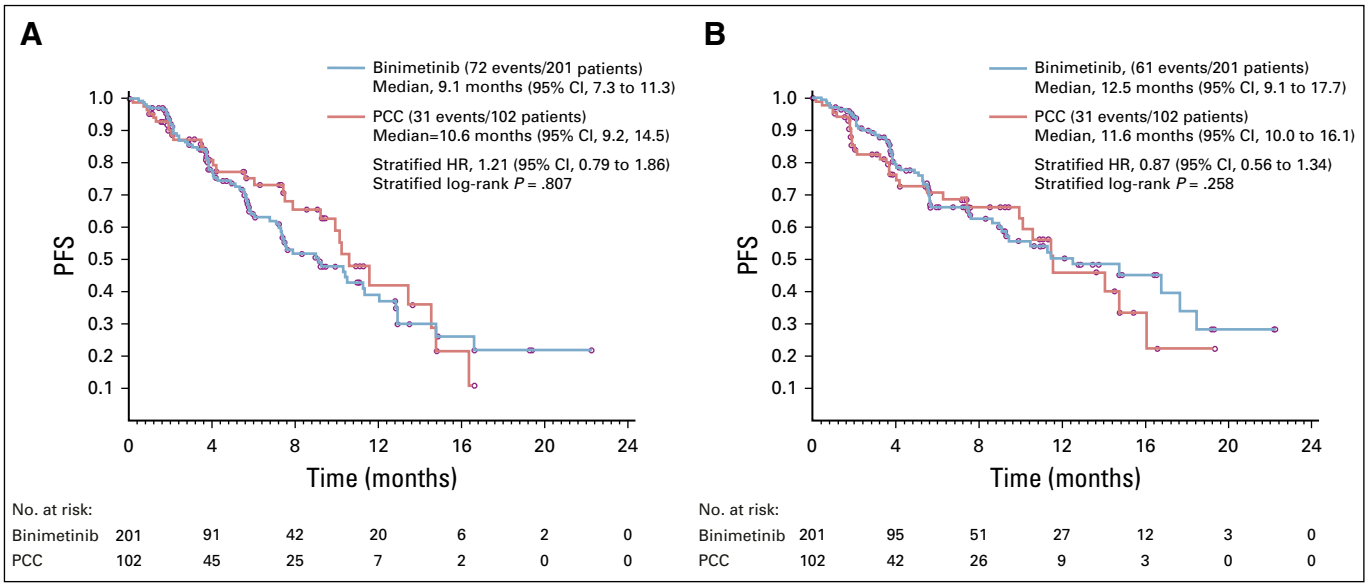

FIG 2. Kaplan-Meier plot of progression-free survival per (A) blinded independent central review and (B) local assessment. HR, hazard ratio; PCC, physician's choice chemotherapy; PFS, progression free survival.

receiving PCC) in the safety population (Fig 1). At the time of data cutoff, (January 20, 2016), 107 patients (53%) and 48 patients (47%) had discontinued treatment of binimetinib and PCC, respectively. The most common reasons for discontinuing initial treatment were disease progression (binimetinib, 24%; PCC, 20%) and adverse events (binimetinib, 20%; PCC, 11%; Fig 1). Patient baseline demographics and disease characteristics were generally well balanced between the two groups (Table 1).

The median duration of exposure to binimetinib was 4.1 months (range, 0-24 months) and the median relative dose intensity was 67.6% (range, 6%-100%). The median duration of exposure to any of the PCC was 4.1 months (range, 0-18 months). Patients in the PCC group received PLD (n = 64 patients; 68%); paclitaxel (n = 25 patients; 27%), or topotecan (n = 5 patients; 5%). The median (range) relative dose intensity was 71.3% (40%-100%) for topotecan, 95.9% (0%-116%) for PLD, and 89.4% (33%-102%) for paclitaxel.

Efficacy

The primary end point of PFS by BICR is shown in Figure 2. The median PFS was 9.1 months (95% CI, 7.3 to 11.3) in the binimetinib group and 10.6 months (95% CI, 9.2 to 14.5) in the PCC group. The HR from the stratified Cox model was 1.21 (95% CI, 0.79 to 1.86). Based on a point-estimate futility boundary of HR > 0.84 for the 103 events observed in the interim analysis, the futility boundary was crossed, indicating a low probability of reaching statistical significance in favor of binimetinib with continued follow-up. In the local investigator assessment, patients in the binimetinib arm had a median PFS of 12.5 months (95% CI, 9.1 to 17.7) compared with 11.6 months (95% CI, 10.0 to 16.1) in the PCC group. The stratified HR was 0.87 (95% CI, 0.56 to 1.34).

The OS results are depicted in the Data Supplement. They were similar between groups, with 164 patients (82%) in the binimetinib group alive at the time of data cutoff for interim analysis compared with 82 patients (80%) in the PCC group. The median OS was 25.33 months (95% CI, 18.46 to not reached [NR]) in the binimetinib group and 20.83 months (95% CI, 17.45 to NR) in the PCC group. The HR from the stratified Cox model was 0.85 (95% CI, 0.49 to 1.48).

The response analysis is shown in Table 2. The ORR by BICR was 16% in the binimetinib group and 13% in the PCC group. The median DOR in the binimetinib group was 8.05 months (95% CI, 5.55 to NR) compared with 6.67 months (95% CI, 3.71 to NR) in the PCC group; 23 patients in the binimetinib group and 8 patients in the PCC group had responses ongoing at the data cutoff date. For the response assessment by local investigator, the ORR was 18% in the binimetinib group and 13% in the PCC group. Median DOR was 15.84 months (95% CI, 10.41 to NR) in the binimetinib group and 9.89 months (95% CI, 6.41 to 9.89) in the PCC group. A waterfall plot displaying percent change in sum of longest diameters per BICR is displayed in the Data Supplement.

At the time enrollment to the study ended in April 2016, patients being treated with binimetinib or PCC were notified of the interim results, but if desired, they were allowed to continue receiving treatment until treatment discontinuation criteria were met. Crossover was stopped at that time. An updated analysis was conducted when the remaining data were collected after the discontinuation of enrollment, with a data cutoff of January 2019 (n = 341). In this

TABLE 2. Summary of Best Overall Response and Duration of Response

	Confirmed Best Overall Response[a]	
Type of Review	**Binimetinib (n = 198)**	**PCC (n = 101)**
BICR		
Best overall response		
CR+PR (ORR)	32 (16)	13 (13)[b]
CR	1 (1)	2 (2)
PR	31 (16)	11 (11)
SD	119 (60)	61 (60)
PD	8 (4)	8 (8)
Non-nodal	1 (1)	0
Not done	0	0
Not evaluable for response	19 (10)	11 (11)
Unknown	19 (10)	8 (8)
ORR difference (95% CI)	3.29 (−8.78 to 15.26)	—
Duration of response, months		
Ongoing response	23 (12)	8 (8)
Median (95% CI)	8.05 (5.55 to NR)	6.67 (3.71 to NR)
Range	0.03-11.99	0.03-9.69
Local assessment		
Best overall response		
CR+PR (ORR)	35 (18)	13 (13)
CR	3 (2)	1 (1)
PR	32 (16)	12 (12)
SD	122 (62)	57 (56)
PD	6 (3)	10 (10)
Not evaluable for response	2 (1)	0
Not done	11 (6)	9 (9)
Unknown	22 (11)	12 (12)
ORR difference (95% CI)	4.81 (−7.28 to 16.75)	—
Duration of response, months		
Ongoing response, No. (%)	29 (15)	9 (9)
Median (95% CI)	15.84 (10.41 to NR)	9.89 (6.41 to 9.89)
Range	0.03-18.73	0.03-9.89

NOTE. Data are reported as No. (%) unless otherwise indicated.

Abbreviations: —, no value; BICR, blinded independent central review; CR, complete response; NR, not reached; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.

[a]Confirmed responses per RECIST 1.1.

[b]The objective response rates in the subgroups of patients who received topotecan, liposomal doxorubicin, and paclitaxel within the PCC arm were 0% (0/9), 14% (9/66), and 15% (4/26), respectively.

analysis, median PFS by BICR was 10.4 months (95% CI, 7.5 to 12.9) in the binimetinib group and 11.5 months (95% CI, 9.9 to 14.8) in the PCC group (HR, 1.15;95% CI, 0.76 to 1.74; Data Supplement). Median OS was 34.6 months (95% CI, 28.0 to NR) and 34.2 months (95% CI, 21.6 to NR) for the binimetinib and PCC groups, respectively (HR, 0.93; 95% CI, 0.65 to 1.33; Data Supplement). Updated ORR by local investigator assessment was 24% in both groups (Data Supplement). It is important to note the median OS estimates in both arms increased at the follow-up analysis, possibly as a result of the instability of the median estimates at the time of the initial analysis, when the potential follow-up was substantially (3 years) shorter.

Molecular testing was performed on all consenting patients with adequate archival tissue. At the time of the January

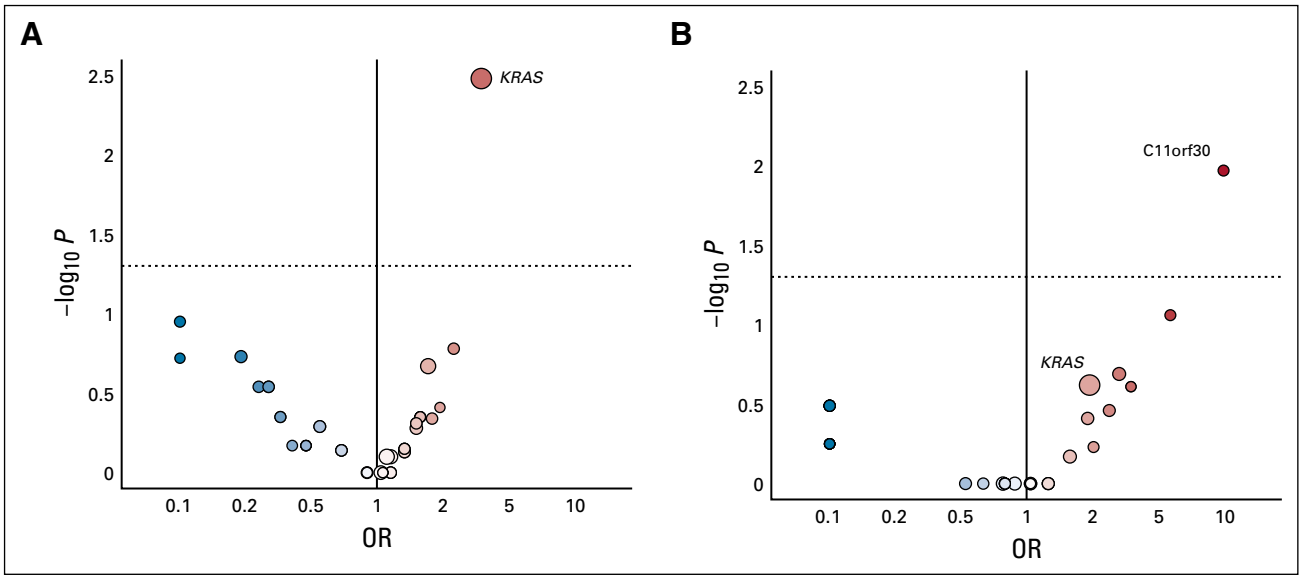

FIG 3. (A) Binimetinib treatment group: univariate analysis of molecular alterations and response to therapy. (B) Physician's choice chemotherapy group: univariate analysis of molecular alterations and response to therapy. OR, odds ratio.

2019 data cutoff, 215 patients had tumor tests available. There were 47 mutations detected in at least 5% of patients, most commonly *KRAS*, which was found in 33% of patients. The frequency of *KRAS* mutation was evenly distributed between the two groups and was found in 46 patients (32%) treated with binimetinib and 24 patients (34%) treated with PCC. Unbiased univariate analyses evaluating best ORR to therapy as a binary response showed *KRAS* mutation was significantly associated with response to treatment with binimetinib (odds ratio [OR], 3.4; 95% CI, 1.53 to 7.66; unadjusted $P = .003$; Fig 3A) but not PCC (OR, 2.13; 95% CI, 0.67 to 6.81; $P = .2$; Fig 3B). *KRAS* mutation was also associated with prolonged PFS in patients treated with binimetinib (median PFS: *KRAS* mutant: 17.7 months [95% CI, 12 to NR]; KRAS wild-type (WT): 10.8 months [95% CI, 5.5 to 16.7]; $P = .006$), but not PCC (median PFS: *KRAS* mutant: 14.6 months [95% CI, 9.4 to NA]; *KRAS* WT: 11.5 months [95% CI, 5.7 to 26.6]; $P = .502$).Among those patients treated with binimetinib for whom updated local RECIST 1.1 response data and molecular data were available (n = 133), *KRAS* mutation status was significantly associated with local best response ($P = .004$); 44% of patients with *KRAS* mutation versus 19% of patients with *KRAS* WT had CR or PR (Table 3). Mutations identified by Foundation Medicine FoundationOne Panel in ≥ 1 tumor sample are listed in the Data Supplement.

TABLE 3. Best Response by Local RECIST 1.1 Radiology Read in those patients treated with binimetinib

Local Best Response	*KRAS* Mutant (n = 43), No. (%)	*KRAS* Wild-Type (n = 90), No. (%)	*P*
			.004
CR/PR	19 (44)	17 (19)	
SD/PD	24 (56)	73 (81)	

Abbreviations: CR, complete response; PD, progressive disease; PR, partial response; SD, stable disease.

Safety

Grade ≥ 3 adverse events were reported in 76% and 44% of patients for binimetinib and PCC, respectively (Table 4). Adverse events that led to permanent discontinuation of study drug were reported by 62 patients (31%) for binimetinib and 16 patients (17%) in the PCC group. Adverse events leading to binimetinib discontinuation in ≥ 5 patients were decreased ejection fraction (n = 8 patients; 4%), vomiting (n = 6 patients; 3%), intestinal obstruction and retinal vein occlusion (n = 5 patients; 2% each). The adverse event leading to discontinuation of PCC in ≥ 5 patients was palmar-plantar erythrodysesthesia syndrome (n = 5 patients; 5%). A total of six patients (3%) in the binimetinib group experienced a retinal vein occlusion event, all of which resulted in treatment discontinuation. All events were considered resolved or resolving, two with sequelae. No permanent blindness or permanent loss of vision was observed.

DISCUSSION

Binimetinib did not demonstrate a significant difference in the primary end point of PFS versus PCC in patients with recurrent or persistent LGSOC. In addition, the proportion of patients achieving an objective response and the median DOR appeared similar between arms. Of note, the responses to chemotherapy in this study were greater than anticipated on the basis of previously reported, single-institution retrospective case series.

Although the MILO/ENGOT-ov11 trial did not meet its primary end point, binimetinib did display a clinically

TABLE 4. Adverse Events Reported in > 20% of Treated Patients in Either Arm

	Binimetinib (n = 200)		PCC (n = 94)	
Event[a]	Any Grade[b]	≥ Grade 3	Any Grade	≥ Grade 3
Total no. of patients with any adverse event[c]	194 (97)	151 (76)	92 (98)	41 (44)
Diarrhea	141 (70)	13 (6)	30 (32)	0
Nausea	110 (55)	9 (4)	43 (46)	
Vomiting	107 (54)	20 (10)	23 (24)	2 (2)
Blood creatinine phosphokinase increased	99 (50)	52 (26)	1 (1)	0
Fatigue	97 (48)	7 (4)	43 (46)	4 (4)
Edema peripheral	93 (46)	1 (< 1)	8 (9)	0
Dermatitis acneiform	92 (46)	12 (6)	4 (4)	0
Abdominal pain	63 (32)	9 (4)	21 (22)	0
Ejection fraction decreased	57 (28)	7 (4)	10 (11)	1 (1)
Dry skin	56 (28)	3 (2)	14 (15)	0
Constipation	52 (26)	3 (2)	25 (27)	0
Alopecia	50 (25)	0	25 (27)	0
Stomatitis	46 (23)	2 (≤ 1)	27 (29)	4 (4)
Decreased appetite	45 (22)	2 (≤ 1)	17 (18)	2 (2)
Rash, maculopapular	45 (22)	2 (≤ 1)	16 (17)	2 (2)
Palmar-plantar erythrodysesthesia syndrome	9 (4)	0	31 (33)	5 (5)

NOTE. Data are reported as No. (%) unless otherwise indicated.

Abbreviation: PCC, physician's choice chemotherapy.

[a]Any single patient may have experienced adverse events under multiple terms (ie, not mutually exclusive).

[b]Grade is based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.

[c]Reported using standard MEDRA dictionary coding.

meaningful PFS and ORR and, therefore, should be considered a viable treatment option in this setting. The median OS for patients with advanced LGSOC approaches 10 years, with patients often experiencing significant morbidity from their disease during that time.[2] Currently, treatment options are limited for patients with this disease and few offer objective decreases in disease burden or delays in tumor progression. Recent results from another phase II/III trial in 260 patients with recurrent LGSOC showed trametinib was associated with significantly improved PFS (median, 13.0 *v* 7.2 months; HR, 0.48; 95% CI, 0.36 to 0.64; $P < .0001$) and ORR (trametinib: 26.2% *v* control:6.2%; OR, 5.4; 95% CI, 2.39 to 12.21; $P < .0001$) compared with physician's choice standard of care, also indicating the potential of MEK inhibition in this patient population.[14] Of note, the control arm in that study did not appear to perform as well as in the current study, possibly because of differences in inclusion criteria. The trametinib study allowed for an unlimited number of prior chemotherapies, whereas the binimetinib study was limited to patients who had received a maximum of three prior lines of chemotherapy. Differences in study design and inclusion criteria likely selected for a more chemotherapy-resistant population in the trametinib study, explaining the similar activity of MEK inhibitors between the two studies (response rate of 24% on updated analysis of binimetinib study; 26.2% in the trametinib study) but difference in activity within the control arms. Safety results from this study show that patients treated with binimetinib had higher rates of nonserious and serious adverse events overall, as well as grade ≥ 3 adverse events compared with the PCC group, and there were more frequent dose reductions, dose interruptions, and permanent discontinuations due to adverse events experienced by patients in the binimetinib group, resulting in a lower relative dose intensity for the binimetinib group compared with any of the drugs in the PCC group. The majority of adverse events assessed as related to binimetinib were reversible with or without drug interruption. The safety profile observed in this study is consistent with the known binimetinib profile and consistent with those for the class of MEK inhibitors.[15]

There are several limitations of the study. First, the lack of suitable, validated biomarkers led to a design with an unselected patient population. Post hoc analysis suggests a possible association between *KRAS* mutation and response to binimetinib. Additional exploration is warranted to determine if patients with *KRAS* mutation may derive greater benefit from binimetinib. Although KRAS has been an elusive target across multiple cancer types, prior early-phase studies have found promising response rates to MEK inhibitors and MEK inhibitor combinations in those

patients with *KRAS*-mutant LGSOC.[16-18] This has led to considerable interest in the use of mutation status when weighing the expected adverse effects versus benefits of MEK inhibitor therapy. Adverse events in the binimetinib group led to study discontinuations and a low dose intensity. The safety events noted in this study were resolved with conservative supportive care and could potentially be mitigated in future protocols with more proactive management.

In conclusion, although this study did not meet its primary end point, binimetinib showed activity in LGSOC across the efficacy end points evaluated. Chemotherapy responses were greater than predicted. The safety results observed in this study are generally consistent with the known safety profile of binimetinib and with MEK inhibitor class effects. Forthcoming biomarker analysis may ultimately identify a subset of patients who selectively benefit from binimetinib, and additional clinical evaluation is warranted.

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CLINICAL TRIAL INFORMATION

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

Disclosures provided by the authors and data availability statement (if applicable) are available with this article at DOI https://doi.org/10.1200/JCO.20.01164.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

MILO/ENGOT-ov11: Binimetinib versus Physician's Choice Chemotherapy in Recurrent or Persistent Low-Grade Serous Carcinomas of the Ovary, Fallopian Tube, or Primary Peritoneum

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No other potential conflicts of interest were reported.

APPENDIX

TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant

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(continued on following page)

TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant (continued)

Site No.	Principal Investigator	Sub-Investigators and Other Key Personnel	Study Site
Czech Republic			
2093	David Cibula, MD, PhD, Prof	Roman Kocian, MUDr; Bohdan Kousal, MUDr	Gynecologic Oncology Center, Department of Obstetrics and Gyn, General University Hospital in Prague Apolinarska 18, Prague 120 00, Czech Republic
2133	Bohuslav Melichar, PhD, Prof	Hana Kalabova, MUDr; Hana Studentova, MUDr; Ondrej Vlacil, MUDr	Fakultni nemocnice Olomouc, Onkologicka klinika I.P. Pavlova 6, Olomouc 77520 Czech Republic
2134	Libor Sevcik, MUDr, PhD	Ondrej Simetka, Prim MUDr; Sylva Bajsova, MUDr, PhD, MBA; Jaroslav Klat, MUDr; Tomas Veiser, MUDr; Jana Dvorackova, MUDr; Ales Mladenka, MUDr, PhD MIAC; Petar Graf, MUDr; Petr Masek, CSc, MUDr	Fakultni nemocnice Ostrava Gynekologicko-porodnicka klinka 17. listopadu 1790, Ostrava-Poruba 708 52, Czech Republic
2135	Jiri Spacek, MD, PhD, IFEPAG, Associate Professor	Adam Rezae, MD; Peter Skapinee, MD; Ondrej Lulonsky, MD	Teaching Hospital Hradec Kralove Sokolska 581 Obstetrics and Gynecology Department, Hradec Kralove 50005, Czech Republic
Denmark			
2137	Mansoor Raza Mirza, MD	Aida Muhic, MD; Henrik Roed, MD; Morten Jorgensen, MD; Zaza Ujmajuridze, MD; Peter Bjerre Toft, MD; Henrik Hansen, MD; Hanne From Mathiesen, MD; Heidi Ryssel, MD; Dorthe Skov Noroxe, MD; Ea Papso Lowenstein, MD; Cecilie Hollander, MD; Katrine Hedengran, MD; Tordis Kristiansdottir, Senior Registrar, MD; Kristine Madsen, MD	Rigshospitalet Onkologisk Klinik, 5073 Blegdamsvej 9, Kobenhavn ø 2100, Denmark
2152	Bente Lund, MD	Charlotte Haslund, MD; Alan Del Carpio Carrera Barreda, MD; Kristen Baggesen, MD	Department of Oncology Aalborg University Hospital, Hobrobej 18-22 Aalborg, North Jutland 9000, Denmark
Finland			
2136	Johanna Mäenpää	Sami Saarelainen, MD; Hannu Uusitalo, MD	Tampere University Hospital Department of Obstetrics and Gynecology Teiskontie 35 Finnmedi tutkimusvastaanotto Biokatu 10, Tampere F1-33521, Finland
France			
2158	Isabelle Ray-Coquard, Dr	Pierre-Etienne Heudel, Dr; Nathalie Marques, Dr; Louis Tassy, Dr; Olivier Tredan, Dr; Jacques Fleury, Dr; Olivia Bally, Dr; Maria Chelghoum, Dr	Centre Leon Berard - Department de Cancerologia Medicale, 28 rue Laennec, Lyon Cedex 08 69373, France
2159	Anne Lesoin, Dr	Annick Chevalier-Place, Dr; Edith Vanlerenberghe, Dr; Hugues Courteville, Dr	Centre Oscar Lambret, Department de Gynecologie 3 rue F. Combemale, Lille 59000, France
2160	Alexandra Leary, Pr	Michel Paques, Pr	Institut Gustave Roussy, 114 rue Edouard Vaillant, Villejuif Cedex 94805, France
2161	Jacques Medioni, Dr	Eric Pujade-Lauraine, Pr; Antoine Angelergues, Dr; Pierre Combe, Dr; Christopher Orssaud, Dr; Michel Paques, Pr	Hopital Européen Georges Pompidou Service de Cancerologie Medicale, 20 rue Leblanc, Paris Cedex 15 75908, France
2162	Magali Provansal, Dr	Francois Devin, Dr; Frederique Rousseau, Dr; Jean-Marc Extra, Dr; Renaud Sabatier, Dr; Anthony Goncalves, Dr; Maria-Antonietta Cappiello, Dr	Institut Paoli Calmettes Department d'Oncologie Medicale, 232 Blvd, Sainte Marguerite Cedex 9, Marseille 13273, France
2163	Dominique Berton-Rigaud, Dr	Carole Gourmelon, Dr; Jean-Sebastien Frenel, Dr; Emmanuelle Bourbouloux, Dr; Mathilde Cabart, Dr; Xavier Zanlonghi, Dr; Axelle Alphandari, Dr; Helene Castanie, Dr; Emeline Meriaux, Dr	Institut de Cancerologie de l'Ouest Rene Gauducheau, Department of Oncology, Boulevard Jacques Monod, Saint-Herblain Cedex 44805, France
2164	Michel Fabbro, Dr	Veronique D'Hondt, Pr; Ernesto Lopez Martinez, Dr; Pierre Andre Duval, Dr	Institut Regional du Cancer Montpeillier, 208 rue des Apothicaires, Montpellier Cedex 534298, France
2165	Elsa Kalbacher, Dr	Theirtty N'guyen, Dr; Fernando Bazan, Dr; Aurelien Prongue, Dr	CHU Jean Minjoz Service d'Oncologie Medicale 3, boulevard Alexander Fleming, Besançon 25000, France
2167	Alain Lortholary, Dr	Jean Francois Ramee, Dr; Claire Garnier-Tixidre, Dr; Claude El Kouri, Dr; Helene Castanie, Dr; Chrystele Le Gouill-Jaijarat, Dr; Patrick LaFargue, Dr; Xavier Zanlonghi, Dr	Centre Catherine de Sienne 2 rue Eric Tabarly BP20215, Nantes 44202, France
2181	Anne-Claire Hardy-Bessard, Dr	Dominique Besson, Dr; Pierre-Luc Etienne, Dr; Arnaud George, Dr	Clinique Armoricaine de Radiologie – Service d'Oncologie, 21 rue du Vieux Seminaire, Saint-Brieuc 22015, France
Germany			
2142	Eva-Maria Grischke, Prof Dr	Eva Stauss, Dr med; Carina Kelbsch, Dr med	Universitäts-Brustzentrum Calwerstraße 7 Tüebingen, Baden-Wurttemberg 72076, Germany
2172	Ulrich Canzler, Dr med	Karin Kast, Dr med; Theresa Link, Dr med; Irmela Maria Schrettenbrunner, Dr med; Karolin Franke Helen Urban, Dr med; Naim Terai, Dr med	University Hospital Carl Gustav Carus Department of Gynecology and Obstetrics; Fetscherstraße 74, Dresden, Saxony D-01307 Germany
2173	Felix Hilpert, Dr med	Madalena Schwarz; Ortrud Stremme, Dr; Antje-Marie Hempel; Nadine Sallach; Solveig Lindeman, Dr	Universitatsklinikum Schleswig-Holstein Arnold-Heller-Straße.3 Kiel, Schleswig-Holstein 24105, Germany
2174	Phillip Harter, Dr med	Florian Heitz, Dr med; Andreas du Bois, Prof, Dr med; Beyhan Ataseven, Dr med; Jacek Grabowski, Dr med; Christian Kurzeder, Dr med; Natalia Stefanidou, Dr med; Mareike Sporkmann, Dr med; Petra Scholtzova, Dr med; Johannes Holtschmidt, Dr med; Ozgur Aydin, Dr med	Kliniken Essen Mitte Henricistr 92, Essen North Rhine-Westphalia 45136, Germany
2176	Barbara Schmalfeldt, Prof Dr med	Hannah Schmalzried, Dr med; Holger Bronger, Dr med; Anna Schneider	Klinikum rechts der Isar Ismaninger Straße 22, Munich, Bavaria 81675, Germany
2203	Jalid Sehouli, Prof Dr med	Rodoslav Chekerov, Dr med; Ioana Braicu, Dr med; Jessica Olschewski, Dr med; Uwe Pleyer, Prof, Dr med; Dominika Rachwalik	Charite – Universitaetsmedizin Berlin, Augustenburger Platz 1, Berlin 13353, Germany

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TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant (continued)

Site No.	Principal Investigator	Sub-Investigators and Other Key Personnel	Study Site
2239	Alexander Mustea, Prof, Dr	Antje Kristina Belau, Dr med; Katja Barz, Dr med; Margrit Nehmzow, Dr med; Dominique Konsgen-Mustea, Dr med; Stefanie Kruger-Rehberg Frank Tost, Prof Dr	Klinik und Poliklinik fur Frauenheilkunde und Geburtshilfe Ferdinand Sauerbruch-Straße, Greifswald 17475, Germany
2241	Gabriele Feisel- Schwickardi, Dr med	Daniela Borries, Dr med	Klinik fur Frauenheilkunde und Geburtshilfe, Monchebergstr 41-43, Kassel, Hessen 34125, Germany
2355	Nikolaus De Gregorio, Dr	Jens Huober, Dr; Inga Bekes, Dr; Amelie M. Schramm, Dr; Jessica Christine Salmen Fabienne Schochter, Dr; Lukas Schwendtner, Dr; Wolgand Janni, Prof Dr; Bernadette Jager, Dr	Universitatsfrauenklinik Ulm Prittwitzstr 43, Ulm Baden- Württemberg 89075, Germany
2423	Frederik Marme, PD Dr	Andreas Schneeweiss, Prof Dr; Klaus Rohrschneider, Prof Dr	NCT National Centrum fur Tumorerkrankungen Heidelberg Im Neuenheimer Feld 460, Heidelberg 69120, Germany
2424	Mignon Denise Keyver-Paik, Dr	Alina Abramian, Dr; Monika Fleckenstein, Dr	University of Bonn, Department for Obstetrics and Gynaecology, Sigmund Freud-Str. 25, Bonn 53105, Germany
2425	Beate Rautenberg, Dr med	Annette Hasenburg, Prof Dr; Daniel Boehringer, Prof Dr	Universitaetsklinik Freiburg Hugstetter Straße 49 Freiburg, Baden-Württemberg 79106, Germany
Hungary			
2096	Tamás Pintér, Dr	Kofi Agyemang-Prempeh, Dr; Istvan Sipocz, Dr; Peter Mezes, Dr; Norbert Pesztenlehrer, Dr	Petz Aladar Megyei Oktato Korhaz Onkoradiologiai Osztaly Vasvari P.u. 2-4, Gyor 9024, Hungary
2098	Imre Pete, Dr	Andrea Bagameri, Dr; Katalin Koranyi, Dr; Eva Bajko, Dr; Miklos Schneider, Dr; Illes Kovacs, Dr; Eva Voleg, Dr; Robert Gergely, Dr; Tamas Dancs, Dr; Kinga Kranitz, Dr	Orszagos Onkologiai Intezet Nogyogyaszati Osztaly Rath Gorgy utca 7-9, Budapest 1122, Hungary
2099	Zsuzsanna Papai, Dr	Peter Nagy, Dr; Marta Sikter, Dr; Noemi Nyolcas, Dr; Gabor Vogt, Dr	Magyar Honvedseg Egeszsegugyi i Kozpont Onkológiai Osztaly Podmaniczky u.111, Budapest 1062, Hungary
Italy			
2083	Sandro Pignata, MD	Marilena Di Napoli, MD; Gaetano Facchini, MD; Carmela Pisano, MD; Rosa Tambaro, MD; Carlo Loffredo, MD; Carla Cavaliere, MD; Sabrina Chiara Cecere, MD	Istituto Nazionale Tumori di Napoli, "G. Pascale" Oncologia Medica Dipartimento Uro-Ginecologico, Via M. Semmola, 52 Napoli 80131, Italy
2084	Francesco Raspagliesi, MD	Stefano Lepori, MD; Giuseppa Maltese, MD; Domenica Lorusso, MD; Francesco Maria Bandello, MD; Giulio Maria Modorati, MD; Elisabetta Miserocchi, MD	Fondazione IRCCS Istituto Nazionale dei Tumori–SC Oncologia Ginecologica Via Venezia 1, Milano 20133, Italy
2085	Nicoletta Colombo, MD	Rosanna Mancari, MD; Mario Romano, MD; Annalisa Garbi, MD; Maria Teresa Achilarre, MD; Giovanni Codacci-Pisanelli, MD; Mariateresa Lapresa, MD; Gabriella Maria Parma, MD; Fedro Alessandro Peccatori, MD; Federica Tomao, MD; Raffaele Piscopo, MD; Fabrizio Camesasca, MD; Maria Cristina Petrella, MD	Istituto Europeo Oncologia – Divisione di Ginecologia Oncologica Via Ripamonti 435, Milano 20141, Italy
2086	Giovanni Scambia, MD	Giulia Amadio, MD; Vanda Salutari, MD; Andrea Giudiceandrea, MD; Tommaso Salgarello, MD; Eleonora Palluzzi, MD	Policlinico Agostino Gemelli – Dip per la Tutela della Salute Donna e della Vita Nascente del Bambino e dell'Adolescente L.go A. Gemelli, 8 Roma 00168, Italy
2113	Salvatore Siena, MD	Mario Giuseppe Meroni, MD; Fabio Sanguineti, MD; Schiavetto Ilaria, MD; Valerio Marino, MD; Elena Magni, MD; Maria Teresa Di Lauro, MD; Emiliana Tarenzi, MD; Paolo Lapadula, MD	Divisione (Struttura Complessa) Oncologia Falck–Dipartimento Oncologico Piazza Ospedale Maggiore 3, Milano 20162, Italy
2114	Stefano Tamberi, MD	Laura Amaducci, MD; Francesco Carrozza, MD; Alessandro Gamboni, MD; Luca Brandi, MD; Claudia Casanova, MD; Caludia Dazzi, MD; Daniele Turci, MD; Enrico Campadelli, MD; Maria Rosa Gentili, MD; Gianni Michele Turolla, MD; Giorgio Papiani, MD; Anna Cariello, MD; Antonio Canella, MD; Chiara Carli Moretti, MD; Mariateresa Minguzzi, MD; Vittoria Benelli, Pharmacist; Cristina Rondoni, Pharmacist	Ospedale Civile degli Infermi Unita Operativa di Oncologia Medica Dipartimento di Onco- Ematologia di Ravenna Presidio di Faenza Viale Stradone 9 Faenza, Ravenna 48018, Italy
2115	Sabino De Placido, MD	Rossella Lauria, MD; Fausto Tranfa, MD	Universita degli Studi Federico II di Napoli Oncologia Medica – Dipartimento di Medicina Clinica e Chirurgia Via Sergio Pansini 5, Napoli 80131, Italy
2116	Antonella Savarese, MD	Gianluigi Ferretti, MD; Paola Malaguti, MD; Vito Fenicia, MD; Alessandra Felici, MD	Istituto Nazionale Tumori Regina Elena – Oncologia Medica A Via Elio Chianesi 53, Roma 00144, Italy
2143	Pierlugi Benedetti Panici, MD	Claudia Marchetti, MD; Angela Musella, MD; Innocenza Palaia, MD; Ilaria Sabatucci, MD; Marco Marenco, MD; Seila Perrone, MD	Policlinico Umberto I- Universita Sapienza – Dipartimento di Scienze Ginecologiche, Ostetriche e di Scienze Urologiche V.le del Policlinico 155, Roma 00155, Italy
2210	Paolo Scollo, MD	Giuseppa Scandurra, MD; Giuseppe Scibilia, MD; Massimo Fichera, MD;	Azienda Ospedaliera Cannizzaro- Dipartmento di Ostetricia e Ginecologia Via Messina 829, Catania 95216, Italy
2211	Claudio Zamagni, MD	Elena Barbieri, MD; Alessandra Bernardi, MD; Nicoletta Cacciari, MD; Angela Fini, MD; Rossella Hakim, MD; Manuela Lenzi, MD; Franco Minardi, MD; Santino Minichillo, MD; Daniela Rubinio, MD; Antonio Ciardella, MD; Sara Querica, MD; Marta Cubelli, MD	SSD Oncologia Medica Addarii- Zamagni – Policlinico S. Orsola- Malpighi Viale Ercolani 4/2, Bolonga 40138 Italy
Norway			
2139	Gunnar Kristensen, MD	Janne Kærn Tone Skeie-Jensen, MD; Torbjørn Paulsen, MD; Elisabeth Smogeli, MD; Olesys Solheim, MD; Bente Vilming Elgaaen, MD; Ane Gerda Zahl Eriksson, MD; Brynhildur Eyjolfsdottir, MD; Yun Wang, MD; Christine Tvedt, MD	Avd.for gynekologisk kreft Radiumhospitalet Oslo universitetssykehus HF Ullernchausseen 70, Oslo 0379, Norway

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TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant (continued)

Site No.	Principal Investigator	Sub-Investigators and Other Key Personnel	Study Site
Poland			
2104	Cezary Szczylik	Lubomir Bodnar, MD, PhD; Lukasz Milewski, MD	Klinika Onkologii, Centralny Szpital Kliniczny MON Wojskowy Instytut Medyczny ul. Szaserow 128, Warszawa, 04-141, Poland
Spain			
2118	Aleix Prat Aparicio, Dr; formerly Laura Vidal Boixader, Dr	Ivan Victoria, Dr; Lydia Gaba, Dr; Maria Jose Capella Elizalbe, Dr; Cecilia Orbegoso, Dr; Sonia Viver, Dr	Hospital Clínic de Barcelona (Servicio de Oncologia) C/ Villarroel 170, Barcelona 08036, Spain
2146	Isabel Bover Barcelo, Dr	Neus Ferrer Tur, Dr; Emeterio Orduna Domingo, Dr	Hospital Son Llatzer (Servicio de Oncologia) Crta. Manacor, km 4, Palma de Mallorca 07198, Spain
2183	Beatriz Pardo Burdalo, Dr	Eva Muinos Gallart, Dr, Noemi Casamajo Quella, Dr; Maria Ochoa de Olza, Dr; Marta Gill Martin, Dr; Alicia Garcia Arias, Dr	Hospital Duran i Reynals Institut Català d'Oncologia (ICO), Av Gran Via, 199-203 L'Hospitalet de Llobregat, 08908 Spain
2186	Cristina Churruca Galaz, Dr	Nerea Ancizar Lizarraga, Dr; Ane Gibelalde Gonzalez, Dr; Isabel Alvarez Lopez, Dr; Ana Paisan Ruiz, Dr	Hospital Universitario Donostia (Servicio de Oncologia C/ Doctor Beguiristain, 117 San Sebastian 20014 Spain
2187	Ferran Losa, Dr; formerly Alicia Garcia Arias, Dr	Ferran Losa Gaspa, Dr; Andres Bujan Rivas, Dr; Helena Verdaguer, Dr; Luis Anselem, Dr	Hospital de Sant Joan d'Espi Moises Broggi (Servicio de Oncologfa) Carrer de Jacint Verdaguer, 90 Barcelona 08970, Spain
2189	Ignacio Romero Noguera, Dr	Andres Poveda, Dr; Francisco Pendades San Valero, Dr	Fundacion IVO-Instituto Valenciano de Oncologia C/ Beltran Báguena, 8 Valencia 46009, Spain
2190	Maria Jesus Rubio Perez, Dr	Raquel Serrano Blanch, Dr; Mariano Rodriguez Maqueta, Dr	Hospital Universitario Reina Sofía/Provincial Servicio de Oncología Av, Menéndez Pidal, s/n Córdoba 14004, Spain
2191	Carmen Esteban Esteban, Dr	J. Ignacio Chacon Lopez-Muniz, Dr; Rosa Maria Jimenez Escribano, Dr	Hospital Virgen de la Salud (Servicioi de Oncologia) Av Barber 30, Toledo 45004, Spain
2242	César Mendiola Fernandez, Dr	Luis Manso Sanchez, Dr; Tomas Pascual Martinez, Dr; Beatriz Sarmiento Torres, Dr; Alicia Julve San Martin, Dr; Maria del Mar Galera Lopez, Dr	Hospital Universitario 12 de Octubre-Edificio Materno-Infantil (Servicio de Oncología) Av de Cordoba, s/n Madrid 28041, Spain
2243	Eva Maria Guerra Alia, Dr	Elena Lopez Miranda, Dra; Alfredo Carrato Mena, Dr; Noelia Martinez Janez, Dr; Maria Luisa Garcia de Paredes, Dr; Esther Ciancas Fuentes, Dr	Hospital Universitario Ramón y Cajal (Servicio de Oncología), Ctra de Colmenar Viejo km 9.100, Madrid, 28034 Spain
2420	David Vicente Baz, Dr	Teresa Garcia Manrique, Dr; Ana Maria Grueso, Dr; Antonio Jose Gomez, Dr	Hospital Universitario, Virgen Macarena Avd Dr Fedriana, n°3, Sevilla 41009, Spain
Sweden			
2195	Bengt Tholander	Antoula Koliadi, Dr; Anne von Heideman, Dr; Ann-Marie Lejon, Dr	Onkologkliniken Akademiska Sjukhuset, Uppsala 751 85, Sweden
2204	Elisabet Hjerpe	Alexandra Hofsjo, Dr; Caroline Lundgren, Dr; Susanne Fridsten, Dr; Daria Glaessgen, Dr; Hanna Dahlstrand, Dr;	Onkologiska kliniken Karolinksa Universitetssjukhuset, Stockholm 171 76, Sweden
The Netherlands			
2117	R. Lalisang, Dr.	Tjan-Heijnen, Dr; Hoeben, Dr; Aarts, Dr; Jansen, Dr; de Boer, Dr; Van den Biggelaar, Dr; Van der Zanden, Dr; Vriens, Dr; de Vos, Dr; Pleunis, Dr; Aaldering, Dr; Soetekouw, Dr	Maastricht University Medical Cente, P Debyelaan 25, Maastricht 6229 HX, The Netherlands
2145	Anneke Westermann, Dr	J. Wilmink, MD; R. Schlingemann, Prof., Dr; S. Krausz, Dr; J. Tromp, Dr; H. J. Klumpen, Dr; B. Flameling, Dr; B. van Zaane, Dr; L. J. M. Mekenkamp, Dr; S. E. Siegelaar, Dr; M. A. J. Beerepoot, Dr; van Laarhoven, Dr; Wensing, Dr	Medical Oncology, Academic Medical Centre, Meibergdreef 9, Amsterdam Noord-Holland 1105 AZ, The Netherlands
2153	Anna K.L. Reyners, Dr	Mathilde Jalving, Dr; Corina Oldenhuis, Dr	University Medical Center Groningen, Medical Oncology Hanzeplein 1, Groningen 9713 GZ, The Netherlands
United Kingdom			
2105	Susana Banerjee, Dr	Juan Martin Liberal, Dr; Tiana Kordbacheh, Dr; Anna-Maria Bielinska, Dr; Stefan Diem, Dr; Roger Whitelocke, Dr; Amna Sheri, Dr; Saoirse Oliva Dolly, Dr; Lavinia A. Spain, Dr; Alicia Okines, Dr; Aislinn Macklin-Doherty, Dr; Alexandros Georgiou, Dr; Alexander Lee, Dr; Nadia Yousaf, Dr; Joao Paulo Lima, Dr; Andrea Biondo, Dr; Michael Eric Gore, Dr; Paul G. Ursell, Dr; Benjamin Kasenda, Dr; Rita Canario, Dr; Angela George, Dr; Georgios Rigakos, Dr; Maria Vasilakopoulou, Dr; Lucy Dumas, Dr; Alison Reid, Dr; Margarita Romeo, Dr; Jennifer McLachlan, Dr; Saira Khalique, Dr; Joo Ern Ang, Dr; Nadza Tokaca, Dr; Tom Waddell, Dr; Eugenie Younger, Dr; Stergios Boussios, Dr; Saira Khalique, Dr; Sophia Frentzas, Dr; Thubeena Manickavasagar, Naila Kaudeer, Dr; Michele Moschetta, Dr; Emily Grist, Dr; Gayathri Devi Shankragall Anandappa, Dr; Michael Edward Davidson, Dr	The Royal Marsden NHS Foundation Trust, Downs Rd, Sutton, Surrey SM2 5PT, United Kingdom
2105B	Susana Banerjee, Dr	Joao Paulo Lima, Dr; Juan Martin Liberal, Dr; Rodger Whitelocke	The Royal Marsden NHS Foundation Trust, Downs Rd, Sutton, Surrey SM2 5PT, United Kingdom
2106	Andrew Clamp, Dr	Laura Horsley, Dr; Nerissa Mescallado, Dr; Gordon Jayson, Prof; Claire Mitchell, Dr; Jurjees Hasan, Dr; Paul Bishop, Prof; Tariq Aslam, Prof; Serena Salvatore, Dr; Saeed Rafii, Dr	The Christie NHS Foundation Trust, Wilmslow Rd, Withington, Manchester, Lancashire M20 4BX, United Kingdom
2120	Anjana Anand, Dr	Stephen Chan, Dr; Mohamed Elalfy, Dr	Nottingham University Hospitals NHS Trust, City Campus, Hucknall Rd, Nottingham, Nottinghamshire NG5 1PB, United Kingdom

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TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant (continued)

Site No.	Principal Investigator	Sub-Investigators and Other Key Personnel	Study Site
2154	Hendrik-Tobias Arkenau, Dr	Matilde Saggese, Dr; Ioannis Binas, Dr; Charlotte Lemech, Dr; Mark Voskoboynik, Dr; Rebecca Kristeleit, Dr.; Gabriel Mak, Dr	Sarah Cannon Research Institute United Kingdom, 93 Harley St, London W1G 6AD, United Kingdom
2416	Jennifer Pascoe, Dr	None	Sandwell & West Birmingham Hospitals NHS Trust, City Hospital D46 Sheldon Block, Birmingham B18 7QH, United Kingdom
United States			
1001	Robert Coleman, MD	Diane Bodurka, MD; Michael Frumovitz, MD; David Gershenson, MD; Charles Levenback, MD ;Karen H. Lu, MD; Alpa Nick MD; Pedro Ramirez, MD; Lois Ramondetta, MD; Kathleen Schmeler, MD; Pamela Soliman, MD; Anil Sood, MD; Shannon Westin, MD; Dan Gombos, MD; Bita Esmaeli, MD; Stella Kim, MD; Jade Schiffman, MD; Priya Bhosale, MD; Preetha Ramalingam, MD	University of Texas MD Anderson Cancer Center, 1515 Holcombe Blvd, Unit 1362, Houston, TX 77030
1005	Angela Jain, MD	Lainie Martin, MD; Stephanie King, MD; Robert Burger, MD; William Foster, MD; Nyree Tedesco-Garofano, CRNP; Gina Mantia-Smaldone, MD	Fox Chase Cancer Center 333 Cottman Ave, Philadelphia, PA 19111
1013	Kian Behbakht, MD; formerly Susan Davidson, MD	Kian Behbakht, MD; Monique Spillman, MD; Saketh Guntupalli, MD; Carolyn Lefkowits, MD	University of Colorado Denver, Anschutz Medical Campus, 12631 E 17th Ave, B1984, Room 4411, Aurora, CO 80045
1018	Robert Thomas Morris, MD	Gunter Deppe, MD; Shelly Seward, MD; Leigh Ann Solomon, MD; Robert Frank, MD; Mark Juzych, MD; Gabriel Sosne, MD; Asheesh Tewari, MD; Nesrine Khoury, PA-C; Ira Winer, MD, PhD	Barbara Ann Karmanos Cancer Institute, 4100 John R, Suite 721, Detroit, MI 48201
1019	Edward Sausville, MD	Guatam Rao, MD; Marena Patronas, MD; Dana Roque, MD; Bethany Danner, NP; Katherine Tkaczuk, MD	University of Maryland Greenebaum Cancer Center, 22 South Greene St, Baltimore, MD 21201
1020	Robert Wenham, MD	Denise Dorman, RN; Sachin Apte, MD; Hye Sook Chon, MD; Patricia Judson, MD; Johnathan Lancaster, MD; Mian Shahzad, MD; Donna Fabri, ARNP; Sharon Tollin, ARNP; Marilyn Plattner, ARNP	H. Lee Moffitt Cancer Center and Research Institute, 12902 Magnolia Dr, Tampa, FL 33612
1800	David Michael O'Malley, MD	David E. Cohn, MD; Jeffrey M. Fowler, MD; Larry J. Copeland, MD; Floor J. Backes, MD; Ritu Salani, MD; John L. Hays, MD; Shelly G. Jain, MD; Andrew J. Hendershot, MD; Thomas F. Mauger, MD	320 West 10th Ave, Starling Loving Hall M210, Columbus, OH 43210
1803	Premal Thaker, MD	David Mutch, MD; Matthew Powell, MD; L. Stewart Massad, MD; Andrea Hagemann, MD; Nora Kizer, MD; Yevgeniya Ioffe, MD; Akiva Novetsky, MD; Gunjal Garag, MD; Ivy Wilkinson-Ryan, MD; Nancy Tecu, RN; David Vollman, MD	Washington University School of Medicine, 4911 Barnes-Jewish Hospital Plaza, St Louis, MO 63110
1805	Gottfried Konecny, MD	Alexander C. Black, MD; Anita Kaul, MD; John Anthony Glaspy, MD; John L. Barstis, MD; Martin Clive Palmer, MD; Melissa Jill Cohen, MD; Olga Michelle Olevsky, MD; Rena Desai Callahan, MD; Saeed Sadeghi, MD; Shahryar Ashouri, MD; Tara McCannel, MD; Denise Karen Oseguera, FNP; Colin McCannel, MD	University of California Los Angeles, Hematology-Oncology Clinic, UCLA Medical Plaza, Suite 550, Box 956970, Los Angeles, CA 956970
1821	Peter Rose, MD	Chad Michener, MD; Medhi Moslemi-Kebria, MD; Robert De Bernardo, MD; Jason Knight, MD; Rishi Singh, MD	Cleveland Clinic/Main Campus 9500 Euclid Ave, A81, Cleveland, OH 44195
1869	Rachel N. Grisham, MD	Carol A. Aghajanian, MD; Katherine M. Bell-McGuinn, MD, PhD; Karen Cadoo, MB; Martee L. Hensley, MD, MSc; David Hyman, MD; Jason A. Konner, MD; Vicky Makker, MD; Roisin E. O'Cearbhaill, MB BCh; Paul Sabbatini, MD; David R. Spriggs, MD; William P. Tew, MD; Dmitriy Zamarin, MD; Jessica Gahres, PA; Stefanie S. Jacobs, MD; Hebert A. Vargas Alvarez, MD; Murk Hein Heinemann, MD; Jasmine Francis, MD	Memorial Sloan Kettering Cancer Center, 300 East 66th St, New York, NY 10065
1875	Michael S. Gordon, MD	David S. Mendelson, MD; Giraldo Kato, MD; Gary H. Greene, OD	Oncology Research Associates, PLLC d/b/a Pinnacle Oncology Hematology, 9055 East Del Camino, Suite 100, Scottsdale, AZ 85258
1886	Kathleen Moore, MD	Anil Patel, MD; Alex Cohen, MD; Camille Gunderson, MD; Lisa Landrum, MD; Teresa Larson, MD; Robert S. Mannel, MD; D. Scott McMeekin, MD; Katherine Moxley, MD; Michelle Rowland, MD; Rachel Ruskin, MD; Vinay Shah, MD; LaToya Perry, MD; Katrina Slaughter, MD; Adam Walter, MD; Joan L. Walker, MD	800 NE 10th St, 5th Fl, Oklahoma City, OK 73104
1901	Mark A. Rettemaier, MD	John V. Brown, MD; Lisa N. Abaid, MD, MPH; Alberto A. Mendivil, MD; David Wirta, MD; Katerina Kurteeva, MD; Erin Tinnerman, PA-C; Amber Palmer-Chapman, PA-C; Michelle Stone, PA-C; Crystal Gray, PA-C	Gynecologic Oncology Associates, 351 Hospital Rd, Suite 507, Newport Beach, CA 92663
1902	Agustin Garcia, MD; formerly Yvonne Lin-Liu, MD	Lynda Roman, MD ;Huyen Pham, MD; Laila Muderspach, MD; Annie Yessaian, MD; Agustin Garcia, MD; Koji Matsuo MD; Srinivas Sadda, MD; Katherine Tierney, MD; Eijean Wu, MD; Laurie Brunette, MD; Kristy Watkins, RN; Grace Facio, RN; Shahram Bonyadlou, MD; Jesse Berry, MD; Jocelyn Garcia, MD	USC/Norris Comprehensive Cancer Center, 1441 Eastlake Ave, Rm 7419, Los Angeles, CA 90033
1903	Bradley Monk, MD; formerly John Farley, MD	John Farley, MD; Dana Chase, MD; Lyndsay Willmott, MD; Stephanie Casey, MSN, ACNP-BC; James M. Goldman, MD	St Joseph's Hospital & Medical Center, 500 W Thomas Rd, Suite 660, Phoenix, AZ 85013
1908	Alessandro Santin, MD	Peter E. Schwartz, MD; Masoud Azodi, MD; Dan-Arin Silasi, MD; Elena Ratner, MD; Stephanie Cerrito, PA-C; Shirley McCarthy, MD, PhD; Lisa Baker, RN, BSN, OCN; Martha Luther, RN, MPH; Diana English, MD; Carlton Schwab, MD; Martha Mitchell, APRN; Andrea Brennan, APRN	Yale School of Medicine, 333 Cedar St, New Haven, CT 06520
1914	Meaghan Tenney, MD	S. Diane Yamada, MD; Jeffrey Nichols, MD; Ernst Robert Lengyel, MD, PhD; Gini Fleming, MD; Juliana Lutz, APN; Constance Stewart, BSN; Julie A. Sharpe, PA-C	University of Chicago Medical Center, 5841 S Maryland Ave MC2050, Chicago, IL 60637

(continued on following page)

TABLE A1. MILO-ENGOT-ov11 Study Investigators: List of Investigators Who Consented a Study Participant (continued)

Site No.	Principal Investigator	Sub-Investigators and Other Key Personnel	Study Site
1915	Carolyn Muller, MD	Teresa Rutledge, MD; Sarah Adams, MD; Frank J. Mares, MD; Barbara C. Marsh, PhD, MD; Michael L. DiMonaco, DO	New Mexico Cancer Care Alliance, 1201 Camino de Salud NE Admin Wing, 2nd Fl, Albuquerque, NM 87106
1923	Alexander Olawaiye, MD; formerly Robert Edwards, MD	John Comerci, MD; Robert Edwards, MD; Alexander Olawiye, MD; Paniti Sukmvanich, MD; Joseph Kelley, MD; Madeleine Courtney-Brooks, MD; Marilyn Huang, MD; Andrew Eller, MD; Denise Gallagher, MD; Joseph Martel, MD	Department of Obstetrics and Gynecology Magee-Womens Hospital of UPMC, 300 Halket St, Pittsburgh, PA 15213
1924	Randall Gibb, MD	James Cometet, MD; Caroline Deigert, PA; Doreen Kenfield, PA; Erin E. Stevens, MD	Billings Clinic, 801 N 29th St, Billings, MT 59101
1927	Robert W. Holloway, MD	Glenn E. Bigsby, IV, DO; James E. Kendrick, IV, MD; David B. Auerback, DO; Lorna Brudie, DO; Victory B. Thomas, MD	Florida Hospital Cancer Institute Gynecologic Oncology, 2501 N Orange Ave, Suite 800, Orlando, FL 32804
1928	Gloria S. Huang, MD	Gary L. Goldberg, MD; Mark H. Einstein, MD, MS; Denis Yi-Shin Kuo, MD; Harriet Smith, MD; David Smotkin, MD; June YiJuan Hou, MD; Merieme Klobocista, MD; Rebecca Phaeton, MD; David C. Gritz, MD	Montefiore Medical Center, 1695 Eastchester Rd, Suite 601, Bronx, NY 10461
1929	Jayanthi S. Lea, MD, FACOG	Isabel Villalobos, MS; David S. Miller, MD; Debra L. Richardson, MD; Siobhan M. Kehoe, MD; Ken Y. Lin, MD, PhD; Dustin B. Manders, MD; Christa I. Nagel, MD; Yu-Guang He, MD; Rafael Ufret-Vincenty, MD	University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd, E6. 102 Dallas, TX 75390-9032
1932	Michael Goodheart, MD	David Bender, MD; Priyal Dholakiya, MD; Jesus Gonzalez-Bosquet Erin Salinas, MD; Jean-Marie Stephan, MD; Chelsea Ward, MD; Anna S. Kitzmann, MD; Khadija S. Shahid, OD	University of Iowa Hospital and Clinics, 200 Hawkins Dr, 31506 PFP, Iowa City, IA 52242
1973	Sharad Ghamande, MD	Michael Macfee, MD; Bunja Rungruang, MD; Julia Donovan, MD; Anne Smith, APRN	Georgia Regents University Cancer Center, 1120 15th St, BA-7411, Augusta, GA 30912
1992M	Michael Birrer, MD, PhD	MGH: Cesar M. Castro, MD; Marcela G. del Carmen, MD, MPH; Don S. Dizon, MD; Annekathryn Goodman, MD; Whitfield B. Growdon, MD; Carolyn N. Krasner, MD; Richard T. Penson, MD; John O. Schorge, MD; Tina Atkinson, RN, CCRC; Mary Campbell, NP, DFCI; Joyce Liu, MD; Christin Hurley-Whalen, RN; Stephanie Morrissey, RN; Victoria Patterson, RN; Lisa Arvine, NP; Suzanne Berlin, DO; Susana Campos, MD; Kelly Cummings, NP; Catherine Earley, NP; Neil Horowitz, MD; Panagiotis Konstantinopoulos, MD; Anne-Marie Wilson, NP; Alexi Wright, MD; Ann Stewart, NP; Colleen Chin, RN, BSN; Ursula Matulonis, MD. BIDMC: Mary Buss, MD, MPH; Carol Delaney, RN; Christina Herold, MD; Stephen Cannistra, MD	Massachusetts General Hospital Cancer Center Yawkey, 55 Fruit St, Boston, MA 02114
2015	Daniel Spitz, MD	Deidra A. Brown-Brinson, ARNP; Todd Adam Gersten, MD; Robert Jeffrey Green, MD; James Noel Harris, MD; Robert Julian Jacobson, MD; Elisabeth Anne McKeen, MD; Shachar Peles, MD; Ruby W. Pontello, ARNP; Marilyn Meeks Raymond, MD; Neal Evan Rothschild, MD; Augustin J. Schwartz III, MD; Avram Jonathan Smukler, MD; Robin A. Stehlin Stevens, ARNP; Sumithra Vattigunta, MD	Florida Cancer Specialists, 1309 N. Flagler Dr W, Palm Beach, FL 33401
2050	Eric L. Eisenhauer, MD	Thomas Reid, MD; Heather Pulaski, MD; W. Michael Gaynier, DO; Amanda Jackson, MD; Thomas Herzog, MD	University of Cincinnati Physicians Company, 200 Albert Sabin Way, Holmes Hospital Bldg, Rm 4027, Cincinnati, OH 45267-0457
2069	Leigh Cantrell, MD	Yevgeniy Shildkrot, MD; Susan Modesitt, MD; Linda Duska, MD; Charles Landen, MD; Tyson Ward, MD;	University of Virginia, Department of OB/GYN, GYN/ONC 81 Hospital Dr, Private Clinics 3rd Fl, Rm 3619, Charlottesville, VA 22908
2072	Leslie Randall, MD	Krishnansu Tewari, MD; Fong Liu, MD; Philip DiSaia, MD; Gareth Forde, MD Michael Berman, MD; Lauren Krill, MD; Ramez Eskander, MD; Krista Pfaendler, MD; Robert Bristow, MD; Sara Jordan, MD; Teresa Longoria Robert Bristow, MD; Valerie Bianca Galva-Turner, MD; Marjan Farid, MD	University of California, Irvine-Medical Center, 101 The City Dr South, Bldg 56, Suite 800, Orange, CA 92868
2179	Michael Callahan, MD; formerly Gregory Sutton, MD	Michael Callahan, MD; Hubert Fornalik, MD; Georgiann Linnemeir, MD; Ramana S. Moorthy, MD; Rodney S. Bucher, MD; Susan M. Rivers, RN; Rachele A. Willett, RN; Laura Erin Long, PA-C; Nicole L. Flanders, PA-C	St Vincent Gynecologic Oncology, 8402 Harcourt Rd, Suite 420, Indianapolis, IN 46260