Real-world Assessment of Patients with Ovarian Cancer Who Received Niraparib as Second-Line Maintenance Therapy in the United States: Did First-Line Maintenance Approval Change the Patient Profile for Second-Line Maintenance Therapy?

Presentation ID 708

Floor Backes,[1] Tirza Areli Calderón Boyle,[2] Jessica Perhanidis,[3] Jonathan Lim,[2] Linda Kalilani,[4] Jean A. Hurteau,[3] Amanda Golembesky,[4] Ritu Salani[5]

[1]The Ohio State University Comprehensive Cancer Center–The James Cancer Hospital and Solove Research Institute, Columbus, OH, USA; [2]GSK, Upper Providence, PA, USA; [3]GSK, Waltham, MA, USA; [4]GSK, Durham, NC, USA; [5]Department of Obstetrics and Gynecology, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

Background

- Approximately 70% of patients with ovarian cancer (OC) will experience disease recurrence following first-line (1L) treatment[1]
- In patients with platinum-sensitive recurrent OC, maintenance treatment with poly(ADP-ribose) polymerase (PARP) inhibitors has been shown to extend progression-free survival (PFS)[2,3]
- The PARP inhibitor niraparib was approved on 27 March 2017 in the US as once daily monotherapy for the maintenance treatment of patients with recurrent platinum-sensitive epithelial OC (EOC) regardless of biomarker status[4]
- Subsequently, niraparib maintenance monotherapy was also shown to extend PFS in the 1L setting and was approved in the US on 29 April 2020 for the 1L maintenance (1LM) treatment of patients with advanced EOC regardless of biomarker status who respond to 1L platinum-based chemotherapy[5]
- Real-world data investigating niraparib maintenance use in the second-line (2L) setting are lacking

Objective

- To describe the characteristics of real-world patients with EOC who initiated second-line maintenance (2LM) with niraparib before and after niraparib 1LM approval in the US

Conclusions

- This real-world analysis found that niraparib remained an important treatment option for 2LM in patients with recurrent EOC following niraparib 1LM approval in the US
- The demographic and clinical profiles of patients receiving niraparib maintenance therapy in the 2L setting did not markedly change after 1LM approval
  - However, the percentage of patients with *BRCA* wild-type disease was higher in the post-1LM approval cohort than in the pre-1LM approval cohort

Scan to download a copy of this poster or the conflicts of interests

Presenting author email: Floor.Backes@osumc.edu

Presented at the European Society of Gynaecological Oncology (ESGO) 2022 Congress; 27–30 October 2022; Berlin, Germany

References

1. Giornelli GH. *SpringerPlus*. 2016;5(1):1197.
2. Mirza MR, et al. *N Engl J Med*. 2016;375(22):2154–2164.
3. Pujade-Lauraine E, et al. *Lancet Oncol*. 2017;18(9):1271–1284.
4. United States Food and Drug Administration. Published March 27, 2017. Accessed September 17, 2022. https://www.fda.gov/news-events/press-announcements/fda-approves-maintenance-treatment-recurrent-epithelial-ovarian-fallopian-tube-or-primary-peritoneal.
5. United States Food and Drug Administration. Published April 29, 2020. Accessed July 19, 2022. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-niraparib-first-line-maintenance-advanced-ovarian-cancer.
6. Ma X, et al. *medRxiv*. Preprint posted online May 30, 2020. https://doi.org/10.1101/2020.03.16.20037143.
7. Birnbaum B, et al. *arXiv*. Preprint posted online January 13, 2020. https://arxiv.org/abs/2001.09765.

Acknowledgments

This study (OneCDP 217870) was funded by GSK (Waltham, MA, USA). The authors thank Ramsanjay RK and Sachi Mehra of GSK for their statistical programming support. Writing and editorial support, funded by GSK and coordinated by Hasan Jamal, MSc, of GSK, were provided by Betsy C. Taylor, PhD, and Jennifer Robertson, PhD, of Ashfield MedComms, an Inizio company (Middletown, CT, USA).

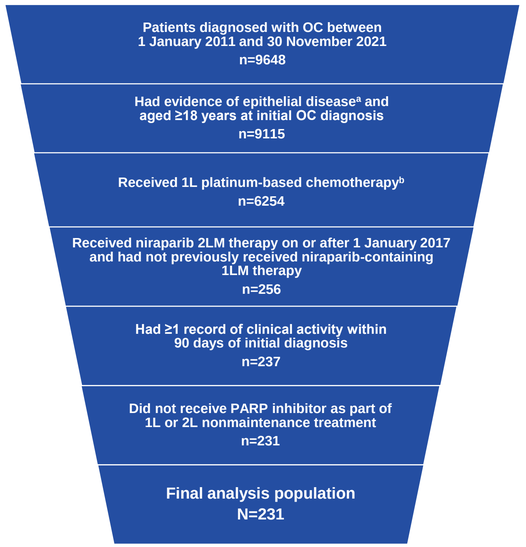
Methods

- This retrospective cohort study used the US nationwide Flatiron Health electronic health record–derived database, a longitudinal database consisting of de-identified patient-level structured and unstructured data, curated via technology-enabled abstraction.[6,7] During the study period of 1 January 2011 and 30 November 2021, the data originated from approximately 280 cancer clinics (≈800 sites of care); of note, the majority (≈80%) of patients in the database originate from community oncology practices
- The study included adult patients diagnosed with EOC, including ovarian, fallopian tube, and primary peritoneal cancer, during the study period
  - Eligible patients received 1L platinum-based chemotherapy after the initial OC diagnosis and niraparib 2LM monotherapy initiated on or after 1 January 2017
  - Patients were excluded if they had an incomplete medical history (no clinical activity within 90 days of initial diagnosis), received a PARP inhibitor as part of 1L or 2L nonmaintenance treatment, or had previously received niraparib-containing 1LM therapy
- The index date was defined as the initiation date of niraparib 2LM monotherapy
- Demographic and clinical characteristics of the study cohort were assessed
- Patients were stratified by index date: before 29 April 2020 (niraparib pre-1LM approval cohort) or on or after 29 April 2020 (niraparib post-1LM approval cohort)

Results

- A total of 231 patients with advanced EOC who received niraparib 2LM therapy met all inclusion criteria and were included in the analysis (Figure 1)

Figure 1. Patient Attrition

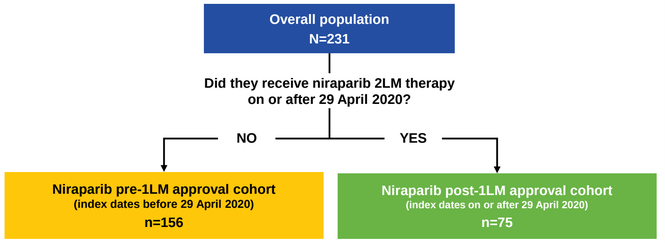


[a]Evidence of epithelial disease included the following histologies: serous, clear cell, mucinous, endometrioid, transitional cell, epithelial not otherwise specified, and unknown.
[b]All patients included in the study cohort (N=231) received 2L platinum-based chemotherapy.
1L, first-line; 1LM, first-line maintenance; 2L, second-line; 2LM, second-line maintenance; OC, ovarian cancer; PARP, poly(ADP-ribose) polymerase.

Results *(cont'd)*

- Patients were stratified into 2 cohorts based on whether they were prescribed niraparib 2LM therapy before or on or after the US approval of niraparib for 1LM therapy (Figure 2)
- 67.5% of patients were in the niraparib pre-1LM approval cohort, and 32.5% of patients were in the niraparib post-1LM approval cohort

Figure 2. Cohort Assignment Based on Index Date



1LM, first-line maintenance; 2LM, second-line maintenance.

- Patient demographics are detailed in Table 1
- In the overall population, the median age at index was 68 years, and most patients were White (62.8%)
- Most (90.0%) patients were treated in community practices
- Patient demographics were generally similar in the niraparib pre- and post-1LM approval cohorts (Table 1)

Table 1. Patient Demographics[a]

	Overall population (N=231)	Niraparib pre-1LM approval cohort (index dates before 29 April 2020) (n=156)	Niraparib post-1LM approval cohort (index dates on or after 29 April 2020) (n=75)
Age at index, years			
Median (Q1, Q3)	68.0 (61.0, 75.0)	67.0 (60.0, 74.5)	69.0 (62.0, 75.0)
Race, n (%)			
White	145 (62.8)	105 (67.3)	40 (53.3)
Black or African American	16 (6.9)	9 (5.8)	7 (9.3)
Other	59 (25.5)	37 (23.7)	22 (29.3)
Unknown	11 (4.8)	5 (3.2)	6 (8.0)
Ethnicity, n (%)			
Hispanic or Latino	23 (10.0)	16 (10.3)	7 (9.3)
Unknown	208 (90.0)	140 (89.7)	68 (90.7)
Region of residence, n (%)[b]			
Midwest/Northeast	37 (16.0)	30 (19.2)	7 (9.3)
South	126 (54.5)	83 (53.2)	43 (57.3)
West	27 (11.7)	19 (12.2)	8 (10.7)
Other/unknown	41 (17.7)	24 (15.4)	17 (22.7)
Practice type, n (%)[c]			
Academic	39 (16.9)	24 (15.4)	15 (20.0)
Community	208 (90.0)	144 (92.3)	64 (85.3)
Median follow-up time (Q1, Q3), months	13.6 (6.2, 26.9)	20.7 (10.7, 32.0)	6.2 (3.2, 10.0)

[a]Results with counts less than 5 were masked by combining categories to protect patient confidentiality.
[b]Midwest/Northeast: CT, ME, MA, NH, RI, VT, NJ, NY, PA, IL, IN, MI, OH, WI, IA, KS, MN, MO, NE, ND, SD; South: DE, FL, GA, MD, NC, SC, VA, DC, WV, AL, KY, MS, TN, AR, LA, OK, TX; West: AZ, CO, ID, MT, NV, NM, UT, WY, AK, CA, HI, OR, WA; other/unknown: Puerto Rico or missing. Patients from academic practices had unknown geographic region.
[c]Patients with records in academic and community practices were counted in both categories; therefore, patient counts and percentages may sum to more than 100%.
1LM, first-line maintenance; Q1, quartile 1; Q3, quartile 3.

- Patient clinical and tumour characteristics are detailed in Table 2
- The proportion of patients with *BRCA* wild-type disease was 68.6% in the pre-1LM approval cohort and 85.3% in the post-1LM approval cohort
- The proportion of patients with no surgery or visible residual disease after surgery for the initial diagnosis was 39.1% in the pre-1LM approval cohort and 24.0% in the post-1LM approval cohort

Table 2. Patient Clinical Characteristics[a]

	Primary study population (N=231)	Niraparib pre-1LM approval cohort (index dates before 29 April 2020) (n=156)	Niraparib post-1LM approval cohort (index dates on or after 29 April 2020) (n=75)
ECOG performance score, n (%)			
0–1	186 (80.5)	130 (83.3)	56 (74.7)
2–4	21 (9.1)	12 (7.7)	9 (12.0)
Unknown/missing	24 (10.4)	14 (9.0)	10 (13.3)
Stage at initial diagnosis, n (%)			
I/II	22 (9.5)	14 (9.0)	8 (10.7)
III	114 (49.4)	80 (51.3)	34 (45.3)
IV	67 (29.0)	45 (28.8)	22 (29.3)
Unknown/not documented	28 (12.1)	17 (10.9)	11 (14.7)
Epithelial histology, n (%)			
Serous	178 (77.1)	118 (75.6)	60 (80.0)
Epithelial NOS, other	39 (16.9)	NR	NR
Endometrioid	8 (3.5)	NR	NR
Unknown	6 (2.6)	NR	NR
BRCA mutation status, n (%)[b]			
*BRCA*m	44 (19.0)	NR	NR
*BRCA*wt	171 (74.0)	107 (68.6)	64 (85.3)
Unknown	16 (6.9)	NR	NR
HRD status, n (%)			
HRd	11 (4.8)	10 (6.4)	8 (10.7)
HRp	7 (3.0)		
Unknown	213 (92.2)	146 (93.6)	67 (89.3)
Residual disease status after surgery for initial OC diagnosis, n (%)			
No surgery	17 (7.4)	61 (39.1)	18 (24.0)
NVRD	109 (47.2)		
VRD	62 (26.8)	67 (42.9)	42 (56.0)
Unknown	43 (18.6)	28 (17.9)	15 (20.0)
Duration of 2L platinum-based chemotherapy, months			
Median (Q1, Q3)	4.2 (3.5, 4.9)	4.2 (3.5, 4.9)	4.2 (2.6, 4.9)
≥6 months from end of 1L chemotherapy to initial 2L chemotherapy, n (%)			
Yes	197 (85.3)	135 (86.5)	62 (82.7)
No	34 (14.7)	21 (13.5)	13 (17.3)
Time from initial diagnosis to 2LM, months			
Median (Q1, Q3)	26.4 (20.0, 35.0)	26.4 (20.7, 35.0)	26.6 (19.0, 36.8)

[a]Results with counts less than 5 were masked by combining categories or were not reported to protect patient confidentiality.
[b]Data do not differentiate between somatic and germline mutations.
1L, first-line; 1LM, first-line maintenance; 2LM, second-line maintenance; *BRCA*m, *BRCA* mutated; *BRCA*wt, *BRCA* wild-type; ECOG, Eastern Cooperative Oncology Group; HRD, homologous recombination deficiency; HRd, homologous recombination–deficient; HRp, homologous recombination–proficient; NOS, not otherwise specified; NR, not reported; NVRD, no visible residual disease; OC, ovarian cancer; Q1, quartile 1; Q3, quartile 3; VRD, visible residual disease.