OVARIO

Phase 2 Study of Niraparib + Bevacizumab in Patients with Advanced Ovarian Cancer

TRIAL DESIGN AND PATIENT CHARACTERISTICS

N=105 PATIENTS

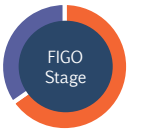
First-line platinum-based chemotherapy + bevacizumab (with or without primary debulking/interval debulking surgery)

Niraparib 200 or 300 mg QD (3 years) + **Bevacizumab** 15 mg/kg Q3W (15 months)

Individualized dosing

N=82 received 200 mg due to <77 kg weight or platelet count <150,000/µL at baseline

N=23 received 300 mg due to ≥77 kg weight AND platelet count ≥150,000/µL at baseline



79% Stage III
21% Stage IV

63% CR/NED
37% PR

49%

63%

36% HR-proficient

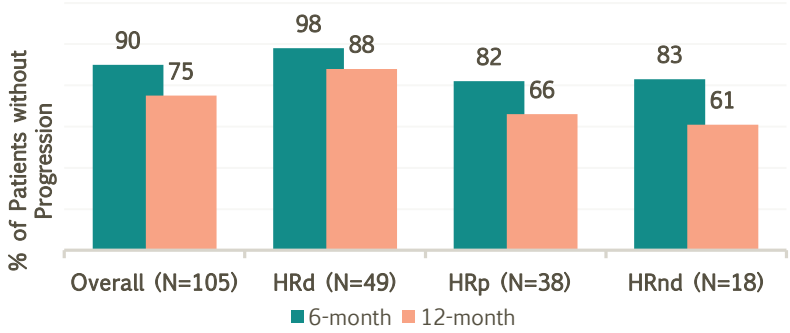
47% HR-deficient

28% *BRCA*-mutant
15% *BRCA*-wildtype

17% HR-not determined

EFFICACY

Exploratory Endpoints: PFS Rate at 6 and 12 months (per investigator)



Primary Endpoint: PFS Rate at 18 months (per investigator)
Key Secondary Endpoints: OS, TFST, TSST, Safety, PROs, PFS

SAFETY (TREATMENT-RELATED TEAEs)[a]

GR≥3	Treatment Discontinuation	Dose Reduction	Dose Interruption
TEAEs 73% (n=77)	25% (n=26)	71% (n=75)	81% (n=85)

5 MOST COMMON GR ≥ 3 TEAEs

- ANEMIA[b] 32% (n=34)
- THROMBOCYTOPENIA[c] 37% (n=39)
- HYPERTENSION 26% (n=27)
- NEUTROPENIA[d] 12% (n=13)
- FATIGUE 9% (n=9)

[a]Treatment-related TEAEs as assessed related to niraparib [b]anemia includes hemoglobin decreased; [c]thrombocytopenia includes platelet count decreased; [d]neutropenia includes neutrophil count decreased;

PFS rate: the proportion of patients who have not progressed or died within a pre-specified timepoint after initiation of treatment AE: adverse event; CR: complete response; FIGO: International Federation of Gynecology and Obstetrics; GR: Grade; HRd: homologous recombination-deficient; HRp: homologous recombination-proficient; HRnd: homologous recombination status not determined; HTN: hypertension; NACT: neoadjuvant chemotherapy; OS: overall survival; PDS: primary debulking surgery; PFS: progression-free survival; PR: partial response; PRO: patient-reported outcome; TEAE: treatment-emergent adverse events; TFST: time to first subsequent treatment; TSST: time to second subsequent treatment

For the full medical information letter, click here or scan the QR code.

References: Hardesty et al., Phase 2 OVARIO Study of Niraparib + Bevacizumab Therapy in Advanced Ovarian Cancer Following Front-Line Platinum-Based Chemotherapy With Bevacizumab. SGO 2020 Webinar Series #6.

Some information contained in this response is outside the approved local label for niraparib. This product is not approved for the use described.

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Jun-20