Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer

TRIAL DESIGN AND PATIENT CHARACTERISTICS

N=733 PATIENTS

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

2:1 randomization

- **Niraparib** 300 mg QD (n=484)
- **Placebo** (n=244)

3 years

Individualized Dosing (n=255)

- **200 mg** if <77 kg weight or platelet count <150,000/µL at baseline
- **300 mg** if ≥77 kg weight AND platelet count ≥150,000/µL at baseline

Overall Population

65% Stage III
35% Stage IV

69% CR
31% PR

45% after PDS/IDS

67%

34% HR-proficient

15% HR-not determined

51% HR-deficient

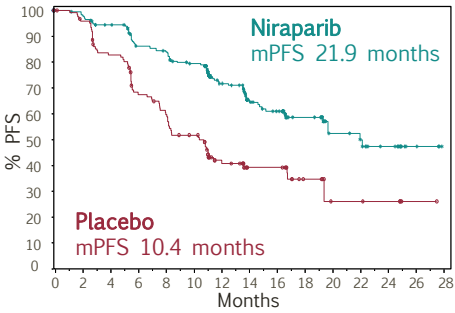
30% *BRCA*-mutant
20% *BRCA*-wildtype

[a]stratification factors

EFFICACY

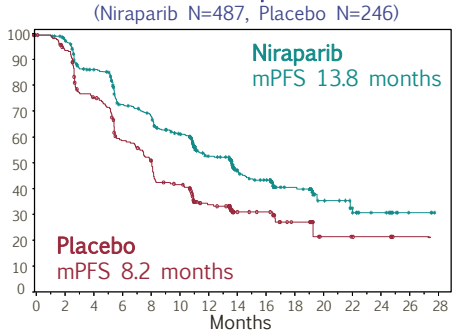
Primary Endpoint: Progression-free survival (PFS by BICR)

Homologous Recombination-Deficient (Niraparib N=247, Placebo N=126)



HR 0.43 (95% CI 0.31–0.59)

Overall Population (Niraparib N=487, Placebo N=246)



HR 0.62 (95% CI 0.50 – 0.76)

Progression-free survival in Biomarker Subgroups

HRd–*BRCA*mut	HR 0.40 (95% CI 0.27-0.62)
HRd–*BRCA*wt	HR 0.50 (95% CI 0.31-0.83)
HRp	HR 0.68 (95% CI 0.49-0.94)

Secondary endpoints: OS, TFST, PFS2, and PROs

SAFETY (Niraparib N=484, Placebo N=244)

GR≥3

TEAEs	Treatment Discontinuation	Dose Reduction	Dose Interruption
71% Niraparib 19% placebo	12% Niraparib 3% placebo	71% Niraparib 8% placebo	80% Niraparib 18% placebo

5 MOST COMMON GR≥3 TEAEs

ANEMIA	31% Niraparib 2% placebo
THROMBOCYTOPENIA	29% Niraparib <1% placebo
NEUTROPENIA	13% Niraparib 1% placebo
FATIGUE	2% Niraparib <1% placebo
HYPERTENSION	6% Niraparib 1% placebo

AE: adverse event; BICR: blind independent central review; *BRCA*mut: *BRCA* mutation; *BRCA*wt: *BRCA* wildtype; CR: complete response; FIGO: International Federation of Gynecology and Obstetrics; GR: Grade; HR: hazard ratio; HRd: homologous recombination-deficient; HRp: homologous recombination-proficient; HRnd: homologous recombination status not determined; IDS: interval debulking surgery; OS: overall survival; PDS: primary debulking surgery; PFS: progression-free survival; PFS2: second PFS post-initiation of 2nd-line treatment; PR: partial response; PRO: patient-reported outcome; TEAE: treatment-emergent adverse events; TFST: time to first subsequent treatment;

References: 1. Gonzalez-Martin A, et al. *N Engl J Med*. 2019;381(25):2391-2402 2. CT.gov identifier NCT02655016. 3. Gonzalez-Martin A, et al. Niraparib therapy in patients with newly diagnosed advanced ovarian cancer after chemotherapy: PRIMA/ENGOT-OV26/GOG-3012 Study. Presented at European Society of Gynaecological Oncology (ESGO), Nov 2-5, 2019. Athens, Greece.

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

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