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Abstracts of the 2023 Society of Gynecologic Oncology Annual Meeting

ORAL PRESENTATIONS – Scientific Plenary I: Progress: Therapeutic Innovations

GOG 3026 A phase II trial of letrozole + ribociclib in women with recurrent low-grade serous carcinoma of the ovary, fallopian tube or peritoneum: A GOG foundation study (001)

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Objectives

The combination of endocrine therapy plus a CDK 4/6 inhibitor has demonstrated superior activity to endocrine therapy alone in multiple clinical trials of women with HR+ breast cancer. We aimed to evaluate the clinical activity of ribociclib (R), an orally bioavailable, highly selective small molecule inhibitor of CDK4/6 plus letrozole (L) in women with recurrent low-grade serous ovarian/peritoneal cancer (LGSOC). We conducted an open-label, single-arm, multi-institution, phase II trial evaluating the efficacy of RL for women with this disease.

Methods

Eligibility included the following: 1) histologically confirmed diagnosis of ovarian/peritoneal LGSOC, 2) recurrent, measurable disease, and 3) an unlimited number of prior lines of therapy, excluding aromatase inhibitors. R was administered orally at 600 mg daily every 21 days, followed by 7 days off, and L was administered orally at 2.5 mg daily. Each cycle consisted of 4 weeks of therapy. Patients were treated until disease progression or toxicity. The primary endpoint was the confirmed response rate (RR), which was defined as partial (PR) or complete response (CR) by RECIST 1.1 criteria. Secondary endpoints included clinical benefit rate (CBR) and progression-free survival. This study had a safety lead-in using an optimal flexible 2-stage design. If >14% of the patients responded, the regimen was considered worthy of additional investigation.

Results

Forty-one patients were enrolled (median age: 57.5 years, range: 21.7–85.8). Thirty-seven patients were evaluable for response. The RECIST 1.1 best overall RR was 24% (9 of 37 patients; all were PR; 90% CI: 13.3% - 38.6%, median: 26 cycles, range: 11 to 38). The CBR was 86% (32 of 37 patients; 90% CI: 73.7% - 94.5%); the median number of cycles among those with CBR was 9.5 (range: 1–38). As of July 26, 2022, 46% were still on treatment. Two patients discontinued treatment as a result of toxicity.

Conclusions

The combination of letrozole plus ribociclib demonstrated promising activity in women with recurrent LGSOC compared to reported response rates associated with an aromatase inhibitor alone. Further development of this combination, including an FDA approval strategy, is warranted. Translational studies are ongoing.

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Now: Neoadjuvant Olaparib window trial in patients with newly diagnosed BRCA mutant ovarian cancer (LBA 1)

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Objectives

PARP inhibitors (PARPi) have demonstrated efficacy as first and second-line maintenance treatment in ovarian cancer. We sought to determine the feasibility of olaparib given in the neoadjuvant (NA) setting and the ability to undergo subsequent tumor reductive surgery (TRS) and chemotherapy (CT).

Methods

This was a single-arm, open-label pilot study of olaparib monotherapy for patients with advanced-stage high-grade epithelial ovarian, peritoneal, or fallopian tube carcinoma (NCT03943173). All patients had germline mutation in *BRCA1, BRCA2, RAD51C, RAD51D,*