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Philadelphia, PA, USA, March 25, 2023, The GOG Foundation, Inc. (GOG) announced positive results from an investigator-initiated phase II trial, sponsored by the GOG, investigating the combination of ribociclib and letrozole in patients with recurrent low-grade serous ovarian cancer (LGSOC) (GOG-3026). The results were presented at The Society of Gynecologic Oncology's 2023 Annual Meeting on Women's Cancer ™ in Tampa, Florida.

Ribociclib and letrozole combination is active in patients with advanced or recurrent LGSOC: Phase II trial results:

ORR, PFS, DOR compare favorably to most active agents previously investigated.

In this trial, the reported response rate was 23%, the progression-free survival 19.1 months, and the duration of response of 19.1 months. Sixty-four percent of evaluable patients experienced a reduction in target tumor size.

"These results are promising. Women with this disease have limited treatment options. The progression-free survival and duration of response are both 6 months greater than what we have observed with the current standard treatments," stated Brian Slomovitz, MD, Professor of Obstetrics/Gynecology and Division Director at Mount Sinai Medical Center in Miami Beach, Florida, and the Principal Investigator for this trial.

LGSOC is a rare subtype of ovarian cancer, which typically occurs in younger women and may arise from a non-invasive precursor disease (serous borderline tumor). Approximately 80% of women with LGSOC suffer disease recurrence following primary therapy. Traditional treatment options, including chemotherapy, hormonal therapy, and biologic targeted therapies, have limited clinical efficacy and short durations of response. In particular, response rates to chemotherapy range from 0-15%. Treatment options for women with recurrent disease remains an unmet need.

"For years, we have not had a great understanding of this disease. We have learned that effective treatments are often similar to those used to treat women with hormone positive breast cancer," added David M. Gershenson, MD, professor at MD Anderson Cancer Center in Houston, Texas, and Co-Principal Investigator.

"The GOG Foundation sponsors investigator-initiated trials with the intent of improving the outcomes for patients with gynecologic cancers. This trial is an example of achieving this focused mission. The trials that we support and sponsor are meant to help patients with gynecologic cancers to not only live longer, but with a better quality of life", stated Larry Copeland, MD, professor at The Ohio State University and President of the GOG Foundation.

Dr. Slomovitz added, "The next steps will be to compare this regimen of ribociclib and letrozole versus the best current therapies in a head-to-head study. Hopefully this work can lead to an FDA approval for this combination."

The GOG Foundation is excited about this promising advancement for gynecologic cancer patients dealing with rare tumors. This is yet another opportunity to help transform the standard of care in gynecologic oncology.





About The GOG Foundation, Inc. (www.gog.org)

The GOG Foundation, Inc. is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and translational scientific research in the field of gynecologic malignancies. The GOG Foundation is committed to maintaining the highest standards in clinical trials development, execution, analysis, and distribution of results. The GOG Foundation is the only clinical trialist group in the United States that focuses its research on patients with pelvic malignancies, such as cancer of the ovary (including surface peritoneal malignancies), uterus (including endometrium, soft tissue sarcoma, and gestational trophoblastic neoplasia), cervix, and vulva. The GOG Foundation is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, oncology nurses, biostatisticians (including those with expertise in bioinformatics), basic scientists, quality of life experts, data managers, and administrative personnel.

About the GOG Partners Program

Supported by industry, GOG Partners program is structured to work directly with pharmaceutical organizations and operate clinical trials outside the National Cancer Institute (NCI) framework. The GOG Partners program promotes the mission of the GOG Foundation dedicated to transforming the care in Gynecologic Oncology. By providing an alternative venue for patient accrual and site infrastructure support, GOG Partners has helped provide additional trials and opportunities for patients outside the national gynecologic clinical trials network.

About Low Grade Serous Ovarian Cancer

Ovarian cancer is the eighth leading cause of cancer-related death among women worldwide. LGSOC make up 5-10% of all serous carcinomas of the ovary. They tend to occur in younger women than high grade serous cancers. 80% of the women who are diagnosed have stage III disease. Current treatment options include surgery, chemotherapy, hormonal therapy, and biomarker driven therapies. Better treatment options clearly represent an unmet need.

About GOG Investigator Initiated Trials

In support of our dedication to transforming the standard of care in gynecologic oncology, the GOG Foundation, Inc. sponsors Investigator Initiated Trial (IIT) studies with scientific merit. In some instances, through sponsorship and in collaboration with individuals or companies, the GOG will work collaboratively with these entities that provide partial support, drugs or technology. These trials are designed to have a direct impact on patients by assessing cost-effective treatments and generating data applicable to the local population at both academic and community-based sites through the GOG Partners Program. The GOG physician leadership provides mentorship for the next generation of investigators leading these IITs. The GOG has a committee that periodically reviews and evaluates applications during a request for proposals process. More details on how to apply can be found at https://www.gog.org/gog-partners/iit-loi-application/.

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