TAPUR Study Shows Encouraging Results for Olaparib in BRCA-Mutated Advanced Prostate and Pancreatic Cancers

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ALEXANDRIA, Va. — Positive results from two cohorts of the Targeted Agent and Profiling Utilization Registry (TAPUR) Study provide real world evidence to support recent clinical trial data that demonstrate a role for olaparib (Lynparza) in the treatment of advanced prostate and pancreatic cancers with BRCA1/2 inactivating mutations. The findings will be presented as part of the virtual scientific program of the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting.

In two small cohorts, olaparib treatment resulted in objective responses or stable disease for at least 16 weeks in more than two-thirds (68%) of patients with advanced prostate cancer and BRCA1/2 inactivating mutations, and nearly a third (31%) of patients with advanced pancreatic cancer and BRCA1/2 inactivating mutations.

"It makes sense that a targeted therapy that works well and has been approved for one type of cancer with a particular mutation could also be effective for other types of cancer with the same mutation," said Chief Medical Officer and Executive Vice President Richard L. Schilsky, MD, FACP, FSCT, FASCO. "TAPUR provides data from a broader population of patients than were included in pivotal trials of olaparib in these indications and supports its safety and effectiveness in patients with extensive prior treatment."

TAPUR: Understanding How Targeted Therapies Perform in Patients With Advanced
Cancer

The TAPUR Study is the first clinical trial conducted by ASCO. Focusing on patients with advanced cancers without remaining treatment options, TAPUR investigates whether specific targeted therapies can benefit patients based on specific genomic profiles of the tumors and lead to more personalized therapies.

TAPUR is a type of study known as a basket trial that groups tumors by specific genomic alterations regardless of the location in the body where the cancer originates. By looking at tumors with specific mutations, researchers can match an advanced cancer with an approved treatment that has been effective in patients with a similar genomic profile. The findings provide hints at which drug-target matches merit further investigation. TAPUR offers a treatment option for patients with late-stage disease for whom there are no other options.

Today, the TAPUR Study has nearly 1,900 patients enrolled at more than 115 participating cancer centers, hospitals, and oncology practices in the United States. TAPUR has served as a model for similar studies around the world.

Why Olaparib?

Olaparib has been shown to have efficacy against several tumors with germline BRCA mutations. The unique mechanism of poly ADP-ribose polymerase (PARP) inhibitors like olaparib exemplifies the role of targeted therapies. PARP inhibitors promote cancer cell death by interfering with DNA replication in cancers that have faulty DNA damage repair genes as a result of genetic mutations (e.g., BRCA 1/2). When BRCA 1/2 genes are mutated—and do not repair damaged DNA—PARP enzymes can repair DNA enough to allow cancers to live and multiply. Olaparib blocks PARP. As a result, DNA damage is not repaired, and cancer cell death is accelerated.

Olaparib Appears Effective for Prostate Cancer With BRCA1/2 Inactivating Mutations

The first study included 29 patients with advanced prostate cancer with germline or somatic BRCA1/2 inactivating mutations. Patients had no remaining standard treatment options, measurable disease, adequate organ function and an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2. Twice daily, patients received either olaparib capsules or tablets. Treatment continued until disease progression.
In the 25 patients evaluable for efficacy, 68% of patients had either an objective response (9 patients) or stable disease for at least 4 months (8 patients). Three patients had at least one grade 3 adverse or serious adverse event possibly related to olaparib. Reported events were consistent with the drug label.

These data support the recent FDA approval of olaparib for treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

**Response Seen in Patients With Olaparib for Advanced Pancreatic Cancer with BRCA 1/2 Mutations**

The second cohort included 30 patients with advanced pancreatic cancer and BRCA1/2 inactivating mutations previously treated with platinum-based therapy. These patients had no standard treatment options remaining, measurable disease, adequate organ function, and an ECOG Performance Status of 0-2. Twice daily, patients received either olaparib capsules or tablets, until disease progression.

In the 26 patients evaluable for efficacy, 31% of patients had either an objective response (partial response in 1 patient) or stable disease for at least 4 months (7 patients). Four patients had at least 1 grade 3 adverse or serious adverse event possibly related to olaparib. Reported events were consistent with the drug label.

These findings support the recent FDA approval of olaparib for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic pancreatic adenocarcinoma and potentially extend its use to patients with more far advanced disease.

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**View the abstracts:**
• Abstract 5567: Olaparib (O) in patients (pts) with prostate cancer with BRCA1/2 inactivating mutations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) study.
• Abstract 4637: Olaparib (O) in patients (pts) with pancreatic cancer with BRCA1/2 inactivating mutations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) study.

ATTRIBUTION TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING IS REQUESTED IN ALL COVERAGE.

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