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APOLLO: A randomized phase II double-blind study of olaparib versus placebo following curative intent therapy in patients with resected pancreatic cancer and a pathogenic BRCA1, BRCA2 or PALB2 mutation-ECOG-ACRIN EA2192

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PANCREATIC CANCER



TPS763

Trials in Progress Poster Session

APOLLO: A randomized phase II double-blind study of olaparib versus placebo following curative intent therapy in patients with resected pancreatic cancer and a pathogenic *BRCA1*, *BRCA2* or *PALB2* mutation—ECOG-ACRIN EA2192.

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Background: A meaningful subset of PDAC is characterized by a homologous recombination deficiency (HRD). The most well-defined patients within this group are those with pathogenic variants in BRCA1, BRCA2 and PALB2. In the metastatic setting, PARP inhibitor maintenance provides a progression-free survival benefit after a period of platinum based chemotherapy^{1,2}, but the role of PARP inhibitors in the curative intent setting is undefined. The OlympiA study established one year of olaparib as the standard of care for patients with BRCA-related, early stage breast cancer who completed all other curative-intent treatment³. Therefore, we have designed a randomized, phase II double-blind study of one year of olaparib vs placebo in patients with pancreatic cancer and a germline or somatic variant in BRCA or PALB2 who have completed all curative intent therapy. Methods: We have enrolled and treated 23 of 152 planned patients on study NCT 04858334/EA2192. Eligibility criteria include: a pathogenic germline or somatic variant in BRCA1, BRCA2 or PALB2 as determined by local laboratory (central review required); completion of curative-intent resection and ≥ three months of multi-agent chemotherapy; no evidence of recurrent disease. At enrollment, patients must be within 12 weeks of their last anti-cancer intervention. Patients are randomized 2:1 to receive oral olaparib 300 mg twice daily or placebo for 12 28-day cycles. The primary endpoint is relapse-free survival. Overall survival is a secondary endpoint. Tumor tissue, fecal material (for microbiome analysis) and serial ctDNA samples are being collected. 1. Golan T, Locker GY, Kindler HL: N Engl J Med 381:1492-1493, 2019. 2. Reiss KA, Mick R, O'Hara MH, et al: J Clin Oncol 39:2497-2505, 2021. 3. Tutt ANJ, Garber JE, Geyer CE, Jr.: N Engl J Med 385:1440, 2021. Clinical trial information: NCT04858334. Research Sponsor: U.S. National Institutes of Health, PANCAN.