Tempus Announces Open Enrollment for Study in Collaboration with GSK to Evaluate Niraparib in Advanced Solid Tumor Patients with PALB2 Mutations

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Tempus, a leader in artificial intelligence and precision medicine, today announced the commencement of an open label phase II study, in collaboration with GlaxoSmithKline (GSK) to evaluate the efficacy and safety of ZEJULA (niraparib), a poly (ADP-ribose) polymerase (PARP) inhibitor used for patients with advanced or metastatic solid tumors and a germline or somatic PALB2 mutation. The study, titled "Niraparib in the Treatment of Patients With Advanced PALB2 Mutated Tumors" (the PAVO study, NCT05169437) is sponsored by Tempus and opened for enrollment on January 7, 2022.

Patients with PALB2 mutations have been shown to be at an increased risk of being diagnosed with breast and pancreatic cancers. Recent studies demonstrate that patients with metastatic breast and pancreatic cancers with germline PALB2 mutations have benefited from treatment with PARP inhibitors. ZEJULA is an oral, once-daily PARP inhibitor approved by the FDA in 2017 for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. Phase 3 clinical trials are underway to evaluate the efficacy and safety of niraparib alone or in combination in additional solid tumors, including breast and lung cancers.

The PAVO study applies an innovative, data-driven approach designed to accelerate and streamline study timelines, and the signal-seeking process for niraparib. Additionally, Tempus leveraged its multi-modal dataset to expedite the protocol development and intelligent site selection in under 60 days.

The PAVO study is designed to enroll solid tumor patients with germline or somatic PALB2 mutations. Tempus is leveraging its TIME Trial Program, a just-in-time network of providers, to support rapid patient identification, site activation, and clinical trial enrollment. Under the study protocol, every patient sequenced through Tempus' genomic sequencing platform will be pre-screened for PALB2 somatic and germline mutations.

"For this collaboration, our data produced insights led to the design of a new trial that we can expedite through our robust diagnostic and just-in-time trial network," said Dr. Kimberly Blackwell, Chief Medical Officer at Tempus. "We look forward to working together to evaluate niraparib's potential for other populations who could benefit from this treatment."

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of clinical and molecular data, and an operating system to make that data accessible and useful, Tempus enables physicians to make near real-time, data-driven decisions to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit www.tempus.com.

[1] Hofstatter, Erin W, et al. "PALB2 Mutations in Familial Breast and Pancreatic Cancer." *Familial Cancer*, U.S. National Library of Medicine, June 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3836668/.

[1] Reiss KA;Mick R;O'Hara MH;Teitelbaum U;Karasic TB;Schneider C;Cowden S;Southwell T;Romeo J;Izgur N;Hannan ZM;Tondon R;Nathanson K;Vonderheide RH;Wattenberg MM;Beatty G;Domchek SM; "Phase II Study of Maintenance Rucaparib in Patients with Platinum-Sensitive Advanced Pancreatic Cancer and a Pathogenic Germline or Somatic Variant in BRCA1, BRCA2, or palb2." *Journal of Clinical Oncology : Official Journal of the American Society of Clinical Oncology*, U.S. National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/33970687/.