ASCOS Expands TAPUR Study Enrollment After Promising Initial Treatment Outcomes Seen

Four Cohorts to Enroll Additional Patients; Total Enrollment Exceeds 500 as Immunotherapy Combo is Added

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ALEXANDRIA, Va. -- The American Society of Clinical Oncology's (ASCO) Targeted Agent and Profiling Utilization Registry (TAPUR) Study has expanded four cohorts for enrollment of additional participants and continues to grow with more than 500 participants and 16 therapies now available.

"This study just reached a key milestone and we’re excited to explore these treatments further," said ASCO Chief Medical Officer Richard L. Schilsky, MD, FACP, FASCO. “While no conclusions about drug efficacy should be drawn at this point, we are very pleased with the growth and expansion of the TAPUR Study."

The TAPUR Study is designed to identify signals of activity of commercially available, targeted anticancer drugs in advanced cancer patients whose tumor harbors one or more genomic variants known to be a drug target.

The TAPUR Study Data Safety and Monitoring Board (DSMB) has recommended enrollment of additional participants for the following cohorts:

- Ovarian cancer patients with KRAS, NRAS and BRAF wildtype variants treated with cetuximab
- Breast cancer patients with a high tumor mutation burden treated with pembrolizumab
- Colorectal cancer patients with a BRAF_V600E mutation treated with vemurafenib plus cobimetinib
- Non-small cell lung cancer patients with CDKN2A loss or mutation treated with palbociclib as monotherapy

Given this recommendation for expansion to Stage II, the TAPUR Study clinical trial sites will continue to enroll eligible patients in these cohorts.

The TAPUR Study DSMB has also recommended the permanent closure of the following cohort:
- Pancreatic cancer patients with CDKN2A loss or mutation treated with palbociclib as monotherapy

TAPUR Study participants are enrolled into cohorts based on tumor type (advanced solid tumors, multiple myeloma, or B cell non-Hodgkin lymphoma), genomic variant and study drug. Stage I enrolls up to 10 participants in a cohort and monitors for objective response or stable disease at 16 or more weeks. If two or more participants have successful outcomes, the cohort is expanded to Stage II, where an additional 18 participants are enrolled in the cohort and monitored. A positive trial at Stage II requires objective response or at least 16 weeks of stable disease in at least 7 of 28 participants. While expansion of enrollment in a cohort indicates that sufficient drug activity has been observed in a small number of patients to warrant further study of the drug in that cohort, no conclusions should be drawn as to whether the drug will ultimately be shown to meet the protocol-specified definition of a positive trial. Once full data from Stage II is available, the TAPUR Study Data and Safety Monitoring Board will again review the data and determine if these criteria are met.

If fewer than two participants in a cohort have successful outcomes, the cohort is then closed. Closure of a cohort is an indication that there is lack of an efficacy signal in the drug-variant-disease cohort.

Currently, 510 participants are enrolled in the TAPUR Study, which is available at 83 clinical sites in 20 states. Bristol-Myers Squibb is now providing a new drug combination for the study, nivolumab + ipilimumab, an immunotherapy treatment that unleashes the patient’s immune system to attack their cancer. With this addition, there are a total of 19 drugs yielding 16 different targeted therapy options (some drugs are used in combination).

The TAPUR Study is registered on ClinicalTrials.gov (NCT 02693535), which includes general information on inclusion/exclusion criteria and other information. Patients and clinicians can also find study information such as general eligibility criteria, participating clinical sites, and contact information for the site study teams at www.TAPUR.org. Researchers and practices interested in participating can visit the TAPUR study website for more information or contact the ASCO study team at http://www.tapur.org/contact-us.

About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is
healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.