Latest Findings from ASCO TAPUR Study Trial Presented at AACR Annual Meeting

All collaborating companies extend participation, enabling oncology community to extend learning from pragmatic study
For immediate release
April 1, 2019
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ALEXANDRIA, Va.—Three completed cohorts reporting findings in non-small cell lung cancer, breast, and metastatic colorectal cancer from the American Society of Clinical Oncology, Inc.’s Targeted Agent and Profiling Utilization Registry (TAPUR™) Study were presented in poster sessions during the American Association for Cancer Research (AACR) Annual Meeting 2019. In addition, all seven pharmaceutical companies currently participating in the TAPUR Study have recently renewed their commitment to support it and provide study drugs at no cost for an additional one to three years.

TAPUR Study participants are enrolled in cohorts based on their tumor type (e.g., any advanced solid tumor, multiple myeloma, or B cell non-Hodgkin lymphoma), the genomic alteration of their tumors, and the targeted drug(s) that correspond to those alterations. Participants are enrolled in two stages and monitored for treatment response. Patient cohorts are either permanently closed after Stage I (less than two responses in 10 participants) or expanded to Stage II for further study and confirmation of a signal of drug activity.

“When we’re engaged in this type of research, learning what doesn’t work is just as important as finding a signal of response,” said ASCO Chief Medical Officer Richard L. Schilsky, MD, FACP, FASCO. “Each patient’s response to treatment contributes to our ever-growing body of knowledge about which therapies may best target the cancer. We are grateful to all of the participants, the oncology team members providing care at the participating clinical sites, and the pharmaceutical companies involved in supporting this endeavor.”

The TAPUR Study is designed to evaluate molecularly targeted cancer drugs and collect data on clinical outcomes to learn about potential additional uses of these drugs outside of Food and Drug Administration (FDA) approved indications. It provides a clinical trial opportunity for patients with
advanced cancer who have genomic alterations in their tumors that can be targeted with a TAPUR Study drug.

The AACR Annual Meeting 2019 is taking place from March 29 to April 3 at the Georgia World Congress Center in Atlanta. Both of the following abstracts, which will be presented at “Phase II-III Clinical Trials: Part 1” poster sessions on April 2 from 8 a.m. to noon, examine TAPUR Study cohorts that closed after stage I due to lack of anti-tumor activity over a 16-week period:

- **Cetuximab in patients with breast cancer and non-small cell lung cancer without reported KRAS, NRAS, BRAF mutations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study** by Julie Fisher, MD, et al.
- **Sunitinib in patients with metastatic colorectal cancer with FLT-3 alterations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study** by Ricardo H. Alvarez, MD, MSc, et al.

The full list of TAPUR Study patient cohort expansions and closures is available on the study’s website, TAPUR.org under “News.”

There are currently 113 TAPUR Study sites in 20 states and nearly 1,400 participants who have received study therapy. The various drugs and their different targeted therapy options (some drugs are used in combination) are provided to patients at no cost by the seven pharmaceutical companies currently participating: AstraZeneca; Bayer; Bristol-Myers Squibb; Eli Lilly and Company; Genentech, a Member of the Roche Group; Merck; and Pfizer. ASCO is seeking to add relevant targeted therapies.

Based on collaborative work with the FDA and Friends of Cancer Research (Friends), ASCO lowered the age of TAPUR Study eligibility in 2017 from 18 to 12 years to extend the opportunity for participation to adolescent patients with advanced cancer. Last month, the FDA finalized guidance for industry on expanding clinical trial eligibility criteria based on input from ASCO and Friends.

The TAPUR Study is registered on ClinicalTrials.gov (NCT 02693535), which includes a list of inclusion/exclusion criteria and other information. The TAPUR Study website has information for patients, such as general eligibility criteria and participating clinical sites, as well as for researchers and practices interested in participating. The website also has contact information for the study team.

Watch a video overview of the TAPUR Study.

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**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 nearly 45,000 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.