

Positive Findings from Two TAPUR™ Study Cohorts to Be Presented at 2019 ASCO® Annual Meeting

Trial expanded to include patients with brain metastases and three new cancer therapies, including one from new collaborator Boehringer Ingelheim

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ALEXANDRIA, Va. Positive findings from fully enrolled cohorts in non-small cell lung cancer and metastatic breast cancer from the American Society of Clinical Oncology, Inc.'s (ASCO) [Targeted Agent and Profiling Utilization Registry \(TAPUR™\) Study](#) will be presented in poster sessions at the 2019 ASCO® Annual Meeting. In addition, the study is being expanded to include patients with active brain metastases and three new drug therapies. Pharmaceutical company Boehringer Ingelheim has also joined the study and, later this year, will provide afatinib (Gilotrif®) to participants who enroll in a tissue-agnostic cohort of patients with an NRG1 gene fusion. That same month, the TAPUR Study also will add two new drugs from existing pharmaceutical company collaborators: abemaciclib (Verzenio®, Eli Lilly and Company) and talazoparib (Talzenna®, Pfizer).

“Many of the patients participating in the TAPUR Study have tried multiple treatment options that did not work, so to see anti-tumor activity in these cohorts is encouraging,” said ASCO Chief Medical Officer Richard L. Schilsky, MD, FACP, FASCO. “Further research is needed to confirm the efficacy of the drugs for patients with these genomic alterations and cancers, but we’re encouraged by the results thus far. We’re pleased to be expanding the study to enroll participants with active brain metastases, who often have few clinical trial options, as well as adding new drug therapies to bolster our treatment options and thus our knowledge base.”

The 2019 ASCO® Annual Meeting is taking place from May 31 to June 4 at McCormick Place in Chicago. Both TAPUR Study abstracts report positive results in study cohorts that expanded in 2017 to include additional patients because two or more patients had a positive response (which includes stable disease):

- **Palbociclib (P) in patients (pts) with non-small cell lung cancer (NSCLC) with CDKN2A alterations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study** by Eugene R. Ahn, MD, *et al.*, which found that monotherapy with palbociclib demonstrated evidence of anti-tumor activity in non-small cell lung cancer patients with a *CDKN2A* gene loss or mutation whose cancer had been heavily treated.
 - This abstract (#9041) will be featured at a poster session on June 2 from 8–11 a.m. (CT) in Hall A (poster board #364).
- **Pembrolizumab (P) in patients (pts) with metastatic breast cancer (MBC) with high tumor mutational burden (HTMB): Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study** by Ajjai Shivaram Alva, MD *et al.*, which found that pembrolizumab demonstrated anti-tumor activity in metastatic breast cancer patients with high tumor mutational burden whose cancer had been heavily treated.
 - This abstract (#1014) will be featured at a poster discussion on June 2 from 11:15 a.m. to 12:45 p.m. (CT) in Hall D2. The poster will be displayed at a poster session prior to the discussion from 8–11 a.m. in Hall A (poster board #95).

The [full list](https://www.tapur.org/news) of TAPUR Study patient cohort expansions and closures is available on the study's website, at: <https://www.tapur.org/news>.

TAPUR Study participants are enrolled in cohorts based on their tumor type (e.g., an advanced solid tumor), the genomic alterations of their tumors, and the targeted drug(s) matched to those alterations in the TAPUR Study protocol. Boehringer Ingelheim is joining the TAPUR Study to further investigate afatinib for fusions in the *NRG1* gene, based on preliminary observations that suggest drug activity in tumors with these fusions.

“Our collaboration with ASCO is grounded in a passion for leading science and a shared goal of advancing cancer research as Boehringer Ingelheim continues its focus on rare cancers,” said Matthew Frankel, MD, Vice President, U.S. Clinical Development & Medical Affairs at Boehringer Ingelheim. “While *NRG1* gene fusions have emerged as a potential therapeutic target in non-small cell lung cancer, including potential response to afatinib, they are not well-understood across different tumor types due in part to the very low incidence of these genomic alterations. Collaborative research through the TAPUR study is essential to understanding common features that we hope will inform diagnostics, patient sub-sets and—hopefully—potential treatment for such tumor types.”

About the TAPUR™ Study

The TAPUR Study evaluates molecularly targeted cancer drugs and collects data on clinical

outcomes to learn about additional uses of these drugs outside of Food and Drug Administration (FDA)-approved indications. It also 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 and who are no longer benefitting from standard anti-cancer treatments or for whom no acceptable standard treatment is available.

TAPUR Study participants are enrolled into cohorts in two stages to enable early stopping or expansion based on treatment response. If fewer than two of 10 participants have successful outcomes at Stage I (according to the independent TAPUR Data and Safety Monitoring Board), the cohort is closed. If two or more participants have successful outcomes, the cohort is expanded to Stage II to enroll an additional 18 participants. If seven or more of 28 participants respond or have stable disease lasting at least 16 weeks, the study reports a positive efficacy signal.

With the addition of Boehringer Ingelheim, there are now eight companies currently providing cancer drugs at no cost to TAPUR Study participants: AstraZeneca; Bayer; Boehringer Ingelheim; Bristol-Myers Squibb; Eli Lilly and Company; Genentech, a Member of the Roche Group; Merck; and Pfizer.

There are currently 119 TAPUR Study sites in 22 states and nearly 1,500 participants who have received a therapy through the trial.

The TAPUR Study is registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02693535) (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.](#)

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.
