The NCCN Oncology Research Program (ORP) strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. Since the program's establishment in 1999, the NCCN ORP has brought millions of dollars in research grants to investigators at NCCN Member Institutions. Research grants are provided to NCCN through collaborations with pharmaceutical and biotechnology companies; these grants are in turn used to support scientifically meritorious cancer research efforts.

NCCN ORP studies typically explore new avenues of clinical investigation and seek answers to important cancer-related questions. All studies are approved and funded through a scientific peer-review process and are overseen by the ORP.

This feature highlights an NCCN study funded through the grant mechanism.

A Phase II Study of TAS-102, Irinotecan, and Bevacizumab in Pretreated Metastatic Colorectal Cancer (TABAsCO)

Principal Investigator: Christos Fountzilas, MD
Condition: Colorectal cancer
Institution: Roswell Park Comprehensive Cancer Center

This is an open-label, nonrandomized, multicenter phase II study of TAS-102, irinotecan, and bevacizumab in participants with advanced (metastatic or unresectable) colorectal cancer who have received prior treatment with a fluoropyrimidine (5-FU or capecitabine) and oxaliplatin or who have experienced a recurrence within 12 months of adjuvant therapy with a regimen that included oxaliplatin. For study purposes, a cycle is defined as 28 days. Patients will receive the following on each treatment cycle: irinotecan (180 mg/m^2) intravenously and bevacizumab (5 mg/kg) intravenously on days 1 and 15, and TAS-102 (25 mg/m^2) orally twice daily on days 2 through 6 and days 16 through 20. TAS-102 will be self-administered (in tablet form) by the study participant and documented in a provided drug diary. Response assessment via CT imaging (or MRI) will be obtained every 8 weeks. Treatment will continue until disease progression, in the absence of unacceptable toxicity or patient/provider choice. After completion of study treatment, patients will be followed up at 30 days, and medical record review will be performed approximately every 6 months for up to 2 years to assess survival status.

Primary Objective:

- Determine median progression-free survival benefit of FOLFIRI-naïve patients treated with TAS-102 + irinotecan + bevacizumab compared with historic control groups treated with FOLFIRI + bevacizumab

Secondary Objective:

- Estimate objective response rate, median overall survival, and adverse event profile

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ClinicalTrials.gov Identifier: NCT04109924

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For more information on specific trials, including patient selection criteria, use the contact information listed with each study.

For more information on the NCCN ORP, including a complete detailing of the clinical studies currently underway at NCCN Member Institutions, go to www.NCCN.org/clinical_trials/clinicians.asp.