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.

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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.

A Phase I Dose-Escalation Safety and Tolerability Study of Mirvetuximab Soravtansine (IMGN853) and Gemcitabine in Patients With FR α -Positive Recurrent Ovarian, Primary Peritoneal, Fallopian Tube, Endometrial, or Triple-Negative Breast Cancer

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Sub-Investigators: Edward Wang; Mark T. Wakabayashi, MD, MPH; Ernest Soyoung Han, MD, PhD; Thanh H. Dellinger, MD; Stephen J. Lee, MD; and Christopher P. Chung, MD

Conditions: Recurrent folate receptor α (FR α)-positive triple-negative (estrogen receptor-negative, HER2/neu-negative, progesterone receptor-negative) breast cancer, breast carcinoma, fallopian tube carcinoma, ovarian carcinoma, primary peritoneal carcinoma, uterine corpus carcinoma, and ovarian cancer

Institution: City of Hope National Medical Center

This phase I trial is studying the side effects and best dose of mirvetuximab soravtansine (IMGN853) and gemcitabine hydrochloride for treating patients with recurrent FR α -positive ovarian, primary peritoneal, fallopian tube, endometrial, or triple-negative breast cancer (TNBC). This trial also includes 3 expanded disease-specific cohorts based on the recommended phase II dose for each disease site (breast [cohort A]; endometrial [cohort B]; and ovarian/primary peritoneal/fallopian tube [cohort C]) to evaluate efficacy in each cohort and help ensure adequate assessment of biological correlates on biopsy (archival and posttreatment) material for cohort C.

Primary Objective:

- Determine the maximum tolerated dose (MTD) and recommended phase II dose (RP2D) of gemcitabine when given in combination with IMGN853 to patients with FR α -positive recurrent ovarian, primary peritoneal, fallopian tube, or endometrial cancer, or TNBC

Secondary Objectives:

- Explore toxicity, response rate, and progression-free survival in 3 expanded cohorts of heavily pretreated patients with FR α -positive TNBC, endometrial cancer, or ovarian/primary peritoneal/fallopian tube cancer, all treated with the initial RP2D
- Provide additional safety data from the expanded cohorts to help inform on the RP2D for each cohort
- Evaluate the relationship between intratumoral levels of DM4, tumoral expression of FR α , and plasma concentration of DM4 at 48 and 72 hours after the first dose
- Determine the pharmacokinetics of DM4 and gemcitabine when given in combination

Exploratory Objective:

- Evaluate the role of archival FR α expression as a substitute for the 48- to 72-hour expression in determining intratumoral concentration of DM4

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