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

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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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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.

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