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

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Conditions: Recurrent folate receptor α -positive, triple-negative breast carcinoma, fallopian tube carcinoma, ovarian carcinoma, primary peritoneal carcinoma, and uterine corpus carcinoma

Institution: City of Hope National Medical Center

This phase I trial evaluates the maximum tolerated dose (MTD) and recommended phase II dose (RP2D) of mirvetuximab soravtansine (IMGN853) in combination with gemcitabine hydrochloride in patients with relapsed folate receptor α (FR α)-positive ovarian, primary peritoneal, fallopian tube, endometrial, or triple-negative breast cancer (TNBC). This trial also evaluates the efficacy and toxicity of this regimen in 3 expanded cohorts of patients with FR α -positive eligible tumor types (the same as included in the phase I).

Primary Objective:

- Determine MTD and RP2D of gemcitabine when given in combination with IMGN853 to patients with recurrent FR α -positive ovarian, primary peritoneal, fallopian tube, TNBC, or endometrial cancer

Secondary Objectives:

- Explore toxicity, response rate, and progression-free survival in 3 expanded cohorts of heavily pretreated patients with FR α -positive (1) TNBC, (2) endometrial cancer, or (3) ovarian, primary peritoneal, or fallopian tube cancer, all treated at the 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 following 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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