SORAYA: A Phase 3, Single Arm Study of Mirvetuximab Soravtansine in Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression

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ISTITUTO DI CANDIOLO

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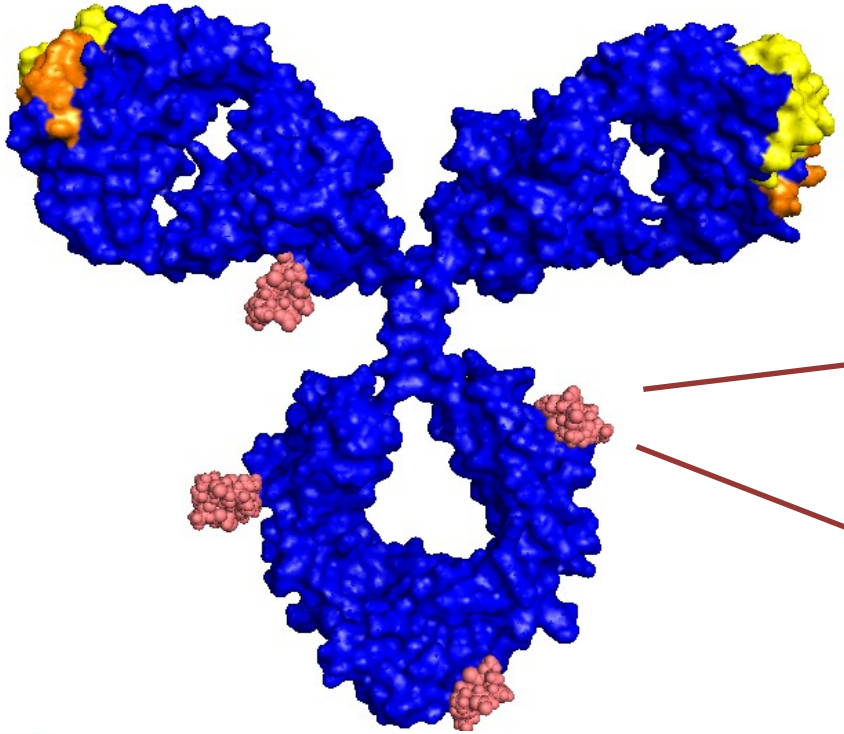
MIRVETUXIMAB

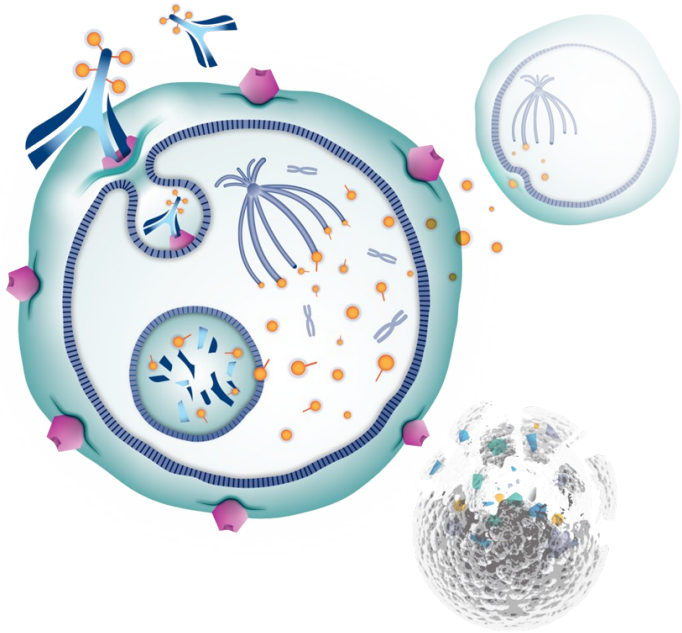


Monoclonal Antibody
- Fully humanized
- High affinity for FRα

sulfo-SPDB Linker
- ADC stable in the circulation

DM4 Payload
- Maytansine derivative with anti-microtubule activity
- 100-1000-fold more potent than vinca alkaloids
- Average of 3-4 DM4 molecules per antibody.

MIRVETUXIMAB



1. The antibody portion of MIRV **binds to FRα** found on the surface of epithelial ovarian cancer cells
2. MIRV is **internalized** via endocytosis
3. MIRV is **degraded** within the lysosome to release its cytotoxic payload (DM4)
4. DM4 **disrupts tubulin** resulting in mitotic arrest and apoptosis
5. DM4 also diffuses through the lipophilic cell membrane allowing **bystander killing on adjacent tumor cells**

STUDY DESIGN, PRIMARY OBJECTIVE and ENDPOINT

Design

- Single arm study of MIRV

- Approximately 110 patients will be enrolled to achieve a total of 105 efficacy evaluable patients

Primary Objective

- To determine the efficacy of MIRV in patients with platinum-resistant ovarian cancer (PROC) and high folate receptor alpha (FRα) expression

Primary Endpoint

- Objective response rate (ORR), which includes best response of complete response (CR) or partial response (PR) as assessed by the Investigator

TARGET POPULATION

Patients with platinum-resistant* high-grade EOC, primary peritoneal, or fallopian tube cancer whose tumors express a high level of FRα

*Defined as progression within ***6 months from completion of a minimum of 4 cycles of platinum-containing therapy*** Note: This should be calculated from the date of the last administered dose of platinum therapy to the date of the radiographic imaging showing progression

Primary Platinum refractoriness implies disease progression either during or within three months of completion of first platinum-containing chemotherapy

This is an exclusion criterion for SORAYA

1-3 prior lines, which must include prior treatment with Avastin® (bevacizumab)