

A Randomized, Double Blind, Placebo Controlled, Multicentre Trial of Abagovomab Maintenance Therapy in Patients with Epithelial Ovarian Cancer After Complete Response to First Line Chemotherapy

This study is currently recruiting patients

SPONSOR: Menarini Ricerche S.p.A.

INTERVENTION: Abagovomab 2 mg/ml subcutaneous vs Placebo subcutaneous.

THERAPEUTIC INDICATION: Ovarian Cancer.

STUDY TYPE & DESIGN: Phase II/III , Randomized, Double-Blind, Parallel Group, Placebo Control study.

MAIN CRITERIA FOR INCLUSION: At a maximum of 8 weeks after the last cycle of 1st line standard platinum/taxane chemotherapy, patients must fulfil all the following inclusion criteria to be eligible for entry into the study:

- Age \geq 18 years;
- History of histological and CA125 ($>$ 35 U/ml) confirmed diagnosis of stage III-IV epithelial ovarian, fallopian tube, or primary peritoneal cancer;
- History of debulking surgery and standard platinum/taxane based non-investigational chemotherapy;
- Complete clinical response defined as:
 - ✓ Normal physical examination;
 - ✓ No symptoms suggestive of persistent cancer;
 - ✓ No definite evidence of disease by computed tomography (CT) of the abdomen and pelvis within the previous 4 weeks;
 - ✓ Negative chest x-ray (or chest CT scan) within the previous 4 weeks;
 - ✓ Serum CA125 level $<$ 35 U/ml.
- Adequate hematologic, renal and hepatic function:
- ECOG Performance Status (PS) $<$ 2.

MAIN CRITERIA FOR EXCLUSION: Patients are ineligible to participate in the study, if any of the following criteria are present:

- any other invasive malignancies, with the exception of non-melanoma skin cancer or cervical carcinoma in situ, within the last 5 years or whose previous cancer treatment contraindicates this protocol therapy;
- known active autoimmune disease requiring chronic treatment with immunosuppressive agents (e.g., rheumatoid arthritis, ulcerative colitis, etc.);
- known immune deficiency (e.g. HIV, hypogammaglobulinemia, etc.);
- known infection with hepatitis B, or hepatitis C;
- history of recent myocardial infarction ($<$ 6 months) or decompensated heart failure (NYHA class $>$ III);
- previous or concomitant use of any anti-cancer therapy other than the platinum-taxane 1st line chemotherapy;
- concomitant use of any other investigational agent;
- any prior investigational anti-cancer vaccine or monoclonal antibody;
- known allergy to murine proteins;
- any significant medical or psychiatric condition, drug or alcohol abuse that might prevent the patient from complying with all study procedures;
- clinically significant active infection;
- concomitant use of any immunosuppressive agent (e.g., steroids, cyclosporin, etc.);
- major surgery within the previous 2 weeks;
- radiotherapy within the previous 4 weeks;
- any significant toxicity from prior chemotherapy;
- unreliability or inability to follow protocol requirements.