GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

GUSTAVE ROUSSY AT ASCO 2017

Press release / Oral presentation / Friday 2nd June

Encouraging results for an immunotherapy in gynaecological cancer

Nivolumab might be a new effective therapy in patients with failed treatment of uterine cervical, vaginal and vulval cancers. On 2nd June Dr Antoine Hollebecque, Head of the Day Hospital Unit in the Drug Development Department (DITEP) at Gustave Roussy, will present these results at an oral session at the ASCO Congress.

Nivolumab is an immunotherapeutic agent that has previously been shown to be effective in various cancers including lung and melanoma. This clinical study shows its role in gynaecological cancers and offers new hope for patients in a therapeutic impasse.

The CheckMate 358 clinical trial is a phase 1 / 2 international trial sponsored by the BMS Company. It is evaluating the efficacy of nivolumab in 5 different types of cancer, in all of which a viral infection may play a part. Dr Antoine Hollebecque coordinated the French wing of the study for Gustave Roussy in a cohort of women with cancers of the uterine cervix, the vagina or vulva, linked to the human papilloma virus (HPV).

In this cohort, 24 patients received injections of nivolumab at a fixed dose of 240 mg (the standard dose used in other cancers) every two weeks. Nineteen of them had cervical cancer and 5 had vaginal or vulval cancer. After a median follow-up period of 31 weeks, the objective response rate (marked tumour regression) was found in 20.8% of them and the disease control rate (objective response + stable disease) was 70%. All the responses were observed among patients with cervical cancer.

Cervical cancer affects about 3,000 women in France each year. Its incidence is falling as a result of advances in screening by means of smears, but its mortality remains substantial with some 1,100 deaths per year. More than 90% of cervical cancers are due to HPV infection, usually one dating back decades to the start of the individual's sexual activity. Cancers of the vagina or vulva are rarer but in 40 to 70% of cases these too may result from HPV infection.

The treatment of these cancers is based on surgery, sometimes combined with chemotherapy and radiotherapy for advanced forms. When these treatments fail, if the disease relapses or distant foci (metastases) appear, there is no useful option to offer these patients.

The anti-PD1 agents, a group to which nivolumab belongs, are one of the major types of immunotherapy. This anti-cancer mechanism was developed recently and acts by helping the patient's own defence mechanisms to fight the cancer.

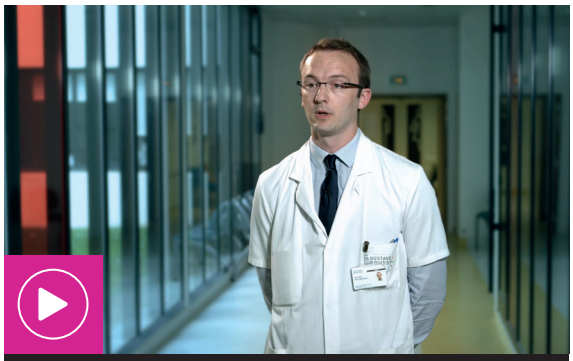
Oral presentation by
Dr ANTOINE HOLLEBECQUE
Gustave Roussy

Session :
Gynecologic Cancer
Friday 2nd june, 16h12
(local time)
Place : S406

READ ABSTRACT
N° 5504

PD-1 and PD-L1 are known to be present in gynaecological cancers, which encouraged the hope that nivolumab might be effective in treating these tumours. The evidence is now available. The trial also showed that the drug was well tolerated by patients with its side effects being manageable. The follow-up period is still too short to draw firm conclusions but overall survival of these patients also seems to have improved. If these results are confirmed, nivolumab would become the first immunotherapeutic agent to be approved for these conditions.

Titre : An Open-Label, Multicohort, Phase 1/2 Study of Nivolumab in Patients With Virus- Associated Tumors (CheckMate 358): Efficacy and Safety in Recurrent or Metastatic (R/M) Cervical, Vaginal, and Vulvar Cancers.



VIDEO OF
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