GUSTAVE ROUSSY AT ESMO 2018

GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

GUSTAVE ROUSSY PRESENTATIONS AT ESMO 2018

This year, the European Society for Medical Oncology (ESMO) will take place in Munich, Germany, from 19 to 23 October. It is Europe's biggest cancer congress and the number of delegates increases year-on-year. Experts from all over the world visit the congress to share the latest clinical innovations in oncology. Around 20,000 delegates from 130 countries are expected to attend ESMO 2018.

Gustave Roussy will undoubtedly be one of the main stakeholders at this congress and specialists will present results during oral presentations, poster discussions and special symposia/posters. This document unveils the oral presentations and poster discussions presented solely by physicians/researchers (investigators) at Gustave Roussy. Professor Fabrice André's verbal presentation of the results of the SOLAR-1 breast cancer study during the plenary session on Saturday, 20 October, is the highlight of the congress.

Renowned for their specialist knowledge, approximately ten experts will act as moderators in the verbal sessions, symposia or discussions. Professor Karim Fizazi will officiate during a plenary session oral presentation on prostate cancer on Sunday 21 October.

ESMO

FROM 19 TO 23 OCTOBER 2018

European Society for Medical Oncology
Munich, Germany

ABOUT GUSTAVE ROUSSY

Gustave Roussy, Europe's leading anti-cancer centre, is a global, patient-focused centre of excellence. It brings together 3,100 professionals dedicated to treatment, research and teaching.

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1
IN THE SPOTLIGHT

ADVANCED HORMONE-DEPENDENT BREAST CANCER

Is the first medication to target a genome anomaly in the pipeline?

Results of phase III SOLAR-1 study

Hormone therapy is the standard reference treatment for women presenting advanced hormone-dependent breast cancer. However, most patients develop resistance after a few months or years. A new class of hormone therapy is initiated in the event of recurrence.

Detected in 40% of advanced, recurrent hormone-dependent breast cancers, *PIK3CA* mutation triggers hyperactivation of PI3 kinase, an enzyme stimulating the cell cycle. This enzyme is involved in the transformation of healthy cells into cancerous cells, cancer progression and even the development of resistance to hormone therapy.

The phase III, SOLAR-1 study compares the benefit of adding a new molecule, namely alpelisib, which targets the alpha isoform of PI3 kinase, to a placebo during disease recurrence in addition to hormone therapy (fulvestrant). This treatment was assessed in patients with or without *PIK3CA* mutation. Alpelisib was seen to have a beneficial effect on these women in a previous phase Ib study.

Sponsored by Novartis, SOLAR-1 is a phase III, multicentre, international, randomised, double-blind study versus placebo with an overall cohort of 572 patients enrolled between July 2015 and July 2017.

A press release presenting the study outcomes will be available as soon as the embargo is lifted.

SOLAR-1 results will be presented during the presidential session at 5:30pm October 20th by Prof. Fabrice André, oncolgist at Gustave Roussy and research director.

Professor André will present these results during the ESMO press conference at 08:15 on Saturday morning. The study will also be covered in an ESMO press release.

▶ EMBARGO IN PLACE UNTIL 16:30 ON SATURDAY, 20 OCTOBER

Presidential symposium, Saturday 20 October, 17:30-17:45 Hall 2. Room 18
LBA3 - Alpelisib (ALP) + fulvestrant (FUL) for advanced breast cancer (ABC): results of the Phase III SOLAR-1 trial
Abstract n° LBA3_PR

▶ LINK ITW PROF. FABRICE ANDRÉ VIDEO PENDING

BREAST CANCER

Treatment compliance for women receiving tamoxifen?

First prospective study to assess non-compliance with adjuvant therapy in premenopausal breast cancer patients by measuring Tamoxifen blood levels.

Until now, the patient's word was the only method used to check treatment compliance. Dr. Barbara Pistilli, medical oncologist at Gustave Roussy, will present the initial results of this study carried out in the CANTO COMPLETE context. In this study, treatment compliance was routinely tested by measuring the concentration of the medicinal product in the patient's blood sample.

Carried out during the first year of follow-up, the results show that one in six premenopausal patients fails to comply with hormone therapy prescribed to prevent disease recurrence.
This study analysed the various biological, clinical and social factors involved in order to recommend targeted behavioural intervention in an attempt to improve treatment compliance amongst patients at risk.

From November onwards, a qualitative study will be launched via focus groups including patients and professionals to discover the best resources to assist these women.

Sponsored by Unicancer and co-ordinated by Professor Fabrice André, CANTO (CANcer TOxicities), this is a cohort study targeting the long-term follow-up of a large number of people, 12,000 women receiving breast cancer treatment, in order to describe toxicities, identify populations likely to develop toxicities and to consequently adjust treatments for a better quality of life. CANTO is sponsored by Programme d'Investissements d'Avenir from the French government. The study is part of the Cancer 2 Plan approach – life after cancer.

Various additional studies have been initiated based on the CANTO cohort including CANTO COMPLETE, partly financed by Inca.

▶ EMBARGO IN PLACE UNTIL 00:05 ON FRIDAY, 19 OCTOBER

Oral presentation, Friday 19 October at 16:12-16:24. ICM - Room 13
Serum assessment of non-adherence to adjuvant endocrine therapy (ET) among premenopausal patients in the prospective multicenter CANTO cohort.
Abstract n° 1850_PR

NOTA BENE

The results of this study will be covered in an ESMO press release

2
CHANGE OF PRACTICES

HIGH-RISK, LOCALISED PROSTATE CANCER
Is it better to use a chemotherapy right from the outset?

GETUG 12 results with 12 years of follow-up.

With over 53,000 new cases diagnosed in France each year, prostate cancer was the most common form of cancer in men in 2012.

On Friday, 19 October, Professor Karim Fizazi, oncologist specialising in genital-urinary tumours, will present the results of GETUG 12 - a French, multicentre, randomised, phase III trial sponsored by Unicancer, with a 12-year follow-up period.

The aim of the GETUG 12 study was to assess the benefit of chemotherapy on progression-free survival in high-risk, localised prostate cancer patients in addition to standard reference treatment (local treatment and hormone therapy).

In this study, the patients were treated with hormone therapy (gosereline) for 3 years and received local radiotherapy or underwent surgery. The cohort was divided into two groups, only one of which received four courses of chemotherapy (combination of docetaxel and estramustine). Chemotherapy was initiated at the same time as hormone therapy and prior to local treatment.

After 12 years of follow-up, the study results not only confirm that the use of chemotherapy reduces the risk of recurrence diagnosed by elevated levels of PSA (prostate cancer marker in the blood) but, above all, also show for the first time that the risk of clinical recurrence (i.e. the onset of metastases or local recurrence in the region of the prostate) is significantly reduced. Overall, the addition of chemotherapy reduces the risk of recurrence or death by 29%.
The good results obtained with GETUG 12 will fuel discussions on practice changes to add chemotherapy to the initial treatment strategy for these patients.

The GETUG 12 study has received funding from the Anti-Cancer League and Sanofi Aventis.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Oral, Friday,19 October 2018 at 14:00 -14:15 - ICM. Room 13
Updated results of GETUG-12, a phase 3 trial of docetaxel-based chemotherapy in high-risk localized prostate cancer, with a 12-year follow-up
Abstract n° 7910

À NOTER

Prof. Karim Fizazi will be invited discussant during a presidential symposium on prostate cancer Sunday, 21 October at 16:30

SQUAMOUS CELL CARCINOMA

Evidence of intensity-modulated radiotherapy

Carcinomas are malignant tumours of epithelial origin. Amongst them, squamous cell carcinoma (cutaneous and mucosal) is one of the most common human cancers although, paradoxically, it is not well documented in cancer registers.

Combined radio-chemotherapy is current standard treatment for patients presenting locally advanced head and neck squamous cell cancer.

Until now, there was no evidence to confirm whether intensity-modulated radiotherapy could improve locoregional control compared to other techniques (2D/3D with no intensity modulation).

Dr. Yungan Tao, a radiotherapist at Gustave Roussy, presents a study that evaluates the assumption that an increased dose of radiotherapy via the IMRT technique together with cisplatin chemotherapy could ensure better tumour control.

This is a randomised, phase III study with new evidence in favour of IMRT for patients with locally advanced head and neck squamous cell cancer.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY 19 OCTOBER 2018

Poster Discussion, Saturday 20 October 2018 at 15:50 – Hall B3. Room 23
Concurrent cisplatin and dose escalation with intensity-modulated radiotherapy (IMRT) versus conventional chemo-radiotherapy for locally advanced (LA) head and neck squamous cell carcinomas (HNSCC): GORTEC 2004-01 randomized phase III trial
Abstract n° 1054PD

3

NEW AND PROMISING AVENUE IN PHASE I TRIAL

NEUROENDOCRINE TUMOURS

Good perspective with an epigenetic target

Neuroendocrine tumours (NET) are a group of rare tumours that can develop anywhere in the body. The annual incidence of this disease is of the order of 2 to 5 new cases per year, per 100,000 individuals. The age of onset is mostly between 40 and 60.

Dr. Antoine Hollebecque, Head of the Conventional Hospitalisation Department at the Department for Therapeutic Innovation and Early Trials (DITEP) at Gustave Roussy, outlines a phase I study aimed at assessing the tolerance, preliminary efficacy and correct dosage of a medicinal product (CC-90011) inhibiting enzyme LSD1, the epigenetic target (gene expression), for patients presenting neuroendocrine lung and prostate tumours. Indeed, LSD1 plays an important role in the epigenetics of numerous tumours.

At this stage in the study, the results show that three out of four patients have a stable tumour at one year. The only notable side effect is a drop in the platelet count.

Chemotherapy or metabolic radiotherapy are the only relevant protocols for patients presenting these tumours. This new avenue would therefore extend the therapeutic options available.

The next step is to confirm these efficacy data by treating a larger patient cohort and by progressing to a phase II study of the management of small cell lung cancers and neuroendocrine lung tumours.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster Discussion, Monday 22 October 2018 11:15 – Hall B3. Room21
Phase I study of CC-90011 in patients with advanced solid tumors and relapsed/refractory non-Hodgkin lymphoma (R/R NHL)
Abstract n° 1832PD

4
IMMUNOTHERAPY

Gustave Roussy is an international pioneer in immunotherapy and launched a specific programme as far back as 2015: GRIP which stands for the Gustave Roussy Immunotherapy Program. Dr Aurélien Marabelle is the clinical director of the program and Prof. Laurence Zitvogel is the scientific director.
With over 200 clinical trials (133 in the pipeline) and nearly 2 800 patients treated since 2013, Gustave Roussy is Europe's leading cancer immunotherapy centre, both in terms of the number of clinical trials carried out and the number of patients treated.

METASTATIC RENAL CANCER

A review of the use of Nivolumab in the management of cerebral metastases

Immunotherapies are now the approved treatments for current forms of renal and clear cell carcinomas. However, they have not yet been assessed in patients with cerebral metastases, who account for almost 10% of patients presenting metastatic renal cancer. The prognosis for these patients is very poor and the treatments available for this condition have only been moderately effective.

Sponsored by Unicancer, trial GETUG AFU 26 - NIVOREN, designed by Drs. Escudier and Albigès, has assessed the use of Nivolumab in a population of 730 patients with metastatic renal cancers. This large-scale national study has also facilitated the first prospective investigation of the cerebral metastatic response to Nivolumab in these patients.

It shows that Nivolumab displays very limited antitumour activity in this context and that the implementation of local radiotherapy prior to the introduction of nivolumab can be used to delay the onset of cerebral disease progression. Treatment strategies can therefore be optimised in these patients.

Whilst new treatment combinations are also being assessed as first-line therapy, it is important to assess their cerebral efficacy. Finally, the NIVOREN trial emphasises the importance of continuing dedicated clinical trials in this high-risk population.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster Discussion, Saturday 20 October 2018 at 14:45-16:05 – I CM. Room 1
Brain metastases response to nivolumab in patients with renal cell carcinoma (RCC): Prospective analysis from the GETUG-AFU 26 (NIVOREN) trial
Abstract n° 868PD

NOTA BENE

Professor Alexander Eggermont, Gustave Roussy Director General, will be the speaker at a "special symposium" session focussing on therapeutic strategies for melanoma and outlining future plans for adjuvant immunotherapy treatments.

Special Symposium, Saturday 20 October 2018 at 12:05-12:30. ICM. Room 14b

TREATMENT BY IMMUNOTHERAPY

What is the link between efficacy and adverse events?

No link found between immune-system related adverse events and efficacy in patients receiving anti-PD-(L)1.

Immune check-point inhibitors anti-PD-1 and anti-PD-L1 have undergone significant development, revolutionising the management of patients with melanoma, lung, renal and urothelial cancers.

Patients treated with anti-PD-1 and anti-PD-L1 are at risk of experiencing immunotherapy-related adverse events known as immuno-mediated effects. Studies conducted in melanoma patients have shown a correlation between the onset of skin erythema or vitiligo and improved global survival. However the results of the studies assessing the link between immuno-mediated adverse events and survival in patients with non-small-cell lung cancer are contradictory.

The study presented by Dr. Maria Kfoury, medical oncologist within the Département d'Innovation Thérapeutique et Essais Précoces (DITEP) (Department of Therapeutic Innovation and Early Trials) at Gustave Roussy, sought to establish whether the development of immuno-mediated adverse events was correlated to improved survival in patients treated with PD-1 and anti-PD-L1. The prospective cohort study involving over 600 solid tumour patients has not revealed any significant correlation between immunity-related adverse events and overall survival or progression-free survival.

Large-scale prospective studies are needed to confirm results. A better understanding of immuno-mediated adverse events is essential and the assumption of a cross-reactive immune response between the tumour and healthy tissue has yet to be confirmed.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster Discussion, Monday 22 October 2018 at 10:20 – Hall B3. Room21
Association between immune-related adverse events and efficacy in patients treated with anti-PD-(L)1
Abstract n° 1141PD

GUSTAVE ROUSSY
RENOWNED EXPERTISE IN IMMUNOTHERAPY-RELATED TOXICITIES

- A REISAMIC multicentre, national study aimed at the prospective and proactive collection, via a specific web portal or mobile app, of the immunological and/or severe adverse events (AE) experienced by patients treated with immunomodulatory monoclonal antibodies in oncology.
- ImmunoTox multidisciplinary meetings (MDM) which are organised on a monthly basis with "ImmunoTox" experts to present register results (type, severity and frequency of events collected per molecule and indication, etc.) and to discuss sensitive and/or complex cases.
- Guidelines, recommendations for the management of patients receiving immunotherapy and toxicity management are incorporated in the "Manuel pratique d'oncologie de Gustave Roussy" (Gustave Roussy Practical Oncology Manual) available on mobile app from the Apple store and Google Play

5
EXPERT IN THE MANAGEMENT OF SARCOMA

Sarcomas, rare cancers, need an ultra-specific management. Gustave Roussy is the co-ordinating centre in Paris for the French Sarcoma Network recognised by the French National Cancer Institute.
The treatment strategy outlined to the patient is universally agreed by specialists in various disciplines (surgery, radiotherapy, oncology, imaging, anatomopathology) and always considers the unique context of each patient.

RARE PERITONEAL MALIGNANT DISEASE

A cure is possible for patients with a dermoplastic small round cell tumour

Dermoplastic small round cell tumours are a rare peritoneal malignant disease affecting (mainly male) children and young adults with a dreadful prognosis. Gustave Roussy has been investigating the optimum treatment sequence for 3 years.

Dr. Charles Honoré, Head of the Gustave Roussy Sarcoma Committee, presents a study which has identified an effective sequence combining chemotherapy, total cytoreductive surgery, chemotherapy and pan-abdominal radiotherapy offering long-term cure for 5% of patients.

At the present time, this treatment cannot, unfortunately, be administered to all those affected primarily because of the fact that the disease extends beyond the abdomen.

It is, however, promising for patients with this condition. From now on, the Institute would like to run several basic research programmes dedicated to the treatment of patients with a dermoplastic small round cell tumour.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster discussion, Monday 22 October 2018 11:00 - 12:15 - ICM. Room 13
Concurrent cisplatin and dose escalation with intensity-modulated Can we cure patients with abdominal desmoplastic small round cell tumor? Results of a retrospective multicentric study on 100 patients
Abstract n° 1608PD

METASTATIC SARCOMAS

Quality of life maintained with trabectedine

Soft tissue sarcomas (STM) account for approximately 1% of adult cancers and 2% of cancer-related deaths. The 5-year survival rate following STM diagnosis is 58%.

Professor Axel Le Cesne, medical oncologist at Gustave Roussy, presents the results of a study which proves that trabectedine can boost progression-free survival without altering the quality of life of patients presenting advanced soft tissue sarcomas.

This study completes the multicentre T-SAR study sponsored by Gustave Roussy, the results of which were presented at ESMO 2017 and ASCO 2018. Co-ordinated by the French Sarcoma Group, this randomised study compared trabectedine to the best supporting care for patients presenting advanced soft tissue sarcoma and highlighted a significant improvement in progression-free survival in these patients.

▶ EMBARGO IN PLACE UP TO 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster discussion, Monday 22 October 2018 at 11:00 - ICM. Room 13
Health-related quality of life in patients with advanced soft tissue sarcoma (ASTS): Results from the TSAR randomized phase III trial of the French Sarcoma Group
Abstract n° 1604PD

6
IMPROVE TREATMENT TOXICITY AND ADVERSE EVENTS

PHYSICAL ACTIVITY AND WEIGHT
Important parameters in combating chemo-induced neuropathies

Although the number of individuals with breast or colorectal cancer has increased considerably over the last two decades, a substantial proportion of survivors are expected to present with chronic toxicity related to anticancer treatments. Chemo-induced peripheral neuropathy may affect 30% of patients 6 months after chemotherapy has ended, and up until now, no treatments have been authorised to treat this condition.

Recent studies suggest that health behaviours such as physical activity and weight control can influence the onset and severity of chemo-induced neuropathy. The study presented by Dr. Margarida Matias, oncologist at Gustave Roussy, shows that among the 877 survivors of breast and colorectal cancer treated by adjuvant chemotherapy, 36% presented neuropathy two years after the cancer was diagnosed. Furthermore, 17% of patients had gained weight and 59% had reduced their physical activity or were inactive; 12% consumed alcohol more than 4 times a week and 22% were smokers.

These observations confirm the significant correlation between inactivity and weight gain, and the onset of neuropathy. The onset and severity of neuropathy could therefore be improved if appropriate action were taken to rectify the situation.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY 19 OCTOBER 2018

Poster discussion, Monday 22 October 2018 at 16:55 - Hall B3. Room 21
Neuropathy and health behaviors in cancer survivors treated with chemotherapy (CT)
Abstract n°1687PD

SEVERE FATIGUE FOLLOWING BREAST CANCER
Identify the patients at risk

Most patients who have had breast cancer have suffered from fatigue at some point during treatment, and 30% still experience severe fatigue several years after treatment has ended. However, few large-scale data are available to help predict and prevent post-cancer fatigue.

Presented by Dr. Ines Vaz Luis, oncologist at Gustave Roussy, the study involving more than 4,500 patients in the CANTO cohort, identified groups at risk of developing severe fatigue (global as well as emotional, physical and cognitive fatigue). Psychological distress and certain symptoms such as insomnia, apparent from diagnosis and during the disease, are significant factors for predicting whether a patient is at increased risk of severe fatigue after breast cancer. The study shows that there are groups of patients with a 90% plus risk of developing severe fatigue two years after diagnosis.

In future, individualised procedures could be developed based on these data in an attempt to reduce the risk of severe fatigue developing over time.

▶ EMBARGO IN PLACE UNTIL 12:00 ON FRIDAY, 19 OCTOBER 2018

Poster discussion, Monday 22 October 2018 at 16:55 - Hall B3. Room 21
Breast cancer (BC) related fatigue: A longitudinal investigation of its prevalence, domains and correlates
Abstract n°1689PD

ADJUVANT CHEMOTHERAPY IN BREAST CANCER

Impact of physical activity on quality of life

The side effects of chemotherapy may have a negative impact on the quality of life of patients who have had breast cancer. It is essential to have a better understanding of the impact of physical activity on the quality of life of patients receiving adjunct chemotherapy. Involving over 2,500 patients from the CANTO cohort, this study presented by Dr. Antonio Di Meglio, oncologist at Gustave Roussy, shows that over one-third of patients do not follow physical activity recommendations which would offset the risk of a deterioration in quality of life following breast cancer.

Individualised procedures based on physical activity should be implemented and directed more specifically towards patients more likely to experience a downward trend in quality of life after breast cancer.

▶ EMBARGO IN PLACE UNTIL 00:05 ON SATURDAY 20 OCTOBER 2018

Poster discussion, Monday 22 October 2018 at 09:30 - Hall B3. Room 21
Physical activity (PA) and patterns of quality of life (QOL) after adjuvant chemotherapy (CT) for breast cancer (BC)
Abstract n°1684PD_PR

NOTA BENE

This poster which received a Merit Award* will be covered by an ESMO press release

**A limited number of rewards is reserved for candidates under 40 years of age. Merit Award winners are selected on the quality of their accepted abstracts, which are examined by the Congress Scientific Committee.*

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