Save the date

Gustave Roussy at ASCO 2016

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CANCER CAMPUS
GRAND PARIS

ASCO ANNUAL MEETING
COLLECTIVE WISDOM
2016
THE FUTURE OF PATIENT-CENTERED CARE AND RESEARCH

June 3-7, 2016
McCormick Place | Chicago, Illinois
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GUSTAVE ROUSSY, LEADING COMPREHENSIVE CANCER CENTER IN EUROPE, AT ASCO ANNUAL MEETING

At this 52nd annual meeting of the world's most important oncology conference, Gustave Roussy will confirm its leading role in the development of three therapeutic strategies that are changing practice and transforming patient treatment. Immunotherapy, which is extending its application to new conditions, and precision medicine are becoming routine therapeutic options. This 2016 meeting will also be noteworthy for throwing light on the optimisation of existing treatments, as reflected by the presentation in plenary session of childhood neuroblastoma treatment, for which Dr Dominique Valteau-Couannet, Head of the Gustave Roussy Paediatric Department, will be a discussant.

This year, Gustave Roussy medical researchers will be revealing their work in a total of 75 presentations. The ASCO Scientific Committee has selected 21 oral communications, 6 of which will be delivered by doctors from the Institute; 11 poster-discussions, 6 of which are to be presented by Gustave Roussy researchers; and 42 posters and 1 educational session authored by doctor researchers from the Institute. Gustave Roussy is the sponsor of four clinical trials, the results of which will be communicated during the conference.

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3 – 7 JUNE 2016

52nd Conference of the American Society of Clinical Oncology (ASCO, Chicago, USA, 3 – 7 June 2016)

ABOUT GUSTAVE ROUSSY

Gustave Roussy is the leading Cancer Centre in Europe.
It is a centre where all the skills in cancer care are focused on the patient. It comprises 3,000 professional staff who are engaged in care, research and teaching.
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AFTER MELANOMA, IMMUNOTHERAPY IS EFFECTIVE IN OTHER PATHOLOGIES

Gustave Roussy is one of the leading Comprehensive Cancer Centres in the world. It is in the vanguard of progress in immunotherapy. «By the end of this year, some forty immunotherapy-based clinical trials will be ongoing at the Institute» states Dr. Aurélien Marabelle, Clinical Director of the immunotherapy programme at Gustave Roussy.

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One of the new immunotherapeutic techniques is inhibition of checkpoint PD-1/PD-L1. This is being rolled out, in particular, in genito-urinary cancers. The PD-L1 ligand is expressed within tumours or in their micro-environment, while the PD-1 receptor is expressed on immune system cells. When the ligand binds to this receptor, the immune cells no longer recognise cancer cells as needing to be eliminated. By using an antibody to block this interaction (anti-PD-1 or anti-PD-L1 immunotherapy), the immune system is unlocked, so that it can participate in the process of elimination of cancer cells.

ADVANCED MELANOMA // 40 % OF PEMBROLIZUMAB-TREATED PATIENTS ARE ALIVE 3 YEARS LATER

Professor Caroline Robert, Head of the Dermatology Unit within the Gustave Roussy Medical Oncology Department, will present the first overall survival results after 3 years of follow-up of pembrolizumab-treated patients in the KEYNOTE-001 phase Ib trial. The 655 patients included in the trial had recently been diagnosed with advanced melanoma or had previously been treated for the same condition with ipilimumab, another immunotherapeutic agent.

At 3 year follow-up, 40 % of patients with advanced melanoma were still alive. The median overall survival was 24.4 months. The survival figures were similar whatever treatment had been administered previously. This rose to 45 % for those patients who had not been treated for melanoma by any other agent before receiving pembrolizumab.

It should be noted that 15 % of the patients appeared to be in complete remission according to assessment criteria labelled «immune-related response criteria» and that these responses persist with a median value of 32 months in 89 % of these patients.

Pembrolizumab is an anti-PD-1 immunotherapeutic agent, which potentiates T cell responses, including those directed against tumour cells. It obtained marketing authorisation in the United States and Europe on the basis of the findings in three clinical studies, two of them pivotal ones (KEYNOTE-006 and KEYNOTE-002), and one a support study (KEYNOTE-001) involving more than 1,500 patients. It is indicated for the treatment of advanced, inoperable or metastatic melanoma and is well tolerated. In most cases the side effects are manageable (fatigue, pruritus and rash).

Oral presentation, Monday 6th June at 14h15 (Chicago time), Arie Crown Theatre
Abstract available on http://abstracts.asco.org/176/AbstView_176_167363.html
3-Year Overall Survival For Patients With Advanced Melanoma Treated With Pembrolizumab in KEYNOTE-001.

N.B.
Professor Caroline Robert's presentation was the subject of an ASCO press conference on 18th May 2016, for which 5 presentations had been chosen from more than 5,000
http://www.asco.org/about-asco/press-center/news-releases/pd-1-inhibitor-pembrolizumab-provides-long-term-survival

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UTERINE CERVICAL CANCER // EARLY TRIAL // FIRST RESULTS WITH PEMBROLIZUMAB

Dr. Andrea Varga, Oncologist in the Gustave Roussy Drug Development Department (DITEP), is the last author of a presentation of the first results of the KEYNOTE-028 phase Ib study.

This study is evaluating the efficacy and safety profile of pembrolizumab in patients with solid tumours.

The findings to be presented at ASCO concern 24 women with advanced cervical squamous cell carcinoma, the most frequently seen type of these cancers.

At present, women in this category have a survival period of only 7 months when metastatic disease is present or when relapse has followed treatment. With 530,000 new cases annually in the world, cervical cancer is the 2nd most common cancer in women.

The initial results suggest that pembrolizumab is promising in these patients, with an overall survival rate of 66.7 % at 6 months and a progression free survival rate of 13 %.

The clinical benefits of pembrolizumab will be assessed at a later stage in the KEYNOTE-158 phase II study.

Oral presentation, Sunday 5th June at 10h09 (Chicago time), Room E450ab
Abstract available on
http://abstracts.asco.org/176/AbstView_176_167980.html

Pembrolizumab in patients with advanced cervical squamous cell cancer: Preliminary results from the Phase 1b KEYNOTE-028 study.

BLADDER CANCER // EARLY TRIAL // FIRST EVALUATION OF DURVALUMAB, A NEW IMMUNOTHERAPEUTIC AGENT

Bladder cancer is a common condition. It has a poor prognosis, particularly when it has metastasised. Until very recently, therapeutic options were limited mainly to the use of various cytotoxic chemotherapies such as cisplatin. Recently, new immunotherapeutic agents have been yielding encouraging results in this condition. Several trials have already been conducted at Gustave Roussy with anti-PD-1 or PD-L1 antibodies such as atezolizumab.

Dr. Christophe Massard, Head of the Early Trials Committee within DITEP and Oncologist in the Gustave Roussy Department of Medical Oncology, will be presenting intermediate results of a multicentre phase I/II study evaluating durvalumab, an anti-PD-L1 antibody, in patients with inoperable or metastatic bladder cancer in whom standard treatment has failed.

The results of this trial are encouraging with an objective response rate of 38.1%. This response rate is even higher when PD-L1 is present in the tumour or its micro-environment.

Oral presentation, Sunday 5th June at 8h24 (Chicago time), Hall D2
Abstract available on
http://abstracts.asco.org/176/AbstView_176_163749.html

Safety and efficacy of durvalumab (MEDI4736), a PD-L1 antibody, in urothelial bladder cancer.

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METASTATIC RENAL CANCER // CONTINUING ADMINISTRATION OF IMMUNOTHERAPY EVEN WHEN THE DISEASE IS PROGRESSING?

Dr. Bernard Escudier, Oncologist in the Gustave Roussy Department of Medical Oncology, will present an analysis of the results of the Phase III CheckMate 025 study in order to look at the role of continued nivolumab treatment when the disease is progressing (monitored by imaging according to RECIST criteria). The objective of his analysis is to determine the characteristics of those patients who might benefit from continuing treatment. This is an important question for oncologists who are treating patients with these novel agents, as it is generally held that disease progression substantiated according to RECIST criteria should lead to a change in therapy.

Nivolumab is an anti-PD-1 antibody. It has been shown to be effective in patients with metastatic renal cancer after failure of therapy with one or 2 anti-angiogenic agents. There is an overall survival advantage of 5 months with nivolumab by comparison with everolimus.

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Poster-discussion, Monday 6th June, 13h00 to 16h30 (Chicago time), Hall A, followed by a discussion the same day at 16h45 in the Arie Crown Theatre. Abstract available on http://abstracts.asco.org/176/AbstView_176_163172.html

Treatment beyond progression with nivolumab (nivo) in patients (pts) with advanced renal cell carcinoma (aRCC) in the phase III CheckMate 025 study.

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PRECISION MEDICINE // TARGETED THERAPIES, AS MONOTHERAPY OR IN COMBINATION

Targeting a protein or a mechanism of action specifically involved in the development of a tumour in order to maximise the sparing of healthy cells is the goal of targeted therapy. In recent years progress in genomics has contributed to this goal by facilitating the determination of the genetic characteristics specific to a given tumour. It is becoming more and more common to test combinations of two targeted therapies or of a targeted therapy and a standard one, and promising results are emerging.
Gustave Roussy is one of the leading centres in this area and is conducting numerous research studies in the field.

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A PROMISING COMBINATION IN PAEDIATRICS OF A CHEMOTHERAPEUTIC DRUG WITH RITUXIMAB AS A TARGETED THERAPY IN ADVANCED BURKITT'S LYMPHOMA.

Dr. Véronique Minard-Colin, Medical Oncologist in the Department of Paediatrics at Gustave Roussy, will be presenting very good data from an intermediate analysis of the Inter-B-NHL ritux 2010 phase III randomised international clinical trial.

This academically-led trial is sponsored by Gustave Roussy and conducted in collaboration with the Children Oncology Group (COG), the European Intergroup for Childhood NHL (EICNHL) and Roche laboratories.

The 310 children enrolled in this study have leukaemia or advanced Burkitt's lymphoma. The objective is to compare results using the standard chemotherapy for these conditions alone against those found when rituximab is added to this standard chemotherapy. Rituximab is a monoclonal antibody targeting CD20, the latter being expressed on the surface of these tumour cells.

The results show a reduction of 70 % in the risk of events (death,

relapse, progression, development of a second cancer, etc.) with combined therapy compared with chemotherapy alone.

These very good results led the Data Monitoring Committee to recommend cessation of randomisation to allow all the patients to benefit from the rituximab-chemotherapy combination, which has become the new standard therapy for such patients.

Oral presentation, Friday 3rd June 17h12, Room 504 (Chicago time),
Abstract available on
http://abstracts.asco.org/176/AbstView_176_164975.html

Results of the randomized intergroup trial Inter-B-NHL ritux 2010 for children and adolescents with high risk B-cell non Hodgkin's lymphoma (B-NHL) and mature acute leukemia (B-AL): Evaluation of rituximab (R) efficacy in addition to standard LMB chemotherapy (CT) regimen.

TWO TARGETED THERAPIES TO OVERCOME RESISTANCE IN LUNG CANCER

Dr. David Planchard, Pneumo-Oncologist in the Gustave Roussy Department of Medical Oncology, conducted a phase II study in patients with metastatic BRAF-V600E mutant non- small cell lung cancer. Dual targeted therapy was employed as second-line treatment: dabrafenib (inhibitor of the BRAF pathway) and trametinib (inhibitor of the MEK pathway).

The results show that the combination was very effective as second-line treatment in this rare patient sub-group with a manageable adverse event profile. This is the first study combining these two agents in this disease.

Oral presentation, Monday 6th June 9h57 (Chicago time), Hall D1
Abstract available on
http://abstracts.asco.org/176/AbstView_176_163554.html

An Open-Label Phase 2 Trial of Dabrafenib (D) in Combination with Trametinib (T) in Patients (pts) with Previously Treated BRAF V600E–Mutant Advanced Non-Small Cell Lung Cancer.

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THE ULTIMATE STUDY COMBINING A TARGETED THERAPY AND CHEMOTHERAPY IN LUNG CANCER

The randomised phase III ULTIMATE clinical trial evaluated a bevacizumab-paclitaxel combination versus docetaxel, in second or third-line treatment in patients with advanced or relapsed non-squamous NSCLC (non-small cell lung cancer). **Dr. Benjamin Besse**, Pneumo-Oncologist in the Gustave Roussy Department of Medical Oncology, led this study and is its last author. It was found that the bevacizumab-paclitaxel combination was superior to monotherapy.

The median progression free survival was 5.4 months for patients receiving bevacizumab-paclitaxel compared with 3.9 months with docetaxel alone. The objective response rates were 22.5 % and 5.5 % respectively, with a manageable safety profile.

Oral presentation, Monday 6th June 11h09 (Chicago time), Arie Crown Theatre
Abstract available on http://abstracts.asco.org/176/AbstView_176_167643.html

Weekly paclitaxel plus bevacizumab versus docetaxel as second or third-line treatment in advanced non-squamous non-small cell lung cancer: results from the phase III study IFCT-1103 "ULTIMATE".

ACSÉ CRIZOTINIB TRIAL: MAKING A TARGETED THERAPY AVAILABLE FOLLOWING TUMOUR GENOMIC ANALYSIS

AcSé crizotinib is a programme designed to allow access to crizotinib for those adults, adolescents or children in a situation of therapeutic failure, where the tumour has genetic abnormalities in at least one of the crizotinib targets (ALK, MET or ROS1).

Since 2013, 8,000 patients have had molecular analysis of their tumours and 180 have received crizotinib treatment in the context of a phase II trial. **Professor Gilles Vassal**, Director of Clinical Research at Gustave Roussy and principal investigator, will present the results seen in the paediatric cohort. A molecular tumour portrait was obtained for 107 children and 18 of these had a tumour which was positive for one of the crizotinib targets (ALK, ROS ou MET). Of the 11 children aged 3 to 16 years with a malignant tumour in treatment failure, who participated in the trial, 5 had a tumour response which lasted more than 6 months.

The AcSé crizotinib trial is the first one launched in the context of the INCa (National Institute for Cancer) AcSé programme. It is sponsored by UNICANCER and coordinated scientifically by **Professor Gilles Vassal**.

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AcSé-eSMART, sponsored by Gustave Roussy, the next trial in the programme, will be devoted just to children and adolescents and is to be launched in 2016.

Oral presentation, Monday 6th June 9h45 (Chicago time), Room 404
Abstract available on http://abstracts.asco.org/176/AbstView_176_168844.html
Crizotinib in children and adolescents with advanced ROS1, MET, ALK Rearranged cancer : results of the Acsé Phase II trial

VINILO STUDY COMBINING VINBLASTINE AND NILOTINIB IN CHILDHOOD LOW-GRADE GLIOMA

In a phase I clinical trial, **Dr. Jacques Grill**, Paediatric Neuro-Oncologist in the Gustave Roussy Department of Paediatric Oncology, studied the efficacy and safety of treatment with a combination of nilotinib, a targeted therapy, and vinblastine chemotherapy (VINILO), in 35 young patients with low-grade glioma (LGG) in relapse after conventional treatment. The objective was to determine the recommended dose of VINILO for phase II trial in refractory/recurrent LGG.

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Low-grade glioma is the commonest brain cancer seen in children. These often relapse.

VINILO is a European therapeutic trial sponsored by Gustave Roussy.

Poster, Monday 6th June from 8h to 11h30 (Chicago time), Hall A
Abstract available on http://abstracts.asco.org/176/AbstView_176_167010.html
Dose-finding study of vinblastine in combination with nilotinib in children, adolescents and young adults with refractory or recurrent low-grade glioma: Results of the ITCC/SIOPE-Brain VINILO phase I trial (NCT01887522).

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OPTIMISATION OF CHEMOTHERAPIES

For some cancers, cure rates today can be high, even in the presence of metastatic disease. The clearest example is testicular cancer. However, for other patients it is necessary to improve the standard therapeutic strategy in order to maximise their chances. This new approach depends both on the development of new drugs and on optimisation of existing treatments, in particular through the use of polychemotherapy. Major international trials, in which Gustave Roussy has played the primary role, will be presented at the ASCO Conference. These will transform management and will introduce new standard treatments for these patients.

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POOR PROGNOSIS TESTICULAR CANCER // MATURE RESULTS OF A PERSONALISED OPTIMISATION OF CHEMOTHERAPY (GETUG 13)

Professor Karim Fizazi, Head of the Department of Medical Oncology at Gustave Roussy, will present the results of GETUG 13 with 5 years follow-up of patients affected by a very serious form of testicular cancer. This was a phase III comparative, international, multicentre study sponsored by Unicancer.

In the GETUG 13 study, all patients with severe testicular cancer embarked on the same chemotherapy, the standard BEP protocol comprising three drugs. Blood markers were assayed 3 weeks later and subsequent treatment was based on the values found. If the marker levels had fallen substantially, the patients just continued on the BEP protocol and the study showed that the great majority of such patients were cured. However, when the fall in marker levels was unsatisfactory, the BEP protocol was found not to be sufficiently effective and a more intensive protocol involving 6 anti-cancer drugs resulted in a clear reduction in the risk of relapse or death.

The good 5-year results in the GETUG 13 study should lead to general adoption of intensive chemotherapy, labelled «dose-dense», as the new standard treatment in patients with poor prognosis testicular cancer in whom the decline in blood tumour marker levels is slow. For these patients this

is the first therapeutic advance seen in more than 25 years.

Oral presentation, Sunday 5th June 09h24 (Chicago time), Hall D2
Abstract available on
http://abstracts.asco.org/176/AbstView_176_167210.html

Mature results of the GETUG 13 phase III trial in poor-prognosis germ-cell tumors GCT.

EWING SARCOMA AT HIGH RISK OF RELAPSE // A MAJOR INTERNATIONAL STUDY ESTABLISHES A NEW STANDARD TREATMENT

Chemotherapy is an essential component of the treatment of Ewing's sarcoma, a cancer of bone. It is a rare tumour mainly affecting adolescents and young adults.

EURO-EWING 99 (R2Loc and R2Pulm) was a large international phase III trial conducted by European research groups. Its objective was to compare high-dose Busulfan-Melphalan chemotherapy with conventional therapy. The R2Loc trial assessed 3 year follow-up event-free and overall survival in patients with localised Ewing's sarcoma at high risk of relapse. Patients were treated either with Busulfan-Melphalan or with standard VAI (vincristine, actinomycin, ifosfamide) chemotherapy.

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In the R2Pulm trial, the patients had Ewing's sarcoma with lung metastases. They were treated either with Busulfan-Melphalan chemotherapy or with conventional chemotherapy plus pulmonary radiotherapy.

The significant results seen at 3 years in the R2Loc trial are going to change the management of patients with localised Ewing's sarcoma at high risk of relapse. Busulfan-Melphalan chemotherapy will become standard treatment for such patients.

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France was the principal contributor to this international programme. 477 patients were recruited (31 % of these from France, included in R2Loc and R2Pulm) from 15 European countries and the United States. It was sponsored in France by UNICANCER with the support of Ligue nationale contre le cancer, the Fédération Enfants et Santé, and the Société Française des Cancers et Leucémies de l'Enfant (SFCE). **Dr. Odile Oberlin** of the Department of Paediatric Oncology was the Coordinator of the study in France and **Dr. Marie Cécile Le Deley**, Paediatric Statistician in the Department of Biostatistics and Epidemiology, organised the data and performed the statistical analyses.

The EURO-EWING 99 programme demonstrates the strength of international collaboration between Paediatric Oncology and Medical Oncology when carrying out major trials of therapeutic strategies for rare cancers in adolescents and young adults. Gustave Roussy is one of the leading players on the international stage for the treatment of young patients with cancer and in the development of new therapies.

Oral presentation, Sunday 5th June at 08h00 (Chicago time), Room S406
Abstract available on http://abstracts.asco.org/176/AbstView_176_164836.html
Efficacy of busulfan-melphalan high dose chemotherapy consolidation (BuMel) in localized high-risk Ewing sarcoma (ES): Results of EURO-EWING 99-R2 randomized trial (EE99R2Loc).

Oral presentation, Sunday 5th June at 08h12 (Chicago time), Room S406
Abstract available on http://abstracts.asco.org/176/AbstView_176_166982.html
Efficacy of busulfan-melphalan high dose chemotherapy consolidation (BuMel) compared to conventional chemotherapy combined with lung irradiation in ewing sarcoma (ES) with primary lung metastases: Results of EURO-EWING 99-R2pulm randomized trial (EE99R2pul).

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/ DIRECTION DE LA COMMUNICATION

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