GUSTAVE ROUSSY AT ASCO

PRESS RELEASE

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MELANOMA

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GUSTAVE ROUSSY AT ASCO

PRESS RELEASE

ASCO

MAY 30th - JUNE 3rd 2014

50th congress
American Society of Clinical Oncology (Asco, Chicago, USA, may 30th - june 03rd 2014).

ABOUT GUSTAVE ROUSSY

Gustave Roussy in 2013:
First comprehensive cancer centre in Europe
2 630 professionals dedicated to care, research and learning
356 beds et 89 beds/chairs in day-car
47 000 patients
of which 11,200 first visits
3 690 patients included in a clinical trial
366 clinical studies
321 patients included in phase-1 early trials
88 patients included in phase-2-3 early trials
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MELANOMA:
THREE CLINICAL TRIALS ON INNOVATIVE THERAPIES. IMMUNOTHERAPY AND TARGETED THERAPY

Gustave Roussy's medical researchers will be presenting their clinical and translational research papers at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO), the world's biggest oncology gathering. This year there will be 18 oral papers presented by the Institute's physician-researchers, including 10 on work carried out and 37 posters.

Latest news from Gustave Roussy at ASCO
from May 30th on
www.gustaveroussy.fr/asco2014

MELANOMA: THREE CLINICAL TRIALS ON INNOVATIVE THERAPIES. IMMUNOTHERAPY AND TARGETED THERAPY

SKIN CANCER

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#LBA9008

1. Ipilimumab versus placebo after complete resection of stage III melanoma: Initial efficacy and safety results from the EORTC 18071 phase III trial.
Alexander M. Eggermont, Vanna Chiarion-Sileni, Jean Jacques Grob, Reinhard Dummer, Jedd D. Wolchok, Henrik Schmidt, Omid Hamid, Caroline Robert, Paolo Antonio Ascierto, Jon M. Richards, Celeste Lebbe, Virginia Ferraresi, Michael Smylie, Jeffrey S. Weber, Michele Maio, Cyril Konto, Ravichandra Karra Gurunath, Veerle de Pril, Stefan Suciu, Alessandro Testori.

Two oral communications and one written (poster) presented the results of clinical trials on melanoma. The oral communications focused on the good results obtained with monoclonal antibodies (MK-3475 et Yervoy) and were the subject of a press conference on June 2nd at the 50th ASCO Congress. The written communication focused on the improvement obtained with a BRAF inhibitor targeted therapy on May 31st.
Metastatic melanoma is a difficult disease to treat. Up until recently, the therapeutic arsenal was limited with a low patient survival level. However, the treatment of metastatic melanoma has been revolutionized by the development of targeted therapies and by immunotherapy, notably BRAF inhibitors and monoclonal antibodies.

PHASE III CLINICAL TRIAL SHOWING THE EFFICACY AND TOLERANCE OF THE ANTI-CTLA4 MONOCLONAL ANTIBODY, IPILIMUMAB (YERVOY) IN PATIENTS SUFFERING FROM A STAGE III MELANOMA AFTER TUMOUR RESECTION

Professor Alexander Eggermont, oncologist and Director General of Gustave Roussy, presented a double blind, randomized phase III clinical trial comparing the effect of ipilimumab (an anti-CTLA 4, Yervoy) versus placebo in patients suffering from a stage III melanoma after tumour resection. This trial shows that ipilimumab, as adjuvant therapy, brings about an improvement in survival without relapse compared to placebo in these high risk patients. Among the secondary effects observed, colitis and endocrinological disorders were the most frequent. 5 drug-related deaths were observed.

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2. Efficacy and safety of the anti-PD-1 monoclonal antibody MK-3475 in 411 patients (pts) with melanoma (MEL).
Antoni Ribas, F. Stephen Hodi, Richard Kefford, Omid Hamid, Adil Daud, Jedd D. Wolchok, Wen-Jen Hwu, Tara C. Gangadhar, Amita Patnaik, Anthony M. Joshua, Peter Hersey, Jeffrey S. Weber, Roxana Stefania Dronca, Hassane M. Zarour, Kevin Gergich, Xiaoyun (Nicole) Li, Robert Iannone, Soonmo Peter Kang, Scot Ebbinghaus, Caroline Robert.

The study included 951 patients, 475 of whom received 10mg/kg of ipilimumab (Yervoy) every three weeks for 4 doses then every three months for 3 years. The 476 other patients received the placebo. The results showed a 25% reduction in the risk of recurrence or of death. At the end of 3 years, 46.5% of patients treated with ipilimumab (Yervoy) were free of disease compared to an estimated 34.8% of patients on placebo. The median relapse-free survival was 26.1 months for the treated patients versus 17.1 months for patients on placebo with a median follow-up of 2.7 years.

EFFICACY AND TOLERANCE OF THE ANTI-PD1 MONOCLONAL ANTIBODY, MK-3475 IN PATIENTS SUFFERING FROM METASTATIC MELANOMA

Dr Caroline Robert, dermatologist and cancer specialist and head of the Dermatology Department at Gustave Roussy (Villejuif) presented new results obtained with MK-3475, an anti-PD1 monoclonal antibody, on an increased number of patients (411 versus 135 patients in the previous study*). This compound enabled a long lasting response to be obtained in the majority of patients with an acceptable toxicity profile irrespective moreover of the treatment they were given.

Analysis involved two cohorts, one randomized, the other not. One group of patients were pretreated with an anti-CTLA4 (Ipilimumab). The anti-PD1 treatment, MK-3475, was administered every two or three weeks by intravenous injection at a rate of 2mg/kg or 10mg/kg. The anti-tumour response was analyzed every 12 weeks.

The results show that the overall response rate was 40% in patients having never received monoclonal antibodies and 28% in the others. The responses were durable, and 91% were ongoing at analysis. The benefits of treatment could be seen irrespective of the dose of MK-3475 given. Treatment was fairly well tolerated, 12% of patients had acceptable adverse effects.

IN ORDER TO BETTER UNDERSTAND RESISTANCE TO TARGETED THERAPIES

Dabrafenib and Trametinib are two targeted therapies having shown their efficacy in monotherapy or in combination in patients suffering from an inoperable metastatic melanoma.

Dr Christine Matéus, dermatologist and oncologist, presented a phase II clinical trial the objective of which was to study tumour biomarkers with different sequential treatments. The purpose was to determine the best treatment sequence in order to understand the mechanism of action of Dabrafenib and Trametinib alone or in combination and the manner in which resistance to these treatments develops and their toxicity.

54 patients suffering from metastatic melanoma and carrying the BRAF V600E/K mutation are being recruited in this phase II randomized open 3 arm study. Patients are randomized into 3 arms, 2 arms initially with Dabrafenib (150mgx2 per day) or Trametinib (2mg per day) as monotherapy over 8 weeks, then the two compounds will be combined. In the third treatment arm, the two compounds are combined from the start at the same doses. The study will focus on the impact of these two drugs, alone and in combination, on

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the immune system, on progression free survival and on duration response.

MELANOMA

Melanoma is a cancer increasing in prevalence: approximately 9,700 new cases per year in France and 1,600 deaths. The number of patients doubles every 10 years in the Caucasian population with a peak incidence between 40 and 50 years of age. Melanoma is one of the cancers in which the survival at 5 years is the highest, with over 80% survival at 5 years if it is treated appropriately and is not complicated by metastases. In the case of metastatic melanoma, the prognosis is poor, 6 months on average. A recent improvement has been observed thanks to targeted therapies (BRAF inhibitor) and immunotherapy (ipilimumab and anti-PD1).

THE MELANOMA GROUP MANAGED BY DR CAROLINE ROBERT

A team of seven investigators is managed by **Dr Caroline Robert** and by **Dr Stephan Vagnerau** in the mixed research unit « Predictive biomarkers and new molecular strategies in anti-cancer therapeutics » (UMR981: Gustave Roussy – INSERM – University Paris-XI).
The unit is the result of the merger of several translational research units of Gustave Roussy. Its objective is the identification of molecular predictors and new therapeutic targets. It works in close collaboration with the department of Medical Oncology at the Institute, which enables predictors and new targets to be validated in the context of therapeutic trials. Within UMR 981, the objectives of the Melanoma group are the identification of resistance mechanisms to melanoma treatments, the demonstration of biomarkers for efficacy and resistance vis a vis therapeutics and the implementation of new therapeutic strategies. In clinical research, several therapeutic trials have been undertaken at different stages of melanoma. New anti-cancer agents have been tested: molecular targeted therapies, anti-angiogenic agents, new cytotoxic agents and immunotherapies.

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3. Biomarker study evaluating the combination of dabrafenib (D) with trametinib (T) versus the combination after 8 weeks of monotherapy with dabrafenib or trametinib in patients with metastatic and unresectable stage IIIC or IV melanoma: GSK study 116613.
Christine Mateus, Emilie Routier, Severine Roy, Marina Thomas, Lise Boussemart, Isabelle Girault, Nathalie Chaput-Gras, Stephan Vagner, Hugo Cazenave, Lindi D Dalland, Mike R Lau, Maureen R Bleam, Anthony Michael D'amelio, Sylvie Pfersch, Caroline Caty, Caroline Robert.

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