

GUSTAVE ROUSSY AT ASCO

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PRESS RELEASE

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2014



RARE CANCERS /
SARCOMAS

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CANCER CAMPUS
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American Society of Clinical Oncology
Making a world of difference in cancer care

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GUSTAVE ROUSSY AT ASCO

PRESS RELEASE



ASCO

MAY 30th - JUNE 3rd 2014

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50th congress
American Society of Clinical
Oncology (Asco, Chicago, USA,
May 30th - June 03rd 2014).
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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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TO SUSPEND OR OTHERWISE
THE USE OF TRABECTEDIN
BEYOND 6 CYCLES /
**TO ACCENTUATE THE EFFECTS
OF RADIOTHERAPY THANKS
TO NANOPARTICLES**

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.

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



TWO STUDIES TO MORE EFFECTIVELY TREAT ADVANCED SOFT TISSUE SARCOMAS

RARE CANCERS / SARCOMAS



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Flash and find
#10523

1. Results of the prospective T-DIS randomized phase II trial comparing interruption versus continuation of trabectedin after six cycles of treatment in patients (pts) with advanced soft tissue sarcoma (ASTS).

Axel Le Cesne, Jean-Yves Blay, Thomas Ryckewaert, Christine Chevreau, François Bertucci, Corinne Delcambre, Esma Saada, Sophie Piperno-Neumann, Jacques-Olivier Bay, Julien Domont, Isabelle Laure Ray-Coquard, Thibaud Valentin, Emmanuelle Tresch, Stephanie Clisant, Nadia Badri, Nicolas Penel, French Sarcoma Group (GSF/GETO)

*Retrospective on database analysis; ASCO 2013

Two written communications (Poster Highlights and Poster) have presented the results of two studies on advanced soft tissue sarcomas during the 50th ASCO congress in Chicago. The phase II trial carried out by Dr Axel Le Cesne, in-charge of the sarcoma and complex tumour committee, has evaluated the benefit of maintaining Trabectedin beyond 6 cycles in metastatic patients. In patients presenting with a locally advanced sarcoma, the phase I/II trial presented by Dr Sylvie Bonvalot studied the amplification effect on radiotherapy of Hafnium (NBTXR3) nanoparticles developed by Nanobiotix.

TO INTERRUPT OR TO MAINTAIN TREATMENT IN ADVANCED SOFT TISSUE SARCOMAS

The effect of the withdrawal of Trabectedin on progression-free survival and on overall survival has been analyzed prospectively by the French Sarcoma Group in this randomized, non-comparative phase II trial. It had been shown previously in a retrospective study that maintaining this treatment beyond 6 cycles might increase the survival rate of patients suffering from advanced soft tissue sarcomas.*

In this study presented by Dr Axel Le Cesne, 178 patients, all presenting with histological sub-types of sarcoma and pretreated

with anthracyclines/ifosfamide, were included from February 2011 to March 2013. Their median age on inclusion was 57.5 years.

Responding patients (objective response or stabilization) having therefore a clinical benefit after 6 courses of trabectedin, were divided into two groups after random allocation, one continuing with trabectedin up to tumour progression, intolerance, or the refusal of the patient to continue on this therapy, the other halting treatment until tumour progression, the date at which trabectedin was re-administered.

Thirty percent approximately of the initial cohort of patients received the six first courses of chemotherapy.

This level is higher than expected, probably due to a better selection of patients and to better treatment management.

Patients randomized to the trabectedin interruption arm had a significantly lower survival without progression (half) compared to those in whom trabectedin was maintained.

Treatment must therefore be maintained in all patients responding after the 6 initial courses.

||| NANOPARTICLES TO AMPLIFY THE EFFECT OF RADIOTHERAPY

The effects of radiotherapy can be amplified by the use of nanoparticles. These enable radiation to be more effective inside the tumour cell itself without harming healthy tissue.

This innovative approach was tested by **Dr Sylvie Bonvalot** during a clinical phase I/II trial with Hafnium (NBTXR3) nanoparticles produced by Nanobiotix in patients suffering from locally advanced soft tissue sarcomas.

Patients received a single intratumoral injection of NBTXR3 followed by an irradiation of 50 Gy.

The results showed the feasibility of this injection and the good tolerance to treatment.

All patients received the planned irradiation dose following the surgical resection of the sarcoma.

Anti-tumour activity was moreover observed in the various sub-types of sarcoma, including in poorly

radiosensitive sub-types such as undifferentiated sarcomas, rhabdomyosarcomas and synovial sarcomas, which constitutes a notable improvement for patients suffering from a locally advanced sarcoma with a high risk of relapse.

||| THE MANAGEMENT OF SARCOMAS AT THE GUSTAVE ROUSSY INSTITUTE

Gustave Roussy is one of three national reference centers for sarcoma care.

In 2013, more than 600 new patients underwent the multidisciplinary sarcoma consultations, putting the Institute amongst the five most active centers worldwide in this area.

A one-day consultation for suspicious tumours has also been put in place. It allows patients to be diagnosed and receive tailored care : percutaneous biopsy under imaging and staging.

As a result, the risk of relapse for sarcomas can be halved, and reduced to less than 10% for limb sarcomas, with only a 1% risk of amputation in the reference centers.

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#10563

2. Phase I study of NBTXR3 nanoparticles, in patients with advanced soft tissue sarcoma (STS).

Sylvie Bonvalot, Cecile Le Pechoux, Thierry De Baere, Xavier Buy, Antoine Italiano, Eberhard Stockle, Philippe Terrier, Nathalie Lassau, Axel Le Cesne, Paul Sargos, Mikael Antoine, Naima Lezghed, Fouzia Azzouz, Alejandro Goberna, Laurent Levy, Borghi Elsa, Mikaela Dimitriu, Jean-Charles Soria, Eric Deutsch

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