Highlights

GUSTAVE ROUSSY AT ASCO 2018

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GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

GUSTAVE ROUSSY PRESENTATIONS AT ASCO 2018

As in every year for more than half a century, the world's leading Oncologists are meeting in Chicago early in June to discuss the latest clinical advances in the field. Gustave Roussy will, of course, be among the main protagonists at this Congress. In addition to the opportunities Gustave Roussy specialists will have to communicate with their peers from around the world with the mutual benefit this represents, they will be participating in 15 oral presentations, 6 poster discussions and 49 posters, chosen by the Scientific Committee of the American Society of Clinical Oncology (ASCO). At this 54th gathering of the premier world oncology conference, Gustave Roussy will confirm its place as a leader in developing the therapeutic strategies which are transforming patient management and resulting in changes in practice.

ASCO

FROM THE 1ST TO THE 5TH JUNE 2018

American Society of Clinical Oncology (ASCO)
Chicago, Illinois
United States

REGARDING GUSTAVE ROUSSY

Gustave Roussy, the leading Cancer Centre in Europe, is a comprehensive centre of expertise in Oncology entirely devoted to patients. It employs 3,100 professional staff engaged in patient care, research and teaching.

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Find all the news about Gustave Roussy at ASCO 2018 on
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"Post-Chicago" meeting 20 June 2018 at Gustave Roussy, Espace Maurice Tubiana at 5 pm

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UNDER THE SPOTLIGHT

The plenary session of the ASCO Congress is an international showpiece reserved for presentation of the most innovative advances and the findings which promise to revolutionise the treatment of certain patients or give rise to a new generation of drugs.
This year, of the four studies presented during this session, the two to which Gustave Roussy has contributed have been selected in this way by the ASCO Scientific Committee. The results will be revealed only on the morning of the oral presentations, but the background is outlined below.

KIDNEY CANCER WHICH IS METASTATIC AT THE TIME OF DIAGNOSIS:
Do we have to continue to initiate treatment with nephrectomy?

At the time when drugs such as interferon were used, studies showed that performing a nephrectomy at the outset in patients with metastatic disease at diagnosis did improve results of treatment, although in a number of other cancers ablation of the primary tumour was not carried out. Since the advent of more effective drugs such as the anti-angiogenic agents, sunitinib being used extensively in kidney cancer, the appropriateness of commencing treatment of these patients with nephrectomy was in question, as avoiding surgery both prevents the risk of complications of nephrectomy and allows medical treatment to be started immediately.

In this way, there is no delay in treating the entire disease load. The CARMENA study was initiated by the AFU (French Association of Urology) and GETUG (Urogenital Tumour Study Group) and sponsored by the Paris Public Hospitals. It was a multicentre, phase III non-inferiority, randomised trial designed to answer this question. Its results measuring overall survival, progression-free survival and patient response rates will be presented in the ASCO plenary session by Professor Arnaud Méjean (Paris Public Hospitals). They will be published simultaneously in the New England Journal of Medicine

Dr. Bernard Escudier, Medical Oncologist specialising in kidney cancer at Gustave Roussy and last author of the article, was part of the committee that designed this study. The results are embargoed until Sunday 3 June at 1.30 pm.

There are about 10,000 new cases of kidney cancer per year. Of these, some 2,000 concern metastatic disease present at the time of diagnosis. Metastatic cancer is very frequently revealed by systemic symptoms (fatigue, weight loss), blood in the urine due to the presence of the tumour or by symptoms resulting from the anatomical situation of the metastases (cough or respiratory problems, bone pain, etc.).

Results embargoed until Sunday 3 June at:
2.30 pm, Paris time – 7.30 am in Chicago

Oral presentation, Sunday 3 June at 1 pm (Chicago time), Hall B1
CARMENA: Cytoreductive nephrectomy followed by sunitinib versus sunitinib alone in metastatic renal cell carcinoma—Results of a phase III noninferiority trial.

▶ ***Abstract No. LBA3 available at:***
http://abstracts.asco.org/214/AbstView_214_220283.html

▶ **SEE DR BERNARD ESCUDIER'S DISCUSSION ON VIDEO**

CHILDHOOD AND ADOLESCENT SARCOMA:
Should initial chemotherapy be consolidated with maintenance therapy?

The conventional treatment of children and adolescents with rhabdomyosarcoma at high risk of relapse comprises nine courses of treatment known as induction chemotherapy. Depending on the nature of the disease and its location, surgery and radiotherapy may also be used to complete the treatment. About 70% of patients are cured by this method of treatment.

The RMS2005 study was launched in 2005 by the EpSSG (European Paediatric Soft Tissue Sarcoma Study Group) cooperative group. It attempted to find out whether prolongation of treatment by 6 months of maintenance therapy was of benefit. This maintenance therapy, administered on a daily basis (vinorelbine-cyclophosphamide) was shown to be effective in a clinical phase II trial sponsored by Gustave Roussy in relapsed disease. Cyclophosphamide was administered daily by the oral route (syrup or tablet according to age) and vinorelbine given by weekly injection. Maintenance therapy was usually well tolerated and children were able to resume normal schooling.

This present randomised, phase III international study was sponsored in France by Gustave Roussy and Dr Véronique Minard, Paediatric Oncologist in the Gustave Roussy Childhood and Adolescent Oncology Department, was the chief investigator for the randomised part of this study in France. The results to be presented at ASCO by Dr Gianni Bisogno (University Hospital of Padua, Italy) will concern disease-linked event-free survival as well as overall survival in 370 children and adolescents aged from 1 to 21 years. Rhabdomyosarcomas are rare diseases of the sarcoma family and are the commonest form of muscle cancer in childhood. About 100 children and adolescents develop this disease each year in France. The tumour can be found anywhere in the body but mainly presents around the head and neck, in the limbs or in urogenital territory.

Results embargoed until Sunday 3rd June at 2.30 pm, Paris time – 7.30 am Chicago time

Oral presentation, Sunday 3rd June at 1 pm (Chicago time), Hall B1
Maintenance low-dose chemotherapy in patients with high-risk (HR) rhabdomyosarcoma (RMS): A report from the European Paediatric Soft Tissue Sarcoma Study Group (EpSSG).

▶ ***Abstract No. LBA3 available at:***
http://abstracts.asco.org/214/AbstView_214_217433.html

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FROM PHASE I TO PHASE III

Gustave Roussy's strength is derived from its ability to integrate fundamental, translational and clinical research and its innovative skills. In the field of clinical research, the Institute is equally capable of conducting early trials (phase I and II) or advanced ones (randomised phase II and phase III).
In 2017, 417 clinical studies were completed, 64 of which were sponsored by Gustave Roussy. With 28% of its patients included in a study, the Institute maintains a national and international standard for clinical trials.

SMALL CELL LUNG CANCER:
An effective immuno-conjugated drug

Small cell lung cancer is an aggressive form of cancer developing rapidly and affecting 10 to 15% of cancer patients in France.
Professor Benjamin Besse, Head of the Department of Medical Oncology at Gustave Roussy, will present the Trinity study in which 339 patients received 2 doses of rovalpituzumab tesirine (ROVA-T).
This is an immunoconjugate, i.e. an antibody combined with a chemotherapeutic drug. The antibody guides the chemotherapeutic agent to the tumour cells, which, in this case, express the DLL3 specific marker. 18% of the patients included in the trial showed a significant reduction in tumour size. That is a high figure for 3rd-line therapy, especially as the response in some patients was quite long-lasting.
The measure of efficacy is, therefore, high and the drug is being assessed as a 1st or 2nd-line agent and is also being evaluated in combination with an immunotherapeutic agent in a phase I study in the Drug Development Department (DITEP).

Oral presentation, Monday 4 June 2018 from 8 to 11 am (Chicago time), Hall B1.
Efficacy and safety of rovalpituzumab tesirine in patients with DLL3-expressing, ≥ 3rd line SCLC: Phase2 TRINITY results.

▶ ***Abstract No. 8507 available at:***
http://abstracts.asco.org/214/AbstView_214_216691.html

▶ **SEE PROFESSOR BENJAMIN BESSE'S DISCUSSION ON VIDEO**

CANCER OF THE URINARY TRACT:
Erdafitinib, promising in patients carrying genetic abnormalities of the FGFR genes.

Cancer of the urinary tract is common and despite recent progress, in particular in immunotherapy, it is hard to treat in its advanced stages. Genetic analysis of tumours showed that a type of gene abnormality affecting the FGFR genes was partly the cause of progression in this type of cancer in 20% of cases.
Erdafitinib is a drug developed specifically to block these abnormalities.
Dr Yohann Loriot, Medical Oncologist at Gustave Roussy, will be presenting at ASCO the first promising results of this international study which assessed the anti-tumour effects of erdafitinib in these patients. In 75% of the patients, lesions diminished in size with erdafitinib treatment. In 40% of these, tumour size fell by at least 30%.
Survival was prolonged by comparison with that seen on standard treatment. Erdafitinib is a drug which was developed in phase I work in the Drug Development Department. Its use in oncology is a perfect illustration of the continuum between clinical research and patient care. In view of these results, a larger scale study was initiated to demonstrate clearly that patients carrying these genetic abnormalities live longer on erdafitinib treatment than with chemotherapy or immunotherapy. If this study achieves its objective, erdafitinib could be used in day-to-day practice, thus becoming the first targeted therapy in urinary tract cancer.

Oral presentation, Sunday 3rd June 2018 at 9 am (Chicago time), Arie Crown Theatre.
First results from the primary analysis population of the phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRalt).

▶ ***Résumé n° 4503 disponible sur***
http://abstracts.asco.org/214/AbstView_214_217469.html

METASTATIC SARCOMAS:
Validation of the efficacy of trabectedin

Soft tissue sarcomas (STM) account for about 1% of cancers in adults and 2% of cancer mortality. Estimated 5-year survival from diagnosis of STM is 58%.

Professor Axel Le Cesne, Medical Oncologist at Gustave Roussy, will be presenting the T-SAR study at ASCO. This multicentre study was coordinated by the French Sarcoma Group and compared trabectedin with best supportive care in patients with advanced soft tissue sarcoma.

This agent has been marketed in France since 2007 but, in the final analysis, had never been compared with best supportive care (anti-inflammatories, analgesics, etc.). 103 patients participated in the study which showed that trabectedin significantly improved progression-free survival.

The difference was even more significant in liposarcoma and leiomyosarcoma.

This drug is a component of the therapeutic arsenal for metastatic soft tissue sarcomas, which, by contrast to that in other malignant diseases, is relatively limited. It is an active agent whose effect on progression-free survival has now been established.

Oral presentation, Monday 4th June 10.24 am (Chicago time), S100a
Results of a prospective randomized phase III T-SAR trial comparing trabectedin (T) vs best supportive care (BSC) in patients with pretreated advanced soft tissue sarcoma (ASTS): a French Sarcoma Group (FSG) trial.

▶ ***Abstract No. 11508 available at:***
http://abstracts.asco.org/214/AbstView_214_227341.html

▶ **SEE PROFESSOR LE CESNE'S DISCUSSION ON VIDEO**

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In order to develop its programme of competitive and high quality Clinical Research on novel projects, Gustave Roussy decided to establish a sponsorship structure to promote certain studies. To comply with the conditions of the European Directive in relation to the conduct of clinical trials, this structure was strengthened in 2005 by the creation of the Department for Sponsorship of Clinical Studies (SPEC). This department falls within the Gustave Roussy Clinical Research Directorate which was awarded ISO 9001 certification in December 2016 and, in terms of sponsorship, works in collaboration with The Functional Pharmacovigilance Unit (UFPV) and the Department for Biostatistics and Epidemiology (SBE).
99 Gustave Roussy sponsored studies of which
64 are in the process of recruitment and 16 are international

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PERSONALISED MEDICINE

New anti-cancer agents no longer function blindly but are targeted solely on one protein, enzyme or mechanism of action within a specific type of cancer cell in a particular patient.
Advances in genomics facilitate the selection of patients who can benefit from access to these drugs. Gustave Roussy is one of the world leaders in this personalised molecular medicine.

FINAL RESULTS OF THE ACSÉ-CRIZOTINIB NATIONAL PROGRAMME:

Demonstration of equal and safe access to a targeted therapy beyond its initial indications.

The AcSé-crizotinib programme's objective was to offer molecular screening of their tumour to patients with failure of therapy in order to look for one of the targets (ALK, MET or ROS1) of crizotinib, a targeted therapeutic agent. The AcSé programme was launched by the National Cancer Institute in June 2013. The AcSé-crizotinib study was sponsored by Unicancer and supported by the Cancer Research Association (ARC) Foundation.
At the outset of the study, this drug was only licensed in adult patients with non-small cell lung cancer carrying the ALK biomarker. But patients with other cancers (breast, bowel, some childhood and adolescent cancers, etc.) may also have crizotinib targets in their tumour. To aid patient access to the agent outside its licensed indication in the safe context of a clinical trial, INCA (National Cancer Institute) launched the AcSé-crizotinib programme.
Between 2013 and 2017 this ambitious programme recruited about 13,000 children and adults ranging from the age of 1 to 92 years with failure of therapy. It was open on 198 sites including overseas ones. Patients had access to molecular analysis of their tumours by virtue of 28 hospital sequencing facilities established by INCA to cover the whole country.
Professor Gilles Vassal, Director of Clinical Research at Gustave Roussy and chief investigator for the study, will be presenting the final results of this phase II study at an oral session. Firstly, this demonstrated that it was feasible to obtain patient molecular portraits on a national scale thus enabling 246 patients to enter the study and obtain the drug outside its original licensed indication in the safe context of a trial. Secondly, it showed that crizotinib was active in several types of non-small cell lung cancer (MET and ROS1) and most particularly ALK, in some oesophagogastric cancers, in childhood and adult lymphoma and in some sarcomas that arise in both children and adults. In addition it resulted in a better understanding of what constitutes a molecular marker.

Please note: this study will also be presented in the "Highlights of the day" in Chicago in the morning of the 2nd June.

Oral presentation Friday 1st June 2.45 pm (Chicago time), room S406
Biomarker-driven access to crizotinib in ALK, MET or ROS1 positive (+) malignancies in adults and children: the French national AcSé Program.

▶ ***Abstract No. 2504 available at:***
http://abstracts.asco.org/214/AbstView_214_226901.html

▶ **SEE DISCUSSION BY PROFESSOR GILLES VASSAL ON VIDEO**

LIQUID BIOPSY:
New in lung cancer

To offer the best possible treatment, doctors and researchers develop and perfect their methods so as to obtain a precise diagnosis, predict the course of the condition or the efficacy of one or other treatment and follow the disease actively.
These features have nowadays become more essential than ever with the proliferation of personalised treatments guided by biomarkers.
Gustave Roussy teams are therefore striving to develop new diagnostic approaches and new tools to assess disease which are more effective and precise and, if possible, less onerous for the patient. This applies most particularly to lung cancer where tumour biopsies are invasive and not always possible.
Two studies performed by Gustave Roussy doctors and researchers have furnished new information derived from blood samples (liquid biopsy) in patients with non-small cell lung cancer treated with a tyrosine kinase inhibitor (targeted therapy). In this cancer, the degree of response to the drug and its duration is impossible to foresee and the development of resistance is very variable, appearing between several months and a number of years afterwards. The identification of a biomarker is an important step for these patients as other drugs are now available.
The first study, conducted by Dr Laura Mezquita, has shown that it is now possible to detect ALK and ROS1 rearrangements in circulating DNA prior to and during the response to a tyrosine kinase inhibitor such as crizotinib, and at the time of disease relapse. This study of 51 patients also detected the appearance of other types of resistant mutations in circulating DNA which might direct a therapeutic decision towards the most suitable tyrosine kinase inhibitor in the near future. If it is validated, this test on a simple blood sample will detect abnormalities in the ALK and ROS1 genes and monitor the response to treatment and the appearance of resistance.
The second study, sponsored by Gustave Roussy, conducted by Emma Pailler and directed by Françoise Farace, examined circulating tumour cells (CTC) in patients' blood and addressed additional information derived from these cells. By analysing circulating tumour cells in 17 patients who had developed resistance to a tyrosine kinase inhibitor (crizotinib or lorlatinib), the team demonstrated for the first time the appearance of resistance mutations in these cells as well the presence of novel mutations responsible for resistance mechanisms. These results suggest that it may be possible to use CTC as a liquid biopsy to detect resistance mutations which might be used as future treatment targets.

Poster session, Monday 4th June from 8 am to 11.30 am (Chicago time), Hall A
An amplicon-based liquid biopsy for detecting ALK and ROS1 fusions and resistance mutations in advanced non-small cell lung cancer (NSCLC) patients.

▶ ***Abstract No. 9095 available at:***
http://abstracts.asco.org/214/AbstView_214_221447.html

Poster session, Monday 4th June from 1.15 pm to 4.45 pm (Chicago time), Hall A
Analysis of Single Circulating Tumor Cells (CTCs) Identifies Resistance Mutations to ALK-Inhibitors in Both ALK-Gene and Bypass Oncogenic Pathways

▶ ***Abstract No. 12038 available at:***
http://abstracts.asco.org/214/AbstView_214_223931.html

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PRIMARY CEREBRAL TUMOURS:
Precision medicine proves its worth

Although there have been recent advances in understanding of the biology of primary cerebral tumours, there is still progress to be made in their treatment as the prognosis remains poor with 5,551 new cases and 3,806 deaths in 2017 in France. The heterogeneity of the tumours and their microenvironment limit their responsiveness to standard treatment which relies mainly on surgery, radiotherapy and chemotherapy. Efforts are being made to recruit these patients into early trials (from which they have historically been excluded) in order to offer them innovative treatment such as targeted therapy or immunotherapy. Between 2008 and 2017, 70 patients with recurrence of primary cerebral tumours were included in an early phase trial in the Gustave Roussy Drug Development Department (DITEP).

The objective of the trial was to measure the effect of a precision medicine programme on treatment response and survival. As a result of molecular medicine programmes such as MOSCATO, these patients' tumours were sequenced and more than half of them (59%) were entered into a precision medicine programme. A benefit was seen in those patients who could be directed along this path and, in particular, in a sub-population with the worst prognosis (IDH wild-type) where the patients gained 5 months of life. Dr Capucine Baldini, DITEP Oncologist at Gustave Roussy, will be presenting the results of this study during an ASCO oral session.

These findings suggest that molecular screening and access to early trials carry benefits also for patients with primary cerebral tumours.

Oral presentation Friday 1st June at 2.45 pm (Chicago time), room S102
Feasibility and benefit of molecularly-informed enrollment into early phase trials for patients with recurrent gliomas.

▶ ***Abstract No. 2004 available at:***
http://abstracts.asco.org/214/AbstView_214_224013.html

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THE DEVELOPMENT OF SKILLS IN IMMUNOTHERAPY

SOLID TUMOURS:

PEMBIB test of a combination of an anti-angiogenic and an immunotherapeutic agent

There is a considerable need for novel therapeutic strategies to improve treatment of patients with advanced or metastatic cancer.
The PEMBIB trial has established the dose and the safety profile of combined therapy with pembrolizumab (anti-PD1 immunotherapy) and nintedanib (antiangiogenic VEGFR inhibitor).
The combination has been studied in common cancers where immunotherapy was known to be effective and in less common cancers which respond poorly to immunotherapy: cancers of thymus, mesotheliomas and cervical cancer.
This phase I DITEP study is sponsored by Gustave Roussy. Eight cohorts are now open.

Poster session, Monday 4th June 2018 from 8 am to 11.30 am (Chicago time), Hall A
Safety and efficacy results from a phase I dose-escalation trial of Nintedanib in combination with Pembrolizumab in patients with advanced solid tumors (PEMBIB trial).

▶ ***Abstract No. 3080 available at:***
http://abstracts.asco.org/214/AbstView_214_228491.html

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ENT CANCERS:

The effect of immunotherapy on the efficacy of a chemotherapeutic agent

Up to now, the prognosis of patients with locally advanced or metastatic ENT cancer is poor. The level of response to second-line treatment is around 6%. Recently, immunotherapy has been found to be effective as a second-line treatment. Current data show that immunotherapy improves the rate of response to salvage chemotherapy after progression on immunotherapy in non-small cell lung cancer. This study, presented by Dr Khalil Saleh, Medical Oncologist at Gustave Roussy, studied the effect of immunotherapy on the efficacy of chemotherapy administered later in ENT cancers.
The data were collected from four French Cancer Centres. The least response in the 58% of 82 patients who responded was stabilisation of the disease. The cancer regressed in 31% of patients. This study seems to demonstrate that immunotherapy increases responsiveness to chemotherapy in ENT cancer.

Poster session, Saturday 2nd June 2018 1.15 – 4.45 pm (Chicago time), Hall A, followed by poster discussion, Saturday 2nd June 2018 from 4.45 pm to 6 pm (Chicago time), S100a
Response to salvage chemotherapy after progression on immune checkpoint inhibitors in patients with squamous cell carcinoma of the head and neck.

▶ ***Abstract No. 6015 available at:***
http://abstracts.asco.org/214/AbstView_214_224923.html

KIDNEY CANCER:
Our bacteria are gutsy

It is known that altering the composition of the intestinal flora (microbiome), for example by administering an antibiotic, reduces the efficacy of immunotherapy. What connection may we therefore make between the composition of the intestinal flora and checkpoint inhibitors? Does the intestinal microbiome profile in a patient with kidney cancer play an important role in resistance or responsiveness to immunotherapy?
This question has been investigated by Dr Lisa Derosa, winner of the Fondation Philanthropia thesis bursary, working in Professor Laurence Zitvogel's laboratory at Gustave Roussy, and will be presented by her. In the phase II trial evaluating the safety of nivolumab in 85 patients with metastatic renal carcinoma (NIVOREN study), the intestinal microbiome of 69 patients was studied using "metagenomics".
Two strains appeared to have a particularly beneficial role. In those patients who responded best to immunotherapy and those in whom the disease was stabilised for at least six months, large amounts of Akkermansia muciniphila or Bacteroides species were present. In mice with immunotherapy-resistant renal cancer, "recolonisation" of their microbiome with these "good bacterial strains" restored responsiveness to immunotherapy.
While we await confirmation of these findings in a larger scale study, evidence is accumulating which demonstrates the role of the microbiome in health and disease and the effect of the intestinal microbiome on the response to treatment of cancer. This raises significant questions in the context of immunotherapy: Ought we to be analysing the microbiome in patients receiving anti-cancer treatment? Should we be monitoring closely the administration of antibiotics and considering a particular diet during therapy or the use of pro-biotics? Should we also be considering the role of the microbiome in pre-clinical models?

Please note: This presentation obtained an ASCO distinction: MERIT AWARD.

Poster session, Saturday 2nd June from 8 am to 11.30 am (Chicago time) Hall A, followed by a discussion Saturday 2nd June at 1.15 pm, Hall 2.
Gut microbiome composition predicts resistance in renal cell carcinoma (RCC) patients on nivolumab.

▶ ***Abstract No. 4519 available at:***
http://abstracts.asco.org/214/AbstView_214_221035.html

UNITS AND A PROGRAMME DEVOTED TO IMMUNOTHERAPY AT GUSTAVE ROUSSY

Gustave Roussy is numbered among the international pioneers of immunotherapy. In 2015 it launched a specific programme (GRIP: Gustave Roussy Immunotherapy Programme) doubling the number of patients treated with immunotherapy in the year 2016.
With more than 140 clinical trials in progress and 1,600 patients treated since 2010, Gustave Roussy is the largest immunotherapy of cancer centre in Europe, both in the number of clinical trials and in the number of patients treated.
Dr Aurélien Marabelle is the clinical director of this programme and Professor Laurence Zitvogel, the scientific director.

For further information:
https://www.gustaveroussy.fr/en/main-research-axes-immunotherapy

www.gustaveroussy.fr/en/asco2018

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