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# THE FRENCH GETUG 12 STUDY SUGGESTS THAT CHEMOTHERAPY IS OF BENEFIT IN LOCALLY ADVANCED PROSTATE CANCER OR AT A HIGH RISK OF RELAPSE

CANCER OF THE PROSTATE



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#5005

**Docetaxel-estramustine in localized high-risk prostate cancer: Results of the French Genitourinary Tumor Group GETUG 12 phase III trial**

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Prof. Karim Fizazi, specialist oncologist in genito-urinary tumours and Head of the Department of Oncological Medicine at Gustave Roussy (Villejuif), presented on Sunday June 1<sup>st</sup>, during the 50<sup>th</sup> ASCO Congress in Chicago, the results of GETUG 12: a phase III randomized multicentric French study sponsored by UNICANCER, undertaken in 413 patients suffering from a locally advanced prostate cancer or at high risk of relapse. The results, with 8 years of follow-up, suggest that the association of chemotherapy (docetaxel and estramustine) with benchmark treatment reduces the risk of relapse or of death.

The objective of the GETUG 12 study was to quantify the impact of chemotherapy on survival without progression of cancer of the prostate in patients suffering from locally advanced or at a high risk of relapse types on benchmark treatment.

The patients were therefore treated with radiotherapy and hormone therapy (gosereline) administered over 3 years.

The cohort was randomly divided into two groups of which one alone received chemotherapy.

Initiated with hormone therapy, this chemotherapy included 4 cycles of a docetaxel and estramustine combination.

The median survival time of patients was close to 8 years (7.6 years).

The results of GETUG 12 suggest that chemotherapy combined with benchmark treatment reduces the risk of relapse or of death: survival without relapse at 8 years was 62% for patients treated with chemotherapy versus only 53% in the control group.

#### **ABOUT UNICANCER AND R&D UNICANCER**

The only hospital group exclusively dedicated to the fight against cancer in France, the UNICANCER group combines the Centers for the Fight against Cancer (CLCC) and their federation, the French Federation of Centers for the Fight against Cancer Centers.

The fight against cancer centers are non-profit, private healthcare institutions involved in public hospital service. They carry out healthcare tasks, research and training, with a management which is in compliance with conventional tariffs and the absence of private practices.

R&D UNICANCER is an academic sponsor and an operative in research in cancerology. It has the statute of delegation to clinical research and innovation (DRCI). R&D UNICANCER houses the French Liaison Office of the European Organization for Research and Treatment of Cancer (EORTC).

R&D UNICANCER in numbers (in 2013): 61 active clinical trials, 4,400 patients recruited, more than 150 French and foreign recruiting centers.

[www.unicancer.fr](http://www.unicancer.fr)



In this study, patients who were suffering from a particularly bulky form of their cancer or who presented with a high blood marker level (PSA), (>20 mg/mL), benefited even more from chemotherapy.

In patients having been given chemotherapy, the incidence of long term secondary effects was not any greater. These effects were most often slight to moderate.

Published in the European Journal of Cancer in 2012, the preliminary results of GETUG 12 showed that the addition of the chemotherapy to the standard treatment, without changing the quality of life of patients at 1 year, significantly reduced their PSA levels (Prostatic Specific Antigen) at 3 months.

The results of GETUG 12 are the first to suggest a favorable impact of chemotherapy in patients suffering from a localized prostate cancer at high risk of relapse.

However a longer follow-up as well as the subsequent publication of other similar studies will be necessary prior to its widespread use.

These results support interest in the International PEACE 2 (GETUG-AFU 23) trial launched in December 2013.

This trial, which will include over 1,000 patients, aims to evaluate the efficacy of neoadjuvant chemotherapy with cabazitaxel and that of pelvic radiotherapy in combination with hormone therapy in patients at very high risk of relapse.

The GETUG 12 study has benefited from financing from The League Against Cancer and from Sanofi-aventis France.

#### **PROSTATE CANCER**

Prostate cancer is the commonest cancer in man, with more than 53,000 new cases per year in France in 2012.

It is very rare under the age of 50 years.

The mean age at diagnosis is approximately 70 years.

This is most often a cancer which develops slowly.

It can be completely silent or responsible for urinary signs such as difficulty in urinating or a more frequent desire to urinate.

Prostate cancer is often suspected in the presence of an elevated Prostatic Specific Antigen (PSA) concentration in the blood.

However, only the microscopic examination of biopsies from the prostate enables the diagnosis of cancer to be confirmed.

The aggressiveness of the cancer is mainly determined by three factors: the spread of the cancer (localized within the prostate or extending beyond the prostate, nodal spread or the spread to other organs), the aggressiveness of cancer cells seen under the microscope (Gleason score: from 6 to 10) and the PSA level in blood.

It has been the subject of numerous studies at Gustave Roussy.

Studies aim at evaluating treatments and innovative techniques, as well as various administration regimens.

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## III GETUG TRIALS

Cancers of the bladder, prostate, kidney and testes form part of the tumours of the urogenital tract.

The Uro-Genital Tumour Study Group (GETUG) which includes the Centers for the fight against cancer and hospital centers in France, are currently carrying out 12 trials requiring in total the participation of over 6,000 patients.

The research department of the UNICANCER group is actively participating in the GETUG group in the piloting of a specific research on these tumours.

The League Against Cancer supports the large therapeutic strategy trials undertaken by GETUG.

## ABOUT THE FIGHT AGAINST CANCER LEAGUE

First independent voluntary funder for research against cancer, the League against Cancer is an independent non-governmental organization dependant on the generosity of the public and on the commitment of its activists. Powerful, with nearly 652,000 members and 13,000 volunteers, the League is a popular movement organized into a federation of 103 departmental committees. Together, they fight in three complementary directions; investigate to cure, prevent to protect and accompany to provide help. Today, the League against Cancer has created a social issue, combining the largest possible number of healthcare professionals and also economic, social or political protagonists in all regions. By shattering taboos and fears, the League contributes to changing the image of cancer in those who are suffering from it.

[www.ligue-cancer.net](http://www.ligue-cancer.net)



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