

GUSTAVE ROUSSY A T A S C O 2 0 1 7

Press release / Plenary lecture / Sunday 4th June

By showing a 38% reduction in the risk of death, a medical researcher from Gustave Roussy is transforming the treatment of patients with metastatic prostate cancer

The findings of a large clinical study are going to change the preferred methods of treatment of metastatic prostate cancer which have remained almost unchanged for 70 years.

On Sunday June 4th, Professor Karim Fizazi, Head of the Department of Cancer Medicine at Gustave Roussy, will be presenting the LATITUDE study in a plenary lecture at the American Society of Clinical Oncology (ASCO) Congress in Chicago. The favorable results from this trial will likely change how these patients are being treated. The data will be published in the New England Journal of Medicine on Sunday June 4th either.

"Although prostate cancer is very responsive to conventional hormonal therapy, it does not completely eradicate all malignant cells and residual hormone production persists. **The LATITUDE** trial demonstrates that abiraterone, administered upfront in combination with standard hormonal therapy reduces the risk of death by 38% and the risk of progression of cancer or death by more than 50% at 2½ years of follow-up. These important findings will very likely change the standard of care of patients who have evidence of metastatic disease at the time of prostate cancer diagnosis "explained Professor Fizazi.

LATITUDE is a major phase III international multicentre comparative clinical study (double blind, placebo-controlled) involving 235 sites in 34 countries. 1,200 patients were enrolled between February 2013 and December 2014. The objective was to assess the beneficial effects of abiraterone on overall survival and survival without cancer progression in patients newly diagnosed with metastatic prostate cancer. It is sponsored by Janssen Biotech and Professor Fizazi is the principal investigator.

Until 2015, patients with metastatic prostate cancer were treated with standard hormonal therapy aiming to inhibit the testicular production of testosterone. In the LATITUDE study, patients were randomised to receive either abiraterone acetate, a next-generation hormonal therapy which inhibits the synthesis of androgens from the adrenal glands and the cancer cells themselves, or a placebo, in addition to standard treatment (conventional hormonal therapy). Prednisone was associated to abiraterone to prevent the risk of hypertension and hypokalaemia.

The results show that the addition of abiraterone to conventional hormonal therapy not only considerably improves the outcome of these patients (overall survival and progression-free survival) but also all of the disease-related complications, such as bone pain, fractures, and spinal cord compression secondary to tumor spread to the vertebrae.

Plenary lecture Pr KARIM FIZAZI

Plenary lecture Sunday 4 June at 14h40 (local time) Place: Hall B1

Latitude Study Results:

ABSTRACT No LBA3 Abiraterone has had Marketing Authorisation since 2012. It is currently used as salvage therapy in patients with metastatic prostate cancer which have become refractory to conventional hormonal therapy ("castrationresistant prostate cancer").

"One other advantage of this drug is that it is taken orally and is usually very well-tolerated. These major results represent very good news for our patients and we believe that the beneficial effects may even be greater with longer follow-up," says Professor Fizazi. Data from an English phase III clinical trial of the same agent are also awaited.

The next step is the European PEACE-1 study sponsored by UNICANCER and directed by Professor Fizazi. This is evaluating the addition of abiraterone to "reinforced background" treatment consisting of standard hormonal therapy and chemotherapy. The first results are expected in 2020.

Prostate cancer is the commonest cancer in France, with more than 55,000 new cases diagnosed each year. At the time of diagnosis, some 10 to 15% of patients have metastases, which in most cases are located in the bones and the lymph nodes. It is responsible for 8,000 to 9,000 deaths per year in France.

ESSAI LATITUDE:

A phase III, double-blind, randomized trial of androgen deprivation therapy with abiraterone acetate plus prednisone or placebos in newly diagnosed high-risk metastatic hormone-naive prostate cancer.

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/ 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, www.gustaveroussy.fr/en







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