

GUSTAVE ROUSSY IN ASCO 2019

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Press release / Oral session / Chicago, 31st May 2019
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PROSTATE CANCER

Darolutamide reduces the risk of pain and does not worsen the quality of life in patients treated for prostate cancer

Darolutamide reduces the risk of pain and does not worsen the quality of life in patients treated for non-metastatic prostate cancer, according to the findings of the ARAMIS study. These results, presented at the ASCO meeting by Professor Karim Fizazi, principal investigator and oncologist at Gustave Roussy specialised in prostate cancer, confirm the role of this agent, which increases survival of these patients by almost two years without disease spread.

“In addition to an improvement in metastasis-free survival, a good safety profile is a major feature for these patients (the great majority being asymptomatic) with prostate cancer that has become resistant to hormone therapy. The choice of therapeutic agent may impinge on their general well-being and adherence to treatment with the agent and with other drugs being taken concomitantly. Supplementary data from the ARAMIS study not only show significant efficacy of darolutamide in prevention of cancer progression, but also demonstrate that its freedom from side effects enables patients to continue their daily activities without developing further complications,” explained Professor Fizazi. “Moreover, darolutamide reduces the incidence of metastatic bone pain and urinary symptoms related to local relapse”.

Darolutamide is a new androgen-receptor inhibitor, these steroid hormones (androgens) being implicated in the genesis of prostate cancer. The drug was developed for use in men with non-metastatic disease who had received local treatment and who had become resistant to standard hormone therapy. Its safety and efficacy were evaluated in the ARAMIS study, a phase 3 placebo-controlled trial, conducted in 409 centres in 36 countries. 1,509 patients were recruited. The intermediate results were presented in February of this year at the ASCO genitourinary cancer meeting in San Francisco and published simultaneously in the New England Journal of Medicine. They demonstrated that this agent reduced the risk of metastasis or death by 59%. The researchers continued to analyse the data in order to assess a variety of factors determining the good safety profile of the drug and patient quality of life. The latter was assessed via scores obtained on a number of questionnaires. One of these (BPI-SF, Brief Pain Inventory – Short Form) measured the effects of pain; another (FACT-P, Functional Assessment of Cancer Therapy-Prostate) evaluated the impact of the disease and its treatment; and there were several quality of life questionnaires. Patients were reviewed at evaluation visits at 16 week intervals through to the end of treatment assessment, then at each visit until the end of the study or up to their death when that was the case. Worsening of the quality of life was examined in a post-hoc analysis of the ARAMIS data during the weeks following cessation of treatment, so as to assess the effects of darolutamide on symptoms and on the overall health status of the patients.

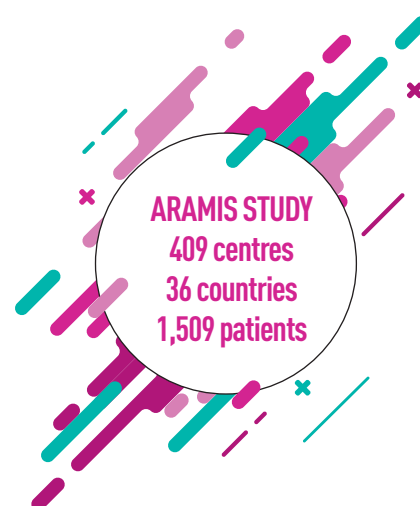
In comparison with placebo, darolutamide delayed the appearance of pain by 15 months (25.4 months vs 40.3 months), and reduced by 57% the incidence of occurrence of the first symptomatic bone event (fracture, spinal cord compression, tumour-related orthopaedic surgery, etc.). The drug did not increase the rate of serious adverse events including, in particular, epileptic seizures, falls, fractures, skin



Oral session
Pr. KARIM FIZAZI
Gustave Roussy

ORAL SESSION
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rash, cognitive disorder, mental illness or hypertension. Only fatigue was seen more frequently (12.1% vs 8.7%) but this small difference disappeared when data were analysed as a function of the duration of exposure to medication. As for withdrawal, the rate was similar in the two groups (8.9 and 8.7% respectively).

These latest ARAMIS study results show therefore that the quality of life of patients taking darolutamide is not only maintained through the treatment period but continues to be so during the weeks following cessation of treatment. In addition, compared with placebo, darolutamide delays the appearance of urinary or intestinal symptoms, first signs of a deterioration in the quality of life (11.1 months vs 7.9 months).

The ARAMIS trial was sponsored by Orion Pharma and Bayer HealthCare.

ABOUT PROSTATE CANCER¹

Cancer of the prostate is the commonest cancer found in men with about 55,000 new cases diagnosed per year in France . It is rare below the age of 50 and two thirds of cases arise after the age of 65. In general, it progresses slowly (10 to 15 years), usually insidiously; when it has advanced it may declare itself in terms of urinary symptoms (infection, blood in the urine or semen or difficulty in passing urine) or low back or bone pain.

In the great majority of cases (90%), it is an adenocarcinoma resulting from malignant transformation of epithelial cells lining the inside of the boundary of the prostate. Other prostate cancers include carcinomas and sarcomas.

It is usually discovered following measurement of PSA and/or on the basis of a finding of an abnormality of consistency of the gland on rectal examination. Confirmation of the diagnosis depends on the results of these two tests which may be supplemented by a biopsy of the prostate and imaging investigations.

Various treatments of this cancer are available for doctors if it has not spread at the time of diagnosis: (external radiotherapy, brachytherapy, surgery, hormone therapy and active monitoring). The choice depends on the characteristics of the tumour as defined by the results of the various tests performed during the diagnostic process. Recommendations for treatment are always the results of multidisciplinary meetings and should still be approved by the patient.

Prostate cancer is the third most common cause of cancer death in men but a clear reduction in deaths was observed between 2013 and 2017: 8,625 vs 8,2072.

¹ Institut national du cancer (INCa) (National Cancer Institute). *Cancers of the prostate: key points.*

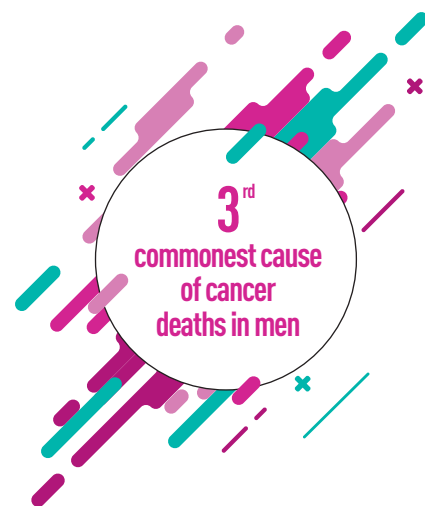
<https://www.e-cancer.fr/Patients-et-proches/Les-cancers/Cancer-de-la-prostate/Points-cles>

² Health Insurance Website. www.ameli.fr/assure/sante/themes/cancer-prostate/comprendre-cancer-prostate

▶ LISTEN TO Pr. KARIM FIZAZI'S EXPLANATIONS



AROLUTAMIDE: Appearance of pain delayed by 15 months



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