GUSTAVE ROUSSY AT ESMO 2018

Press release / Presidential symposium

FIRST EVIDENCE OF THE BENEFICIAL EFFECT OF A NEW DRUG GUIDED BY GENOME ANOMALY ON BREAST CANCER

Presented during the plenary session of the ESMO (European Society for Medical Oncology) Annual Conference on Saturday, 20 October, by Professor Fabrice André, oncologist at Gustave Roussy and Inserm Research Director, the phase III SOLAR-1 study clearly confirms the benefit of adding alpelisib to treatment for women with advanced, recurrent, hormone-dependent breast cancer. For these women, disease recurrence is delayed by 5 months and the risk of disease progression is reduced by 35%. This is the first genomic driven targeted therapy used in breast cancer.

Hormone therapy and CDK4 inhibitors are the standard reference treatment for women presenting advanced hormone-dependent breast cancer. However, most patients develop resistance after a few months or years. A new class of hormone therapy is initiated on recurrence.

Detected in 40% of advanced, recurrent, hormone-dependent breast cancers, PIK3CA mutation triggers hyperactivation of PI3 kinase, an enzyme stimulating the cell cycle. This enzyme is involved in the transformation of healthy cells into cancerous cells, cancer progression and even the development of resistance to hormone therapy. **explains Professor Fabrice André**

SOLAR-1 study compares the benefit of adding a new molecule, namely alpelisib, which targets the alpha isoform of PI3 kinase, to a placebo during disease recurrence in addition to hormone therapy (fulvestrant). Alpelisib was assessed in patients with or without *PIK3CA* mutation. This treatment was seen to have a beneficial effect on these women in a previous phase Ib study.

Sponsored by Novartis, SOLAR-1 is a phase III, multicentre, international, randomised, double-blind study versus placebo with an overall cohort of 572 patients enrolled between July 2015 and July 2017.
PIK3CA mutation was investigated in these patients on their enrolment in the SOLAR-1 study. 341 women carrying the *PIK3CA* mutation and 231 women without the mutation received either alpelisib or a placebo via the oral route for approximately five months.

Embargo in place
UNTIL
4:30pm on Saturday, 20th October

Presidential symposium
Prof. FABRICE ANDRÉ
Gustave Roussy

SATURDAY 20TH OCTOBER
from 5:30 to 5:45pm
Place: Hall 2 Room 18

ABSTRACT LBA3_PR

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In the women with *PIK3CA* mutation who took alpelisib, progression-free survival was 11 months compared to 5.7 months in those who received the placebo, i.e. progression-free survival increased by more than five months with alpelisib.

Moreover, in the group of women without the mutation, no significant difference was observed between alpelisib and placebo in terms of progression-free survival. The mutation must, therefore, be present in order for the medication to be effective. In the long term, screening for *PIK3CA* mutation will be carried out in order to prescribe alpelisib only for those women who will benefit from it.

Treatments used in the management of breast cancer to date have targeted protein receptors or protein expression (oestrogen or HER2 receptors). This is the first study to highlight the efficacy of genome-guided therapy. Other diseases are already treated by genome-guided therapies such as crizotinib for lung cancer patients with *ALK* gene rearrangement or vemurafenib for melanoma patients with *BRAF* gene mutation.

LINK ITW PROF. FABRICE ANDRÉ VIDEO PENDING

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/ About Gustave Roussy

Gustave Roussy, Europe's leading anti-cancer centre, is a global, patient-focused centre of excellence. It brings together 3,100 professionals dedicated to treatment, research and teaching.

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