



Press Release

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Olaparib (Lynparza™) in combination with bevacizumab significantly delays disease progression in the phase III PAOLA-1 GINECO/ENGOT-ov25 trial for ovarian cancer in 1st line setting

PAOLA-1 GINECO/ENGOT-ov25 trial met primary endpoint of progression-free survival in women with newly diagnosed advanced cancer with or without *BRCA* gene mutation.

The French cooperative group GINECO (Groupe des Investigateurs Nationaux pour l'Étude des Cancers de l'Ovaire et du sein) announced today positive results from the randomized, double-blind, placebo-controlled, phase III PAOLA-1 trial. The study met its primary endpoint of a statistically significant improvement in progression free interval for women with or without BRCA gene mutation.

PAOLA-1-GINECO/ENGOT-ov25 is a Phase III sponsored study by the Association de Recherche sur les Cancers dont GYNécologiques (ARCAGY)-Research on behalf of GINECO, lead group for the PAOLA-1 trial of the European Network for Gynecological Oncological Trial Groups [ENGOT]. GINECO is also member of the Gynecologic Cancer InterGroup [GCIg].

This study, designed in collaboration with AstraZeneca, assessed the effect of olaparib in combination with bevacizumab as a maintenance treatment for newly diagnosed advanced FIGO Stage III-IV high-grade serous or endometrioid ovarian, fallopian tube, or peritoneal cancer patients responding to standard first line chemotherapy (platinum-taxane) and bevacizumab. As they were not selected according to BRCA status or presence of residual lesions after surgery, women included in PAOLA-1 trial were representative of the global population of patients with advanced ovarian cancer.

Pr Isabelle Ray-Coquard, Principal Investigator of PAOLA-1 study said: « Olaparib in combination with bevacizumab in maintenance is a major step for the treatment of more women whose cancer has spread beyond the ovary which is the majority and offers new hopes for these women.

We would like to thank all the investigators from ENGOT and GCIg and all the patients who took part in this trial, without whom medical advancements would not be possible. »

The full results from PAOLA-1 will be presented at an upcoming scientific meeting.

Olaparib is being jointly developed and commercialized by AstraZeneca and MSD (known as Merck & Co., Inc. inside the US and Canada) under the trade name Lynparza®.

About PAOLA-1

PAOLA-1-GINECO/ENGOT-ov25 is a Phase III assessing the effect of olaparib in combination with bevacizumab as a maintenance treatment for newly diagnosed advanced FIGO Stage III-IV high grade serous or endometrioid ovarian, fallopian tube, or peritoneal cancer patients who are in response to standard first line treatment, containing platinum-taxane chemotherapy and bevacizumab. 806 patients have been randomized in different European countries and in Japan. Randomization was 2:1 to olaparib 300mg tablets twice daily or placebo tablets twice daily for 2 years in combination with bevacizumab (15mg/kg) as per label, as a maintenance treatment.

About ovarian cancer

Worldwide, ovarian cancer is the seventh most common cancer and the eighth leading cause of cancer death in women. The five-year survival rate for ovarian cancer worldwide is 30-40%. In 2018, there were nearly 300,000 new cases diagnosed. For newly diagnosed advanced ovarian cancer, the primary aim of treatment is to delay progression of the disease for as long as possible and maintain the patient's quality of life with the intent of achieving complete remission or cure.

About GINECO

GINECO (Groupe d'Investigateurs National pour l'Etude des Cancers de l'Ovaire et du sein) is the French Cooperative Group in Oncology labelled by INCA (Institut National du Cancer or French NCI) developing and conducting gynecological and metastatic breast cancer clinical trials at the national and international level. The GINECO group was founded in 1993 and is member of international consortia such as ENGOT and GCIG (Gynecologic Cancer InterGroup).

About ENGOT

ENGOT (European Network for Gynecological Oncological Trial groups) is a research network of the European Society of Gynecological Oncology (ESGO) and was founded in 2007. Currently, ENGOT includes 21 cooperative groups from 25 European countries.

About GCIG

The GCIG (Gynecological Cancer InterGroup) aims to promote and facilitate high quality clinical trials in order to improve outcomes for women with gynecological cancer. It was founded in 1998. Currently, GCIG includes 23 cooperative groups from 28 countries worldwide.

For more information, please visit www.arcagy.org

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