Communication of the President of the Office of 22 July 2022 on the recommendations for restrictions on the use of the cancer medicine Rubraca by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

Submitted by m.koszewski on Fri, 22/07/2022 - 13:20

PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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EMA's human medicines committee, CHMP, has recommended that Rubraca (rucaparib camsylate) should no longer be used as third-line treatment for cancers of the ovary, fallopian tubes or peritoneum with a BRCA mutation in patients whose cancer has come back after at least two platinum-based chemotherapies and who cannot have further platinum-based therapy.

The recommendation follows the review of final data from the ARIEL4 study, which compared Rubraca with chemotherapy in patients whose cancer had come back after at least two previous treatments and who were still eligible for further chemotherapy. The final analysis of overall survival showed that Rubraca was not as effective as chemotherapy at prolonging patients' lives: those treated with Rubraca lived for an average of 19.4 months, compared with 25.4 months for patients receiving chemotherapy.

As a result, doctors should not start third-line treatment with Rubraca in new patients. Doctors should inform patients already receiving Rubraca for this indication of the latest data and recommendations, and consider other treatment options.

This recommendation does not affect the use of Rubraca as maintenance treatment following chemotherapy.

The medicine Rubraca should no longer be used to treat cancer of the ovary, fallopian tubes or peritoneum with a BRCA mutation (genetic defect) in patients whose cancer has come back after at least two platinum-based chemotherapies and who cannot have further platinum-based therapy (so-called 'third-line treatment').

This is because a study that was designed to confirm the benefit of Rubraca failed to do so, and showed that treatment may be associated with a higher risk of death.

Rubraca should not be started as third-line treatment. If you are taking Rubraca as third-line treatment, your doctor will consider other treatment options.

If you have any concerns about your treatment, speak with your doctor.

EMA has recommended that Rubraca should no longer be authorised as monotherapy for the treatment of patients with platinum sensitive, relapsed or progressive, BRCA-mutated (germline

and/or somatic), high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, who have been treated with two or more prior lines of platinum-based chemotherapy and who are unable to tolerate further platinum-based chemotherapy.

The recommendation follows the final analysis of data from a phase 3 study, ARIEL4, comparing Rubraca with chemotherapy in patients with relapsed, BRCA-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

A difference in favour of Rubraca was observed for the primary endpoint of progression free survival by investigator (invPFS) (7.4 months for the Rubraca group compared with 5.7 months for the chemotherapy group (hazard ratio (HR)=0.665 (95% CI: 0.516, 0.858); p=0.0017)).

However, overall survival with Rubraca was lower than that with chemotherapy (19.4 months versus 25.4 months, respectively, with a HR of 1.31 (95% CI: 1.00, 1.73); p=0.0507).

The CHMP therefore concluded that the benefit of Rubraca, when used in the above-mentioned indication, had not been confirmed and that treatment may be associated with an increased risk of death. Ongoing treatment in this setting should be reconsidered and patients should be informed of the latest data and recommendations.

This recommendation does not affect the use of Rubraca as maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

A direct healthcare professional communication (DHPC) will be sent in due course to healthcare professionals prescribing, dispensing or administering the medicine. The DHPC will also be published on a dedicated page [1] on the EMA website.

More information available on the website: https://www.ema.europa.eu/en/news/ema-recommends-restricting-use-cancer-medicine-rubraca [2]

on behalf of President
Vice-President for Medicinal Products
Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products
/-/ Marcin Kołakowski

Links
[1] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications
[2] https://www.ema.europa.eu/en/news/ema-recommends-restricting-use-cancer-medicine-rubraca