Dear Healthcare Professionals,

The European Union: EMA reminds physicians to use Tecentriq with nab-paclitaxel for treating breast cancer

The European Medicines Agency (EMA) announces that it is reminding physicians to use Tecentriq (atezolizumab) only in combination with nab-paclitaxel and not with conventional paclitaxel when treating patients with locally advanced or metastatic triple-negative breast cancer that cannot be surgically removed.

EMA’s advice follows the release of results from a study, IMPassion131, which did not show that combining Tecentriq with conventional paclitaxel in these patients slowed down the progression of the cancer or reduced deaths.

Tecentriq is only authorised for the treatment of triple negative breast cancer in combination with nab-paclitaxel. Nab-paclitaxel is a formulation of paclitaxel that is attached to a protein that affects how the medicine works in the body.

There is no indication yet that physicians in the EU have been using paclitaxel in place of nab-paclitaxel. However, EMA’s human medicines committee (CHMP) would like to use this opportunity to remind healthcare professionals to follow the recommendations in the approved product information.

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Tecentriq was approved for the treatment of triple-negative breast cancer in the EU in August 2019. A study reviewed by the CHMP at the time showed that patients whose cancer produced a certain amount of a protein called PD-L1 lived for an average of 25 months when treated with Tecentriq plus nab-paclitaxel, compared with 18 months when given placebo plus nab-paclitaxel. Patients in the Tecentriq group also lived for longer without their disease getting worse (7.5 months versus 5.3 months).

Triple-negative breast cancer is a type of breast cancer that does not produce the usual receptors (targets) which other targeted cancer medicines act on. As such, there are fewer medicines that can treat patients with this type of breast cancer.

The EMA will review data from the IMpassion131 study and decide if any change is needed to the approved use of Tecentriq with nab-paclitaxel.

Please refer to the following website in EMA for details:

In Hong Kong, there is one registered pharmaceutical product containing atezolizumab indicated to be used in combination with nab-paclitaxel for unresectable locally advanced or metastatic triple-negative breast cancer, namely Tecentriq Concentrate for Solution for Infusion 840mg/14ml (HK-66613). The product is registered by Roche Hong Kong Limited, and is a prescription-only medicine. So far, the Department of Health (DH) has received 72 cases of adverse drug reaction related to atezolizumab, but they are not related to progression of disease when use in combination with conventional paclitaxel. The DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,
(Joseph LEE)
for Assistant Director (Drug)

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