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Re-analysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab

EMA is updating the prescribing information for Tyverb (lapatinib) following detection of errors in results of a study involving postmenopausal women who had 'HR+/HER2+' breast cancer and whose disease had worsened despite previous treatment with trastuzumab. The results had indicated a benefit of Tyverb over trastuzumab when each medicine was used together with an aromatase inhibitor.

The detected errors were included in the prescribing information for Tyverb on 30 July 2018. However, these will now be removed while data are being re-analysed. In the meantime, the prescribing information will be amended to state, as before, that no data are available on the effectiveness of Tyverb compared with trastuzumab in this combination in patients previously treated with trastuzumab.

In the light of this new information, doctors currently treating patients with Tyverb in combination with an aromatase inhibitor, whose disease had worsened despite previous treatment with trastuzumab, should decide whether to continue with the same therapy or consider an alternative treatment.

Information for patients

- If you are receiving Tyverb in combination with an aromatase inhibitor for breast cancer, your doctor may decide to continue treatment or to switch you to another treatment in light of new information. This will depend on your particular situation and how well the treatment is working for you.
- Incorrect analysis of data on use of Tyverb with an aromatase inhibitor in previously treated patients with breast cancer is being removed from the prescribing information.
- Your doctor will receive a letter with this information. If you have any concerns about your cancer treatment, speak to your doctor or nurse.

Information for healthcare professionals

- Errors have been detected in the efficacy results of study EGF114299, which evaluated the efficacy and safety of Tyverb in combination with an aromatase inhibitor in postmenopausal women who had HR+/HER2+ metastatic breast cancer which had progressed despite prior trastuzumab-containing regimens and endocrine therapies.

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- While there are no new safety concerns with Tyverb, a benefit over trastuzumab in this patient population has not been shown and data are currently being re-evaluated.
- While the evaluation is ongoing, the prescribing information will be amended to remove the incorrect analysis of the study data (from section 5.1 of the summary of product characteristics) and to reinstate statements (in section 4.1) that no data are available on the relative efficacy of Tyverb- and trastuzumab-based therapy in patients previously treated with trastuzumab and an aromatase inhibitor in this population.
- In view of the new information, for patients whose disease had previously progressed on trastuzumab containing therapy and who are currently receiving Tyverb in combination with an aromatase inhibitor, a decision on continuation of therapy should be made on a case-by-case basis.
- Doctors will be informed of these changes in writing.

More about the medicine

Tyverb is a cancer medicine used to treat patients with breast cancer that has been shown to be expressing HER2. This means that the cancer produces a specific protein called HER2 (also known as ErbB2) on the surface of the cancer cells. Tyverb is used in the following ways:

- in combination with capecitabine (another cancer medicine) when the cancer is advanced or metastatic and got worse following previous treatment including an anthracycline and a taxane (other types of cancer medicines), and following treatment of the patient's metastatic disease with trastuzumab (another cancer medicine). 'Advanced' means that the cancer has started to spread locally and 'metastatic' means that the cancer has spread to other parts of the body;
- in combination with trastuzumab for metastatic cancer that does not respond to hormones (hormone receptor-negative disease), and which got worse when previously treated with a combination of trastuzumab and other cancer medicines (chemotherapy);
- in combination with an aromatase inhibitor (another type of cancer medicine) in women who have been through the menopause, when the cancer is metastatic and responds to hormones. This combination is used in women who do not currently need to receive chemotherapy to treat their cancer.

Tyverb was originally granted a conditional marketing authorisation valid throughout the EU in June 2008 and was switched to a full marketing authorisation on 17 February 2015.

More information about the medicine can be found on the EMA website: ema.europa.eu/medicines/human/EPAR/tyverb.

More about the procedure

The changes to the prescribing information of Tyverb are being carried out as part of a 'type IB variation'. With this variation, the erroneous information that had previously been added to the prescribing information (in variation II/51) will be removed. A separate procedure (variation II/59) on inclusion of the re-analysed data in the prescribing information is ongoing.