Tyverb: data on use following treatment with trastuzumab re-analysed

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Information on Tyverb

- Tyverb is a cancer medicine used to treat breast cancer expressing HER2. HER2 (also known as ErbB2) is a specific protein which is produced on the surface of the cancer cells
- Tyverb is used in combination with capecitabine when the cancer is advanced (cancer has started to spread locally) or metastatic (cancer has spread to other parts of the body) and got worse following previous treatment with other cancer medicines including an anthracycline and a taxane and following treatment of the patient's metastatic disease with trastuzumab
- Tyverb is used 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)
- Tyverb is used in combination with cancer medicine aromatase inhibitor 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.

In Malta Tyverb is authorised through a centralised procedure

Active Ingredients	Product Name	Pharmaceutical Form	Authorisation Number	MAH/license holder
Lapatinib	Tyverb	Film-coated tablet	EU/1/07/440/001 -7	Novartis Europharma Limited Ireland

Information from the EMA about the changes to the prescribing information of Tyverb

- Prescribing information for Tyverb (lapatinib) is being updated by the EMA following results of a study indicating a benefit of Tyverb over trastuzumab when each medicine was used together with an aromatase inhibitor. Errors in the efficacy results of a study involving postmenopausal women who had 'HR+/HER2+' breast cancer and whose disease had worsened despite previous treatment with trastuzumab have been detected.
- On 30th July 2018, the detected errors were included in the prescribing information for Tyverb. During the re-analysis of this data, these errors will be removed, and 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
- 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
- Following 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

In Malta

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
- 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

A DHPC letter about the safety concern has been disseminated to HCPs in Malta. Archived DHPC letters are available online at http://www.medicinesauthority.gov.mt/dhpc

Advice 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.

For more information please see the European Medicines Agency's press release on Tyverb.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Tyverb. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

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