

20 May 2021

The Secretary of the 23rd WHO Expert Committee on the Selection and Use of Essential Medicines -2021
Department of Essential Medicines and Health Products (EMP)
World Health Organization (WHO)
20 Avenue Appia
CH-1211 Geneva 27 Switzerland

Dear Committee Members,

As a scientist and medical oncologist with more than 40 years clinical practice, I support the addition of Pertuzumab to the WHO Model List of Essential Medicines (EML). My experience as a Principal Investigator of more than 50 clinical trials includes as well APHINITY trial, performed in Bulgaria. I am treating about 800 women with breast cancer each year of which 18% with HER2 positive disease.

In my opinion, anti-HER2 therapy is one of the most impressive achievements in oncology. The prognosis of the patients with this aggressive disease was completely changed after the addition of Trastuzumab, followed by Pertuzumab to the treatments regimens of patients with HER2 positive disease. Despite the treatment with Trastuzumab in metastatic setting, many patients are progressing in a short time. The end-of-study analysis of the CLEOPATRA trial of Pertuzumab plus Trastuzumab and chemotherapy in metastatic HER2-positive breast cancer, reported during 2019 ASCO meeting found that 37% of patients were still alive at 8 years, vs 23% in the control arm.

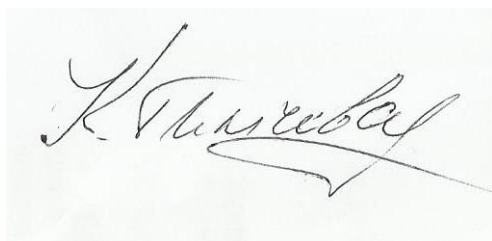
Median overall survival was 57.1 months (!) in the Pertuzumab arm and 40.8 months in the placebo arm, an absolute difference of 16.3 months favoring Pertuzumab. The 8-year landmark overall survival rates were 37% and 23%, respectively.

My personal experience with Pertuzumab is in favor of safety and efficacy. Risk of cardiotoxicity is minimal, sometimes we observed diarrhea gr. 1. The safety profile of Pertuzumab is good and well manageable.

Pertuzumab is approved by EMA for the first line treatment with Trastuzumab and Docetaxel of metastatic HER2 positive breast cancer. It is recommended by the International Clinical Guidelines: ESO-ESMO Guidelines, ASCO and NCCN Guidelines for the treatment of metastatic HER2 positive breast cancer. This drug is included in the Bulgarian Guidelines for the treatment of solid tumors.

As a physician devoted to his work and to the patients' health, I respectfully urge the Committee to consider the additional lives that could be saved or improved with including Pertuzumab to the WHO EML 2021.

Yours faithfully,



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