INAHTA Brief

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Title KADCYLA – A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2984794/fr/kadcyla

Aim

Assessment of KADCYLA (trastuzumab emtansine) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in the indication adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, with residual invasive disease of the breast and/or lymph nodes, after taxane-based neoadjuvant treatment and HER2-targeted therapy.

Conclusions of Transparency Committee

Clinical Benefit

- Early-stage HER2-positive breast cancer is a serous, life-threatening disease.
- This is a specific curative treatment for breast cancer with HER2 receptor amplification.
- The efficacy/adverse effects ratio is high.
- There is an alternative medicinal product: trastuzumab.
- This medicinal product is a first-line adjuvant treatment of early-stage HER2-positive breast cancer in the presence of residual invasive disease, in the breast and/or lymph nodes, and after neoadjuvant taxane-based and HER2-targeted therapy.
- KADCYLA (trastuzumab emtansine) is unlikely to have an additional impact on public health.

Considering all of the above, the clinical benefit of KADCYLA (trastuzumab emtansine) by IV route is substantial in the new MA indication, i.e., "as a single agent, in the adjuvant treatment of adult patients with early-stage HER2-positive breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy".

Clinical Added Value
Considering:
- demonstration of the superiority of KADCYLA (trastuzumab emtansine) compared to the standard treatment, trastuzumab, in terms of invasive disease-free survival with a significant improvement for this clinically-relevant endpoint (HR = 0.50 95%CI [0.39; 0.64]; p<0.0001) in a phase III open-label study,

and despite:
- the immaturity of overall survival data, preventing a conclusion being reached with respect to a benefit of KADCYLA (trastuzumab emtansine) compared to trastuzumab for this endpoint,
- the additional toxicity compared to trastuzumab with, in particular, more grade ≥ 3 adverse events (25.7% vs. 15.4%) or adverse events having led to treatment discontinuation (18.0% vs. 2.1%) and important identified risks (including hepatotoxicity, thrombocytopenia, bleeding events and peripheral neuropathy),
- the absence of any data on quality-of-life with a demonstrative value,

KADCYLA (trastuzumab emtansine) provides moderate Clinical Added Value (CAV III) compared to trastuzumab in the adjuvant treatment of adult patients with early-stage HER2-positive breast cancer who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.

Recommendations

The Transparency Committee issued its approval for the funding of KADCYLA (trastuzumab emtansine) by the French national health insurance system (hospital only) in the indication adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, with invasive residual disease of the breast and/or lymph nodes, after taxane-based neoadjuvant treatment and HER2-targeted therapy.

Methods

The assessment of KADCYLA (trastuzumab emtansine) was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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