FDA Approves Kadcyla for HER2-Positive Early Breast Cancer

Antibody-drug combination reduced the risk of recurrence after surgery by half compared with Herceptin.

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The Food and Drug Administration (FDA) has approved Kadcyla (ado-trastuzumab emtansine), for adjuvant, or postsurgery, treatment for people with HER2-positive early breast cancer who still have residual disease after neoadjuvant, or presurgery, therapy.

This approval is supported by findings from the KATHERINE trial, presented at the 2018 San Antonio Breast Cancer Symposium, which showed that people who received Kadcyla had a 50% lower risk of disease recurrence or death than with those who used Herceptin (trastuzumab), the current standard of care. The approval was made under the FDA's new Real-Time Oncology Review pilot program, which aims to make promising new treatments available sooner.

Breast cancer is classified by the type of receptors it expresses. A majority of breast cancers are hormone receptor-positive (HR-positive), meaning they carry receptors for estrogen or progesterone; treatment usually includes hormone therapy. Around 20% of breast tumors express HER2 (human epidermal growth factor receptor 2) and can be treated with HER2 inhibitors like Herceptin or Perjeta (pertuzumab).

Treatment for HER2-positive early breast cancer typically starts with Herceptin plus chemotherapy to shrink tumors before surgery, known as neoadjuvant therapy. After surgery, some cancer cells may be left behind and trigger recurrence, so people with evidence of residual disease in their surgical specimens—meaning the neoadjuvant therapy was not completely effective—usually receive adjuvant Herceptin for another year.

The Phase III KATHERINE trial compared Kadcyla versus Herceptin, a HER2-targeted antibody. Kadcyla is an antibody-drug conjugate that combines the same antibody with emtansine, a chemotherapy drug that interferes with cell division. This combination enables the antibody to deliver the drug directly to cancer cells. Kadcyla was previously approved for people with metastatic breast cancer.

KATHERINE enrolled 1,486 participants who had residual cancer in the breast or underarm lymph nodes at the time of surgery but did not yet have metastatic cancer that had spread elsewhere in

the body. All had HER2-positive tumors and about three quarters also had HR-positive cancer. Everyone had used neoadjuvant Herceptin plus taxane chemotherapy (drugs like paclitaxel), most had also used anthracyclines (drugs like doxorubicin) and 20% had also used Perjeta.

Within three months after surgery they were randomly assigned to receive adjuvant Kadclya or Herceptin given by IV infusion every three weeks for 14 cycles.

In an interim analysis, 12.2% of participants in the Kadcyla group developed recurrent cancer or died, compared with 22.2% in the Herceptin group. Benefits were seen among both pre- and postmenopausal women and those with HR-positive and HR-negative tumors. At three years post-surgery, 88.3% of people in the Kadcyla group and 77.0% in the Herceptin group were still alive and free of invasive disease—a 50% improvement. Differences in overall survival cannot yet be determined and follow-up is ongoing.

Treatment was generally safe and tolerable. Rates of severe (grade 3 or higher) adverse events were 25.7% and 15.4%, respectively, in the Kadcyla and Herceptin groups. The most common side effects of Kadcyla are fatigue, nausea, elevated liver enzymes, muscle and joint pain, headache, peripheral neuropathy, low platelet count and bleeding. Less common but more serious adverse events may include sever liver toxicity, heart problems, lung problems and severe hemorrhage. Kadcyla can cause fetal harm if used during pregnancy.

Genentech offers patient assistance programs for people prescribed Kadcyla, the company said in a press release. Contact Genentech Access Solutions at (866) 422-2377 or visit http://www.Genentech-Access.com/Kadcyla for more information.

Click here for full prescribing information for full prescribing information for Kadcyla.

Click here for the KATHERINE study abstract in The New England Journal of Medicine.

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