Perjeta OK’d for neoadjuvant use

Jan. 3, 2018—Genentech announced Dec. 20 the FDA’s approval of Perjeta (pertuzumab), in combination with Herceptin (trastuzumab) and chemotherapy (the Perjeta-based regimen), for adjuvant treatment of HER2-positive early breast cancer at high risk of recurrence. People should receive the adjuvant Perjeta-based regimen for one year (up to 18 cycles). The FDA has also converted the previously granted accelerated approval of the Perjeta-based regimen to full approval for neoadjuvant treatment of HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than two centimeters in diameter or node positive). People receiving the neoadjuvant Perjeta-based regimen should continue Perjeta and Herceptin after surgery to complete one year of treatment.

“The goal of treating breast cancer early is to provide people with the best chance for a cure. While we come closer to this goal with each advance, many people still have a recurrence and progress to the metastatic stage,” Sandra Horning, MD, chief medical officer and head of global product development, Genentech, said in a statement. “Today’s approval of Perjeta means people with HER2-positive early breast cancer at high risk of recurrence have a new, clinically meaningful treatment option to reduce the chances of their disease returning.”

The FDA-approved use of the Perjeta-based regimen for adjuvant treatment of HER2-positive EBC at high risk of recurrence is based on results of the phase-three APHINITY study.

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