FDA approves Enhertu for breast cancer

May 18, 2022—Daiichi Sankyo and AstraZeneca's Enhertu (fam-trastuzumab deruxtecan-nxki) has been approved in the United States for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy. Enhertu is a specifically engineered HER2-directed antibody drug conjugate jointly developed and commercialized by Daiichi Sankyo and AstraZeneca.

The approval was based on positive results from the pivotal DESTINY-Breast03 phase three trial that showed Enhertu reduced the risk of disease progression or death by 72 percent versus trastuzumab emtansine (T-DM1) (hazard ratio, 0.28; 95 percent confidence interval, 0.22–0.37; $p<0.0001$) in patients with HER2-positive unresectable and/or metastatic breast cancer previously treated with trastuzumab and a taxane.