FDA approves Herceptin for subcutaneous use

April 2019—The Food and Drug Administration approved trastuzumab and hyaluronidase-oysk (Herceptin Hylecta, Genentech) for subcutaneous injection for the treatment of certain people with HER2-positive early breast cancer in combination with chemotherapy and HER2-positive metastatic breast cancer in combination with paclitaxel or alone in people who have received one or more chemotherapy regimens for metastatic disease. This treatment includes the same monoclonal antibody as intravenous Herceptin (trastuzumab) in combination with recombinant human hyaluronidase PH20, an enzyme that helps to deliver trastuzumab under the skin. Herceptin Hylecta is a ready-to-use formulation that can be administered in two to five minutes, compared with 30 to 90 minutes for intravenous Herceptin.

Genentech, 650-225-1000