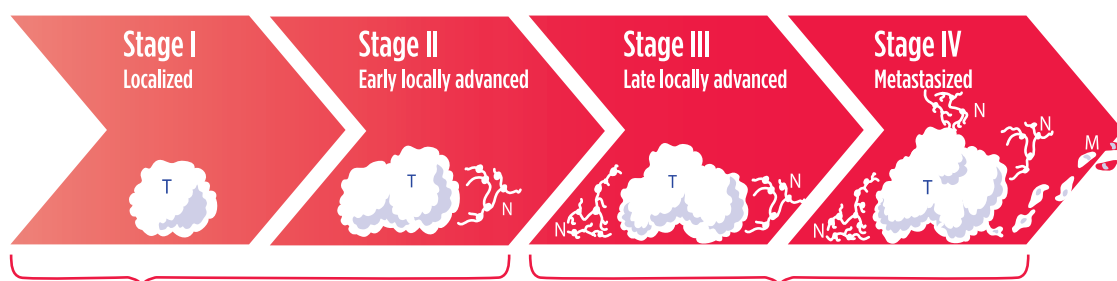


FIGURE 11

NEW FDA APPROVALS TARGET ALL STAGES OF BREAST CANCER



May 2019: FDA expands use of ado-trastuzumab emtansine to include adjuvant treatment of early-stage HER2-positive breast cancer

- May 2019: FDA approves alpelisib for use in combination with fulvestrant for treating advanced or metastatic, hormone receptor-positive breast cancer.
- March 2019: FDA approves atezolizumab for use in combination with nab-paclitaxel for treating metastatic triple-negative breast cancer.

- April 2019: FDA expands use of palbociclib to include men with advanced or metastatic receptor-positive breast cancer.
- October 2018: FDA approves talazoparib for treating metastatic or locally advanced, HER2-negative breast cancer related to an inherited BRCA mutation.

Clinical advances are benefiting patients diagnosed with breast cancer at both early and late stages of disease. During the 12 months covered by this report, August 1, 2018 to July 31, 2019, the U.S. Food and Drug Administration (FDA) approved two new therapeutics, alpelisib (Piqray) and talozaparib (Talzenna), and expanded the use of two previously approved therapeutics, atezolizumab

(Tecentriq) and palbociclib (Ibrance), to treat patients with locally advanced or metastatic breast cancer. During the same period, the FDA also expanded the use of ado-trastuzumab emtansine (Kadcyla), previously approved to treat metastatic HER2-positive breast cancer, to include adjuvant treatment of early-stage HER2-positive breast cancer.