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Breast pathology, proof of principle studies, and drug development

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Human Epidermal Growth Factor Receptor 2 (HER2), also known as ERBB-2, is a 185-kDa member of the erbB family of protein kinase receptors that is widely expressed in breast tissue. Binding with the epidermal growth factor like ligands (EGF-like ligands) will activate downstream signal transduction cascades as the MAPK, Akt, JNK, and JAK2/STAT3 pathways leading to cellular differentiation, mobility, proliferation, and survival. Several cancers are associated with HER2 overexpression including 25-30% of breast cancer invasive ductal carcinoma subtype. The role of histopathology in stage IV metastatic breast cancer has gone beyond diagnosis. Breast pathology biomarkers act as important prognostic and predictive tools to treatment response. Phase I and phase II proof of principle studies involved in the drug development process of anti-HER2 monoclonal antibodies, Tyrosine Kinase Inhibitors (TKIs), and Antibody-Drug Conjugates (ADCs) use breast pathology biomarkers as endpoints.

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