

Titolo:	EmpowHER 303: "A Phase 2, randomized, multicenter, open-label neoadjuvant study evaluating Zanidatamab in combination with chemotherapy in participants with HER2-positive breast cancer."
Patologia:	Tumore della mammella metastatico
Tipo di Studio:	Sperimentale con farmaco Zanidatamab
Fase:	III
Principali criteri di inclusione:	Histologically confirmed HER-2+ Breast Cancer evaluated centrally per ASCO-CAP guideline Participants who have unresectable or metastatic breast cancer that has progressed, is intolerant to or ineligible to be treated with T-DXd. If participant is ineligible to receive T-DXd, they may receive available SOC per institutional or local guidelines prior to study intervention • No more than 4 lines of HER2 directed therapy in the metastatic setting - Life expectancy of at least 6 months • Adequate organ functions • LVEF $\geq 50\%$ by either echocardiogram or multiple gated acquisition scan (MUGA) within 4 weeks of C1D1 • ECOG of 0 or 1
Principali criteri di esclusione:	• Known or suspected leptomeningeal disease (LMD) • Uncontrolled or significant cardiovascular disease, including any of the following: - o History of MI within the previous 6 months - o Troponin levels consistent with MI - o History of CHV NYHA II to IV - LVEF $<40\%$ while receiving anti-HER2 based treatment - o VA requiring therapy • Toxicity related prior cancer therapy that has not resolved to $\leq$ Grade 1, which exception of the following: - o Alopecia - o Neuropathy which must be resolved to $\leq$ Grade 2 - o Congestive heart failure (CHF), which must have been $\leq$ Grade 1 • History of transplantation: allogenic bone marrow, stem-cell or solid organs
Sede e contatti	S.C. Oncologia ASL TO3 – PO di Rivoli Tel 0119551283 cas.rivoli@aslto3.piemonte.it