

# A Study of Sacituzumab Tirumotecan (MK-2870) as a Single Agent and in Combination With Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice in Participants With HR+/HER2- Unresectable Locally Advanced or Metastatic Breast Cancer (MK-2870-010)

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

\* Has unresectable locally advanced or metastatic centrally-confirmed hormone receptor positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) breast cancer \* Has radiographic disease progression on one or more lines of endocrine therapy for unresectable locally advanced/metastatic HR+/HER2- breast cancer, with one in combination with a CDK4/6 inhibitor \* Is a chemotherapy candidate \* Has an eastern cooperative oncology group (ECOG) performance status of 0 to 1 assessed within 7 days before randomization \* Has adequate organ function \* Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on antiretroviral therapy \* Participants who are Hepatitis B surface antigen (HBsAg) positive are eligible if they have received HBV antiviral therapy for at least 4 weeks, and have undetectable HBV viral load \* Participants with a history of Hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable

### Exclusion Criteria:

\* Has breast cancer amenable to treatment with curative intent \* Has experienced an early recurrence (<6 months after completing adjuvant/neoadjuvant chemotherapy) and therefore is eligible to receive second-line (2L) treatment \* Has symptomatic advanced/metastatic visceral spread at risk of rapidly evolving into life-threatening complications \* Has received prior chemotherapy for unresectable locally advanced or metastatic breast cancer \* Active autoimmune disease that has required systemic treatment in the past 2 years \* History of (noninfectious) pneumonitis/interstitial lung disease that requires steroids, or has current pneumonitis/interstitial lung disease \* Has an active infection requiring systemic therapy

## Conditions & Interventions

### Interventions:

DRUG: Sacituzumab tirumotecan, BIOLOGICAL: Pembrolizumab, DRUG: Paclitaxel, DRUG: Nab-paclitaxel, DRUG: Capecitabine, DRUG: Liposomal doxorubicin

### Conditions:

Breast Neoplasms

### Keywords:

Programmed Cell Death-1 (PD1, PD-1), Programmed Cell Death 1 Ligand 1 (PDL1, PD-L1), Programmed Cell Death 1 Ligand 2 (PDL2, PD-L2)

## More Information

**Contact(s):** Toll Free Number - Trialsites@msd.com

**Principal Investigator:**

**Phase:** PHASE3

**IRB**

**Number:**

**System ID:** NCT06312176

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