A Randomized, Open-label, Phase 3 Study of Adjuvant Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician s Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy (ASCENT-05)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- invasive triple negative breast cancer (TNBC) still remains in the breast or lymph nodes after therapy and surgery - unable to do physically strenuous activity but able to walk and carry out work of a light or sedentary nature, e.g., light house work, office work - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- Stage IV (metastatic) breast cancer or previous cancer in the same or other breast - evidence that the cancer has reoccurred after preoperative therapy and surgery - presence of germline breast cancer gene (BRCA) mutations

Conditions & Interventions

Interventions:
Drug: Capecitabine, Drug: Pembrolizumab, Drug: Sacituzumab govitecan-hziy (SG)
Conditions:
Cancer
Keywords:
TNBC, Triple Negative Breast Cancer

More Information

Description: The purpose of this study is to see if sacituzumab govitecan in combination with pembrolizumab can improve outcomes and delay the return of disease in participants with high-risk early Triple Negative Breast Cancer (TNBC) when compared to pembrolizumab alone or pembrolizumab in combination with capecitabine. Participants with low tumor expression of the estrogen and/or progesterone receptors (1 to 10%) will also be included in this study. The study treatment will be chosen by chance—like flipping a coin. There is a 1 out of 2 chances to receive Sacituzumab govitecan in combination with Pembrolizumab and 1 out of 2 chances to receive a study treatment of study doctor's choice of either pembrolizumab alone or pembrolizumab in combination with capecitabine. Participants and their study doctor will know what study drug is being taken.
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