

PRE-I-SPY TRIAL - PRE-Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis: A Phase I/Ib platform trial

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. have HER2+ breast cancer 2. cancer has spread to other organs or returned within 6 months after first treatment

Exclusion Criteria:

1. active heart or liver disease 2. cancer has spread to the brain and is causing current symptoms

Conditions & Interventions

Interventions:

Drug: ABT-888, Drug: AMG 386 and Trastuzumab, Drug: AMG 386 with or without Trastuzumab, Drug: AMG 479 (Ganitumab) plus Metformin, Drug: ARV-471, Drug: ARV-471 + Letrozole, Drug: ARX788, Drug: ARX788 + Cemiplimab, Drug: Amcenestrant, Drug: Amcenestrant + Abemaciclib, Drug: Amcenestrant + Letrozole, Drug: Cemiplimab, Drug: Cemiplimab plus REGN3767, Drug: Datopotamab deruxtecan, Drug: Datopotamab deruxtecan + Durvalumab, Drug: Durvalumab plus Olaparib, Drug: Ganetespib, Drug: Lasofoxifene, Drug: MK-2206 with or without Trastuzumab, Drug: Neratinib, Drug: Oral Paclitaxel + Encequidar + Dostarlimab (TSR-042) + Carboplatin with or without trastuzumab, Drug: Oral Paclitaxel + Encequidar + Dostarlimab (TSR-042) with or without trastuzumab, Drug: PLX3397, Drug: Patritumab and Trastuzumab, Drug: Pembrolizumab - 4 cycle, Drug: Pembrolizumab - 8 cycle, Drug: Pertuzumab and Trastuzumab, Drug: SD-101 + Pembrolizumab, Drug: SGN-LIV1A, Drug: SYD985 ([vic-]trastuzumab duocarmazine), Drug: Standard Therapy, Drug: T-DM1 and Pertuzumab, Drug: Talazoparib plus Irinotecan, Drug: Trilaciclib with or without trastuzumab + pertuzumab, Drug: Tucatinib plus trastuzumab and pertuzumab, Drug: VV1 + Cemiplimab, Drug: Z-endoxifen, Drug: Zanidatamab

Conditions:

Cancer, Women's Health

Keywords:

Clinics and Surgery Center (CSC), Breast Cancer, Breast Cancer, HER2+ breast cancer, ISPY

More Information

Description: This study is intended to find the safest dose of a new combination of drugs (ALX148 and T-DXd) and to start to determine how effective it is at treating advanced or metastatic breast cancer. This study is an addition to the ongoing ISPY study program.

Study Contact: David Potter - dapotter@umn.edu

Principal Investigator: David Potter

IRB

Number: SITE00001846

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