



ROSETTA Breast-01

TRIAL TITLE

ROSETTA Breast-01: The Effects and Safety of Punitamig in Patients with Triple-Negative Breast Cancer

TRIAL STATUS

Recruiting

TRIAL NUMBER

[NCT07173751](https://clinicaltrials.gov/study/NCT07173751)

TRIAL PHASE

Phase 3

PARTICIPANTS MUST MEET THE FOLLOWING ELIGIBILITY CRITERIA*:

- Adults (women and men) diagnosed with locally recurrent inoperable or metastatic triple negative breast cancer (TNBC) or ER-low, HER2-negative breast cancer.
- Not eligible for standard PD-(L)1 immunotherapy plus chemotherapy based on their tumor's PD-L1 status.
- Have not received prior treatment for metastatic breast cancer.
- Are not pregnant or breastfeeding and are not planning to become pregnant during the study.
- Have not undergone major surgery, significant trauma or invasive dental procedures within 28 days before starting treatment.

*Additional eligibility criteria apply.

Punitamig is jointly developed by BioNTech and Bristol-Myers Squibb. ROSETTA Breast-01 is a clinical trial sponsored by BioNTech.



Breast Cancer Breakthroughs FACT SHEET

TRIAL DETAILS:

- ROSETTA Breast-01 is a global, multicenter, randomized, double-blind, phase 3 clinical trial.
- The study plans to enroll approximately 558 participants.
- Participants are randomly assigned (1:1) to each group and will receive either punitamig plus the physician's choice of chemotherapy or placebo plus chemotherapy.
- The goal of the study is to see whether adding punitamig to chemotherapy can improve survival and disease control for people with PD-L1-negative TNBC breast cancer who currently cannot receive combination treatment with PD-L1 targeting immunotherapy plus chemotherapy.
- The study includes a screening period of up to 28 days, followed by a treatment period that continues until cancer progression, intolerable side effects, withdrawal, or study completion. A safety follow-up period continues for up to 90 days after the last dose, and long-term survival follow-up continues thereafter.

ABOUT TRIPLE-NEGATIVE BREAST CANCER AND PUNITAMIG:

- TNBC is an aggressive breast cancer subtype that does not express estrogen receptors, progesterone receptors or HER2. Because it lacks these targets, standard hormone therapies and HER2-targeted treatments are not effective, and chemotherapy has historically been the main treatment option.
- Patients with advanced or metastatic TNBC, especially those with PD-L1-negative tumors, often have limited therapeutic options and poorer outcomes.
- Punitamig is an investigational immunotherapy called a bispecific antibody that attaches to PD-L1 and VEGF-A on tumor cells, helping the immune system recognize tumor cells while also reducing the formation of new blood vessels.
- The data highlight the potential of punitamig in TNBC, including PD-L1-low or -negative TNBC which has limited treatment options and high unmet need.
- Potential side effects of punitamig may include those typically associated with immune-based therapies (such as inflammation) as well as effects seen with VEGF-targeting agents (such as hypertension or bruising and bleeding). Early trials suggest that the safety profile is manageable, but further research is needed to better understand risks.

References:

1. Susan G. Komen. *Triple Negative Breast Cancer*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/diagnosis/triple-negative/>
2. Susan G. Komen. *Chemotherapy for Metastatic Breast Cancer*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/metastatic/metastatic/chemotherapy-for-metastatic-breast-cancer/>
3. Susan G. Komen. *Immunotherapy for Metastatic Breast Cancer*, Susan G. Komen, Accessed February 2026. <https://www.komen.org/breast-cancer/metastatic/metastatic/immunotherapy-for-metastatic-breast-cancer/>
4. P. Schmid, A. et al. Abstract PS1-13-25: Preliminary data from a global multicohort Phase2 randomized trial of punitamig (PD-L1 x VEGF-A bsAb) + chemotherapy for 1L/2L+ locally advanced/metastatic TNBC. *Clin Cancer Res*. 2026. <https://doi.org/10.1158/1557-3265.SABCS25-PS1-13-25>
5. BioNTech SE. ROSETTA Breast01: The Effects and Safety of Punitamig in Patients with Triple-Negative Breast Cancer. <https://clinicaltrials.gov/study/NCT07173751>
6. BioNTech SE. Safety and Preliminary Effectiveness of BNT327, an Investigational Therapy for Breast Cancer, When Given in Combination with Chemotherapy. <https://clinicaltrials.gov/study/NCT06449222>

Clinical trials can be confusing. To learn more about them and some common terms check out this [page](#).