

## **A Phase III, Randomized, Multi-site, Open-label Trial of BNT323/DB-1303 Versus Investigator's Choice of Chemotherapy in Previously Treated Patients With HER2- Expressing Recurrent Endometrial Cancer**

### **Clinical summary**

This study is looking at a new treatment called BNT323 (also known as DB-1303) for people with recurrent endometrial cancer - meaning the cancer has come back after earlier treatment. Everyone joining the study should have already been treated with at least one type of platinum-based chemotherapy and an immune checkpoint inhibitor (ICI).

Participants are placed into one of two groups (cohorts) based on how much HER2, a protein on cancer cells, is found in their tumour sample. This is measured using a test called IHC (immunohistochemistry).

**Cohort 1: People with HER2 IHC 1+ or 2** The group will compare how well BNT323 works versus standard chemotherapy. Participants will be randomly assigned (by chance) to receive one of two treatments:

BNT323 or

standard chemotherapy (doxorubicin or paclitaxel; docetaxel may be used if paclitaxel isn't suitable)

The main goal is to measure progression-free survival, meaning how long people live without their cancer getting worse.

**Cohort 2: HER2 IHC3+** This group will assess how well BNT323 works by looking at how many people have their tumours shrink or disappear after treatment. This is called the objective response rate. All participants in this cohort will receive BNT323.

For both cohorts, the study consists of a screening period, a treatment period, a safety follow-up period, an efficacy follow-up period, and a long-term follow-up. The expected treatment duration per participant is ~6 months, followed by an anticipated long-term survival follow-up period of up to 53 months.

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### **Conditions**

This trial is treating patients with recurrent HER2 expressing endometrial cancer

#### **Trial Acronym**

Fern-EC-01

#### **Cancer**

Endometrium

#### **Trial Identifiers**

NCT06340568

BNT323-01; GOG-3105; ENGOT- EN25/NSGO-CTU

2023-507525-42-00

**Age:** 18+

**Phase:** III

