

This factsheet provides an overview of how we envision our investigational therapy to work and is provided for illustrative purposes only. BNT323/DB-1303 is an investigational medicinal product which is being jointly developed by BioNTech and Duality Biologics. The candidate has currently not received a marketing authorization in any country.

BNT323/DB-1303

A Targeted Chemotherapy Approach for the Treatment of Various Advanced Solid Tumor Types

Challenge

For various advanced cancer indications, chemotherapy is a standard of care treatment to control the disease and reduce mortality. However, due to its low specificity, conventional chemotherapy may also affect healthy cells, resulting in toxicity risks and side effects.

Approach

Delivering a chemotherapeutic drug to its intended site of action, particularly to tumor cells via so-called Antibody-Drug Conjugates (ADCs), might offer the potential to reduce side effects and improve outcomes for patients with advanced, recurrent cancers, who have limited treatment options left. Unlike conventional chemotherapy, ADCs are designed to treat cancer in a targeted way.

What is an Antibody-Drug Conjugate?

Antibody-Drug Conjugates are a type of treatment which combines two treatment approaches: the selectivity of antibodies and the potent cell-killing properties of chemotherapy or other anti-cancer drugs, thereby aiming to better identify and target specific types of cancer cells.

BNT323/DB-1303 uses a protein called HER2, a structure expressed on the surface of the cancer cell, to identify the cell and dock to it

1.



2.



Cancer cell takes up the whole Antibody-Drug Conjugate

3.



Chemotherapeutic drug is released in the cancer cell

4.

Initiation of destruction of cancer cell by chemotherapeutic drug

5.

Chemotherapeutic drug diffuses out of the cell and mediates destruction of surrounding cancer cells aiming to enhance the effect of the treatment

Antibody serves as targeted transport vehicle that can specifically dock to the cancer cells, like a key fits in a lock

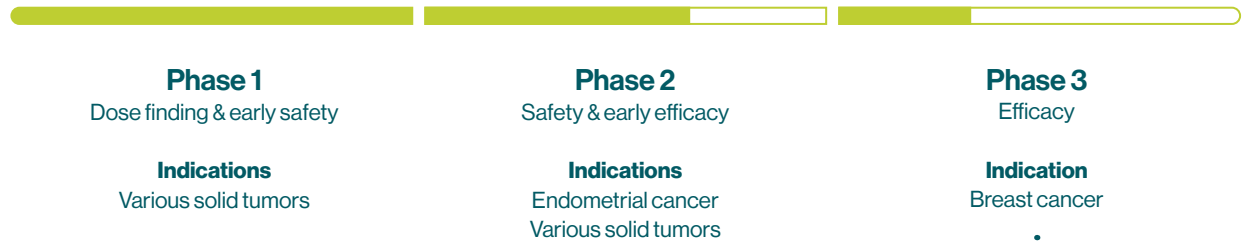


Chemotherapeutic drug the delivery agent that triggers the destruction of the cancer cell

At what stage is the development of the treatment?

The development of novel therapies is a comprehensive and strictly governed research process that is undertaken in several steps, known as "phases".

Study program of BNT323/DB-1303:



Learn more about the Phase 3 clinical study

The cell surface protein HER2 controls cell growth, differentiation, and survival, which are essential functions in human development processes. A malfunction or over-expression can promote aggressive cell growth resulting in formation and spread of tumors.¹

What types of tumors could BNT323/DB-1303 potentially be used for?

BNT323/DB-1303 aims to address solid tumor types which express the cell surface protein HER2. This protein can be found on a variety of cancers including the following indications:



Lung cancer



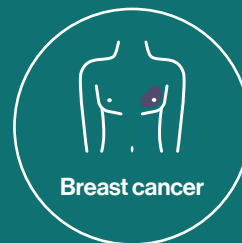
Endometrial cancer



Esophageal cancer



Colorectal cancer



Breast cancer

What is the medical need in breast cancer?

Early disease stage: curable in approx.

70% to 80% of patients²

Breast cancer is the **leading cause of cancer death** in women globally.³

Advanced disease stage: Limited, currently no curative treatment options⁴

Breast cancer accounts for **1 in 8** cancer diagnoses making it to the most commonly diagnosed cancer worldwide.⁵

More than **50%** of breast cancers express the protein HER2 on their cell surface.⁶

¹ Albagoush SA, Limaïem F. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. 2022 Oct 24. Available at: www.ncbi.nlm.nih.gov/books/NBK537134/

² Harbeck N, et al. Nat Rev Dis Primers. 2019 Sep 23;5(1):66.

³ American Cancer Society. Treating Breast Cancer. 2023. Online at: <https://www.cancer.org/cancer/types/breast-cancer/treatment.html>

⁴ Huppert L, et al. CA Cancer J Clin. 2023 Sep-Oct;73(5):480-515.

⁵ Arnold m, et al. Breast. 2022 Dec; 66: 15–23.

⁶ Shirman A, et al. Breast Cancer (Dove Med Press). 2023; 15: 605–616.