BGB-43395 (CDK4 inhibitor)

Disclaimer: This fact sheet is intended for media professionals only.
BGB-43395 is an investigational drug for which safety and efficacy have not been established.

WHAT IS BGB-43395?

BGB-43395 is an investigational oral cyclin-dependent kinase 4 (CDK4) inhibitor in development for the treatment of hormone receptor-positive (HR+), HER2-negative breast cancer.

THE TARGET: CDK4

CDK4 is a protein that helps control how cells grow and divide. In some cancers, CDK4 activity becomes overactive, allowing cancer cells to multiply uncontrollably.

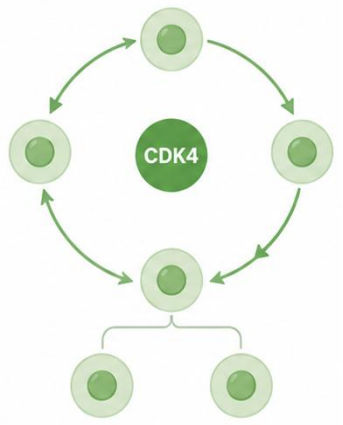
Many currently available therapies target both CDK4 and a related protein called CDK6. While these medicines can be effective, they may also cause side effects.

HOW DOES BGB-43395 WORK?

BGB-43395 is designed to selectively block CDK4, a key driver of cell division in certain cancers, while sparing CDK6.

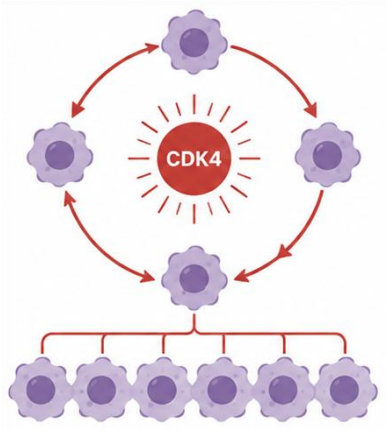
NORMAL CELL GROWTH

CDK4 helps regulate the cell cycle, allowing healthy cells to grow and divide when needed.



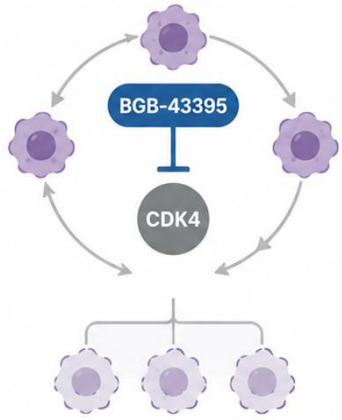
CANCER CELL GROWTH

In some cancers, CDK4 becomes overactive, causing cells to divide continuously and form tumors.



WITH BGB-43395

BGB-43395 blocks CDK4 activity, helping interrupt the cancer cell growth process and potentially slowing disease progression.



Selectively blocking CDK4 may **help slow or stop cancer cells from growing and multiplying**.

DIFFERENTIATION: HIGHLY SELECTIVE CDK4 INHIBITION

Current standard treatments inhibit both CDK4 and CDK6. While effective, off-target CDK6-targeting by these therapies can be associated with hematologic toxicities such as neutropenia.

BeOne Medicines designed BGB-43395 to selectively target CDK4 while largely sparing CDK6. In preclinical and early clinical studies, this approach has several potential advantages:

HIGH POTENCY AND SELECTIVITY	POTENTIALLY IMPROVED TOLERABILITY	COMBINATION POTENTIAL
Preclinical data has shown that BGB-43395 is more potent and selective for CDK4 than the most common currently approved CDK4/6 inhibitors and the investigational CDK4 inhibitor atirmociclib.	**Because it largely spares CDK6, early clinical data has shown that BGB-43395 has lower hematologic toxicity commonly seen with existing CDK4/6 inhibitors. Reducing these hematologic toxicities - often leading to dose reductions and treatment discontinuations - may improve tolerability, thereby enabling deeper CDK4 inhibition.**	**BGB-43395 is being studied in combination with endocrine therapies commonly used in HR+/HER2- breast cancer. With a favorable hematologic profile, BGB-43395 has the potential for broad and synergistic combinability in HR+ breast cancer.**

Disclaimer: The clinical significance of data based on non-clinical studies has not been established

DEVELOPMENT HIGHLIGHTS

BGB-43395 is currently being evaluated in a **global clinical development program for HR+/HER2- breast cancer.**



Early Phase Clinical Data

- Results of the Phase 1 study evaluating the safety, tolerability, dosing, and preliminary anti-tumor activity of BGB-43395 in patients with HR+/HER2- metastatic breast cancer (mBC) were presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Phase 1 efficacy and safety data suggest that BGB-43395 may improve upon currently approved CDK4/6 inhibitors and the investigational CDK4 inhibitor atirmociclib, with the potential to exhibit a more favorable safety profile, particularly hematologic toxicities, with manageable gastrointestinal side effects.

- Phase 1 data presented at ASCO 2026 suggested early efficacy at target efficacious dose with ~70% overall response rate (ORR) in first-line HR+/HER2- mBC, infrequent low-grade hematologic toxicities, and generally manageable gastrointestinal toxicity in a fed state.[i]

Phase 3 Clinical Trial: KANDELA-302

- BeOne Medicines is advancing BGB-43395 through clinical development with the goal of providing a more selective CDK4-targeted treatment option for patients with breast cancer.
- The global KANDELA-302 Phase 3 clinical trial will evaluate BGB-43395 at a dose of 400 mg twice daily plus letrozole compared to the investigator's choice of CDK4/6 inhibitor plus letrozole in patients with endocrine-sensitive HR+/HER2-metastatic breast cancer who have not had previous systemic therapies for mBC.

[i] Goel S, et al. Poster Presentation at ASCO 2026; abstract 1066