

# Results From a Subset of Patients With Brain and Spinal Cord Metastases Who Received Ribociclib and Letrozole for HR+, HER2- Advanced Breast Cancer in the CompLEEment-1 Study

## Executive summary

- CompLEEment-1 is a study that examined the safety and effectiveness of **ribociclib** taken together with **letrozole** in patients with HR+, HER2- advanced breast cancer (ABC).
- This study, which contained over 3000 patients, included 51 patients whose breast cancer had spread to the brain or spinal cord (central nervous system [CNS]).

- The most common side effects of **ribociclib** treatment in patients with brain and spinal cord metastases included a drop in neutrophils (white blood cells that help to fight infection), as well as nausea and vomiting.
- Few patients (8%, 8 out of every 100) with brain and spinal cord metastases stopped **ribociclib** treatment because of side effects.
- A large proportion of patients with brain and spinal cord metastases experienced a treatment benefit after receiving **ribociclib**.

## What is HR+, HER2- ABC?

This type of ABC **does** have hormone receptors on its cells (called hormone receptor-positive, or **HR+**) but **does not** have high levels of a protein called human epidermal growth factor receptor-2 (called HER2 negative, or **HER2-**) on its cells.

It is by far the most common subtype of breast cancer.

In **HR+, HER2- ABC**, estrogen and progesterone interact with hormone receptors on tumor cells and **drive** cancer growth.

## CompLEEment-1 study<sup>1</sup>

- ✓ **CompLEEment-1** is a study that examined the safety and effectiveness of **ribociclib** taken with **letrozole** (a type of endocrine therapy [ET]) in patients with HR+, HER2- ABC.
- ✓ This study included a **larger** and **more diverse group of patients** than previous studies of **ribociclib** and **ET**.
- ✓ This study was designed to test **ribociclib** plus **letrozole** in a group more representative of patients with ABC than those usually seen in clinical trials.

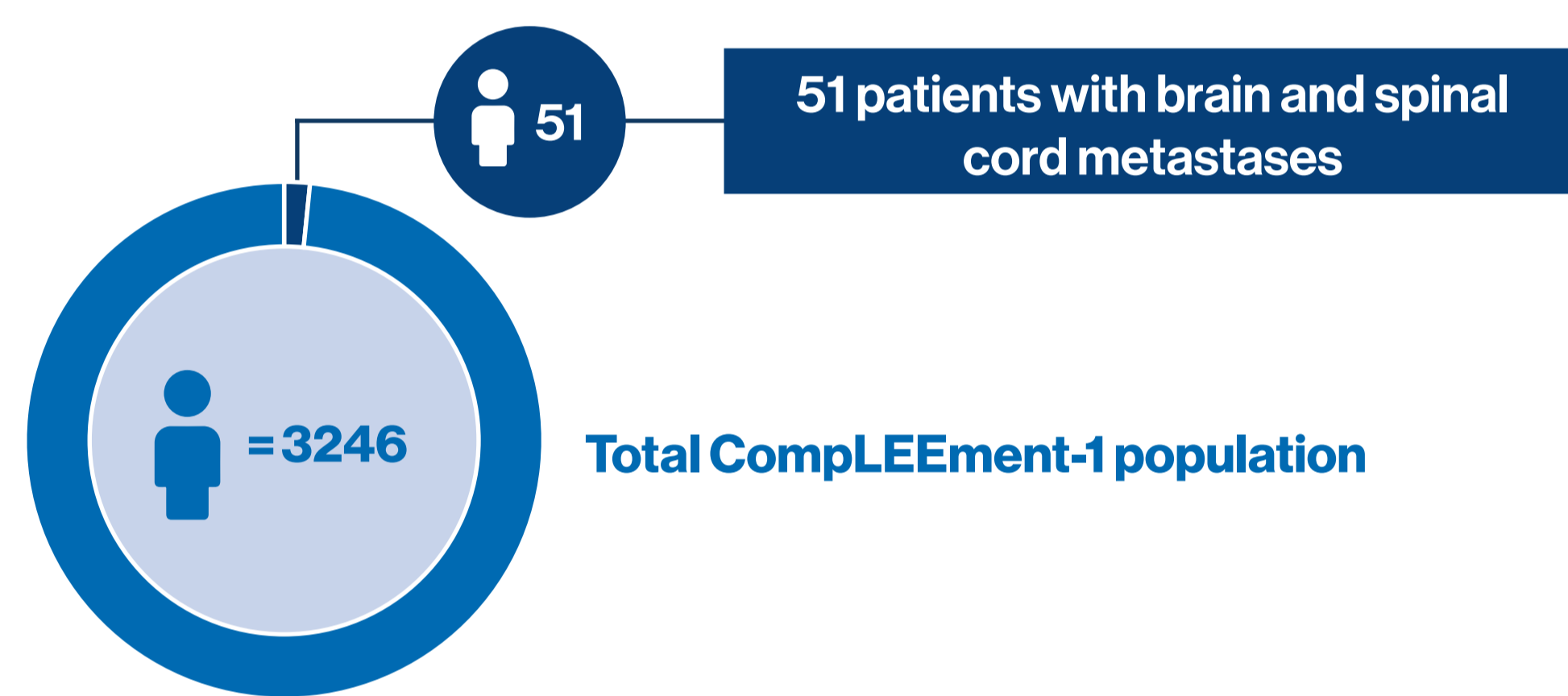
## What was the purpose of this analysis of patients with brain and spinal cord metastases in the CompLEEment-1 study?

The CompLEEment-1 trial allowed patients to enroll who are sometimes excluded from ABC trials.

One group who are usually excluded from these trials are patients with tumors that have **spread to the brain or spinal cord**, also known as the CNS. This occurs in up to 30% of patients with breast cancer.

The spread of cancer to the brain and spinal cord can cause side effects that **severely affect day-to-day life**. It is also associated with a **worse chance of survival**.

Of the 3246 patients included in the CompLEEment-1 trial, 51 had brain and spinal cord metastases.



## About the medications

**Ribociclib** is a targeted therapy used to treat advanced breast cancer that is HR+ and HER2-. Cyclin-dependent kinases 4 and 6 (CDK4/6) are proteins that help breast cancer cells make more copies of themselves. **Ribociclib** can interrupt this process, making it a CDK4/6 inhibitor. **Ribociclib** is given in combination with endocrine therapies to slow tumor growth by blocking estrogen's effects.

**Letrozole** blocks the effects of estrogen on breast cancer cells. Since estrogen can drive the growth of breast cancer cells, blocking the effects of estrogen in the body can slow the growth of cancerous cells and stop the disease from getting worse.

When taken together with ET, **ribociclib** has been shown to be more effective in treating **HR+, HER2- ABC** than ET alone.

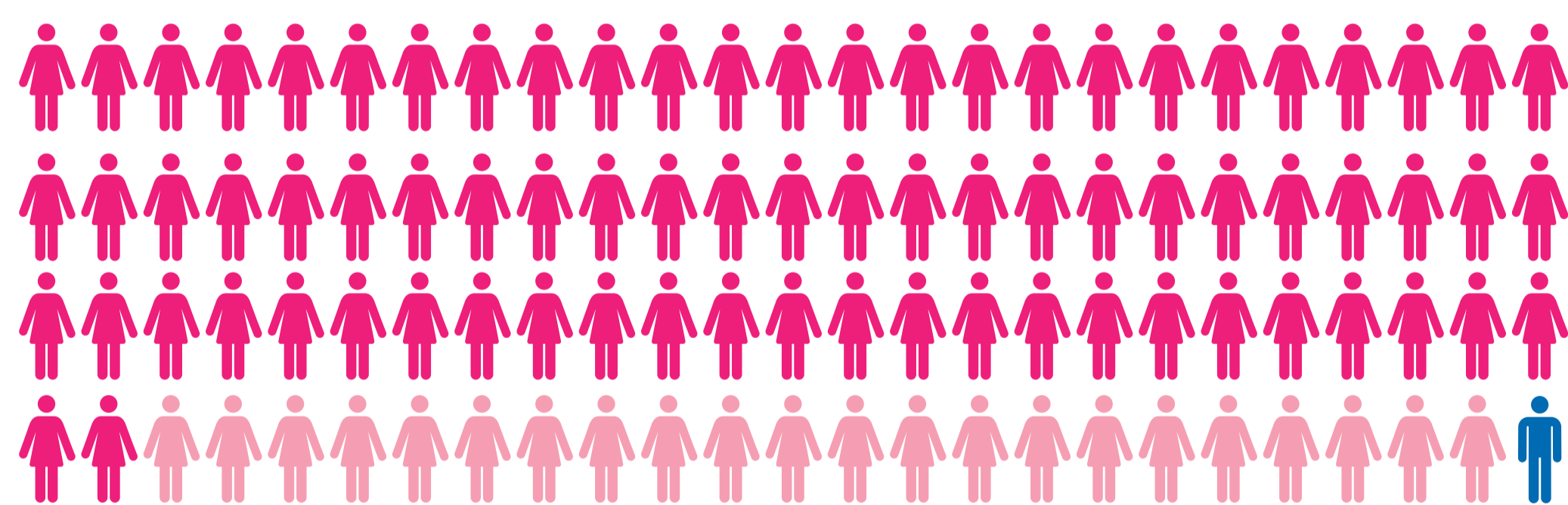
## Who participated in the CompLEEment-1 study?<sup>1</sup>

**3246 patients** with **HR+, HER2- ABC** participated in **CompLEEment-1**.

**CompLEEment-1** is the largest trial of a **CDK4/6 inhibitor** in **ABC** to date.

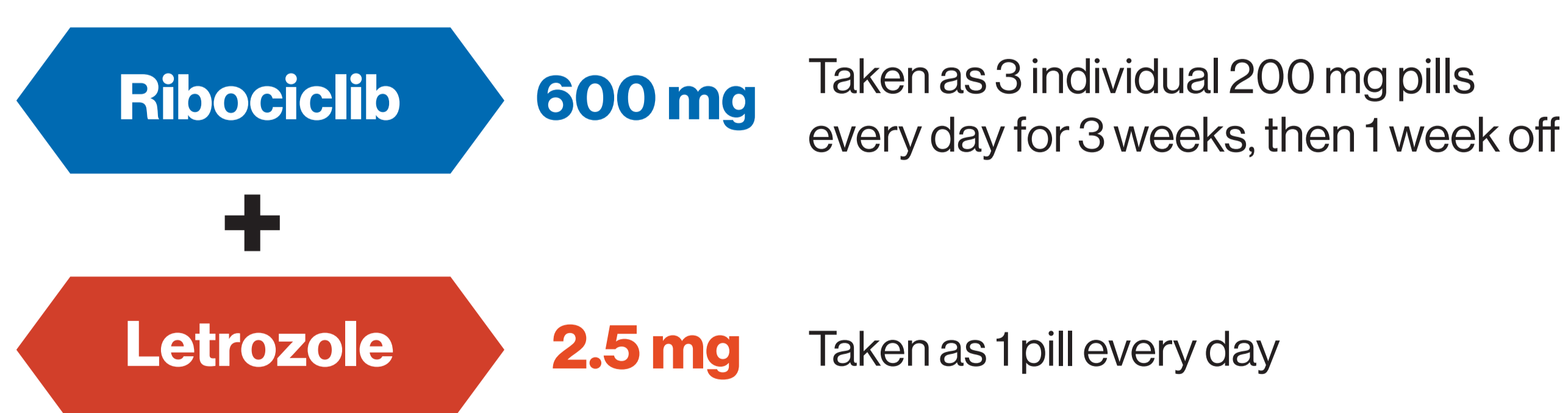
The majority of patients in the study were **women**; about 1 in 100 patients in the study were **men**.

About 22 in 100 patients in the study were **women who were menstruating**.



## What is the CompLEEment-1 study?<sup>1</sup>

Patients in CompLEEment-1 all received **ribociclib** plus **letrozole**.



Women who were menstruating, and men, also received medicine in the study to stop the production of hormones.

## Study Information

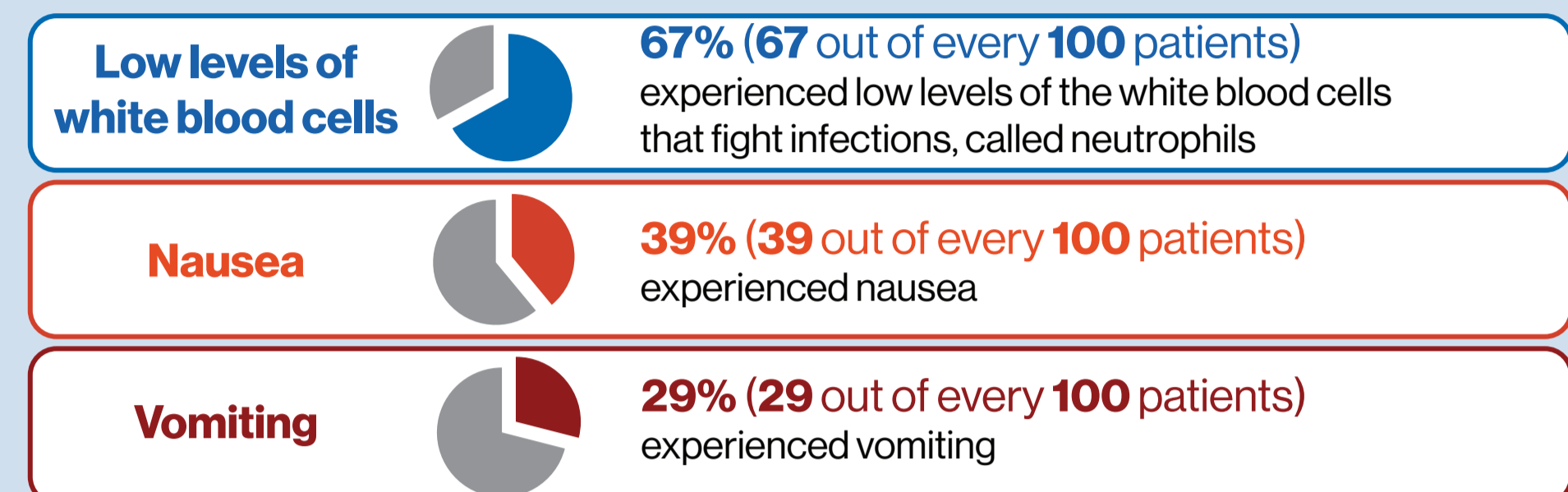
**Study number:** NCT02941926 (CompLEEment-1)

**Study sponsor:** Novartis Pharmaceuticals Corporation

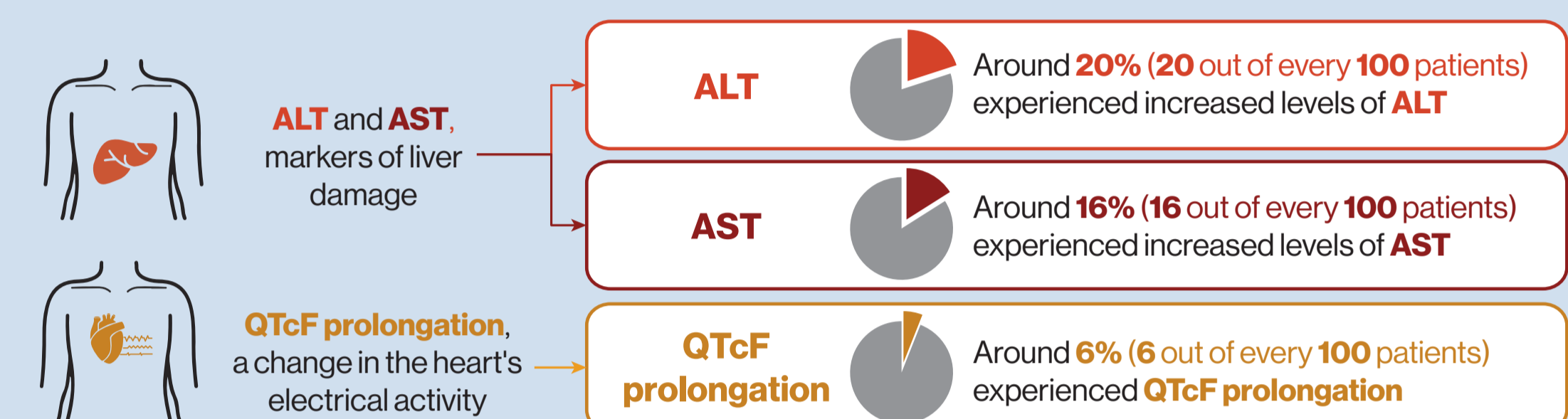
**The full title of the SABCS 2020 poster presentation:** *Ribociclib + Letrozole in Patients With Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer and Central Nervous System Metastases: Subgroup Analysis of the Phase IIIb CompLEEment-1 Trial*

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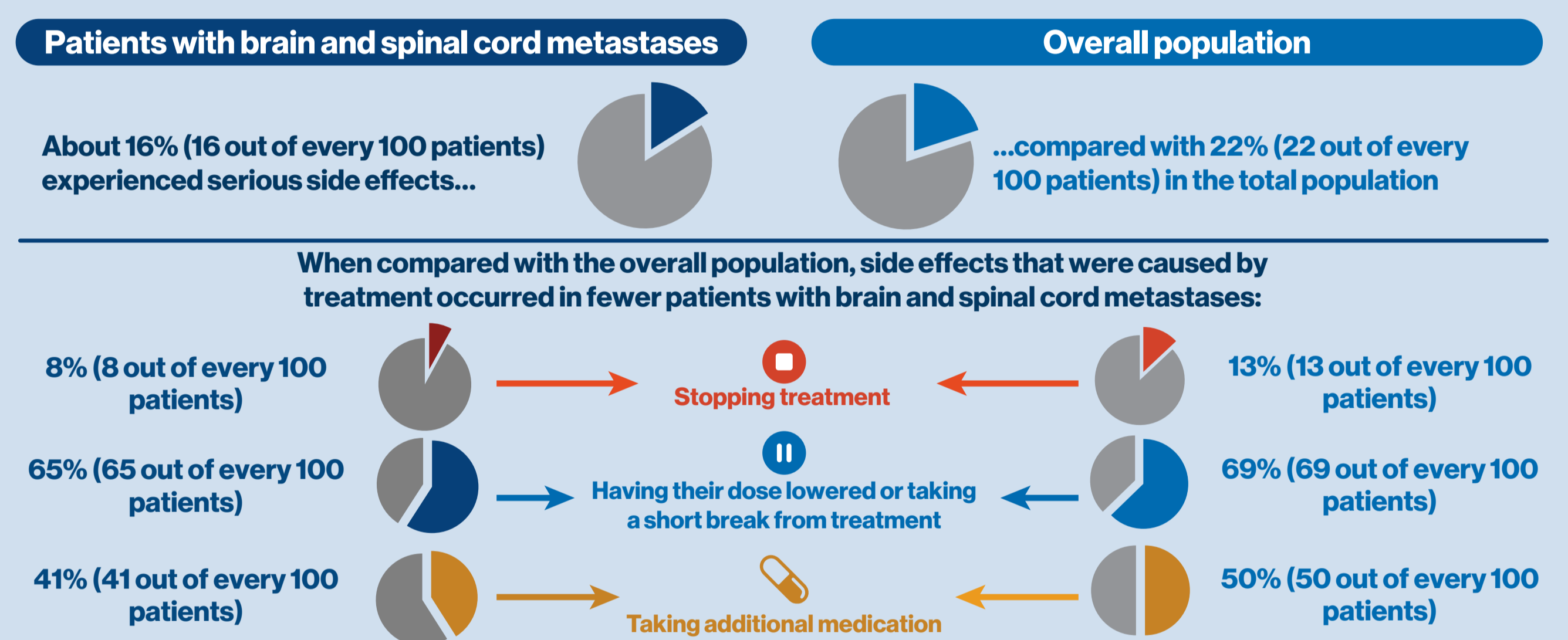
## The three most common side effects in patients with brain and spinal cord metastases were:



## Other side effects identified for particular attention before the trial started were:

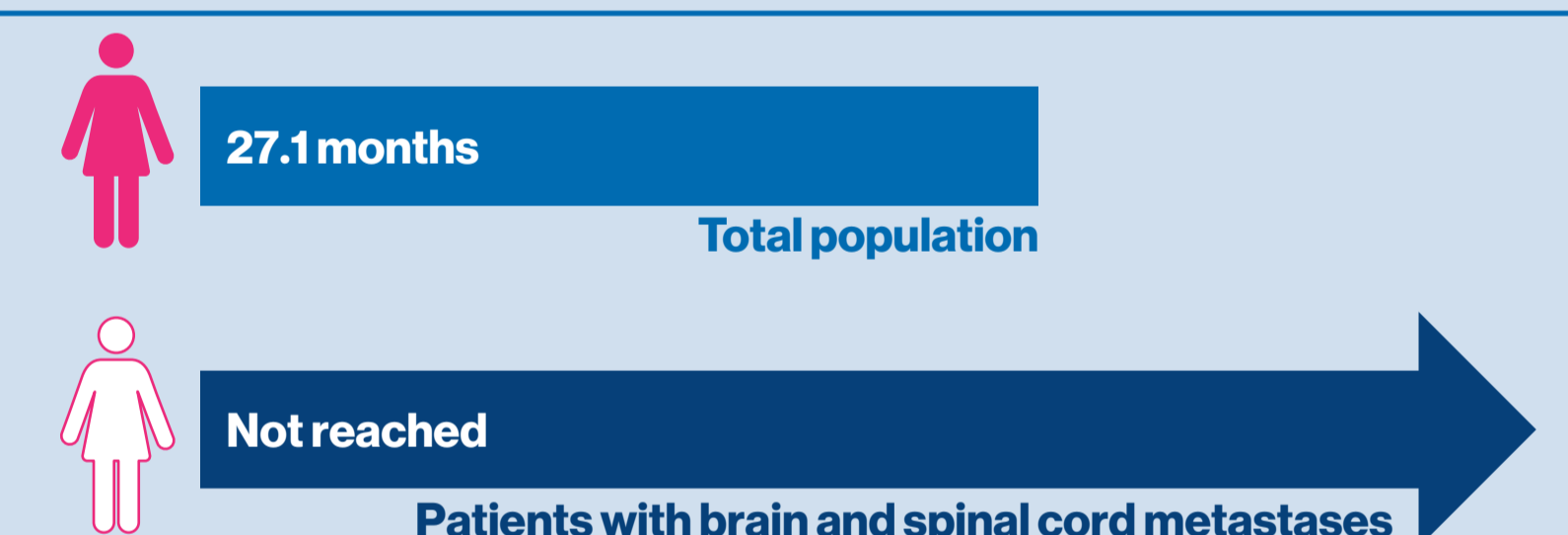


## Fewer patients with brain and spinal cord metastases experienced side effects of treatment

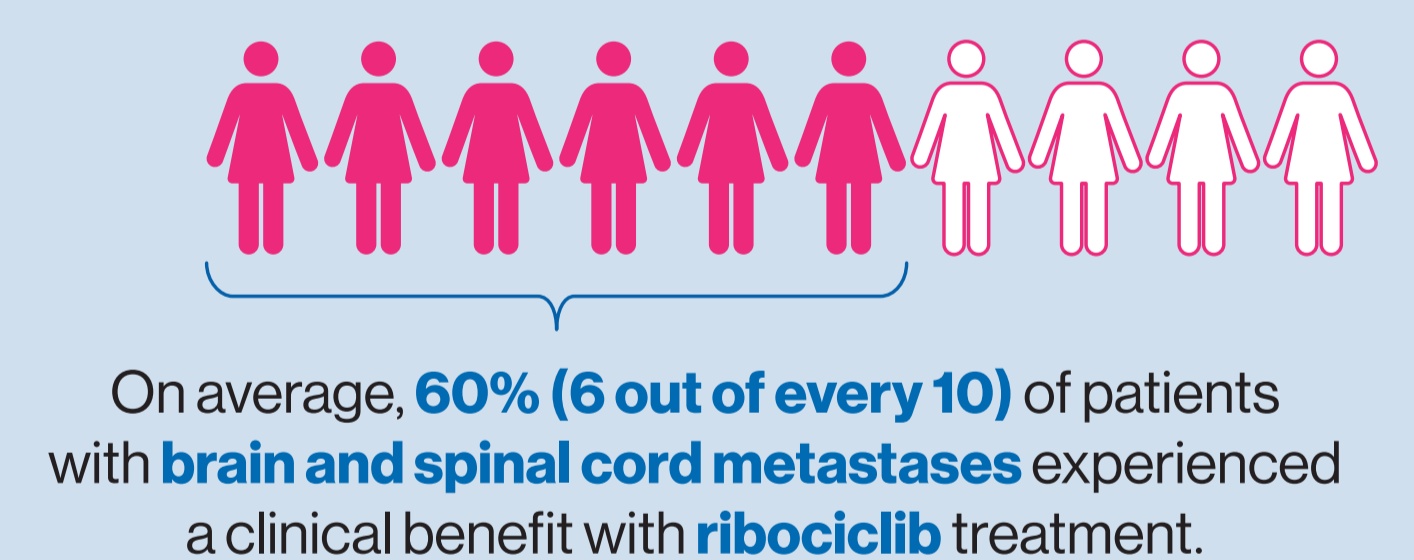


## How effective was ribociclib plus letrozole in patients with brain and spinal cord metastases?

On average, treatment with **ribociclib** plus **letrozole** prevented cancer spread or death for **27.1 months** in the total population. Too few patients with brain and spinal cord metastases have experienced their cancer spreading or have died to be able to calculate an average time for the occurrence of these events.



In patients with brain and spinal cord metastases whose disease could be measured, a large proportion had a reduction in the size of their tumor after receiving **ribociclib**.



## Summary

CompLEEment-1 studied **ribociclib** plus **letrozole** in a larger and more diverse group of patients than in previous studies of **ribociclib**.<sup>1</sup>

This study, which included over 3000 patients and is the largest study of a CDK inhibitor in ABC to date, provided a substantial amount of data on the safety and effectiveness of **ribociclib**.

**In patients with brain and spinal cord metastases, how safe was ribociclib plus letrozole and what side effects were observed?**

The most common side effects of **ribociclib** treatment included a drop in the white blood cells that fight infection, as well as nausea and vomiting.

Few patients (8%) with brain and spinal cord metastases stopped **ribociclib** treatment because of side effects.

**How effective was ribociclib plus letrozole in patients with brain and spinal cord metastases and the overall population?**

On average, the total population included in the CompLEEment-1 study lived without their cancer spreading or causing death for 27.1 months. Not enough data are available to know this figure for patients with brain and spinal cord metastases only.

A large proportion of patients with brain and spinal cord metastases (60%) experienced a treatment benefit after receiving **ribociclib**.

**This analysis from the CompLEEment-1 trial supports the use of ribociclib with ET in patients with HR+, HER2- ABC who have brain and spinal cord metastases.**

## Reference

1. De Laurentis M, et al. [ASCO abstract 1055]. *J Clin Oncol*. 2020;38(15\_suppl).

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