

## E2112 Clinical Trial Results Summary

### Exemestane with or without Entinostat in Treating Patients with Recurrent Hormone Receptor–Positive Breast Cancer that is Locally Advanced or Metastatic

#### What did this trial involve and who was it for?

E2112 was for patients with advanced breast cancer that could not be removed with surgery or that had metastasized (spread to another part of the body). A treatment option often recommended for patients in this situation was exemestane, a hormonal drug. However, for some patients, their breast cancer becomes resistant to hormonal treatment and it becomes less effective. Previous research suggested that another drug, entinostat, may help overcome this problem.

The purpose of E2112 was to see if the addition of entinostat to exemestane would help patients with advanced breast cancer to live longer. A total of 608 patients participated in the study. They were randomly assigned by a computer to one of two treatment groups: exemestane plus entinostat, or exemestane plus a placebo pill. A placebo pill has no medical effect and is used in clinical trials to show the difference between the real drug and a harmless alternative. Participants in both groups received treatment until their cancer worsened or they experienced unacceptable side effects.

#### What are the results?

- There was no significant difference in survival between the two treatment groups. Patients who received entinostat with exemestane had a median of 3.3 months before their cancer worsened, compared with 3.1 months for patients who received exemestane alone.
- Likewise, patients in the entinostat group lived for a median of 23.4 months after starting treatment, compared with 21.7 months for patients in the exemestane-only group.

#### What do the results mean for patients?

- The combination of exemestane and entinostat did not help patients with advanced breast cancer who became resistant to hormonal treatment to live longer.
- More work is needed to continue improving treatment options for patients with advanced breast cancer.

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For more information, go to:

- United States National Institutes of Health (NIH) Library of Medicine: <https://clinicaltrials.gov/study/NCT02115282>
- *Journal of Clinical Oncology*: <https://doi.org/10.1200/jco.21.00944>

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## About ECOG-ACRIN

This trial was led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). ECOG-ACRIN is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN is a component of the National Cancer Institute's National Clinical Trials Network. Learn more at [www.ecog-acrin.org](http://www.ecog-acrin.org).

***To all the patients that participated in this trial, thank you. Without the involvement of patients like you, this research would not have been conducted.***