The median overall survival of patients treated with ribociclib plus letrozole was 63.9 months versus 51.4 months for patients treated with letrozole alone. This difference of more than 1 year was statistically significant (HR 0.75, 95% CI 0.65–0.86; *p* < 0.001).

The results of this overall survival analysis of MONALEESA-2 demonstrate that ribociclib plus letrozole provides significant survival benefit to postmenopausal patients with HR+/HER2− advanced breast cancer when used as the first therapy for advanced disease.

All three MONALEESA trials (1, 2, and 3) have now reported that ribociclib plus endocrine therapy provided significant improvement in overall survival for patients with HR+/HER2− advanced breast cancer regardless of menopausal status.

**MONALEESA-2 study**

- **Phase 3 clinical trial**
- **Patients with HR+/HER2− advanced breast cancer**
- **Patients who had gone through menopause**
- **Patients had not been previously treated with endocrine therapy (ET) or chemotherapy for advanced breast cancer**
- **Included 668 patients in 29 countries (334 patients were randomized to the ribociclib plus letrozole group and 334 patients were randomized to the letrozole alone group)**
- The primary goal of the trial was to evaluate how long patients lived without the disease getting worse.
- Other key goals of this trial were to evaluate how long patients lived overall and any side effects patients may have experienced while on treatment.

**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 targets CDK4/6 to stop cancer cells from growing and is one of three drugs in the class of CDK4/6 inhibitors. Ribociclib is given in combination with ET. ET is a type of treatment that 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 prevent the disease from getting worse.

The type of ET used in MONALEESA-2 was letrozole.

To help you better understand the results:

**Median** is a statistical term that describes the middle, which separates the lower and upper halves of the data. **Median progression-free survival** is an estimate of the time at which 50% of the patients did not have the disease get worse. **Median overall survival** is an estimate of the time at which 50% of the patients were still alive. **Median time to first chemotherapy** is an estimate of the time at which 50% of patients received chemotherapy after stopping study treatment (patients had previously received no chemotherapy for advanced disease).

**Follow-ups** is the length of time that a patient is observed after being randomized in a clinical trial.

**Previous published results**

MONALEESA-2: in patients receiving ribociclib plus letrozole, median progression-free survival was 25.3 months versus 16.0 months for patients receiving letrozole alone.1

**What was the purpose of this analysis of MONALEESA-2?**

This analysis reports overall survival in the MONALEESA-2 trial with an approximately 6.5-year follow-up of postmenopausal patients with HR+/HER2− advanced breast cancer treated with ribociclib plus letrozole or letrozole alone.

**What are the key results of this analysis?**

Postmenopausal patients treated with ribociclib lived longer overall than those who received letrozole alone.

<table>
<thead>
<tr>
<th>Trial Duration</th>
<th>Ribociclib + Letrozole</th>
<th>Letrozole alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>63.9 months</td>
<td>32.9%</td>
<td>29.0%</td>
</tr>
<tr>
<td>51.4 months</td>
<td>21.7%</td>
<td>34.4%</td>
</tr>
</tbody>
</table>

**Conclusions**

- After a follow-up of approximately 6.5 years in the MONALEESA-2 trial, researchers looked at how long patients lived while receiving ribociclib plus letrozole or letrozole alone.
- In the results of this analysis, ribociclib plus letrozole taken as the first treatment for HR+/HER2− advanced breast cancer significantly increased the time that postmenopausal patients lived compared to the standard-of-care ET alone.
- Postmenopausal patients taking ribociclib plus letrozole had a longer time before they received chemotherapy compared with letrozole alone.
- Side effects were similar to those experienced by patients who received ribociclib plus ET in all three MONALEESA trials.
- With this analysis of over 6 years, MONALEESA-2 is the third trial for ribociclib to demonstrate significant clinical benefits for HR+/HER2− advanced breast cancer across different ET partners and regardless of menopausal status.

**References**


*To view or download this presentation associated with this slide language summary, please visit the following website:*


**Study Information**

**Study number:** NCT01958021 (MONALEESA-2)

**Study sponsor:** Novartis Pharmaceuticals Corporation

**Full title of the ESMO 2021 oral presentation:** MONALEESA-2 study1

**Study number:** NCT01958021 (MONALEESA-2)

**Study sponsor:** Novartis Pharmaceuticals Corporation

**Executive Summary**

- MONALEESA-2 is a phase 3 clinical trial in postmenopausal women with HR+/HER2− advanced breast cancer who had received no previous therapy for advanced disease, and this document describes the findings of the overall survival analysis of the trial.
- After following patients for about 6.5 years, postmenopausal patients treated with ribociclib plus letrozole lived longer than those who received letrozole alone.
- Ribociclib plus letrozole extended the time before patients received chemotherapy after discontinuing study treatment.

**Overall survival results from the MONALEESA-2 trial in postmenopausal patients with HR+/HER2− advanced breast cancer**

**Postmenopausal patients treated with ribociclib had a longer median time to first chemotherapy**

Patients treated with ribociclib plus letrozole had a longer time before they received chemotherapy compared with patients treated with letrozole alone.

Ribociclib plus letrozole delayed the time to first chemotherapy by almost 1 year.

**Side effects** were similar between these patients and all the other patients in the published trials of ribociclib.1–6

The most common side effects associated with ribociclib plus letrozole include low white blood cell count, nausea, fatigue, aches and pains, diarrhea, hair loss, constipation, and hot flush.

**Conclusions**

- After a follow-up of approximately 6.5 years in the MONALEESA-2 trial, researchers looked at how long patients lived while receiving ribociclib plus letrozole or letrozole alone.
- In the results of this analysis, ribociclib plus letrozole taken as the first treatment for HR+/HER2− advanced breast cancer significantly increased the time that postmenopausal patients lived compared to the standard-of-care ET alone.
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**References**