Executive Summary

The MONALEESA trials1-3

• There have been 3 MONALEESA trials (MONALEESA-2, -3, and -7).

All MONALEESA trials were phase 3 clinical trials. In these trials, all of the patients had advanced breast cancer. MONALEESA-2 and -3 included patients who had already gone through menopause. MONALEESA-7 included patients who had not gone through menopause.

The primary goals of these trials were to evaluate how long patients lived without the disease getting worse and how long patients lived overall.

• The survival benefit of ribociclib plus endocrine therapy in the HER2-enriched subtype is particularly encouraging because this subtype is usually associated with resistance to endocrine therapy and poor outcomes compared with luminal A and luminal B subtypes.

• There was no survival benefit with ribociclib plus endocrine therapy in the basal-like subtype. This finding is hard to draw any conclusions based on this result because there were fewer patients with basal-like subtype in this analysis.

• The results of this analysis of MONALEESA-2, -3, and -7 demonstrate that in most intrinsic subtypes of HR+/HER2- advanced breast cancer, women treated with ribociclib plus endocrine therapy lived longer than those treated with endocrine therapy alone.

About the combination therapy

Ribociclib is a targeted therapy used to treat advanced breast cancer that is HR+ and HER2−. Cyclin-dependent kinase 4 and 6 (CDK4/6) are proteins that help breast cancer cells to make more copies of their DNA. Ribociclib targets CDK4/6 to stop cancer cells from growing. Ribociclib is given in combination with endocrine therapy.

Endocrine therapy 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.

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 overall survival is an estimate of the time at which 50% of the patients were still alive.

Median progression-free survival is an estimate of the time at which the disease did not get worse in 50% of the patients.

Hazard ratio (HR) is an estimate of how often a particular event happens in one treatment group compared with how often it happens in another treatment group, over time.

What are intrinsic subtypes?

HR+/HER2− breast cancer can be divided into several subtypes based on the expression pattern of key genes in patients with advanced breast cancer. The most common subtypes in HR+/HER2− breast cancer are luminal A and luminal B. The HER2-enriched and basal-like subtypes are less common. Each of these subtypes is associated with different prognosis and response to treatment.1,2 The HER2-enriched and basal-like subtypes are associated with resistance to endocrine therapy and have poorer outcomes compared with luminal A and luminal B.

Why was the information from these studies combined?

As some intrinsic subtypes (for example, HER2-enriched subtype) occur less frequently, each of these subtypes is associated

When comparing survival in increasing the

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What are the key results of this analysis?

In this analysis of 997 patient tumor samples, luminal A was the most common subtype, followed by luminal B, HER2-enriched, and finally basal-like.

Distribution of Patients With Different Tumor Subtype in the MONALEESA Trials

<table>
<thead>
<tr>
<th>Subtype</th>
<th>Patients with luminal A tumors</th>
<th>Patients with luminal B tumors</th>
<th>Patients with HER2-enriched tumors</th>
<th>Patients with basal-like tumors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Overall Survival</td>
<td>44.9 months</td>
<td>44.9 months</td>
<td>29.4 months</td>
<td>19.4 months</td>
</tr>
<tr>
<td>Patients with luminal A tumors</td>
<td>ribociclib plus ET was associated with a reduction in the risk of death by 25% (HR = 0.75)</td>
<td>patients with luminal A tumors</td>
<td>ribociclib plus ET was associated with a reduction in the risk of death by 31% (HR = 0.69)</td>
<td>patients with luminal B tumors</td>
</tr>
<tr>
<td>Median Overall Survival</td>
<td>58.8 months</td>
<td>58.8 months</td>
<td>44.9 months</td>
<td>44.9 months</td>
</tr>
<tr>
<td>Patients with luminal B tumors</td>
<td>ribociclib plus ET was associated with a reduction in the risk of death by 31% (HR = 0.69)</td>
<td>patients with luminal B tumors</td>
<td>ribociclib plus ET was not associated with a reduction in the risk of death in patients with basal-like tumors (HR = 1.89)</td>
<td>patients with basal-like tumors</td>
</tr>
</tbody>
</table>

Conclusions

• Patients with luminal A, luminal B, and HER2-enriched tumor subtypes who were treated with ribociclib plus endocrine therapy lived longer than those treated with endocrine therapy alone.

• The HER2-enriched subtype is usually associated with resistance to endocrine therapy, making poor outcomes compared with luminal A or luminal B. As the benefit with ribociclib plus endocrine therapy treatment in increasing the lifespan of patients with this tumor subtype is particularly noteworthy.

• While ribociclib plus endocrine therapy did not show a benefit for patients with the basal-like tumor subtype, as the size for this group was small, it’s hard to draw any conclusions based on this result. Although this subtype was tested here as a HR+/HER2- subtype, it is known to be difficult to treat with endocrine therapy alone.

• The results of this analysis of MONALEESA-2, -3, and -7 demonstrate that in most intrinsic subtypes of HR+/HER2- advanced breast cancer, women treated with ribociclib plus endocrine therapy lived longer than those treated with endocrine therapy alone.

References


Study Information

NCT01958021 (MONALEESA-2), NCT02422615 (MONALEESA-3), NCT02278120 (MONALEESA-7)

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1. Novartis Pharma S. A. Corporation

Full title of the SABCS 2021 oral presentation: Correlative Analysis of Overall Survival by Intrinsic Subtype Across the MONALEESA-2, -3, and -7 Studies of Ribociclib + Endocrine Therapy in Patients With HR+/HER2− Advanced Breast Cancer

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