Adding Ribociclib to First-Line Endocrine Therapy Significantly Improves Survival for Pre-Menopausal Women With Advanced Breast Cancer

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ASCO Perspective
“Advanced breast cancer in pre-menopausal women can be very aggressive. It is important and encouraging to see a targeted therapy that significantly increases survival for younger women with this disease,” said ASCO Expert Harold J. Burstein, MD, PhD.

CHICAGO – The international, randomized phase III MONALEESA-7 trial found that adding ribociclib to standard-of-care endocrine therapy significantly improved overall survival for premenopausal women with advanced HR-positive/HER2-negative breast cancer compared with endocrine therapy alone. After 42 months of follow-up, the survival rate was 70% for women who took the combination therapy compared with 46% for women who received endocrine therapy only. Advanced breast cancer is the leading cause of cancer death in women 20 to 59 years of age.

The study will be featured in a press briefing today and presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

“This is the first study to show improved survival for any targeted therapy when used with endocrine therapy as a first-line treatment for advanced breast cancer,” said lead study author Sara A. Hurvitz, MD, Director of the Breast Cancer Clinical Research Program at UCLA Jonsson Comprehensive Cancer Center in Los Angeles, CA. “The use of ribociclib as a front-line therapy significantly prolonged overall survival, which is good news for women with this terrible disease.”

Advanced breast cancer is less common in premenopausal women than in older women, and
incidence is increasing. In the United States, in women ages 20 to 39, the incidence of advanced breast cancer increased 2% per year between 1978 and 2008.\textsuperscript{2}

Ribociclib is a therapy that inhibits the activity of cancer-cell promoting enzymes known as cyclin-dependent 4/6 kinases (CDK 4/6). In July 2018, the U.S. Food and Drug Administration approved the expanded indication for ribociclib in combination with an aromatase inhibitor to include pre- and perimenopausal women with hormone receptor–positive, HER2-negative advanced or metastatic breast cancer.\textsuperscript{3}

**About the Study**

MONALEESA-7 is the first trial to focus exclusively on women under age 59 who were premenopausal and had advanced breast cancer for which they had not received prior endocrine therapy.

Investigators randomly assigned women to ribociclib (a tablet), or to a placebo tablet. All women also received goserelin, an injectable endocrine therapy that suppresses estrogen, and one of three other therapies: the nonsteroidal aromatase inhibitors letrozole (Femara) or anastrozole (Arimidex), which lower estrogen production, or tamoxifen, which has been used to treat breast cancer for over 40 years and blocks the effects of estrogen in breast tissue.

Six hundred and seventy-two women were enrolled in the study. After a median follow-up of 34.6 months, 173 (26%) were still receiving the therapies, with 116 (35%) of the women still receiving ribociclib and 57 (17%) still receiving the placebo.

**Key Findings**

The women who received ribociclib lived a median of 23.8 months without the disease progressing compared with 13 months for women who received the placebo.\textsuperscript{4} The researchers observed that after 42 months of follow-up, for patients receiving ribociclib, the survival rate was 70% when given with endocrine therapy compared with 46% when given with placebo. Overall this represented a 29% relative reduction in the risk of death.

In addition, the survival rate of 71% and 70% for women who took ribociclib in combination with tamoxifen or a nonsteroidal aromatase inhibitor, respectively, compared with a survival rate of 55% and 43%, respectively, for women who received placebo in combination with tamoxifen or aromatase inhibitors only.
Next Steps

The researchers are doing analyses of patient-reported outcomes as well as sub-analyses of the clinical findings, including looking at biomarkers and circulating tumor DNA that may help them determine which women might benefit most from ribociclib.

The investigators are studying the use of ribociclib in women and men with early-stage HR+, HER2-negative breast cancer in combination with endocrine therapy and other cancer indications.

This study received funding from Novartis.

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<thead>
<tr>
<th>Study Focus</th>
<th>A CDK4/6 inhibitor for pre-menopausal women with HR+/HER- advanced breast cancer</th>
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<tbody>
<tr>
<td>Trial Type</td>
<td>Phase III randomized clinical trial</td>
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<tr>
<td>Patients on Trial</td>
<td>672</td>
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<tr>
<td>Treatment Tested</td>
<td>Ribociclib</td>
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<tr>
<td>Primary Finding</td>
<td>Women who got ribociclib lived a median of 23.8 months without their disease progressing compared with 13 months for women who received a placebo</td>
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<tr>
<td>Secondary Finding(s)</td>
<td>After 42 months of treatment, 70.8% of women who received ribociclib were alive compared with 46% of women who received a placebo</td>
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3 U.S. Food and Drug Administration: FDA expands ribociclib indication in HR-positive, HER2-negative advanced or metastatic breast cancer. [www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm613803.htm](http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm613803.htm)

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