Ribociclib Improves Overall Survival in Hormone Receptor–Positive Breast Cancer

The cyclin-dependent kinase 4/6 inhibitor ribociclib (Kisqali, Novartis) improves overall survival (OS) in women with hormone receptor (HR)–positive, human epidermal growth factor 2 (HER2)–negative breast cancer, according to interim results from the phase 3 MONALEESA-7 study (Abstract LBA1008). Previous studies had found that the addition of ribociclib to endocrine therapy improves progression-free survival (PFS) in these patients.

For the study, which was led by Dr Sara Hurvitz, 672 premenopausal women with HR-positive, HER2-negative advanced breast cancer were randomly assigned to either ribociclib or placebo, along with goserelin and standard endocrine therapy with an aromatase inhibitor or tamoxifen.

After a median follow-up of 35 months, OS was significantly longer in the ribociclib group than the placebo group, at not reached vs 41 months, respectively (hazard ratio [HR], 0.712; 95% CI, 0.54–0.95; P = .00973). The estimated OS rates with ribociclib vs placebo at 42 months were 70% vs 46%, respectively. The improvement in OS with ribociclib persisted in a subgroup analysis of patients who received an aromatase inhibitor instead of tamoxifen.

This interim follow-up did not reveal any new concerns regarding toxicity of treatment with ribociclib.

Margetuximab Improves PFS in Metastatic HER2-Positive Breast Cancer

Margetuximab improves PFS compared with trastuzumab in women with HER2-positive metastatic breast cancer who previously received at least 2 anti-HER2 regimens, according to results from the phase 3, open-label SOPHIA trial (Abstract 1000). Margetuximab is an investigational monoclonal antibody against HER2.

Researchers led by Dr Hope Rugo randomly assigned 536 women with HER2-positive metastatic breast cancer who had received at least 2 prior HER2-directed regimens for metastatic breast cancer were randomly assigned to receive capecitabine in combination with either margetuximab or trastuzumab.

The investigators reported that at up to 36 months of follow-up, centrally assessed PFS was significantly longer with margetuximab than with lapatinib (HR, 0.76; 95% CI, 0.63–0.93; P = .006). PFS also was significantly longer with margetuximab than with lapatinib in the restricted means analysis, at 8.8 vs 6.6 months (P = .0003). The duration of response was significantly longer with neratinib than with lapatinib (HR, 0.50; P = .0004), but the difference in OS at up to 48 months of follow-up did not reach statistical significance.

The researchers also found that fewer patients in the margetuximab group required intervention for symptomatic central nervous system (CNS) metastases, which suggested a delay in CNS progression with margetuximab. Although the rates of treatment-emergent adverse events were similar between the arms, the rate of grade 3 diarrhea was higher with margetuximab than with lapatinib (24.4% vs 12.5%). No new safety signals were seen with margetuximab.