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Taipei International Breast Cancer Symposium
台北國際乳癌研討會

Speech Abstract

Topic:
Global international-initiated trial (PATHWAY trial) in Asian countries for HR-positive/HER2-negative advanced breast cancer.
Abstract
In Asian countries, the incidence of breast cancer is increasing with a higher population of pre/perimenopausal case than in Western countries. However, treatment options for pre/perimenopausal women with breast cancer remain limited. Palbociclib, CDK4/6 inhibitor, combined with endocrine therapy is approved for treating patients with hormone-receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2−) advanced breast cancer; however, data on palbociclib combined with tamoxifen are limited. We conducted global international-initiated trial in 12 institutes in four Asian countries (Japan, Taiwan, Korea and Singapore) to investigate the efficacy and safety of palbociclib–tamoxifen in patients with HR+/HER2− advanced breast cancer. This double-blind phase 3 study included 184 women who were randomly assigned 1:1 to receive palbociclib–tamoxifen or placebo–tamoxifen. Pre/perimenopausal women also received goserelin. The primary endpoint was investigator-assessed progression-free survival (PFS). Secondary endpoints included overall survival (OS) and safety. Median PFS was 24.4 months (95% confidence interval [CI], 13.1 to 32.4) with palbociclib–tamoxifen and 11.1 months (95% CI, 7.4 to 14.6) with placebo–tamoxifen (hazard ratio [HR], 0.60; 95% CI, 0.43 to 0.85; *P* = 0.002). Palbociclib–tamoxifen improved PFS in patients who were treated with first-line or second-line endocrine therapy and pre-, peri-, and postmenopausal patients. Though OS data are still immature (median not reached in both groups), an overall risk reduction of 27% (HR, 0.73; 95% CI, 0.44 to 1.21) with palbociclib–tamoxifen was observed at the time of PFS analysis. The most common grade 3/4 adverse event with palbociclib–tamoxifen was neutropenia (89.0% [none were febrile] versus 1.1% with placebo–tamoxifen). There were no deaths owing to adverse events in either group. Among patients with HR+/HER2− advanced breast cancer, palbociclib–tamoxifen resulted in significantly longer PFS than tamoxifen alone. Early OS data showed a trend favoring palbociclib–tamoxifen. In this session, we are going to discuss the impact of these results on general clinical practice, about the necessity and difficulties in processing global international-initiated trial in in Asian countries.