

Ribociclib improves progression-free survival in Asian women with advanced breast cancer

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Ribociclib significantly improves progression-free survival in Asian women with advanced breast cancer, according to a sub-analysis of the MONALEESA-2 trial presented at the ESMO Asia 2016 Congress in Singapore.

"Breast cancer is a significant health burden in Asia, with 24% of cases worldwide diagnosed in this region alone," said lead author Dr Yoon-Sim Yap, Senior Consultant, Department of Medical Oncology, National Cancer Centre Singapore. "A higher proportion of patients have advanced disease at diagnosis in certain regions within Asia, with potential differences in tumour biology."

Endocrine therapy is the backbone of treatment for hormone receptor (HR)-positive breast cancer but efficacy is often limited by de novo or acquired resistance. Disease progression eventually occurs in most patients receiving endocrine therapy. The CDK4/6 pathway is implicated in endocrine therapy resistance, and therefore, combined endocrine and CDK4/6-targeted therapy may prolong treatment benefit and delay the use of chemotherapy.

MONALEESA-2 2 is a phase 3 randomised trial of ribociclib (a CDK4/6 inhibitor) plus letrozole (endocrine therapy) versus placebo plus letrozole for the first-line treatment of postmenopausal women with HR-positive, HER2-negative [advanced breast cancer](#). A total of 668 patients were enrolled (334 in each treatment arm). Tumour assessments were performed at screening, every eight weeks during the first 18 months,

and every 12 weeks thereafter. The primary endpoint was locally assessed progression-free survival (PFS). The pre-planned interim analysis was conducted after 243 PFS events had occurred in the full population.

Today researchers presented the findings of a pre-defined subgroup analysis in Asian patients by geographic region (68 patients) and race (51 patients). As previously reported, the addition of ribociclib to letrozole significantly increased PFS by 44% in the full population. This improvement was also observed in Asian patients, regardless of categorisation by geographic region (70% increase in PFS) or by self-reported race (61% increase in PFS). Combined ribociclib and letrozole treatment was well tolerated in Asian patients, with a similar safety profile as that observed in the full population.

Dr Yap said: "First-line ribociclib and letrozole significantly prolonged PFS compared to placebo plus letrozole with an acceptable safety profile in postmenopausal Asian women with HR-positive, HER2-negative advanced breast cancer. This trial shows that the combination of ribociclib and letrozole is an effective first-line therapy for HR-positive advanced breast cancer, including for the Asian patient population."

Commenting on the findings, Dr Sing-Huang Tan, senior consultant, Department of Haematology-Oncology, National University Cancer Institute, Singapore (NCIS), said: "Breast cancer incidence has increased in several East and Southeast Asian countries the past two decades. Ethnic differences in relation to pharmacokinetics and pharmacodynamics are well known for certain drugs. There is consequently a need to evaluate the utility and safety of new breast cancer drugs in Asian [patients](#), who often form a small proportion of the study population in international trials."

She continued: "This predefined subgroup analysis reaffirms the data

obtained in the Western population and provides further evidence that ribociclib in combination with letrozole also demonstrates efficacy in Asians. It highlights another alternative to the various therapies already available, and may serve as an additional combination therapeutic option to those with a higher burden of disease for which [endocrine therapy](#) is still deemed appropriate."

Dr Tan concluded: "The use of this combination could change our practice, although costs and drug availability may be prohibitive especially in certain parts of Asia, and evidence for specific biomarkers which could enhance patient selection would be useful. Research is also needed on its utility with other targeted agents, possible mechanisms of resistance to CDK4/6 inhibitors, and the role of this group of drugs in HER2-positive advanced [breast cancer](#), in both Asian and Western populations."

Provided by European Society for Medical Oncology

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