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ReachMD

www.reachmd.com

info@reachmd.com

(866) 423-7849

Spotlight on Asia-Pacific: Practice Beyond Borders

Dr. Iwata:

This is CE on ReachMD, and I'm Dr. Hiroji Iwata. Today I'll provide my perspective on managing HR-positive, HER2-negative metastatic breast cancer in Asia-Pacific.

So left side of the slide shows the distribution and the incidence and the mortality of breast cancer in the world. And the green area is the Asia region.

So right side slide shows a distribution of a region enrollment in the clinical trial and to DESTINY-Breast04. So Asian population in the study was around 40%, so therefore Asia-Pacific data is an important region in term of the number of breast cancer patients and the enrollment in the clinical trials.

So my perspective on managing HR-positive, HER2-negative metastatic breast cancer according to currently clinical trial data. So as a hormone-sensitive in the first-line setting, AI plus CDK4/6 inhibitor is gold standard of care.

So during this treatment and a switch to camizestrant from AI, when an ESR1 mutation in a clinical non-PD case was detected based on the SERENA-6 result.

So after clinical PD and during AI plus CDK4/6i, we should check the biomarkers. Treatment option for each biomarker in case and with ESR1 mutations, oral SERD may be an option. After ESMO, there are 3 options available—elacestrant, imlunestrant, giredestrant. So additionally, in case of the AKT altered, PIK3CA mutant, and the BRCA1/2 mutant, so drugs tailored to each condition become the candidate.

So case of the recurrence during a postoperative treatment for within 12 months after its completion are classified as acquired hormone resistance. In this case, we also should check the biomarkers to determine the option for each biomarkers, which is similar with endocrine-sensitive case, as you can see here.

So however, the difference of the medical system, including the regulatory issues and health insurance in the Asia-Pacific region compared to US and EU. Furthermore, even within the Asia-Pacific region, they vary from country to country. For example, alpelisib is not approved in Japan; imlunestrant is not approved in Japan yet. So Asian population was not included in the regulatory gedatolisib study.

So companion diagnosis issue in Asia-Pacific region, shown in the slide. Guardant360 is a CDx to detect ESR1 mutation for imlunestrant. FoundationOne liquid CDx assay is approved for detecting a PIK3CA mutant for inavolisib. PIK3CA in the PCR kit is CDx to detect PIK3CA mutant for alpelisib. Guardant360 is used to detect ESR1 mutant for camizestrant in the SERENA-6.

However, the NGS assay is very, very expensive and difficult to use for monitoring in practice, so I believe a simple and inexpensive biomarker test is necessary in the near future.

So, well, this is all the time I have today. I hope this brief overview is useful to you. Thank you for listening.