9/24 (Sun.) 15:00-15:30

Current Experience and Future Perspective in Conducting Biosimilar Clinical Trials in Taiwan

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Biosimilars have gained significant attention in recent years due to their potential to provide affordable treatment options and increase patient access to biologic therapies. Conducting robust clinical trials is crucial to establish the safety and efficacy of biosimilars. Scientific considerations for clinical studies of biosimilars encompass sensitive indications, endpoint selection, biosimilarity margin setting, and immunogenicity evaluation. These factors influence the design and execution of clinical trials and their interpretation. This presentation will share the current experience and future perspective in conducting biosimilar clinical trials in Taiwan, focusing on the EG12014 biosimilar development program for breast cancer. The EG12014 clinical development program includes two studies, namely EGC001 and EGC002. EGC002 is a large multinational phase III study to evaluate the efficacy, safety, and immunogenicity of EG12014 compared to the reference product Herceptin in neoadjuvant treatment of HER2-positive breast cancer. The study result has demonstrated that EG12014 matches reference trastuzumab in terms of efficacy, safety, pharmacokinetic and immunogenicity. Key findings from the EGC002 study in Taiwan subgroup data analysis are also presented. The Taiwan subgroup demonstrated comparable demographic and baseline characteristics to the full study population, except for lower baseline body weight/BMI. Furthermore, the primary endpoint, pathological complete response (pCR), showed comparable rates between Taiwan and non-Taiwan study populations. The pCR rates were 0.400 (95% CI: 0.152; 0.648) for EG12014 and 0.308 (95% CI: 0.057; 0.559) for Herceptin. Safety profiles, including the frequency, intensity, seriousness, and causality of treatment-emergent adverse events (TEAEs), were also similar between Taiwan and non-Taiwan populations. The majority of TEAEs were mild or moderate in severity and not related to trastuzumab. No deaths were reported during the study, and only one patient in the neoadjuvant part showed a de novo anti-drug antibody (ADA) positive result after the first administration of the study drug (negative for neutralizing antibodies). These findings support the potential of biosimilars to provide cost-effective treatment options for patients with HER2-positive breast cancer. As biosimilars continue to emerge as an important component of healthcare, optimizing the design and execution of clinical trials will enhance our understanding of their efficacy, safety, and immunogenicity profiles. Looking ahead, continued efforts in biosimilar research and collaborations between stakeholders will contribute to improving patient care and access to these important therapies in Taiwan and beyond.