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ASIA EDITION

World's second developed shingles vaccine receives biologics license application approval in Malaysia

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SK biosciences plans to launch the zoster vaccine with proven efficacy and safety starting in Southeast Asian market



South Korea headquatered SK bioscience, a global innovative vaccine and biotech company, has received a biologics license application approval of the SKYZoster from the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia.

The vaccine was approved in South Korea from the Ministry of Food and Drug Safety (KMFDS) in September 2017. This is the second overseas approval of SKYZoster after Thailand in May 2020.

SKYZoster is the world´s second developed shingles vaccine. It is a live vaccine that attenuates varicella zoster virus. SKYZoster is shown clinically acceptable immunogenicity and safety at Phase III clinical trial.

It is steadily expanding the market position in the South Korean domestic market. According to the IMS data, a global market research institute, SKYZoster's market share in the third quarter of 2022 reached 56% (based on the number of doses), the highest ever. In particular, the vaccine gradually expanded its influence in the market with a 51% share in the first quarter and a 52% share in the second quarter, proving the efficacy and safety.

SK bioscience plans to submit for the Pre-Qualification(PQ) to the WHO next year to further accelerate the vaccine’s approval for overseas emerging markets, such as Southeast Asia and developing countries.