

SK bioscience's Zoster Vaccine Receives Biologics License Application Approval in Malaysia



NEWS PROVIDED BY
[SK bioscience](#) →
Jan 09, 2023, 08:00 ET

SHARE THIS ARTICLE



- The world-second developed shingles vaccine 'SKYZoster™' is approved by the National Pharmaceutical Regulatory Agency (NPRA)
- SK biosciences plans to launch the zoster vaccine with proven efficacy and safety starting in Southeast Asian market

SEOUL, South Korea, Jan. 9, 2023 /PRNewswire/ -- SK bioscience, a global innovative vaccine and biotech company committed to promoting human health from prevention to cure across the globe, announced that the company has received a biologics license application approval of the 'SKYZoster™' from the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia.

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. The vaccine was approved in South Korea from the Ministry of Food and Drug Safety (KMFDS) in September 2017 based on results of clinical trials conducted in domestic and global institutions.

SKYZoster™ is shown clinically acceptable immunogenicity and safety at Phase III clinical trial. As evaluating immunogenicity by enrolling 824 healthy adults over the age of 50, the result shows that the antibody titer against the varicella zoster virus increased 2.75 times after inoculating SKYZoster™ compared to before vaccination. Furthermore, the result shows that SKYZoster™ is non-inferior compared to the control vaccine (MSD Zostavax), and the cell-mediated immune response was also shown to be at an equal level, proving SKYZoster™ effectively induces immunogenicity against shingles.

In terms of safety, the incidence of adverse reactions that occurred 6 weeks after SKYZoster™ vaccination was similar to that of the control vaccine group, and there were no serious adverse reactions that showed any relationship with the study drug reported during 26 weeks after vaccination. In addition, a post-marketing survey of 651 people for 4 years after the launching of SKYZoster™, the KMFDS' safety evaluation result was recently announced, indicating that no serious adverse reactions occurred after the vaccination.

SKYZoster™ 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 SKYZoster™'s 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.

Jaeyong Ahn, CEO of SK bioscience, said, "It is encouraging that vaccines made by our own technology are gradually expanding their influence in the global vaccine market where big pharmaceutical companies mainly dominate. With the experience of CMO/CDMO and self-development of various vaccines, we will further expand our products to low- and middle-income countries to contribute global public health."

Contact

SK bioscience Communications Team
Changhyun Jin (jin99@sk.com)
Jeannie S. Pak (j.pak@sk.com)
Tae-Gyun Kim (taegyunkim@sk.com)

About SK bioscience

SK bioscience is a global innovative vaccine and biotech company, committed to global pandemic preparedness in vaccine development and manufacturing for more equitable access. In leveraging the strengths of cutting-edge vaccine development technologies, SK bioscience is dedicated to promoting human health from prevention to cure across the globe. Through collaborations with domestic and international governments, regulatory agencies, healthcare providers, doctors and medical experts, SK bioscience has firmly established globally certified R&D and manufacturing technologies. All SK colleagues are passionately committed to providing better public healthcare solutions and offering high-quality vaccines and therapeutics to those who need them.

For further information, please visit: <https://www.skbioscience.co.kr/en/main>

SOURCE SK bioscience