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ASIA EDITION

Korea's GC Biopharma receives regulatory approval for world's first recombinant anthrax vaccine

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BARYTHRAX has improved vaccine stability by overcoming a key limitation of recombinant protein vaccines



GC Biopharma has announced that the Korean Ministry of Food and Drug Safety (MFDS) has approved its anthrax vaccine, BARYTHRAX, jointly developed by GC Biopharma and the Korea Disease Control and Prevention Agency (KDCA).

With the approval by MFDS, BARYTHRAX has become Korea's 39th novel drug. Following the application on 31 Oct 2023, GC Biopharma and KDCA successfully received the product approval from MFDS on 8th this month.

Anthrax, caused by Bacillus anthracis, is class-1 infectious disease capable of surviving extreme conditions and spreading easily through airborne transmission. If untreated, its fatality rate can reach up to 97%, making it a significant threat as a potential biological weapon.

BARYTHRAX utilises protective antigen (PA) proteins produced through genetic recombination techniques. In anthrax infections, PA acts as a gateway for 2 Bacillus anthracis toxins lethal factor (LF) and edema factor (EF), to enter host cells. By utilising PA proteins, the vaccination can train and stimulate an immune response to neutralize anthrax.

Traditional vaccines are made by attenuating Bacillus anthracis or culturing non-pathogenic Bacillus anthracis, which may contain residual toxin components. BARYTHRAX, being the world's first recombinant protein anthrax vaccine, removed this risk and improved vaccine safety.

BARYTHRAX has also improved vaccine stability by overcoming a key limitation of recombinant protein vaccines, which is "the reduction in immunogenicity within the shelf life". In the Phase II clinical trial, healthy adult subjects, who received the vaccination generated sufficient antibodies to neutralize anthrax toxins, while reporting no acute or severe adverse events.

The MFDS's approval, supported by GC Biopharma's production capacity, will pave the way for the company to supply Korea's essential anthrax vaccine reserve.