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ASIA EDITION

Taiwan's ScinoPharm secures US FDA approval of Glatiramer Acetate Injection for MS treatment

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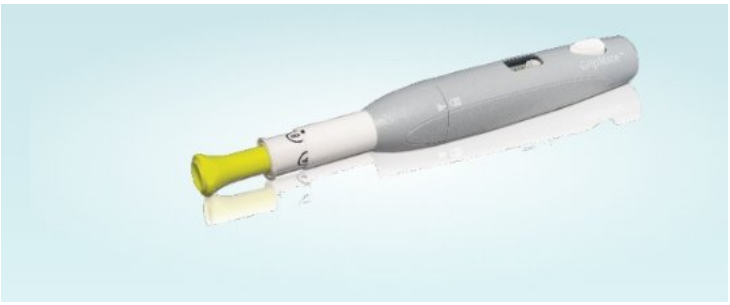
Making it the only pharmaceutical company in Taiwan to achieve this historic milestone



ScinoPharm Taiwan has announced a landmark achievement in the global pharmaceutical landscape, securing US Food and Drug Administration (FDA) approval for Glatiramer Acetate Injection, a treatment for Multiple Sclerosis (MS), making it the only pharmaceutical company in Taiwan to achieve this historic milestone.

Multiple Sclerosis affects approximately 2.9 million people worldwide. According to the US National MS Society, there are nearly 1 million patients in the United States alone. Verified Market Reports estimates that the global market size for Glatiramer Acetate was $1.5 billion in 2024 and is projected to reach $2.8 billion by 2033.

In response to this significant opportunity, ScinoPharm has invested heavily in its process development and manufacturing capabilities, successfully mastering this high-barrier process after years of dedicated R&D and ultimately positioning itself to compete in its ~$700 million US market.

Since its approval in 1996, Glatiramer Acetate (GA) has been recognised as one of the most challenging complex synthetic polypeptides globally. To address the unique nature of such products, the US FDA even established a dedicated regulatory pathway for Non-Biological Complex Drugs (NBCDs).

While the US FDA approval marks a historic first, ScinoPharm is already executing its next phase of global growth. The company is actively advancing regulatory submissions and forging strategic partnerships across Europe, Asia, and emerging markets to broaden its international presence in the generic drug product market and build on its already strong position on the generic API front.