

VERTANICAL Secures First European Marketing Authorisation for Exilby in Chronic Low Back Pain

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The Germany approval positions Exilby as a first-in-class non-opioid treatment option for chronic low back pain with a radicular component, while a pivotal US Phase 3 trial is underway.



VERTANICAL has received marketing authorisation in Germany for Exilby, or VER-01, for the treatment of chronic low back pain with a radicular neuropathic component, marking the product's first European approval.

The authorisation addresses a major unmet need in chronic pain care, where many patients continue to rely on opioids despite risks such as dependence, abuse potential and tolerability concerns. With chronic pain affecting more than one billion people worldwide, non-opioid options with evidence-based positioning remain a priority for healthcare systems seeking safer long-term pain management approaches.

Exilby is a standardised full-spectrum extract derived from a proprietary Cannabis sativa strain, developed with defined cannabinoid, terpene and bioactive compound composition. Its differentiation lies in pharmaceutical-grade standardisation, which is intended to provide consistency across product quality and clinical use.

The German approval was supported by two pivotal randomised, controlled Phase 3 trials involving more than 1,200 patients. The studies demonstrated significant pain reduction, favourable tolerability and no evidence of dependence. In a direct Phase 3 head-to-head comparator study, Exilby also showed superior pain reduction and better gastrointestinal tolerability compared with opioids.

The product is not yet approved in the United States. VERTANICAL has initiated an additional pivotal US Phase 3 trial to support a future FDA submission, with first data read-out anticipated in 2027 and a New Drug Application planned in 2028, subject to positive results. The US FDA has granted Exilby Breakthrough Therapy Designation.