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AnHorn secures US and Taiwan regulatory milestones for CIPN candidate

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The FDA IND clearance and Taiwan CDE Index Case designation support clinical advancement of AH-008 as a preventive therapy for chemotherapy-induced peripheral neuropathy.

AnHorn Medicines has received U.S. FDA Investigational New Drug clearance and Taiwan Center for Drug Evaluation Index Case designation for AH-008, its lead neuroprotective candidate for the prevention of chemotherapy-induced peripheral neuropathy.

The dual regulatory milestones allow AH-008 to move toward human clinical trials and provide regulatory validation for the company's development strategy. The Taiwan CDE Index Case designation also positions AH-008 as a reference programme for novel drug development in its category.

This is relevant because chemotherapy-induced peripheral neuropathy remains a major complication of cancer treatment. It is associated with commonly used therapies such as taxanes, platinum-based agents, vinca alkaloids and antibody-drug conjugates. Patients can experience pain, sensory dysfunction, irreversible nerve damage and long-term impairment, affecting both quality of life and cancer treatment continuity.

The condition also has direct implications for oncology outcomes. CIPN can force chemotherapy dose reductions, treatment delays or discontinuation, which may compromise cancer control. Despite this burden, there are currently no approved therapies to prevent CIPN, creating a clear unmet need in oncology supportive care.

AH-008 is designed as a first-in-class neuroprotective therapeutic candidate that targets the underlying mechanisms of chemotherapy-related nerve damage. Unlike symptomatic approaches that treat established neuropathy, the candidate is being developed as a prevention-first therapy intended to preserve peripheral nerve function during cancer treatment.

AnHorn said the FDA clearance followed review of preclinical pharmacology, toxicology and manufacturing data. The programme's preclinical studies were designed in line with the U.S. FDA's January 2025 draft guidance on developing drugs and biologics for prevention and treatment of chemotherapy-induced peripheral neuropathy.

According to the company, AH-008 demonstrated neuroprotective effects across multiple chemotherapy-induced neuropathy models, preserving peripheral nerve integrity while maintaining chemotherapy efficacy. This is important because any preventive therapy used alongside cancer treatment must not reduce the antitumour effect of chemotherapy.

The development timeline is also notable. AnHorn advanced AH-008 from preclinical stage to FDA IND clearance in 12 months, reflecting its integrated translational, regulatory and CMC development approach.

The company describes itself as an AI-driven biotech focused on novel small molecules and protein degraders across aesthetic medicine, oncology and cancer supportive care. Its AIMCADD platform integrates generative AI and molecular simulation to support candidate design.