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FDA Grants Orphan Drug Designation to XWL-008 to treat Narcolepsy

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XW Laboratories Inc., a China headquartered clinical-stage biopharmaceutical company pioneering the discovery of novel small molecule therapeutics for the treatment of neurological disorders, on 24 June 2019, announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the company's lead proprietary compound XWL-008 for the treatment of patients with narcolepsy.

"We are delighted to receive Orphan Drug Designation for XWL-008 for the treatment of narcolepsy. We continue to be committed to the development of XWLÃ¢â?¬â??008 as the potential first-line treatment for this rare and debilitating disorder," said Dr Jia-Ning Xiang, Founder and CEO of XW Labs. "We have recently reached a major milestone in XWL-008 development by successfully completing Phase 1 studies, yielding robust results demonstrating favourable safety, tolerability, and pharmacokinetics. We are now preparing for late-stage phase 3 clinical research and a 505(b)(2) NDA regulatory pathway as the next step to bringing this novel drug candidate to narcolepsy patients worldwide."

The FDA Orphan Drug Designation program grants orphan status to promising investigational drugs designed to treat, prevent, or diagnose rare medical diseases or conditions that affect fewer than 200,000 individuals in the United States. Orphan designation qualifies sponsors for several key benefits and incentives, including tax credits for clinical testing, exemption from marketing application user fees, and seven-year marketing exclusivity upon FDA approval.