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Maxona receives FDA IND clearance for non-opioid acute pain therapy

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MAX-001 is an extended-release oral nefopam formulation being developed as a non-opioid, non-NSAID treatment for acute and chronic pain.

Maxona Pharmaceuticals has received U.S. FDA clearance of its Investigational New Drug application for a Phase 2 clinical trial of MAX-001 in acute pain.

MAX-001 is a proprietary optimised extended-release oral formulation of nefopam. The company is developing it as a non-opioid, non-NSAID prescription therapy for acute and chronic pain, with potential additional indications.

This is relevant because pain management remains a major therapeutic challenge, particularly in the United States where opioid use has created substantial public health concerns. There is continued need for effective non-opioid options that can provide rapid and sustained analgesia without the risks associated with opioids or the limitations of NSAIDs.

Nefopam has been studied and prescribed outside the United States for more than 40 years in intravenous and oral dosage forms. It acts as a triple monoamine reuptake inhibitor, with activity greatest on norepinephrine, followed by serotonin and dopamine.

MAX-001 is designed to deliver both rapid onset and extended duration of analgesia. Maxona said that if authorised in the United States, it would be the only triple monoamine reuptake inhibitor with an indication for acute pain.

The company has already completed a Phase 1 trial of its proprietary formulation. According to Maxona, the study showed dose-proportional pharmacokinetics and was safe and well tolerated, with no serious adverse events, no premature discontinuations due to related adverse events and no severe adverse events.

The FDA clearance allows Maxona to advance its MAX-001-201 randomised, controlled Phase 2 trial in the United States. The company expects to enrol first patients within the next few months.

Acute post-surgical pain remains a large market where clinicians need alternatives that reduce opioid exposure without compromising pain control. A successful oral non-opioid therapy could be useful in surgical recovery, outpatient procedures and broader acute pain settings.