

PharmNovo secures CTA approval in Spain initiating Phase IIa proof-of-concept trial of PN6047 for neuropathic pain

PN6047 is a first-in-class small molecule that selectively activates the delta opioid receptor (DOR), avoiding interaction with the mu opioid receptor that is the basis of the addiction and other unwanted effects associated with conventional opioids. It is designed to enable safe and effective treatment to deliver clinical proof of concept (POC) in a Phase IIa study of patients with peripheral neuropathic pain.

PharmNovo AB is pleased to announce that the clinical trial application (CTA) for a Phase IIa proof of concept (PoC) study investigating the safety and efficacy of lead candidate PN6047 in patients with neuropathic pain has been approved in Spain. The full title of the study is: "Randomized Double-Blind Placebo-Controlled Cross-Over Trial of the Safety, Tolerability, and Efficacy of PN6047 HCl in Peripheral Neuropathic Pain Characterized by Mechanical Allodynia."

Based on a strategic company decision, PharmNovo submitted the CTA, in the first instance, to the Spanish Health Authorities only. Submission to the Czech Republic and Poland, the two other countries in which the trial will be conducted, is planned to take place. Subject to additional investment, patient enrolment is expected to start by mid-2026

Although the study will run in the EU, it is fully aligned with the FDA requirements defined during a pre-IND (Investigational New Drug) meeting in January 2025 and an IND is currently being compiled.

Per von Mentzer, CEO of PharmNovo says; "We have reached an important milestone with the company's development and I am very proud of the PharmNovo team for their excellent work leading to the CTA approval in Spain. PN6047 offers new hope for the future of neuropathic pain management by enabling a fundamental shift towards safer non-addictive treatments that can redefine standards of care."

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About PharmNovo

PharmNovo AB is a Swedish clinical-stage pharmaceutical company focused on developing safe and effective drugs for neuropathic pain. In this area, there is currently a lack of sufficient treatments. The company has developed a novel compound portfolio based on a new type of selective delta opioid receptor agonists (DORAs), intended to provide effective neuropathic pain relief without the adverse side effects of conventional opioids. The company's lead candidate, PN6047, is currently in the final stages of phase I studies and is shown to effectively reduce neuropathic pain in preclinical studies. PharmNovo is preparing for phase II studies with the lead candidate in chronic neuropathic pain and potentially in other areas, for example chronic cough and opioid withdrawal syndrome (OWS). To learn more, visit pharmnovo.com and follow PharmNovo at LinkedIn.