



PharmNovo receives positive FDA feedback for drug candidate PN6047 and targets IND submission and Phase IIa trial application during 2025

PharmNovo AB is pleased to announce that it has received positive and constructive feedback for its lead drug product PN6047, a selective delta opioid receptor agonist, from the U.S. Food and Drug Administration (FDA). This follows a successful pre-Investigational New Drug (pre-IND) Type B meeting with the FDA held in January 2025. The focus of the pre-IND meeting was to receive FDA feedback and guidance on the chemistry, manufacturing and control (CMC) information, non-clinical data, and Phase II a study design for PN6047 for the treatment of peripheral neuropathy with allodynia.

PharmNovo CEO Per von Mentzer commented: “The FDA had no critical comments on the CMC information or the non-clinical data and gave valuable guidance for the future CMC and non-clinical development program. They also gave clear guidance on the design of the “proof of concept” study (the Phase II a study). This now provides us with a clear and straightforward pathway towards the initiation of the phase IIa study with PN6047.”

Based on the FDA feedback, PharmNovo AB will submit an IND to FDA by end of 2025. The Company also aims to submit a clinical trial application for the phase IIa protocol in Europe in Q3 2025, including Spain, Poland and the Czech Republic.

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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](#).