Request for Proposals (RFP) for Investigator-Initiated Research Examining Opioid Overdose Reversal Using Nalmefene HCl Injection

The FDA approval of Nalmefene HCl Injection has given healthcare professionals an additional treatment option for the management of known or suspected opioid overdose. However, there is limited data on the use of Nalmefene HCl Injection in today's opioid overdose environment.

Proposals to be considered for this RFP should explore outcomes associated with the use of Nalmefene HCl Injection.

Instructions for Submission of Research Proposals

Sponsor investigator applicants must submit their CV and a brief letter of intent (i.e., 1-2 pages) outlining the study concept via email to iitprogram@pharma.com by 5:00 PM ET April 30, 2023. The letter of intent should include:

- Sponsor/investigator CV
- Institutional affiliation/Study Site(s)
- Research Objective(s)
- Study design, methods
- Target population(s)
- Endpoints and intended analysis
- Estimated study duration and preliminary budget
- Anticipated drug supply required and any funding request

Proposal Review and Response

Applicant proposals will be evaluated by a medical and scientific review committee. Selection of proposals will be based on medical and scientific merit, feasibility, and investigator/site qualifications. Review focus will also be on innovation, cost-efficiency, and translatability to medical practice. Following initial Letter of Intent review, a selected set of applicants will be asked to submit a full study proposal which includes a line-item budget reflective of the fair market costs for executing the research.

Financial support and/or drug supply will be issued based upon a fully executed agreement. All approved projects are expected to result in publication of findings in a peer-reviewed journal.

Sponsor Investigators must be willing to assume regulatory responsibility for the research including obtaining an IND or exemptions granted by FDA as applicable.

Important Information About Nalmefene HCl Injection

Nalmefene HCl Injection, a sterile solution containing 2 mg/2 mL (1 mg/mL) in vial form for intravenous, intramuscular, and subcutaneous injection, was FDA approved in February 2022.

Indications and Usage: Nalmefene HCl Injection is an opioid antagonist indicated for the complete or partial reversal of opioid drug effects, including respiratory depression, induced by either natural or synthetic opioids. Nalmefene HCl Injection is indicated in the management of known or suspected opioid overdose.[1]

Contraindications: Nalmefene HCl Injection is contraindicated in patients with a known hypersensitivity to the product.[1]

Warnings and Precautions: Nalmefene HCl Injection is associated with the following Warnings and Precautions: Use of Nalmefene in Emergencies, Risk of Recurrent Respiratory Depression, Cardiovascular Risks with Narcotic Antagonists, Risk of Precipitated Withdrawal, Incomplete Reversal of Buprenorphine, and Use in Pediatric Patients. Patients treated with Nalmefene HCl Injection should be observed until, in the opinion of the physician, there is no reasonable risk of recurrent respiratory depression.[1]

Adverse Events: The most common adverse reactions (>1%) reported in clinical trials with Nalmefene HCl Injection were nausea (18%), vomiting (9%), tachycardia (5%), hypertension (5%), postoperative pain (4%), fever (3%), and dizziness (3%).[1]

Please consult the Nalmefene HCl Injection Full Prescribing Information found here for complete product information.[1]

Questions regarding the process/requirements for submitting may be sent to: iitprogram@pharma.com

Reference 1: Nalmefene HCl Injection [Full Prescribing Information]. Stamford, CT: Purdue Pharma L.P.

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