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News Release

Opiant Pharmaceuticals Announces Development of O Nalmefene, for Treatment of Opioid Overdose

Based on FDA Feedback, Opiant Intends to Pursue 505(b)(2) De

Opiant Anticipates Submitting an NDA for this Product Can

SANTA MONICA, Calif., Feb. 12, 2018 (GLOBE NEWSWIRE) -- Opiant Pharmaceuticals, Inc. (pharmaceutical company developing pharmacological treatments for addictions, today ar study of its product candidate OPNT003 (intranasal nalmefene), and provided an update o U.S. Food and Drug Administration (FDA) regarding its planned development program. OPN opioid antagonist for the treatment of opioid overdose. Based on feedback from the FDA in to pursue a 505(b)(2) development path, and anticipates the potential to submit a New Drug intranasal delivery device combination in 2020. Nalmefene for injection was previously appr confirmed opioid overdose. The 505(b)(2) pathway allows companies to rely in part on the F previously approved product and to supplement these findings with a more limited set of th as opposed to conducting the full array of preclinical and clinical studies that would typical

Data generated in a Phase I study completed under a clinical trial agreement with the Nati the basis for the FDA meeting. These data demonstrate that an intranasal nalmefene formu enhancer (Intravail®, from Aegis Therapeutics) resulted in rapid increases in plasma levels injection and a comparatively long half-life (6.7-7.8 hours). Naloxone, the only FDA medicati overdose, has a half-life of approximately 2 hours.

"We are pleased with the positive outcome of this meeting and the beneficial guidance rec

Chief Executive Officer of Opiant. "We now have a well-defined development and regulator
the U.S. for the treatment of opioid overdose. Following the feedback received from the FDA
development pathway that allows certain information required for NDA approval to be deri
We anticipate submitting an NDA for OPNT003 in 2020. Based on its profile and the Phase I
potential to be a transformative treatment for opioid overdose, a growing U.S. health epider

"Opiant has full commercial rights to OPNT003 and has submitted a grant application to th
development to an NDA ready stage," continued Dr. Crystal. "Based on the NIH calling for lo
optimistic that this grant will be funded."

Synthetic opioids, such as fentanyl, are now responsible for more overdose deaths than eitl
20,000 synthetic opioid overdose deaths in 2016. Fentanyl and derivatives, such as carfent
long half-life of seven to ten hours that may require repeated dosing of naloxone to overdos
overdose-reversal drug may reduce this burden.

NIH leadership recently called for the development of "...stronger, longer-acting formulation
potency synthetic opioids that are now claiming thousands of lives each year." (Volkow and

An easy-to-use nasal formulation of nalmefene with a rapid onset and long duration of acti
medically trained persons to administer. If approved by the FDA, OPNT003 may be especia
growing number of overdoses are occurring, and where access to emergency medical resp

About Opiant Pharmaceuticals, Inc.

Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing pharmac
National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health (NIH),
relapsing brain diseases which burden society at both the individual and community levels.
delivery technology, Opiant is positioned to become a leader in these treatment markets. O
is approved for marketing in the U.S. and Canada by its partner, Adapt Pharma. Opiant owr
rights to OPNT003. For more information please visit: www.opiant.com.

Forward-Looking Statements

This press release contains forward-looking statements. These statements relate to future
and involve known and unknown risks, uncertainties and other factors that may cause our
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predictions based on our current expectations and projections about future events. You sh
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factors. These and other factors may cause our actual results to differ materially from any f obligation to update any of the forward-looking statements after the date of this press relec occurrence of unanticipated events, except as required by applicable law.

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ABOUT OPIANT

Opiant Pharmaceuticals, Inc. is a specialty pharmaceutical company developing treatments for substance use, addictive and eating disorders.

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