

## **Opiant Pharmaceuticals Announces First Patient Dosed in Confirmatory Pharmacokinetic Study Assessing OPNT003, Nasal Nalmefene, for the Treatment of Opioid Overdose**

**SANTA MONICA, Calif., February 8, 2021** -- Opiant Pharmaceuticals, Inc. ("Opiant") (NASDAQ: OPNT) today announced the dosing of the first patient in a confirmatory pharmacokinetic ("PK") study for OPNT003, nasal nalmefene, for the treatment of opioid overdose. Results from the study are anticipated June 2021.

Deaths resulting from opioid overdose are at record levels, driven in large part by high-potency synthetic opioids, such as fentanyl. In 2017, the National Institutes of Health's ("NIH") leadership called for longer lasting and stronger opioid overdose reversal agents in response to this escalating public health crisis<sup>1</sup>.

"OPNT003 represents a potentially promising new approach for treating opioid overdoses," said Roger Crystal, M.D., CEO and President, Opiant. "In our initial pilot PK study, OPNT003 demonstrated its potential to work quickly, while offering a longer duration of action compared to currently available opioid overdose rescue medicines. The availability of another therapeutic option that has the potential to act more quickly and last longer could provide a valuable tool in the fight against opioid overdose at a time when deaths continue to increase to historic proportions."

The open label, randomized, crossover study will enroll 68 healthy volunteers and determine the pharmacokinetic profile of intranasally administered nalmefene compared to intramuscularly administered nalmefene. Opiant also intends to conduct a separate pharmacodynamic study in healthy volunteers later this year. The development of OPNT003 is supported by grants from the National Institute on Drug Abuse ("NIDA"), part of the NIH, and the Biological Advance Research and Development Agency ("BARDA").

The Company plans to file a 505(b)(2) New Drug Application for OPNT003 with the U.S. Food and Drug Administration by the end of 2021.

### **About Synthetic Opioids**

Synthetic opioids, such as fentanyl, are responsible for more overdose deaths than either heroin or prescription opioids, with over 47,000 fatalities linked to synthetic opioids during the 12 months ending May 2020. Synthetic opioids are more potent than heroin (e.g., fentanyl is 50 times more potent than heroin), and especially dangerous because of a rapid onset of action and long half-life. These properties of fentanyl and related synthetic opioids may require continuous monitoring of overdose victims and repeated dosing with short-acting reversal agents like naloxone to initially resuscitate a patient and prevent relapse.

### **About OPNT003**

OPNT003, nasal nalmefene, is in development as a potent, rapid-onset, long-acting opioid antagonist for the treatment of opioid overdose. OPNT003 is designed as a rescue medication that could be especially useful in treating overdose by high-potency synthetic opioids, such as

fentanyl. OPNT003 is also being considered as an antidote in a civilian mass casualty event. The development of OPNT003 is supported by grants from the NIH and the BARDA. Opiant intends to pursue a 505(b)(2) regulatory pathway for OPNT003.

### **About Opiant Pharmaceuticals, Inc.**

Opiant Pharmaceuticals, Inc., the company that developed NARCAN® Nasal Spray, is building a leading franchise of new medicines to combat addictions and drug overdose.

For more information visit: [www.opiant.com](http://www.opiant.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed, implied or inferred by these forward-looking statements, and among other things, our ability to maintain cash balances and successfully commercialize or partner our product candidates currently under development. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue" or the negative of such terms and other comparable terminology. These statements are only predictions based on our current expectations and projections about future events. You should not place undue reliance on these statements. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors. Additional factors that could materially affect actual results can be found in our Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 4, 2020, including under the caption titled "Risk Factors." These and other factors may cause our actual results to differ materially from any forward-looking statement. We undertake no obligation to update any of the forward-looking statements after the date of this press release to conform those statements to reflect the occurrence of unanticipated events, except as required by applicable law.

### **References**

1. Volkow, N., Collins, F. The Role of Science in Addressing the Opioid Crisis. N Engl J Med. 2017. 377:391-394

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