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BioCorRx Announces Submission of IND Application to the FDA for BICX104, Implantable Naltrexone

ANAHEIM, CA, April 13, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- [BioCorRx Inc.](#) (OTCQB: BICX) (“BioCorRx” or the “Company”), a developer and provider of advanced solutions in the treatment of substance use disorders, announced today that the Company has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for initiation of a clinical trial of BICX104, a naltrexone pellet implant for the treatment of Opioid Use Disorder (OUD). During prior nonclinical studies, several variations of BICX102 were evaluated and the current variation, BICX104, was selected for advancement to the IND stage.

BICX104 is a biodegradable, long-acting subcutaneous pellet of naltrexone being developed in partnership with the National Institutes of Health (NIH) and the National Institute on Drug Abuse under RFA DA-19-002, “[Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose \(UG3/UH3\) \(Clinical Trial Optional\)](#).” The Company had a previous pre-IND meeting with the FDA, at which time the FDA deemed the 505(b)(2) pathway acceptable. The Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act (the “FFDCA”) provides a potentially shortened regulatory approval window. The FDA also stated that the Company may seek eventual dual indication on the product for OUD and Alcohol Use Disorder (AUD).

Bal Brar DVM, PhD, BioCorRx SVP of Drug Development and principal investigator for the NIDA funded research, stated, “We are very pleased to announce this regulatory submission of BICX104, a gradual release implantable pellet for opioid use disorder. This medication has the potential to save numerous lives afflicted by the opioid epidemic devastating the country.”

Brady Granier, President, and Director of BioCorRx, Inc., and CEO of BioCorRx Pharmaceuticals, Inc., stated, “I want to thank all of our partners for helping us reach this milestone for our company. What we were able to achieve during a year of uncertainty with the coronavirus pandemic has been remarkable. We look forward to advancing BICX104 to the clinical phase upon IND clearance so that we can move closer to bringing this important medication to the masses. The opioid epidemic has unfortunately gotten worse since COVID-19 and we hope that BICX104 can soon be available to help those in need.”

According to [data provided](#) by the Centers for Disease Control and Prevention (CDC), over 81,000 drug overdose deaths occurred in the U.S. between June 2019 and May 2020. This data represents the most overdose deaths ever recorded in a 12-month period and experts attribute this increase, at least in part, to the COVID-19 pandemic.

“We’ve been working tirelessly to advance our naltrexone pellet for several years now and with the help of NIDA, our partners and our shareholders, it’s very exciting to be able to take

this next step toward potential FDA approval,” BioCorRx CEO, CFO and Director Lourdes Felix said. “The pandemic has exasperated the opioid epidemic and the urgency to find a way to help treat people who are suffering from substance use disorders is more crucial than ever.”

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About BioCorRx

BioCorRx Inc. (OTCQB: BICX) is an addiction treatment solutions company offering a unique approach to the treatment of substance use and other related disorders. Beat Addiction Recovery is a substance use disorder recovery program that typically includes BioCorRx’s proprietary Cognitive Behavioral Therapy (CBT) modules along with peer support via mobile app along with medication prescribed by an independent treating physician under their discretion. The UnCraveRx™ Weight Loss Program is also a medication assisted weight loss program; please visit www.uncraverx.com for more information on UnCraveRx™. The Company also conducts R&D under its controlled subsidiary, BioCorRx Pharmaceuticals. For more information on BICX and product pipeline, please visit www.BioCorRx.com.

Safe Harbor Statement

The information in this release includes forward-looking statements. These forward-looking statements generally are identified by the words "believe," "project," "estimate," "become," "plan," "will," and similar expressions. These forward-looking statements involve known and unknown risks as well as uncertainties. Although the Company believes that its expectations are based on reasonable assumptions, the actual results that the Company may achieve may differ materially from any forward-looking statements, which reflect the opinions of the management of the Company only as of the date hereof.

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