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BioCorRx Announces IRB Approval to Begin Phase I Clinical Trial of BICX104, an Implantable Biodegradable Naltrexone Pellet for the Treatment of Opioid Use Disorder

ANAHEIM, CA, March 16, 2022 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- **BioCorRx Inc. (OTCQB: BICX) (the “Company”)**, a developer and provider of innovative treatment programs for substance abuse and related disorders, today announced it has received Independent Institutional Review Board (IRB) approval for the Company’s Phase I clinical trial of BICX104, an implantable biodegradable naltrexone pellet for the treatment of opioid use disorder (OUD), which is being developed under BioCorRx Pharmaceuticals, Inc., the Company’s controlled R&D subsidiary.

An IRB is a group that operates under FDA regulations and has been formally designated to review and monitor biomedical research involving human subjects. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research[1].

Brady Granier, President and Director of BioCorRx Inc., stated, “IRB approval of the study marks a key step forward in beginning the first-in-human clinical trial of BICX104. BICX104 is being developed with the goal of improving patient compliance to naltrexone therapy compared to other marketed pharmacotherapies. Naltrexone binds to opioid receptors in the brain thereby blocking some of the effects of alcohol and opioids, as well as reduction of cravings. It can eliminate or reduce the euphoric effects of these substances. We believe that better compliance to naltrexone therapy will ultimately lead to better patient outcomes. We are currently working on scheduling the study start date with our third-party partners and hope to begin screening and enrolling volunteers soon.”

The BICX104 clinical study is a Phase 1, open-label, single-center study in two parallel groups of 12 randomized healthy volunteers to evaluate the pharmacokinetics and safety of BICX104 implantable subcutaneous naltrexone pellets and the marketed once a month intramuscular depot naltrexone injection. The study will be led by Dr. Joel M. Neutel M.D., Director of Research at the Orange County Research Center Orange County Research Center (OCRC), located in Tustin, CA.

BICX104 is being developed in collaboration with the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), under RFA DA-19-002, “[Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose \(UG3/UH3\)](#)”

[\(Clinical Trial Optional\)](#).” The Company has an active Investigational New Drug (IND) status and the FDA has deemed the 505(b)(2) abbreviated pathway acceptable, as well the opportunity to seek eventual dual indication on the product for OUD and Alcohol Use Disorder (AUD).

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 that includes access to concierge on-demand wellness specialists: nutritionists, fitness experts and personal support from behavioral experts; please visit www.uncraverx.com for more information on UnCraveRx®. The Company also controls BioCorRx Pharmaceuticals, a clinical stage drug development subsidiary currently seeking FDA approval for BICX104, an implantable naltrexone pellet for treatment of alcohol and opioid use disorders. For more information on BICX and its subsidiary 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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[1] <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials>



Source: BioCorRx Inc