NIH begins clinical trial of new medication for alcohol use disorder

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A clinical trial investigating a potential treatment for alcohol use disorder (AUD) was announced by the National Institute of Alcohol Abuse and Alcoholism (NIAAA). The study will assess the safety and efficacy of gabapentin enacarbil (HORIZANT) in extended-release tablets for treating moderate to severe AUD. NIAAA is part of the National Institutes of Health.

Gabapentin is already widely prescribed to treat pain conditions and epilepsy. HORIZANT contains gabapentin enacarbil, a prodrug of gabapentin that is converted to gabapentin in the body. A prodrug is an inactive form that is converted to an active form through metabolic processes. Gabapentin enacarbil is currently approved in the U.S. for the treatment of restless leg syndrome (RLS) and nerve pain caused by shingles. NIAAA is working in partnership with the biopharmaceutical company XenoPort, Inc., of Santa Clara, California, which will supply gabapentin enacarbil for the study.

"This multi-site, well-controlled clinical trial will allow us to evaluate the safety and effectiveness of gabapentin enacarbil in treating alcohol use disorder," said George F. Koob, Ph.D., director of NIAAA. "Gabapentin has shown promising results in earlier clinical trials, and the development of new medications is an important component of our commitment to broaden the range of treatment options for people with AUD."

NIAAA will enroll 346 patients in a randomized, double blind, placebo-

controlled clinical trial of gabapentin enacarbil in patients with AUD at 10 sites across the United States. The study will assess the safety and efficacy of 1200 mg of gabapentin enacarbil (administered in two daily doses of 600 mg), compared with placebo, to reduce drinking in patients who report four or more symptoms of AUD, as defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Eligible subjects will receive either gabapentin enacarbil or placebo for 26 weeks. The study will evaluate whether participants using the medication are more likely to abstain from heavy drinking during the last four weeks of treatment.

In a recent study supported by NIAAA, researchers at The Scripps Research Institute in La Jolla, California, found that alcohol dependent patients using gabapentin were more likely than those taking placebo to stop drinking or refrain from heavy drinking. Scientists at XenoPort designed gabapentin enacarbil extended-release tablets to address certain limitations of drug levels in the body, which may make it a more attractive treatment option for people with AUD.

Alcohol use disorder affects about 16.6 million adults in the United States and has an estimated societal cost of $223.5 billion each year, primarily from lost productivity, but also from health care and property damage costs. Currently, three medications are approved by the U.S. Food and Drug Administration for treating alcohol dependence: disulfram, an older drug that blocks the metabolism of alcohol and causes nausea; acamprosate, which helps support abstinence and can ease symptoms of withdrawal; and naltrexone, which can help people reduce heavy drinking.

More information: For further information about the NIAAA clinical trial of gabapentin enacarbil for the treatment of AUD, please visit: www.clinicaltrials.gov/ct2/show/NCT02252536.