

**MIAMI-BASED CLINICAL TRIAL COMPANY  
TESTS FIRST DRUG FOR PEOPLE WHO OVERUSE MARIJUANA**

***Segal Trials Runs Phase 2B Study Of Aelis Farma's AEF0117-202***

MIAMI, FL (October 7, 2022) – Segal Trials, a privately held network of clinical research sites throughout South Florida, announced it will conduct a Phase 2B study to investigate a new drug, AEF0117-202, created by Aelis Farma to treat cannabis use disorder. No approved pharmacological treatments exist for people suffering from cannabis use disorder, so this randomized, double-blind, parallel group trial has the potential to pave the way toward a major advancement in the world of substance abuse treatment. For the first time, people who overuse marijuana may have access to a pill that can help them kick their habit.

AEF0117-202 is the first clinical candidate in a new pharmacological class of drugs, sCB1-SSi, for people who use cannabis at least five days per week. The orally administered drug will be given to a group of study participants while a second group will receive a placebo.

“Chronic marijuana use can drastically impact individuals’ social and professional lives in many ways, from poor work or school performance to mood disorders,” said Rishi Kakar, MD, chief scientific officer and medical director at Segal Trials. “This Phase 2B study gets us closer to the prospect of effectively treating people who want to end their reliance on cannabis but don’t have the tools to quit.”

Marijuana is the most commonly used drug in the United States, and, while drugs like cocaine and nicotine are far more addictive, up to 30% of regular cannabis users develop a dependence on the drug. What’s more, people who begin using cannabis before the age of 18 are four to seven times more likely to develop cannabis use disorder than adults.

People with a marijuana or cannabis dependence may feel withdrawal symptoms when not taking the drug, including irritability, mood and sleep difficulties, decreased appetite, cravings, restlessness, and even physical discomfort. Behavioral intervention, including cognitive-behavioral therapy, has shown to help patients treated for marijuana addiction. For some, though, therapy does not work, and few alternatives exist.

“The potency of cannabis products has increased significantly over the past twenty years,” which may have contributed to the rise of cannabis-related adverse effects,” said, Dr. Kakar. “With no approved drugs available to treat chronic cannabis use, Aelis Farma’s drug has the potential to make a significant, positive impact for millions of marijuana users seeking to end their dependence on cannabis.”

The Segal team will conduct the trial at its Center for Psychedelic and Cannabis Research, which was specifically built using pharmaceutical and regulatory feedback to create a structured inpatient environment that ensures both patient safety and patient comfort. Segal Trials also recently announced it was the first in the United States to conduct a large, randomized clinical trial to investigate MM-120 (LSD D-tartrate) to treat Generalized Anxiety Disorder (GAD).

For more information about Segal Trials, or to schedule an interview, please contact Meieli Sawyer at [msawyer@weinbachgroup.com](mailto:msawyer@weinbachgroup.com).

### **About Segal Trials**

[Segal Trials](#), founded in 1998, is a privately held network of research sites throughout South Florida conducting Phase I-IV research trials that have led to 54 FDA-approved medications and devices. The company’s trials focus on psychiatry, neurology, addiction, insomnia, infectious diseases, vaccine development, and women’s health; and it runs trials in outpatient, inpatient, PSG, and residential care facility settings.