



## TECHNOLOGY

# 1-THP/LDN (low dose Naltrexone) combination as medication for substance dependence disorder

## OVERVIEW

Addiction is a complex and costly disorder that is difficult to treat due to the effects on multiple brain circuits involved in reward and motivation, learning and memory, and inhibitory control over behavior(s). Treatment options remain limited and addiction to alcohol and illicit drugs cause significant problems and economic burden on society. UMB inventors address this issue through the combination therapy of 1-THP (dopamine antagonist) and low dose Naltrexone (opioid antagonist) to treat addiction-related diseases and disorders, with particular focus on substance-dependent diseases or disorders. 1-THP, an active compound isolated from the Chinese herbal medicine Yanhusuo, has been used in clinical practice as an analgesic (commercial name: Rotundine) in China for more than 40 years. Naltrexone is a known treatment for addiction in the United States but is limited to the treatment of alcohol dependence. Preliminary studies indicate low-dose Naltrexone in combination with 1-THP show significant improvement in biological activity over Naltrexone or 1-THP alone, as measured with conditioned placement preference, locomotion, and relapse behavior. More specifically, the combinatory effect comes from the inhibition of dopamine (DA) receptors by 1-THP in conjunction with the opioid inhibition of LDN. Additional benefits with the 1-THP/LDN combination was seen with the reduction in the sedation side effect of 1-THP as demonstrated in rodent models.

## APPLICATIONS

A five year national study by The National Center on Addiction and Substance Abuse at Columbia University (CASA Columbia) revealed that 16% of the U.S. population suffers from an addiction illness, yet only an estimated 10% received any form of treatment. However, those that do receive treatment often are treated by under-qualified, under-equipped individuals that cannot provide adequate care. It is estimated 40 million people in the US qualify as addicts with another 80 million that use substances that threaten their health and safety (e.g. tobacco, alcohol, etc). Available medical treatment options are typically geared to address acute conditions and do not address the necessary long term disease management of addiction. Treatment options on the market include Chantix (Pfizer) for the treatment of nicotine addiction, Vivitrol (Alkermes) and Campral (Forest Laboratories) for the treatment of alcohol dependence, and Subutex/Suboxone (Reckitt Benckiser) for the treatment of opiate dependence. The demand for safe, effective treatments will drive the world market for addiction pharmacotherapies and is forecasted to increase by 19% to \$3.8 billion in 2016 with the biggest demands in the areas of alcohol, narcotic, and nicotine dependencies.

## ADVANTAGES

Naltrexone is a non-selective opioid antagonist that was approved by the FDA for the treatment of alcohol and opioid addiction in 1984. Minimal safety concerns 1-THP safety trials currently ongoing by the inventor 1-THP has a long track record of use in China (Rotundine) Reduced effective dose of low dose naltrexone

## STAGE OF DEVELOPMENT

Preliminary studies conducted in cocaine addiction extinction and reinstatement utilizing conditioned placement preference, locomotion, and relapse behavior

## R&D REQUIRED

Dosing optimization and safety studies required

## LICENSING POTENTIAL

UM seeks to develop and commercialize by an exclusive or non-exclusive license agreement and/or sponsored research with a company active in the area.

## CONTACT INFO

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## Additional Information

### INSTITUTION

University of Maryland, Baltimore

### PATENT STATUS

US Patent 10,016,413 issued 07/10/2018

### CATEGORIES

- Therapeutics

### INVESTIGATOR(S)

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### EXTERNAL RESOURCES

- [l-tetrahydropalaminine: a potential new medication for the treatment of cocaine addiction.](#)
- [Naltrexone depot formulations for opioid and alcohol dependence: a systematic review.](#)

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