NOVEL CNS DRUG DELIVERY SCHEME UTILIZING THE OLFATORY NERVE
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Industry Sector(s):
Product Category:

Opportunity Overview

Suicide has become an increasingly formidable opponent for the Army, and with recent increased rates, the challenge continues to escalate. Military leadership has been looking for a solution to this widespread problem which can be triggered differently among the victims, making it difficult to find an effective solution. Dr. Michael Kubek, from the Indiana University School of Medicine believes he has found a solution that may be able to bridge the initial fragile gap of anti-depressant therapies and stabilize soldiers until their medications kick in. A natural releasing compound called thyrotropin-releasing hormone (TRH) has known anti-depressant characteristics. The challenge has been its direct delivery to its effective site, the central nervous system (CNS) due to its inability to cross the blood-brain barrier. Dr. Kubek and his colleagues have developed a novel delivery method for TRH, in the form of a nanoparticle nasal spray, which can effectively deliver the hormone through the olfactory nerve and into the brain. Increased levels of TRH can effectively and quickly reduce suicidal thoughts, depression and bipolar disorders. Dr. Kubek has been awarded a $3 million grant from the Department of Defense to develop this delivery mechanism.

Markets & Applications

The immediate market and applications for intranasal delivery of TRH are in military and civilian patient populations suffering from depressive disorders as a bridge compound during the onset of their anti-depressant medications. TRH’s potential anti-convulsant therapeutic effects have taken Dr. Kubek in another direction as well, evaluating the compound as a possible non-invasive treatment for infantile spasms, a rare, uncontrollable form of epilepsy that affects children 6 to 12 months old. As a delivery method, nanoparticle coated therapeutics administered through a nasal spray could quickly become the preferred pharmacological route to target brain physiology. This would open up many other doors outside of the depressive and anti-convulsant space, potentially resulting in widespread adoption and vast market applications.

Competitive Advantage/Value Propositions

The intranasal nanoparticle delivery of TRH to the CNS via the olfactory nerve is advantageous over oral or injectable vehicles due to its inability to cross the blood-brain barrier. Many of today’s anti-depressants contain a black box warning label for suicidal ideation in young adults, opening opportunities for a bridge compound such as TRH. There are opportunities available in the epilepsy space as well, give that this compound has shown anti-convulsant activity.
Researcher Biography

**Dr. Michael Kubek** received his BS in Biology /Chemistry from the University of Dayton in 1967, followed by his MS in Endocrinology in 1969. He later received his PhD from the University of Rochester School of Medicine in 1975 and followed with a Postdoctoral Fellowship from Northwestern University School of Medicine for three years. He joined the departments of Anatomy and Cell Biology and Psychiatry at the Indiana University School of Medicine in 1987. He is currently an Associate Professor of Anatomy and Cell Biology and an Associated Professor of Neurobiology in the Department of Psychiatry.

Development Plans/Needs

1. As part of the three year DOD grant, Dr. Kubek will be closely collaborating with Dr. Abraham Domb, professor of pharmacology at Hebrew University in Jerusalem, to develop an optimum nanoparticle-neuropeptide combination designed to deliver the drug effectively. This testing will likely take about a year.

2. The second and third years of the grant will focus on clinical trials, which would be directed by Indiana University psychiatry professors Alan Breier and Andrew Goddard through the Clinical Research Center of the Indiana Clinical and Translational Sciences Institute (CTSI).

3. For the other indications such as epilepsy, Citizens United for Research in Epilepsy supported some of the proof of concept re