

**PALUPA Medical Ltd. (Incubator Company by The Cyprus Institute of Neurology and Genetics.)**

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**Project Title:**

**Novel Oral Nutraceutical Intervention PLP10 for the Treatment of Relapsing-Remitting Multiple Sclerosis: A Multicenter, Parallel-group, Phase III, Double-blind, Randomized, Placebo-Controlled, Add-on with Interferon Beta, Trial of Efficacy and Safety.**

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**Clinical Trial Protocol and Project Design**

**FINAL**

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**PALUPA Medical Ltd.**

## **PROTOCOL**

(The Clinical Trial is registered as required ([ClinicalTrials.gov](http://ClinicalTrials.gov)) and the Protocol will be posted on PALUPA and CING Website. PLP10 is a property of PAUPA Medical Ltd under a USA provisional patent Application Number 61469081).

### **Novel Oral Nutraceutical Intervention PLP10 for the Treatment of Relapsing-Remitting Multiple Sclerosis: A Multicenter, Parallel-group, Phase III, Double-blind, Randomized, Placebo-Controlled, Add-on with Interferon Beta, Trial of Efficacy and Safety.**

(Magnetic resonance Image of Nutraceutical Efficacy on Relapsing-MS Autoimmune Lesions)- The **MINERAL** study

#### **Purpose**

The purpose of this study is to determine the safety and efficacy of PLP10 in the treatment of individuals, who have been diagnosed with relapsing remitting multiple sclerosis (MS). This is a phase IIIa trial (supplementary to the previous single center trial), the final stage of development of the intervention. PLP10 in general, is expected to normalize structural molecules of cell membranes, normalize phospholipase function and immune system, normalize endoplasmic reticulum function/stress, gene expression, quench free nitro- and oxo- free radical derivatives, elevate anti-inflammatory cytokines, halt apoptosis, normalize metalloproteinases function, supply major building blocks for myelin formation/reformation, promote remyelination and neuroprotection and so halt inflammation and all related cascade of events leading to the MS pathogenesis. All these simultaneously involved pathogenic mechanisms as a result of multiple factors leading to this complex disease are thought to be the cause that can result in lesions (small areas of damage) in the brain and spinal cord, the central nervous system (CNS). These lesions are thought to be the cause of relapses and disability in MS.

**Condition** : Multiple Sclerosis, Relapsing-Remitting

#### **Intervention**

Drug: PLP10 (oral cocktail formula of structured molecules, lipids and vitamins)

Drug: Placebo

**Phase** : III

**Investigator/Trial Location**: Cyprus/Greece