

PH10

PH10 nasal spray for acute treatment of Depression

An investigational intranasal spray antidepressant known for now as PH10 shows early promise in addressing two major unmet needs in the treatment of major depressive disorder: faster-acting drugs with novel mechanisms of action.

PH10, a representative of a family of our proprietary pherine compounds, is being investigated to provide therapeutic advantages when used as antidepressant treatment, particularly as an adjunct medication during the early stages of the antidepressant treatment period, because of the pherine's potential to have a very rapid onset of effect and very low incidence of side effects. Using PH10 nasal spray, Pherin completed an initial pilot study, outside the U.S., in humans with favorable results.

Subsequently, an exploratory Phase 2A randomized study was conducted in 30 patients diagnosed with major depression, to compare the efficacy and safety of 400 and 800 nanogram PH10 and placebo administered intranasally in spray form. Patients self-administered PH10 nasal spray up to 4 times daily during 9 consecutive weeks and were evaluated in the clinic at the end of each treatment week, using validated psychometric instruments. The preliminary analysis of the results shows significant dose dependent effect of PH10 nasal spray on Hamilton Depression scores, which is different from the effect of treatment with placebo. The clinical efficacy of 800 nanogram PH10 nasal spray on Hamilton Depression scores was greater than that of 400-nanogram PH10, increased progressively starting on the first day of treatment and continued along the 98-week treatment period. The rapid onset of effect of PH10 nasal spray reported in the present study is very promising and may help mitigate the symptoms of depression with a much faster onset of efficacy, and safer than conventional antidepressants.

Depression is a mood disorder characterized by extreme and persistent disruption of a person's usual emotional state, affecting physical health as well as how the sufferer feels, thinks and behaves toward others. Depression is a physical disorder resulting from an imbalance of important chemicals within the brain. Because of its disabling effects and the possibility of suicide, major depression requires treatment. Depression in some form affects 20% of all women, 10% of all men and 5% to 10% of all adolescents worldwide. It is the most common psychiatric illness in the United States, afflicting an estimated 17.6 million people each year. The common time of onset of depression is early middle age, and depression is particularly common among the elderly. It is estimated that untreated depression costs American employers as much as \$43.0 billion per year through sick days, lost productivity, employee turnover and medical bills.

The most commonly used treatments for depression are antidepressant medications, psychotherapy or a combination of the two. The major types of antidepressants currently available commercially include tricyclic antidepressants, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors and so-called new-generation antidepressants. All of these medications have significant side effects, and many have limitations related to the situations and patients in which they can be used. In most cases antidepressant medications must be taken for four to six weeks before they begin to produce substantial improvement in a depressed person's mood. Furthermore, finding the right antidepressant at exactly the right dosage for a given individual usually involves a substantial period of trial and adjustment.