PHERIN PHARMACEUTICALS REPORTS FAVORABLE CLINICAL, REGULATORY, AND INTELLECTUAL PROPERTY ACTIONS ON NOVEL INTRANASAL MEDICATION FOR ACUTE TREATMENT OF SOCIAL ANXIETY DISORDER AND ISSUANCE OF PATENTS IN THE U.S.A. AND OTHER MAJOR COUNTRIES

Press Release
Source: Pherin Pharmaceuticals Inc., Los Altos, California
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Pherin Pharmaceuticals announced today that a Phase II clinical trial showed that its proprietary compound PH94B demonstrated significant benefits in the acute treatment of symptoms of Social Anxiety Disorder (Social Phobia). Based on the positive study results, Pherin has met with the US Food & Drug Administration to plan a Phase III pivotal study of PH94B for the acute treatment of Social Anxiety Disorder. Also, Pherin has received Notification of Issuance from the US Patent & Trademark Office for its patent application covering the acute treatment of Social Anxiety Disorder with PH94B and similar allowances in the European Union, Japan, China and other major countries.

Phase II Study Results
The Phase II study was conducted in three centers to evaluate the effect of PH94B for the acute treatment of symptoms of Social Anxiety Disorder, as well as its safety and tolerability. It was a randomized, double-blind, single-administration, placebo-controlled study in 91 Social Anxiety Disorder patients, using validated psychometric scales. PH94B (800 nanograms) was evaluated against placebo. PH94B significantly improved the primary efficacy endpoints (social performance and social interaction anxiety) within 10 minutes of administration. Secondary efficacy endpoints for the trial included additional anxiety response assessments and other symptom assessments at various time points. Safety evaluations were made throughout the clinical trial period. PH94B showed clinical efficacy to reduce Social Anxiety Disorder symptoms in 75.6% patients as compared with placebo (37% only). The PH94B treated group improvement exceeded the placebo treated group during a Public Speaking challenge (t= 3.16; p< .01) and also during a Social Interaction challenge (t= 2.67; p< .01).

“These results are impressive and position PH94B favorably in efficacy, safety, route of administration and dosing convenience against other existing therapeutic options which require chronic dosing and have concurrent side effects” said Dr. Dr. Louis Monti, Executive Vice President of Pherin Pharmaceuticals. “We are enthusiastic about sharing
data with interested companies to co-develop PH94B. If the magnitude of benefits shown in this Phase IIB study is confirmed in a larger-scale Phase III study, intranasal PH94B could represent a major improvement in the way Social Anxiety Disorder will be treated in the future”.

There were no adverse events associated with PH94B and the medication was well tolerated. Pherin attributes these results to the unique formulation of PH94B.

**Regulatory Interaction**
Pherin Pharmaceuticals also reports that it held a successful End-of-Phase II meeting with the U.S. Food and Drug Administration regarding PH94B. Pherin is in the process of submitting the safety reports of four favorable studies and an updated version of the Phase 3 clinical protocol in order to enable Pherin to move into Phase 3 clinical trials in the very near term.

**Intellectual Property**
Pherin also reports that the US Patent & Trademark Office has issued a Notice of Allowance for Pherin’s patent application covering the acute treatment of Social Phobia with PH94B. A corresponding application in Mexico and Australia have already issued as patent; while corresponding applications in China, Japan and the European Patent Office have been allowed; and applications remain pending in several other countries. Pherin expects these applications and patents to provide broad intellectual property protection for the use of PH94B in the acute treatment of Social Anxiety Disorder.

**About PH94B and Social Anxiety Disorder**
PH94B is one of a new class of Pherin proprietary compounds called *pherines*. With intranasal spray administration, it acts locally on peripheral receptors from nasal chemosensory neurons that connect to the hypothalamic-limbic areas of the brain. This mechanism of pharmacological action, the rapid onset of effect, and the excellent safety and tolerability profile make PH94B an excellent product candidate for the acute treatment of patients with Social Anxiety Disorder.

Social Anxiety Disorder, also called Social Phobia, is reportedly the most common anxiety disorder, with a lifetime prevalence of 13-14%. Social Anxiety Disorder is characterized by a persistent and unreasonable fear of one or more social or performance situations, where the individual fears that he or she will act in a way or show symptoms that will be embarrassing or humiliating, leading to avoidance of the situations when possible and anxiety or distress when they occur. There are two types: generalized Social Anxiety Disorder, where the fears are related to both social and performance situations; and discrete Social Anxiety Disorder, where the fears are related to particular performance anxiety situations only, such as public speaking. These fears can have a significant impact on the person’s employment, social activities and overall quality of life. Social Anxiety Disorder is commonly treated chronically with antidepressants, which have a slow onset of action and side effects that may make them unattractive to sufferers from Social Phobia. There are no acute treatments for generalized Social Anxiety Disorder; and the current acute treatments for discrete Social Anxiety Disorder
are beta-blockers, which must be taken 30-60 minutes before the expected time of the performance situation and are associated with their own side effects.

**About Pherin**

Pherin Pharmaceuticals, Inc. of Los Altos, California, is a clinical stage drug development company that has developed a family of leading and innovative proprietary compounds called *pherines* that bind to peripheral receptors in the nasal passages that affect the hypothalamus and the limbic system and induce proven behavioral, neuropsychiatric and neuroendocrine effects in humans. Among Pherin’s extensive library of pherines there are molecules being studied for their potential therapeutic application including treatment of depression, premenstrual dysphoric disorder and cognition enhancement.

Pherin is the leader in the development of pherines, having pioneered breakthrough discoveries of the behavioral and neuroendocrine effects of a large number of pherines that can be administered airborne to the nasal passages in nanogram or low microgram range. Pherin’s mission is to improve people’s lives by pioneering novel healthcare products that make distinct improvements over other treatments.

**Disclaimer**

This press release contains certain forward-looking statements relating to Pherin and the future development of PH94B, its safety and effectiveness in treating Social Phobia, and its patent position. Such forward-looking statements reflect the current views of Pherin regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with PH94B to be materially different from any future results, performance or achievements expressed or implied by such statements.

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