

CeNeRx BioPharma Initiates Phase II Clinical Trial of Its Novel Antidepressant Agent *Tyrima*[™]

RESEARCH TRIANGLE PARK, NC, October 17, 2008 -- CeNeRx BioPharma, Inc., a clinical stage company developing and commercializing innovative treatments for diseases of the central nervous system, today announced that it has initiated a Phase II clinical trial for its lead product candidate *Tyrima*[™] for the treatment of major depressive disorder (MDD). *Tyrima* is a selective and reversible member of a novel class of drugs known as RIMAs, or reversible inhibitors of monoamine oxidase A (MAO-A). The primary objective of this Phase II trial is to evaluate the antidepressant efficacy of *Tyrima* in patients with confirmed MDD. The trial design incorporates a number of features intended to reduce the variability and placebo response often observed in MDD clinical trials.

The randomized, double-blind, placebo-controlled Phase II trial will enroll approximately 272 patients with moderate to severe MDD who will receive either *Tyrima* or placebo for six weeks. The primary study objective of antidepressant efficacy will be assessed using the Montgomery-Asberg Depression Rating Scale (MADRS). Secondary objectives of the study include evaluation of safety, tolerability, and pharmacokinetics of *Tyrima*. The trial design was supported by a *Tyrima* Phase I safety database of 106 subjects and a PET (positron emission tomography) study that yielded critical insight into the dose-response relationship of *Tyrima*. A number of patients are already randomized in the trial and initial results are expected by the end of 2009.

"*Tyrima* has the potential to be the first triple-action antidepressant with a safety profile appropriate for the treatment of a broad population of patients with depression, and we are committed to generating robust clinical data from this Phase II trial," said Dr. Daniel Burch, Executive Vice President of R&D and Chief Medical Officer of CeNeRx. "We worked closely with experienced MDD clinical trial experts, disease specialists, and biostatisticians to incorporate a number of features in the study design intended to manage the issues that can confound antidepressant clinical trial results."

Depression clinical trial expert Dr. Norman Rosenthal, Medical Director of Capital Clinical Associates and one of the lead investigators of the *Tyrima* Phase II study noted, "The CeNeRx team gets high marks for designing a first-class clinical trial. Recent efforts to test new antidepressants have encountered technical difficulties, such as a high placebo effect, which the current trial works hard to avoid. I am optimistic that the present trial should enable us to assess the potential of *Tyrima* as a potentially valuable new antidepressant agent."

Similar to the mechanism of conventional monoamine oxidase A inhibitors (MAOI), the triple-action mechanism of *Tyrima* elevates the levels of three key neurotransmitters (serotonin, norepinephrine and dopamine) that positively affect mood and anxiety, compared to the one or two neurotransmitters addressed by most current antidepressant drugs. This triple-action mechanism has the potential to provide improved antidepressant efficacy in some patients, while the selectivity and reversibility of *Tyrima* are expected to reduce or eliminate the risk of food-associated cardiovascular side effects of conventional MAOIs.

"A substantial subset of patients suffering from depression responds much better to treatment with MAOIs than other therapies, yet the risk of food-associated cardiovascular side effects of conventional MAOIs have greatly restricted their use, to the disadvantage of our patients," said

Dr. Alexander Bodkin, a Tyrima Phase II investigator and Director of the Clinical Psychopharmacology Research Program at McLean Hospital of Harvard Medical School. “A novel agent such as Tyrima with proven MAOI activity in the CNS and a good safety and tolerability profile would be a valuable option for the many patients whose depression is refractory to treatment with currently prescribed antidepressant drugs.”

CeNeRx has worldwide rights to develop and commercialize Tyrima. This compound, which could be the first RIMA antidepressant available in the U.S. market, has patent protection beyond 2027.

About CeNeRx BioPharma

CeNeRx is a privately held clinical stage biopharmaceutical company developing and commercializing innovative treatments for diseases of the central nervous system. CeNeRx's most advanced compound, a reversible inhibitor of monoamine oxidase, or RIMA, has entered Phase II development for the treatment of major depressive disorder. RIMAs may have efficacy advantages over current agents for depression and are expected to have a good safety profile. The company is also developing its pipeline of selective cannabinoid compounds that have recently completed successful preclinical proof-of-concept studies for the treatment of pain, glaucoma and obesity. More information about CeNeRx BioPharma can be found at www.cenerx.com.

Contact:
GendeLLindheim BioCom Partners
Barbara Lindheim
212 918 4650