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**CENERX ANNOUNCES FDA IND APPROVAL FOR ITS NEUROPROTECTIVE AGENT IN CHEMOTHERAPY-INDUCED NEUROPATHY AND RESULTS FROM FIRST HUMAN STUDY**

***—Orally Active Enhancer of Human Nerve Growth Factor Has Demonstrated Promising Activity and Good Safety in Early Studies—***

***—CEO Barry Brand to Serve as Panelist on BIO CEO Therapeutic Workshop Panel—***

**RESEARCH TRIANGLE PARK, NC, February 9, 2011** -- CeNeRx BioPharma, Inc., a clinical-stage company developing and commercializing innovative treatments for diseases of the central nervous system (CNS), today announced FDA approval of its IND and reported the first clinical results in humans for CXB909, a novel agent that has demonstrated utility in preclinical models of neuroprotection and neurodegenerative disorders. CXB909 is a small molecule, orally active agent that enhances the effects of nerve growth factor (NGF) and is also believed to promote synthesis of acetylcholine. CeNeRx is now preparing to launch further Phase I studies of CXB909 targeting chemotherapy-induced peripheral neuropathy as its first potential indication.

CXB909 appears to enhance cholinergic tone and is a downstream enhancer of the effects of NGF, a naturally occurring neurotrophic factor that is important for the function and survival of several types of neurons. NGF may help prevent or reverse the neuronal damage that is implicated in the peripheral neuropathies associated with cancer chemotherapy, diabetes, kidney disease, and other conditions. The degeneration of certain neurons associated with Alzheimer's disease and Huntington's disease may also be ameliorated by increased levels of NGF.

Past attempts to use recombinant versions of NGF to prevent and treat neuron-damaging conditions were stymied by its lack of drug-like properties. In contrast, CXB909 crosses the blood-brain barrier, has a long half-life and is orally available. Results from an initial Phase I study in 26 subjects showed that single doses of CXB909 administered orally resulted in good levels of drug exposure and were well-tolerated.

"CXB909 has been shown to increase the action of endogenous NGF and enhance cognition and neuroprotection in multiple preclinical models, and it has demonstrated good safety in animal and early human studies," said Dr. Daniel Burch, Executive Vice President of R&D and Chief Medical Officer of CeNeRx. "CXB909's cognitive-enhancing effects are produced by a mechanism that is complementary to current cholinesterase inhibitors, suggesting that it could be developed as a stand-alone, add-on or combination therapy for the treatment of neurodegenerative disorders. We look forward to advancing CXB909 in the clinic for its first indication as a potential treatment for chemotherapy-induced neuropathy."

In preclinical studies, CXB909 enhanced the action of NGF *in vitro* in biochemical and cellular assays, amplifying its activity almost seven-fold. CXB909 was neuroprotective in a variety of cellular assays and in animal models of neuropathies and neurodegenerative diseases, including chemotherapy-induced neuropathy, for which there is currently no approved treatment. In two well-validated preclinical models, CXB909 concomitantly administered with the cancer drug taxane prevented nerve damage as measured by nerve conduction velocity, an objective parameter that is highly predictive of nerve function in humans.

“Our aging population is at risk for devastating neuropathic and neurodegenerative diseases that lack effective therapies, so we view the initiation of our clinical program for CXB909 as especially important,” said Barry Brand, Chief Executive Officer of CeNeRx. “We intend to assess CXB909 in a number of relevant conditions, beginning with chemotherapy-induced neuropathy, a disabling and dose-limiting side effect of cancer treatment that is an attractive commercial target with a relatively straightforward pathway to clinical development and regulatory review.”

CXB909 was licensed from Krenitsky Pharmaceuticals Inc., which also licensed the RIMA series of selective and reversible monoamine oxidase inhibitor compounds to CeNeRx. The lead compound in that program, *TriRima*<sup>™</sup>, is currently in a Phase II trial for treatment resistant depression.

Separately, CeNeRx announced that Mr. Brand has been selected to serve as a panelist for the 2011 BIO CEO Therapeutics Workshop, “Psychiatry: Major Depressive Disorder - A Lifeline for the Pipeline.” The workshop will be held Tuesday, February 15, from 3:00 – 3:55 pm EST. CeNeRx will also participate in the BIO One-on-One Partnering program at the conference.

The 13<sup>th</sup> Annual BIO CEO Investor Conference will be held at the Waldorf Astoria Hotel in New York City February 14-15, 2011. For more information, visit <http://bio.org/bioceo/default.aspx?id=420>

#### **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, is in Phase II development for treatment resistant depression. RIMAs may have efficacy advantages over current agents for depression and are expected to have a good safety profile. The company’s CNS pipeline also includes clinical-stage hypothalamic-pituitary adrenal (HPA) axis modulators for the treatment of a variety of CNS disorders including anxiety and depression; a small molecule, orally active agent for the prevention and treatment of neuropathies and neurodegenerative disorders; and a series of selective cannabinoid compounds that have recently completed successful preclinical proof-of-concept studies for the treatment of pain, glaucoma and spasticity. The company’s investors include Perseus Soros Biopharmaceutical Fund, L Capital Partners and Pappas Ventures. For more information, visit [www.cenerx.com](http://www.cenerx.com)