

DIFFUSION PHARMACEUTICALS INITIATES HUMAN TRIAL OF LEAD DRUG CANDIDATE, TRANS SODIUM CROCETINATE (TSC)

Posted at 16:59h in [Press Releases](#) by [diffusion](#) • [Share](#)

CHARLOTTESVILLE, VA – March 16, 2007 – Diffusion Pharmaceuticals LLC, a clinical-stage drug discovery and development company, today announced the initiation of human testing of *trans sodium crocetinate* (TSC), its lead drug candidate. TSC, which uses a novel mechanism of action to enhance the diffusion of oxygen into tissue, is being studied as a potential treatment for numerous diseases involving oxygen deprivation at the cellular level (hypoxia). The Phase I safety trial began on March 12, 2007, following a successful review by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for TSC, which was completed in February 2007.

“Commencement of human trials is the most important milestone for Diffusion Pharmaceuticals to date, marking our transition from a preclinical drug-development company to a clinical-stage company,” says David G. Kalergis, Chief Executive Officer of Diffusion Pharmaceuticals. “We look forward to rapidly advancing TSC to Phase II trials later this year after successful completion of this initial safety study.”

Diffusion completed FDA-required IND-enabling animal toxicology studies in the third quarter of 2006. These studies confirmed a safety profile for TSC showing no appreciable adverse findings and documenting very high no adverse effect levels (NOAEL). The on-going Phase I safety trial is a double-blind, placebo-controlled, dose-escalation study in 48 normal healthy volunteers to assess TSC’s pharmacokinetics and tolerability.

In preclinical studies, TSC has been shown to increase the body’s ability to use oxygen by up to 30 percent, which is a therapeutically significant result across a range of dangerous physical conditions involving oxygen deprivation. In animals subjected to induced ischemic stroke, the area of damaged brain tissue is significantly reduced in TSC-treated animals compared to untreated (control) animals. Also, animals suffering severe blood loss have a higher rate of survival if treated with TSC. In addition, TSC has been shown in animal models to increase the diffusion of oxygen into hypoxic cancerous tumor tissue, rendering the cancer more susceptible to radiation therapy.

John A. Jane, MD, PhD, David W. Weaver Professor of Neurosurgery and

Director of Neurosurgical Training, University of Virginia and Editor, Journal of Neurosurgery, has noted, “Diffusion’s new pharmaceutical technology will revolutionize healthcare by improving the management of stroke, myocardial infarction, and respiratory disease.”

The ability to enhance oxygen diffusion into hypoxic tissue represents a transformative technology, with potentially far-ranging implications for human health and the practice of medicine. If approved by the FDA, the patient population for successful Diffusion-owned, patent-protected molecules such as TSC could be well over 34 million patients per year in the U.S. alone.

To date, Diffusion Pharmaceuticals, which is privately owned and financed, has received \$2.6 million in research grants from the Office of Naval Research (ONR) to help fund TSC's development.