

BHR PHARMA, LLC

A Besins Healthcare Company

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BHR Pharma Announces Phase 3 SyNAPSe Study of Progesterone as a Neuroprotective Agent for Traumatic Brain Injury

Herndon, VA – (September 8, 2009) – [BHR Pharma, LLC](http://www.bhr-pharma.com) (BHR) announced today that it will initiate a global, Phase 3, multi-center pivotal trial (www.synapse-trial.com) to evaluate the effectiveness of its proprietary BHR-100 intravenous progesterone infusion product as a neuroprotective agent for treating severe traumatic brain injury (TBI) patients in early 2010.

BHR will enroll approximately 1,200 patients with severe (Glasgow Coma Scale scores of 4-8), closed-head trauma TBI at 100-120 medical centers in the United States, Europe, Israel and additional countries.

Randomized patients will receive a five-day (120-hour) intravenous infusion of progesterone or placebo. Unlike intravenous progesterone infusions described in the medical literature, BHR-100 is a ready-to-use infusion designed to meet all U.S. Food and Drug Administration approval requirements.

BHR is collaborating with the American Brain Injury Consortium (ABIC) and the European Brain Injury Consortium (EBIC) to identify the trial sites and help design the clinical study. PRA International is the Contract Research Organization for the trial.

TBI is a non-degenerative, non-congenital insult to the brain from an external mechanical force, possibly leading to permanent or temporary impairments of cognitive, physical and psychosocial functions with an associated diminished or altered state of consciousness.

Approximately 1.5 million Americans per year suffer a traumatic brain injury, resulting in 50,000 deaths, 235,000 hospitalizations and 80,000 cases of long-term disability. Incidence of TBI in all industrialized countries is comparable to that in the U.S., with estimates ranging from 150 to more than 300 per 100,000. There are approximately 66,000 deaths annually attributed to TBI in Europe.

The leading cause of TBI in the world is road traffic accidents, accounting for 40-50 percent of the hospitalizations for TBI.

There are currently no approved medications to improve outcomes following TBI.

The SyNAPSe study will build on promising results achieved in several previous clinical trials that demonstrated a mortality benefit and improved functional outcomes in TBI patients treated with progesterone. BHR has exclusively licensed the rights to a patent family claiming the use of progesterone to treat traumatic brain injury, along with preclinical and clinical data from a Phase 2 TBI study.

About BHR

Founded in January 2008, BHR Pharma, LLC (www.bhr-pharma.com) is a pharmaceutical research and development (R&D) company located near Washington, DC. BHR is committed to bringing to market specialty treatments that employ non-oral delivery systems, with an emphasis on unmet and underserved medical needs.

A wholly owned subsidiary of Besins Healthcare SA (www.besins-healthcare.com), which markets healthcare products in 93 countries, BHR manages all of Besins' global R&D activities. Those activities primarily leverage proprietary parenteral drug formulations, including the Enhanced Hydroalcoholic Gel (EHG[®]) technology pioneered and commercially launched by Besins in 1975.

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