

BHR PHARMA, LLC

A Besins Healthcare Company

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BHR Pharma Files Investigational New Drug Application, Receives Orphan Drug Designation, for Traumatic Brain Injury Treatment

Herndon, VA – (December 8, 2009) – [BHR Pharma, LLC](http://www.bhr-pharma.com) (BHR) announced today that it has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for its proprietary BHR-100 intravenous progesterone infusion product.

In September of this year, the company made public plans to initiate a global, Phase 3, pivotal trial (www.synapse-trial.com) in early 2010 to evaluate the safety and effectiveness of BHR-100 as a neuroprotective agent for treating severe (Glasgow Coma Scale scores of 4-8) traumatic brain injury (TBI) patients. The study will randomize approximately 1,200 patients at 100 – 120 sites to receive a five-day (120-hour) continuous intravenous infusion of progesterone or placebo. The protocol will require that treatment begin within eight hours of injury. Patients will be followed for six months post-injury.

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. An estimated 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.

The leading cause of death and disability in children and young adults worldwide, TBI is involved in nearly half of all trauma deaths. Traffic accidents account for 40-50 percent of the hospitalizations related to the condition.

BHR also announced that its product had recently been granted orphan drug status by the FDA Office of Orphan Products Development for early intervention in the treatment of moderate-to-severe closed-head TBI. The FDA only designates orphan-drug status on novel drugs or biologics that treat a rare disease or condition affecting less than 200,000 Americans. The designation offers a number of incentives to the treatment developer. This includes a seven-year period of U.S. marketing exclusivity if the drug receives marketing authorization by the agency. Funding for clinical studies, study design assistance, waiver of FDA user fees and tax credits are additional potential incentives.

The company plans to request that the treatment be fast tracked during the regulatory approval process.

“Traumatic brain injury is a terrible condition with high rates of mortality and disability, and currently there are no drugs approved for treating these patients,” said Tom MacAllister, BHR president and CEO. “We’re excited about achieving the IND milestone and believe that the orphan status will help facilitate a development program with the potential to give these patients and their families hope for better quality of life.”

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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