



- [About Us](#)
- [Research Areas](#)
- [Advisors](#)
- [News & Events](#)
- [Contact Us](#)

## BHR Pharma News & Events

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# BHR Pharma Enrolls First Patient in Phase 3 SyNAPSe Traumatic Brain Injury Trial

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**Herndon, VA** - (July 23, 2010) - [BHR Pharma, LLC](#) (BHR) announced today that the first patient has been enrolled in its SyNAPSe study ([www.synapse-trial.com](http://www.synapse-trial.com)), a global, Phase 3, pivotal trial to evaluate the safety and effectiveness of its intravenous progesterone infusion product (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 more than 100 sites to receive a five-day (120-hour) continuous intravenous infusion of progesterone or placebo. The study protocol requires that treatment begin within eight hours of injury. Patients will be followed for six months post-injury.

The first patient was enrolled at the University of Pittsburgh Medical Center in Pittsburgh, PA.

TBI is a non-degenerative, non-congenital insult to the brain from an external mechanical force, such as a car accident, a fall or an explosion. The injury can lead to permanent or temporary impairments of cognitive, physical and psychosocial functions with an associated diminished or altered state of consciousness. An estimated 1.7 million Americans per year suffer a TBI, resulting in 52,000 deaths, 275,000 hospitalizations and 80,000 cases of long-term disability.

"This drug has the potential to help a gravely ill population that includes car crash and battlefield injuries and we could not be more pleased to initiate this important trial," said Tom MacAllister, J.D., Ph.D., BHR president and CEO. "The annual incidence of TBI is higher than breast cancer and HIV/AIDS combined, yet it is largely ignored. We are proud to lead the efforts to make a difference for these patients and their families."

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 was notified in June that the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and

Research had completed its special protocol review and the SyNAPSe trial design and planned analysis adequately address the objectives necessary to support a regulatory submission. Under the FDA Special Protocol Agreement, BHR will be able to seek marketing approval of BHR-100 without additional pivotal trials, provided the SyNAPSe study results meet specific statistical significance targets and other measures. The trial is posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Last December, BHR announced that its product had 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 FDA also notified BHR in March that its agent had received a Fast Track Development Program designation. That designation accelerates the approval of investigational new drugs undergoing clinical trials. It is often granted to agents that show promise in treating serious, life-threatening medical conditions for which no other drug either exists or works as well.

## About BHR

Founded in January 2008, BHR Pharma, LLC ([www.bhr-pharma.com](http://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. The company is a wholly owned subsidiary of Besins Healthcare SA ([www.besins-healthcare.com](http://www.besins-healthcare.com)), which markets healthcare products in 93 countries.

## BHR Pharma Fact Sheets

- [BHR Overview](#) (pdf)
- [SyNAPSe](#) (pdf)

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