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Study on drug for traumatic brain injury reaches milestone

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Singapore: BHR Pharma has reached its SyNAPSe clinical trial enrollment midpoint of 590 patients. The company made the announcement during a presentation by Dr David Okonkwo, clinical director of University of Pittsburgh Medical Center Brain Trauma Research Center, at the National Neurotrauma Society's 2012 Annual Meeting.

The milestone for the global phase III multi-center trial was achieved when a study subject was randomized by Songklanagarind Hospital in Thailand. The study is set to complete in 2013.

SyNAPSe is evaluating the effectiveness of BHR-100, a proprietary intravenous progesterone infusion formulation, as a neuroprotective agent for treating severe traumatic brain injury (TBI) patients. The US Food and Drug Administration granted Orphan Drug designation to BHR-100 and placed the drug on a Fast Track status designed to accelerate its potential approval.

The trial currently has 149 participating sites (level 1 and 2 trauma centers) worldwide. The total enrollment target is 1,180 severe TBI patients.

"This significant milestone is a testament to the work of more than 1,000 medical professionals participating in our study around the globe that are committed to advancing scientific understanding of progesterone as a neuroprotective treatment for traumatic brain injury," said Dr Thomas W MacAllister, and President & CEO of BHR Pharma. "Their dedicated efforts are redefining TBI standard of care and getting us closer to the world's first-ever approvable treatment for this unmet medical need."

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TBI is a serious public health problem that affects more than 1.7 million Americans each year. Despite significant efforts in more than 75 clinical trials over the past 20 years, there is still no approved treatment for TBI.

Previous research has shown progesterone exerts its neuroprotective effects by protecting or rebuilding the blood-brain barrier, decreasing development of cerebral edema (brain swelling), down-regulating the inflammatory cascade and limiting cellular necrosis and apoptosis (programmed cell death).

Building on the SyNAPSe study of BHR-100 and promising research conducted by Emory University, BHR is also developing BHR-310, an intranasal progesterone powder. This nasal spray is being evaluated as a potential treatment that can be administered to wounded warriors or athletes with TBI quickly after injury on the battlefield or playing field. Preclinical studies of BHR-310 in rats and monkeys support the feasibility of a high-dose, rapidly absorbed intranasal progesterone product able to deliver clinically meaningful doses of progesterone to the brain.