

## BHR Pharma gets license for brain injury treatment

By Vandana Sinha

Staff Reporter

Tom MacAllister turned the page of his Wall Street Journal, expecting to see the day's most pressing financial news. Instead, he stumbled across his next business idea.

After one cold call to an Emory University scientist, the subject of the story, and several rounds of negotiations with the school's technology transfer office, MacAllister and his new biotech company, BHR Pharma LLC, became the sole licensee of what industry experts think could be the first real fix for traumatic brain injury from a debilitating blow to the head.

BHR Pharma, a 2-year-old Herndon subsidiary of Brussels-based Besins Healthcare SA, is wasting no time on its new find, a treatment that uses progesterone, a common female hormone, to ease the effects of traumatic brain injury.

The seven-person company is finalizing its request to the federal government to start testing the method early next year in the most advanced stage of human drug trials, recruiting 1,200 victims admitted to one of 120 emergency rooms around the world after severe car crashes, although most of the sites will be in the U.S.

Emory will launch its own advanced clinical trials next year with 1,140 patients in 17 medical centers across the U.S., using funds from the National Institutes of Health.

The two trials will be seeking volunteers at the same time, but MacAllister says the research teams are more complementary than competitive.

"We've tried to cast our geographic web such that they don't compete," said MacAllister, BHR Pharma's president, pointing to international sites in Europe, China and India, where the Emory study won't go.

More importantly, he said, BHR Pharma could benefit from both studies. With its exclusive license to use the treatment, invented in the 1980s and refined since then by Emory emergency medicine professor Don Stein, the

**A BIG OPPORTUNITY:** A license from researchers at Emory University gives Tom MacAllister's BHR Pharma access to a potential breakthrough in the treatment of brain injuries from blows to the head.



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company can use the results from either study as ammunition for its eventual bid to be the first to sell a federally approved treatment for traumatic brain injury.

"There's nothing out there like this," said Dr. Gregory O'Shanick, national medical director of the Brain Injury Association of America in Vienna. "That's the issue. There have been hundreds of studies of different chemical compounds over the last 25 years to see if there's some way to reduce the secondary cell damage in this fashion. ... The bottom line is, nothing's really worked."

If BHR Pharma wins approval for the treatment it will target severely injured patients within the first eight hours of a car collision and delivers its proprietary formula of intravenous infusions of progesterone to the patient for five straight days.

According to past studies, the progesterone appears to filter through the brain, reducing inflammation, blocking naturally programmed cell death and stimulating nerve-cell birthing processes along the way.

"A lot of drugs failed because they targeted a specific single mechanism," said Stein, who

began studying the effects of progesterone on traumatic brain injury after noticing that women often recover faster than men. "This works at a number of different levels."

Upward of 50,000 people die each year in the U.S. from traumatic brain injuries, and 1.1 million with similar injuries are checked into emergency rooms.

BHR Pharma has already received orphan drug status for the treatment, providing the company with federal regulatory and market incentives, and plans to apply to place it on a regulatory fast track.

The Food and Drug Administration has yet to greenlight a drug for traumatic brain injury, leaving ER doctors to only respond to the effects of the condition — surgically removing swollen parts of the brain, for example — rather than curing the fundamental injury.

"They treat the symptoms," said Neta Reich Nelson, BHR Pharma's senior director of operations. "They treat it medically and surgically for the acute systems. That's why this looks so promising."

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