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Friday, Feb. 19, 2010

BioWatch: Germantown's Psyadon tackles a 'terribly disfiguring' disease

Pharmaceutical company to launch study of compound for rare genetic disorder

by Robert Rand | Staff Writer



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Almost a year and a half ago, Richard E. Chipkin landed an \$8 million investment in his tiny bioscience company, changed its name and research focus, and licensed a compound that shows promise as a treatment for a debilitating genetic condition that afflicts a relative handful of people.

Chipkin, who holds a doctorate in pharmacology, is president and CEO of Psyadon Pharmaceuticals of Germantown, which was founded in 2004 as Ruxton Pharmaceuticals. The company recently announced that the U.S. Food and Drug Administration had accepted its investigational new drug application to study ecopipam in patients with Lesch-Nyhan disease, a genetic disorder that affects from 500 to 1,000 Americans.

The initial study, to evaluate the safety and tolerability of ecopipam in adults, adolescents and children with Lesch-Nyhan, will be conducted at Emory University in Atlanta. Ecopipam is a selective dopamine D1 receptor antagonist.

Why target Lesch-Nyhan, a disease that is passed from mothers to sons and is characterized by a buildup of uric acid in the body, an inability to walk because of joint problems and, perhaps most disturbing, self-mutilation?

Most importantly for humanitarian reasons, Chipkin said.

"It's a terribly disfiguring problem," he said. Patients, many of whom are institutionalized because they need round-the-clock care and restraints, have their teeth removed to prevent them from biting off their fingers.

An effective treatment "is desperately needed," Chipkin said. "If we can, we should bring it to market."

Some of the other symptoms of Lesch-Nyhan have been brought under control through medication, he said, keeping patients alive past childhood into their 30s.

Ecopipam — which Psyadon licensed from Schering, where Chipkin once worked — acts on the central nervous system and might help Lesch-Nyhan patients control their self-injurious behavior and other motor symptoms, too, he said.

Just because a disease affects relatively few people doesn't mean an effective treatment can't be profitable, Chipkin said, pointing to biotech giant Genzyme, which "makes a living from orphan disease drugs."

Ecopipam has received such orphan drug designation from the FDA, putting the product on a regulatory fast track, letting Psyadon avoid certain fees and giving the company market exclusivity for seven years in the U.S. and 10 years in Europe, he said.

The compound could be effective in treating other disorders involving the central nervous system; Chipkin said he taps consultants for advice on other possible uses.

Psyadon itself is "run as a virtual company," he said, with only one full-time employee — himself. He also constitutes half of the company's board. Its other member is James Barrett, general partner at New Enterprise Associates of Chevy Chase, which made the \$8 million investment in Psyadon in October 2008.

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