

Medical Doctor Tests Disease Vaccine on Himself.

At a critical stage in the race to cure myasthenia gravis, pharmaceutical companies don't see enough profit potential, so Dr. Stephane Huberty acts as his own guinea pig and conducts human trials... on himself.

Rixensart, Belgium 3 September 2010 – Double vision, slurred speech, extreme fatigue, trouble eating, swallowing, breathing... when Belgian doctor Stephane Huberty began having symptoms on a business trip 14 years ago, he quickly learned the hard truth.

He had myasthenia gravis, also called MG... an autoimmune disorder similar to muscular sclerosis (MS). In MS the nerves are under attack, in MG it is the nerve connection to the muscle.

Myasthenia gravis affects just one in 5,000 people, making it an "orphan" disease.

In drug company parlance, that's a disease suffered by too few people to make it highly profitable to develop a cure.

Not that a possible cure for myasthenia doesn't already exist. It does.

J. Edwin Blalock, a professor of medicine at the University of Alabama at Birmingham, developed a potential vaccine in the 1990s with funding from the U.S. Muscular Dystrophy Association and the National Institutes of Health.

But although he was sure the vaccine would be effective in humans, he was only able to test the vaccine on animals. For usual medicine, the Food and Drug Administration requires drug developers to conduct four phases of trials, including human trials on thousands of patients that can last up to 10 years.

For Dr. Blalock, the time and money involved in getting FDA approval for his vaccine made doing it himself impossible. And with relatively few sufferers, big pharmaceutical companies didn't see enough profit at the end of the approval process to make it worth their while. Dr. Blalock had made his point in proving that his theory worked, even if it was just on animal models, it works.

When Dr. Huberty learned of Dr. Blalock's work, they got together and came up with a plan. Dr. Huberty set up a company called Curavac, bought the patent for Dr. Blalock's vaccine, and with donations and investments from family, friends, other myasthenia gravis sufferers ... even a pet owner whose dog suffered from MG ... began working on bringing a cure to market.

The drug was ready for clinical testing in 2009, but Dr. Huberty discovered that, even outside the U.S., it would still take several years and close to \$5 million just to perform the safety and proof of concept phase, the first of three clinical trial phases

before the market. Even with promising market numbers, major pharmaceutical companies did not see enough profit potential to undertake the funding.

So in June 2009, Dr. Huberty injected himself three times with the vaccine.

The results were very encouraging. Dr. Huberty's blood antibody count fell drastically, and he was able to do things he hadn't been able to do in years... take long walks, swim distances, ski. In April of this year, he had a relapse, at the same time the new test developed to track the vaccine efficacy showed that the new "good" antibodies were present but at a low level. In May he re-injected himself with a dose six times as strong as the first dose. It worked... he is again strong enough to lead a normal life with his wife Leone, his 13 year old son Arnaud and their eight-month old daughter, Isalyne.

But Dr. Huberty is committed to bringing this possible new cure to other MG patients and to the market and is still looking for investors in Curavac. He says that, even though the drug works for him, it will still take 2 to 3 years and \$ 5 million to show proof of concept in a well conducted clinical trial and in the range of \$25 million and a total of 5 years or more before he can meet FDA and other requirements to make the drug available to the market and all MG sufferers.

In the U.S., Europe, and Japan, 200,000 people have myasthenia gravis, and 15,000 more are diagnosed each year. If Dr. Huberty can get the vaccine tested and approved, he plans to provide it in a course of three to five injections.

Dr. Huberty intends the course of injections to cure MG. He estimates the cost for the cure at \$30,000 ... the same as the cost for one year's worth of conventional treatment, which provides no cure but only maintains the disease under control.

Providing a complete cure for MG turns out to be another stumbling block in getting funding from some big pharmaceutical companies, says Dr. Huberty, because most drug companies "want a pill they can sell every day. They're much less interested in curing a disease."

In the mean time, Dr. Huberty continues to monitor his own reactions to the vaccine in his search for a final cure for Myasthenia Gravis.

For more information on Myasthenia Gravis and Dr. Huberty's work, contact: info@curavac.com.

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