

First human gets new antibody aimed at rabies virus

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MassBiologics of the University of Massachusetts Medical School today announced the beginning of a Phase 1 clinical trial, testing the safety and activity of a human monoclonal antibody (MAB) developed to neutralize the rabies virus.

The clinical trial is being conducted at the King Edward Memorial Hospital in Mumbai, India, and is sponsored by the Serum Institute of India, which is working in a collaborative partnership with MassBiologics to manufacture and test the new antibody.

"India is an appropriate location to do this study because of the serious problem of rabies that exists in the country," said Donna Ambrosino, MD, executive director of MassBiologics and a professor of pediatrics at the Medical School. "We look forward to seeing the results from this trial, and to advancing this potentially life-saving treatment."

Even though rabies-related deaths in the United States are rare, more than 40,000 people in the U.S. are exposed to the disease each year and require immediate treatment known as post-exposure prophylaxis (PEP). Worldwide, however, rabies remains a major public health problem. The World Health Organization estimates that at least 10 million people are exposed to rabid animals each year, resulting in some 55,000 deaths.

The rabies virus can cause acute encephalitis that is fatal once symptoms appear; however the infection is preventable by prompt treatment following exposure. By using a rabies vaccine and human rabies immune

globulin (hRIG) soon after exposure, patients are protected from the fatal disease. Unfortunately, hRIG, which is derived from human blood, is an expensive material and is often not available in developing countries. To compensate, equine immune globulin derived from horse serum is used in many parts of the world, but it also can be scarce and it can carry significant side effects.

To address the supply problems and side-effect issues, MassBiologics and the U.S. Centers for Disease Control and Prevention launched an effort to develop a MAB that could be used in place of hRIG. The research used, in part, HuMab mice® from Medarex, Inc. (Princeton, N.J.) which are transgenic mice able to produce fully human antibodies. Pre-clinical testing of the new MAB showed that it neutralized all isolates available from a panel of rabies viruses.

"Too often physicians in India and other developing countries only have the rabies vaccine to offer, and that alone isn't always enough to prevent infection," said Deborah Molrine, MD, deputy director of clinical and regulatory affairs at MassBiologics and an associate professor of pediatrics at the Medical School, who helped design the clinical trial and will oversee the analysis. "If this new antibody proves effective in people, it will have a tremendous impact on saving lives."

In the Phase 1 trial just launched in India, a total of 84 healthy volunteers will receive various doses of the new MAB to test the tolerability and biologic activity of the MAB in people. The site investigators will monitor the volunteers' overall health and do clinical laboratory testing for safety. Scientists at MassBiologics will test blood samples drawn from the volunteers to measure the amount of MAB in the bloodstream, and to see if the volunteers produced any of their own antibodies directed against the new MAB. Scientists from the Kansas State Veterinary Diagnostic Laboratory will test the blood samples against the [rabies virus](#) in culture, to determine the dose of MAB

administered to the volunteers that gave the best protective response.

The Serum Institute of India is the world's largest manufacturer of vaccines and is a major supplier of the rabies vaccine. Scientists from the MassBiologics worked with their counterparts in India to help the Serum Institute build its own internal MAB production facility, thereby bringing this leading-edge biologics technology to India for the first time.

Source: University of Massachusetts Medical School ([news](#) : [web](#))

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