First human tests of meth medication completed

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(Medical Xpress)—InterveXion Therapeutics LLC and the University of Arkansas for Medical Sciences (UAMS) have successfully completed dosing in the first human safety study of a medication to help methamphetamine users fight their addictions.

The medication is expected to significantly reduce or prevent the euphoric rush that drug users crave by keeping methamphetamine in the bloodstream and out of the brain, where the drug exerts its most powerful effects.

In the Phase I trial, 40 healthy volunteers who do not use methamphetamine received the medication over the past eight months and experienced no serious side effects.

"While we still have lots of work to do, this is a significant milestone for this research," said Brooks Gentry, M.D., a UAMS professor and InterveXion's chief medical officer who is overseeing the clinical trial phase. "Many experimental drugs fail during the first phase of a clinical trial, so we're excited that we can now look forward to testing in methamphetamine users who want help reducing their meth dependence."

When it has received final approval, the antibody will be given as an integral part of a methamphetamine user's complete treatment program, which consists of counseling and possibly other medications to reduce craving.

The medication, named ch-mAb7F9, is a monoclonal antibody. InterveXion, the trial sponsor, contracted the safety study to the Quintiles Phase 1 unit in Overland Park, Kan. The volunteers in the study, who received doses that ranged from 0.2 to 20 mg/kg, will continue to be followed for 21 weeks. Results of the Phase 1a study are expected in mid-2013.

The next steps in the development of the medication include further nonclinical safety testing followed by a Phase 1b clinical safety trial in current methamphetamine users.

Funding for the project was awarded to UAMS and InterveXion from the National Institute on Drug Abuse (NIDA). Additional support was given by the UAMS Translational Research Institute. NIDA has backed the development, manufacture and toxicology testing of this medication through previous grants to InterveXion and UAMS.

InterveXion, a UAMS BioVentures incubator client company, has licensed the technology for anti-methamphetamine antibody products from UAMS and is working closely with the university during product development.

Methamphetamine abuse has been a significant problem in the United States for the last decade. According to the Substance Abuse and Mental Health Services Administration, there were 439,000 methamphetamine users in the U.S. in 2011. New methamphetamine users numbered 133,000. In 2010, more than 100,000 were admitted to drug abuse treatment with methamphetamine as their primary substance of abuse. In addition, there were 54.9 emergency department visits per 100,000 population aged 21 or older involving methamphetamine use.

Provided by University of Arkansas