

InterveXion Enrolls First Patient in Phase 2 Study of the Effect of IXT-m200 on Methamphetamine PK and PD

STAMPOUT: Phase 2 proof-of-concept trial to test effects of first-in-class anti-methamphetamine antibody in methamphetamine users

LITTLE ROCK, ARKANSAS, USA, May 9, 2018 /EINPresswire.com/ -- InterveXion announces the enrollment of the first patient in STAMPOUT, the first trial in methamphetamine users of the first-inclass anti-methamphetamine antibody IXT-m200. STAMPOUT will be a Phase 2a, parallel-group, placebo-controlled, double-blind study of the effect of IXT-m200 on methamphetamine pharmacokinetics and subjective effects in methamphetamine users. InterveXion has previously conducted a robust nonclinical evaluation of the pharmacology, toxicology, and pharmacodynamics of IXT-m200, and has completed an initial Phase 1 clinical safety study with this investigational product.

IXT-m200, a monoclonal antibody that specifically binds methamphetamine in the blood, is being developed as a pharmacological treatment for use in conjunction with behavioral therapies. IXT m200 is expected to alter methamphetamine pharmacokinetics in human subjects resulting in reduced or blocked subjective effects that reinforce methamphetamine use. STAMPOUT will provide proof-of-concept that IXT m200 can alter methamphetamine disposition. This will be the first clinical study in methamphetamine users of a biological medication developed specifically for patients with methamphetamine use disorders.

Methamphetamine addiction is a serious global healthcare burden, with over 400,000 people addicted to methamphetamine in the US alone, and an overall cost to the US healthcare system in excess of \$20B annually. There are no pharmacologic therapies for methamphetamine addiction, and current treatment is limited to counseling and behavioral modification. There is a sizable population of treatment-seeking methamphetamine users, with >100,000 patients admitted annually to US treatment centers for methamphetamine abuse.

"Our extensive preclinical data demonstrate that IXT-m200 can meaningfully alter the pharmacokinetics and pharmacodynamics of methamphetamine.", noted Dr. W. Brooks Gentry, InterveXion's Chief Medical Officer. "The STAMPOUT study will demonstrate whether these effects translate into methamphetamine users, and we are excited to have the study underway".

STAMPOUT is funded by a three-year \$8 million grant award from the National Institutes of Health/National Institute on Drug Abuse (NIH/NIDA). A sub-award to the University of Arkansas for Medical Sciences (UAMS) is part of the grant and funds researchers who are both founders of the company and also prominent UAMS leaders. InterveXion is a BioVentures, LLC, client company housed on the UAMS campus in Little Rock, AR.

For more information on this study, visit: https://www.clinicaltrials.gov/ct2/show/NCT03336866

InterveXion is a pharmaceutical company whose mission is to discover and advance innovative medications that reduce the impact of human suffering on individuals and communities. Its vision is to

be a leader in the development of antagonist therapies that neutralize toxins in the body and thereby improve patient health. InterveXion's first medications are a monoclonal antibody and an active vaccine for treating methamphetamine abuse. For more information, contact intervexion@gmail.com. STAMPOUT is supported by NIH/NIDA under Award Number U01DA045366. The content of this release is solely the responsibility of InterveXion and does not necessarily represent the official views of the National Institutes of Health.

Misty Stevens InterveXion Therapeutics 501-554-2377 email us here

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