InterveXion Therapeutics Awarded Federal Grant to Fund Phase 2 Study for Methamphetamine Use Disorder

Grant fully funds clinical trial, to be called "OUTLAST", which will initiate in early 2022

LITTLE ROCK, AR, USA, October 4, 2021 /EINPresswire.com/ -- InterveXion Therapeutics, a clinical-stage biopharmaceutical company, today announced the award of additional Federal funds to support ongoing development of IXT-m200, an anti-methamphetamine antibody. This new award will fund a Phase 2 clinical trial for IXT-m200 in patients with methamphetamine use disorder, called the "OUTLAST" trial.

The three-year $13.8 million grant award (U01DA055481) comes from the National Institutes of Health/National Institute on Drug Abuse (NIH/NIDA) which has funded previous and ongoing development of IXT-m200. A sub-award to the University of Arkansas for Medical Sciences (UAMS) is part of the grant, and UAMS will continue to play an important role in the advancement of IXT-m200 development. InterveXion is a BioVentures, LLC company housed on the UAMS campus in Little Rock, AR.

IXT-m200, a monoclonal antibody that specifically binds methamphetamine in the blood, is being developed both for acute methamphetamine overdose and as a chronic therapy for patients seeking to overcome methamphetamine use disorder. InterveXion has released positive data from the Phase 2 STAMPOUT study of IXT-m200 in people who use methamphetamine, and the Meth-OD Phase 2 trial of IXT-m200 in acute methamphetamine overdose is ongoing.

"We are grateful for NIDA's continued support of our development programs," said Keith Ward, PhD, InterveXion's Chief Executive Officer. "Methamphetamine use disorder and methamphetamine overdose are major public health issues for which there are no approved pharmacologic therapies. We are excited about the potential for IXT-m200 to help patients struggling with this powerful addiction, and look forward to launching the OUTLAST trial".

OUTLAST is a randomized, placebo-controlled study of IXT-m200 in people seeking treatment for methamphetamine use disorder. Participants (n=120) will be enrolled in two sequential cohorts, each of which will randomize participants 2:1 to IXT-m200 or placebo, with a low dose of IXT-m200 to be studied in Cohort 1 and a higher dose in Cohort 2. Each participant will also receive standard cognitive behavioral therapy, and will undergo regular self-reporting and saliva testing for drug use. Participants will receive 6 doses of IXT-m200 or placebo, given once monthly, and

safety and efficacy will be evaluated over a period of approximately 33 weeks. OUTLAST will evaluate the efficacy of IXT-m200 in preventing or reducing relapse to stimulant use.

About InterveXion

InterveXion is the leading biopharmaceutical company developing immunotherapies for patients with methamphetamine use disorder. InterveXion's lead product, IXT-m200, is a monoclonal antibody against methamphetamine with positive Phase 2 data and which has received US FDA Fast Track Designation for treatment of methamphetamine use disorder. For more information, visit https://www.intervexion.com.

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