InterveXion Announces Positive Results from Pre-Specified Interim Review of Phase 2 STAMPOUT Study

IXT-m200 produced immediate, dose-dependent, time-dependent changes in primary endpoint parameters of methamphetamine AUC and Cmax

LITTLE ROCK, AR, USA, July 29, 2019 /EINPresswire.com/ -- InterveXion Therapeutics, a private clinical-stage biopharmaceutical company developing immunotherapies for substance abuse disorders with funding from the National Institutes of Health, today announced positive results from the pre-specified interim review of its ongoing Phase 2 study of IXT-m200 (an anti-methamphetamine antibody) in patients with methamphetamine use disorder.

> “These interim data are the first evidence from our program that IXT-m200 alters the pharmacokinetics of methamphetamine in patients.”
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> *InterveXion’s Chief Medical Officer W. Brooks Gentry, M.D.*

STAMPOUT is a parallel-group, placebo-controlled, double-blind study of IXT-m200 in non-treatment-seeking patients with methamphetamine use disorder. Patients receive IXT-m200 (6 or 20 mg/kg) or placebo followed by a series of weekly methamphetamine challenges during an inpatient stay ranging from 22 to 29 days in duration, with outpatient follow-up visits through Day 126. The primary endpoint is change in serum methamphetamine area under the concentration-time curve (AUC) or Cmax resulting from methamphetamine challenge. Secondary endpoints include change in subjective effects of methamphetamine challenge doses as well as safety and tolerability of IXT-m200.

In the pre-specified interim review, evaluable subjects demonstrated clear time- and dose-dependent changes in methamphetamine disposition in the presence of IXT-m200. Dose-dependent changes in methamphetamine pharmacokinetic parameters, including AUC, Cmax, and volume of distribution, were evident at the first dosing challenge, and were maintained through the entire inpatient period. These changes were observational; no statistical comparisons of data were performed. Safety and tolerability data were unremarkable, with no serious adverse events and no apparent imbalance in adverse events, which were mild to moderate in intensity, across placebo and active treatment groups.

“These interim data are the first evidence from our program that IXT-m200 alters the pharmacokinetics of methamphetamine in patients,” said InterveXion’s Chief Medical Officer W. Brooks Gentry, M.D. “The magnitude of change in these parameters in STAMPOUT is impressive, with up to an 8-fold change in Cmax and a 30-fold change in AUC, clearly indicating the ability of IXT-m200 to redistribute methamphetamine away from tissues like the brain and into the blood. We are also pleased with the safety data from STAMPOUT to date, and look forward to completing the study and advancing our development program.”

Based on these results, InterveXion plans to continue enrollment of patients in the STAMPOUT study to gather additional efficacy and safety data in a larger patient population, and if positive, to support progression to pivotal efficacy trials.

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About InterveXion

InterveXion is the leading biopharmaceutical company developing immunotherapies for patients with substance abuse disorders. InterveXion's lead product, IXT-m200, is a monoclonal antibody against methamphetamine which has received US FDA Fast Track Designation and which is currently undergoing Phase 2 proof-of-concept testing in the STAMPOUT study (NCT0333866). For more information, visit: https://www.intervexion.com.

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