InterveXion Announces Positive Data in Phase 2 Study of IXT-m200 in Participants with Methamphetamine Use Disorder

IXT-m200 produced significant changes in primary endpoint of methamphetamine pharmacokinetics, with favorable data for secondary endpoints and safety

LITTLE ROCK, AR, USA, April 19, 2021 /EINPresswire.com/ -- InterveXion Therapeutics, a private clinical-stage biopharmaceutical company developing immunotherapies for substance abuse disorders, today announced positive final results from its Phase 2 study of IXT-m200 (an anti-methamphetamine antibody) in individuals with methamphetamine use disorder.

> We are delighted with the final data from STAMPOUT."
> *W. Brooks Gentry, MD, Chief Medical Officer, InterveXion*

STAMPOUT (NCT03336866) was a parallel-group, placebo-controlled, double-blind study of IXT-m200 in 56 non-treatment-seeking individuals with methamphetamine use disorder. Participants received 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 was change in serum methamphetamine area under the concentration-time curve (AUC) or Cmax resulting from methamphetamine challenge. Secondary endpoints included change in subjective effects of methamphetamine challenge doses as well as safety and tolerability of IXT-m200.

IXT-m200 achieved the primary endpoint, and significantly ($p<0.0001$) altered methamphetamine AUC and Cmax, up to 30-fold and 8-fold respectively, without altering methamphetamine renal elimination. Favorable trends in several secondary endpoints associated with the pharmacodynamic effects of methamphetamine were also observed. IXT-m200 was well-tolerated, with no serious adverse events and no unexpected adverse events.

"We are delighted with the final data from STAMPOUT," said InterveXion's Chief Medical Officer W. Brooks Gentry, M.D. "These positive data are consistent with our earlier interim analysis, and demonstrate a significant and impressive ability of IXT-m200 to redistribute methamphetamine away from its sites of action and into the bloodstream where it can be delivered to its organs of elimination. Safety in STAMPOUT was excellent, and the study data strongly support continued development."

Based on these positive data, InterveXion is continuing development of IXT-m200 in two related indications associated with methamphetamine use. InterveXion is currently initiating the Meth-OD trial (NCT04715230), a study of IXT-m200 in people presenting for treatment with acute methamphetamine toxicity. Meth-OD has been fully funded by a three-year, $8.1 million grant award from the National Institute on Drug Abuse, part of the National Institutes of Health. Additionally, InterveXion has been granted a Type C meeting with the FDA to discuss the OUTLAST trial, a study of IXT-m200 in patients with methamphetamine use disorder, for which IXT-m200 has been granted FDA Fast Track Designation.

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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