Catalent Biologics Supports InterverXion on New Treatment for Methamphetamine Users

Catalent Pharma Solutions, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, today welcomed the news that InterverXion has enrolled the first patient in STAMPOUT, the first trial in methamphetamine users of the first-in-class 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.

SOMERSET, N.J. (PRWEB) May 31, 2018 -- Catalent Pharma Solutions, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, today welcomed the news that InterverXion has enrolled the first patient in STAMPOUT, the first trial in methamphetamine users of the first-in-class 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.

Catalent has supported InterverXion by engineering the cell line which expresses the drug’s antibody employing its proprietary GPEx® technology and completing process development. Catalent provided cGMP manufacturing for the clinical trial at the company’s Madison, Wisconsin, biomanufacturing facility.

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 of a biological medication in methamphetamine users.

“Methamphetamine addiction is a serious global healthcare burden, and we are pleased to be working with InterverXion on this important treatment,” commented Mike Riley, Vice President and General Manager of Drug Substance and Bioanalytical services for Catalent Biologics. He added, “We continue to work closely with innovative organizations such as InterverXion to bring potentially life-changing products to patients.”

Misty Stevens, Ph.D., Operations Director, InterverXion, commented, “This is our second antibody production cell line to be developed by Catalent and we’ve been very pleased with the speed of development and high production rates Catalent can achieve early on with minimal optimization.”

Catalent’s proprietary GPEx technology creates stable, high-yielding mammalian cell lines with high speed and efficiency. The advantages of applying GPEx technology span from early feasibility studies, to clinical manufacturing, through to commercial scale production. To date, seven GPEx-based antibody and protein products are approved and marketed, and more than 40 therapeutic candidates are currently in the clinic across the world.

With the $950 million acquisition of Cook Pharmica LLC, in October 2017, Catalent further strengthened its
position as a leader in integrated biologics development, clinical and commercial-scale manufacturing and finished product supply. The additions of this first-class team and unparalleled facilities have brought deep expertise in liquid and lyophilized sterile formulation and fill-finish across vials, prefilled syringes, auto-injectors, cartridges, and safety devices, and 2,500-liter biomanufacturing capacity to augment Catalent’s existing biologics infrastructure. With this additional capacity and expertise, Catalent can now provide a single, trusted partner to accelerate all aspects of biologic drug development.

For further information visit biologics.catalent.com

About InterveXion
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(at)gmail.com or visit www.intervexion.com. STAMPOUT is supported by NIH/NIDA under Award Number U01DA045366.

About STAMPOUT
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, Arkansas.

About Catalent
Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 11,000 people, including over 1,400 scientists, at more than 30 facilities across five continents, and in fiscal 2017 generated over $2 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com

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