Tergus Pharma
Think Topicals, Think Tergus

Case Study

University of North Carolina
School of Medicine

The Problem

Researchers at the University of North Carolina School of Medicine needed testing, scale-up and manufacturing of intra-nasally administered Oxytocin for a clinical study involving children with Autism. The research, funded by NICHD (National Institute of Child Health and Human Development), originally involved a commercial pharmaceutical company. When the company decided to pull out of the study, researchers needed to find an alternative that met the requirements of the NIH and FDA.

Autism affects 1 in 68 American children, according to the Center for Disease Control (CDC). This estimate has grown 30% since 2012, when it was estimated that 1 in 88 children would have autism.

Treating autism with Oxytocin may have possibilities to either increase motivation to engage in social interaction or increase attention to social cues. This hypothesis is supported by several animal studies, as well as single-dose studies in individuals with autism.

Oxytocin is a naturally-occurring hormonal peptide. The reduced form of this peptide acts as a free radical scavenger. The half-life of the drug is up to three minutes when it is given via injection. Oxytocin is destroyed in the GI tract, so no oral dosages are possible.

The study is looking at extended therapy to children with Autism via a nasal spray, which enhances bioavailability. This method of delivery improves compliance over injection dosage, which requires more frequent administrations. It is non-invasive and avoids the inconvenience of parenteral therapy.

The Solution

Researchers looked at five manufacturing and testing companies and chose Tergus. Tergus has a high-level of cGMP compliance and the ability and know-how to conduct rigorous testing. They liked Tergus's administration, level of organization, willingness to be involved with researchers and the ability to meet timelines and get things done.

"The people at Tergus are actually involved in the project and work as a team with us," said Linmarie Sikich, MD, Associate Professor and Director of the Adolescent and School-age Psychiatric Intervention Research Program (ASPIRE), University of North Carolina School of Medicine, Department of Psychiatry.

Tergus is conducting the scale up and manufacturing of low and high doses of 40 liters each in active batches, along with placebos. It is also conducting release and stability analysis for the project.

The Results

Tergus delivered release and stability testing, as well as scale up and tech transfer for the project. It is in the process of manufacturing clinical supplies for the nationwide study. According to Dr. Sikich, the research team feels comfortable that, with help from Tergus's team of topical pharmaceutical experts, the product will be safe and well-developed for the study. She also expects that any requirements the FDA has for the study will be met or exceeded.

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