

## **Confluence Pharmaceuticals Completes Successful Phase I Clinical Trial for Fragile X Syndrome Drug**

INDIANAPOLIS, IN— **CONFLUENCE PHARMACEUTICALS**, a clinical stage biopharmaceutical company focused on developing therapeutic treatments for core social and communication impairments, caused by Fragile X Syndrome and Autism Spectrum Disorders, has successfully completed a Phase I bioavailability study in Bloemfontein, South Africa. The study examined Confluence's lead sprinkle formulation (CPX1046B) in healthy adults. This study confirmed that the formulation is acceptable for use in future clinical trial work. With this information, the company can now move forward and design a Phase II study where the product will be used to treat a small group of patients with Fragile X.

"The successful completion of our Phase I study moves us one step closer to bringing a new therapy to patients with Fragile X Syndrome," said Confluence's President and Founder Steve Johns. We look forward to starting our Phase II trials in 2020 with a target of filing a New Drug Application with the FDA for marketing approval in 2023."

### **About Fragile X Syndrome**

Fragile X Syndrome (FXS) is associated with an array of intellectual and emotional disabilities. FXS is often accompanied by anxiety, attention-deficit disorder, aggression, seizures, self-injurious behavior and physical deficits. The cause of FXS has been linked to a genetic mutation of the X Chromosome leading to a decreased or absent level of fragile X mental retardation protein (FMRP). The FXS gene (FMR1) has also been a research target for other neurodegenerative disorders like Fragile X-associated tremor/ataxia syndrome and is closely related to conditions of Alzheimer's and Parkinson's disease.

FXS is the most common inherited form of mental impairment and the most known cause of Autism. According to the Centers for Disease Control, two-thirds of patients diagnosed with FXS also have Autism Spectrum Disorders. It is estimated that approximately 180,000 individuals in the U.S. have either the full or partial genetic mutation of Fragile X Syndrome.

### **About Confluence Pharmaceuticals, Inc.**

Confluence Pharmaceuticals is a biopharmaceutical company developing a novel treatment for impairments associated with Fragile X Syndrome and Autism Spectrum Disorders. Dr. Craig A. Erickson, Confluence Founder and Lead Scientific Advisor, conducted open-label pilot studies demonstrating that treatment can improve the core impairments of FSX. These novel actions were patented by Indiana University Research and Technology Corporation and exclusively licensed by Confluence. Confluence's strategy of both repurposing and reformulating an FDA-approved drug for new diseases reduces development risk, time and costs by utilizing the 505(b)(2) NDA approval process. Confluence has assembled a team of experts experienced in drug development, clinical trials and regulatory affairs. The company is headquartered in Indianapolis, IN. For more information about Confluence Pharmaceuticals, please visit the Company's website at <http://confluencepharma.com> or contact Steve Johns, President (317) 379-7498.