

News Release
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FOR MORE INFORMATION

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Altasciences Clinical Research Offers Innovative Cannabis Research Solutions

LAVAL, QC, Canada (August 25, 2017) — Altasciences is pleased to share that they are in the final stages of completing the world's first safety and tolerability study on a cannabis extract being developed as a new chemical entity for approval by the FDA and Health Canada as a drug.

Starting in January 2017, Altasciences combined their decades of experience designing and conducting studies on cannabinoid-based products, products delivered by inhalation, and testing of products that are smoked, to design and conduct the world's first safety and tolerability study on a cannabis extract smoked using a specialized delivery device being developed as a new chemical entity for regulatory approval as a drug.

"The sponsor, Tetra Bio-Pharma, approached us with the desire to conduct a first-in-human test on their product, a cannabis extract that is formed into a pellet and smoked in a specialized titanium pipe. The pellet had been designed to provide consistent dosing in a format that was easy to transport and deliver. The study was designed to test whether the format met the criteria and to establish the safety of the product and device. Innovation is at the core of how we design and conduct clinical studies at Altasciences," explained Dr. Graham Wood, Executive Vice President, Phase I Development, at Altasciences.

Altasciences implemented a smoking technique to minimize variability, and used their well-ventilated specialized smoking rooms to prevent cross-contamination between active and placebo participants. Also, with their 20,000-square-foot bioanalytical laboratory a few kilometers away from their clinic, Altasciences was able to very quickly measure the blood levels of the active ingredients and their metabolites. Finally, Altasciences used iPad-based cognitive assessments and subjective measures of the psychoactive effects to monitor if the subjects were impaired. Together, this enabled us to very quickly collect the data to make the safety decisions for the dose escalation.

If you are interested in learning more, Dr. Marc Lefebvre, Vice President, Scientific and Regulatory Affairs, at Altasciences, will be presenting the details of this innovative study at the [Partnerships in Clinical Trials Europe](#) event in Amsterdam, on November 28, 2017. Dr. Graham Wood will also be providing insight during his presentation at the [BioPharma Forum on Cannabis-Based Science & Medicine](#) in Denver, Colorado, from November 30 to December 1, 2017

Altasciences is currently working with Tetra Bio-Pharma on their future studies for the cannabis extract as well as planning for studies on their second cannabis-based product that will be ready for first-in-human studies this fall.

About Altasciences

[Altasciences Clinical Research](#) encompasses [Algorithme Pharma](#) in Montreal, QC, [Vince & Associates Clinical Research](#) in Overland Park, KS, as well as [Algorithme Pharma USA](#) in Fargo, ND, thereby making it one of the largest early phase clinical CROs in North America. With over 25 years of industry experience, Altasciences provides early phase clinical development services to an international customer base of biopharmaceutical and generic companies. Altasciences' full-service solutions offering in this critical stage of drug development includes medical writing, biostatistics, data management and bioanalysis.